Dynamic Model for Simulating Motion of the Right Ventricle

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2018

Statement of Disclaimer

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Abstract

This report documents all the research, ideation, and mockups used to determine right ventricle motion and develop a system capable of reproducing that motion on a tissue sample. The model is intended for evaluating anchoring systems being developed by Edwards Lifesciences for use with tricuspid valve therapies. Several design solutions were considered for the primary functions of recreating motion of the right ventricle and attaching tissue to the device. From these ideas a primary means of producing motion and attaching tissue was selected. These ideas were then developed over the course of a school year to become the final system hardware delivered to the project sponsor. This document covers the design process including multiple iterations both in CAD and of structural prototypes. The document concludes by discussing the final hardware and the next steps proposed to improve upon the final design.

Acronyms and Abbreviations

DOF	Degree(s) of Freedom
FDA	Food and Drug Administration
LV	Left Ventricle
MDDT	Medical Device Development Tools
MRI	Magnetic Resonance Imaging
NAM	Non-Clinical Assessment Model
QFD	Quality Function Deployment
RV	Right Ventricle

Contents

1. Introduction

The goal of this project is to produce a *dynamic model for simulating motion of the right ventricle*. This project is sponsored by Aric Stone from Edwards Lifesciences. Edwards is currently in the process of developing and testing new anchors for use with their medical devices. This project relates to the anchors that attach to the inside walls of the right ventricle. To better understand the installation and use of these anchors, a robotic platform capable of holding a tissue sample while rotating and translating similar to the motion of the right ventricle must be created. The ability to recreate this motion will allow Edwards to perfect the anchoring mechanism used to secure medical devices into the right ventricle.

The team creating this dynamic simulation is composed of John D'Ambrosio, Brian Larsen, and Sam Porter. All members are 4th and 5th year mechanical engineering students at Cal Poly San Luis Obispo. Each team member has engineering experience through internships working in the medical field and is excited to apply their knowledge to the project.

This document provides an overview of the background research, general timeline, and considerations that went into the project development. In addition to this overview, there will be detailed discussion of our design and how it meets the needs of the project sponsor.

2. Background

This section covers material used to guide design requirements and scope for this project.

2.1. Sponsor Needs

Many of our sponsors needs were documented in an initial presentation to the team. Any questions that remained after this presentation were answered through frequent calls and emails with our sponsor.

Our sponsor requires a better way to test anchoring systems for use on the right ventricle, by simulating clinically relevant right ventricle motion. The anchoring system is used to fix various medical devices, such as the FORMA spacer system, in place. The anchors attach in the right ventricle to the septal wall, free wall, or septal groove.

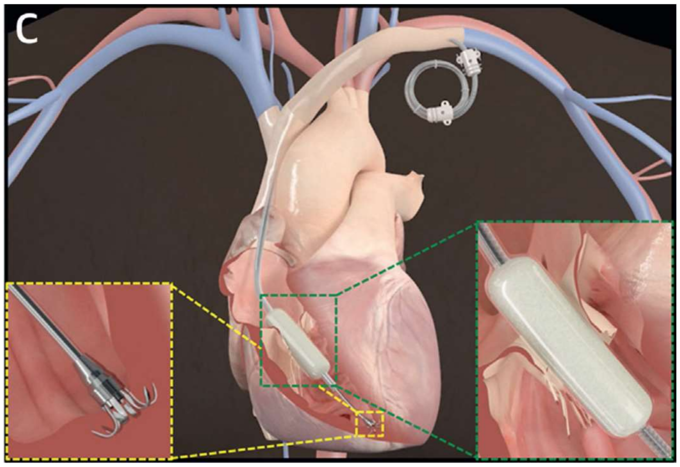


Figure 1. Model of the FORMA Spacer System post-surgery within the heart. The spacer rests between the Tricuspid Valve while the anchor is attached to the septal grove. [1]

Because research into the right ventricle is limited, it is necessary to determine the motion of these locations from radiology images. The motion involves translational and rotational, motion that can be recreated with a six DOF device. Through research and strong technical rationale, a set number of motion profiles capable of covering a wide patient population must be determined. In conjunction with determining motion, a device must be developed that can reproduce the clinically relevant motion profiles by moving a tissue sample.

To produce the most clinically relevant results, the tissue sample will need to be submerged during use. To facilitate testing, the hardware must be able to operate within the constraints of a typical surgical table used by patients, as well as not interfere with the C arm being used for imaging. Finally, all power must come from a standard outlet, and all development costs must remain below three-thousand dollars.

2.2. Existing Solutions

The challenge proposed by Edwards Lifesciences does not have a readily available solution specific to their needs on the market. While solutions may already be in use at other biomedical companies, they are likely limited to other companies performing internal testing.

Despite no readily available solutions for comparison, there are several potential anchor test methods. These methods include in vitro tissue samples, porcine or bovine specimen, and 6 DOF robotic arms, among others. Each of these solutions make tradeoffs between clinical relevance and practicality.

An initial idea suggested by our sponsor was the use of a Stewart Platform. A Stewart Platform is a type of parallel robot that can produce six degrees of freedom (x, y, z, roll, pitch, yaw) by orchestrating the motion of several actuators simultaneously. The end-effector, the portion that interacts with the environment, can be designed for quick tissue sample attachment, allowing for easy anchor testing. While this is just one idea investigated, the notion of using other forms of parallel robots can be expanded upon when considering for the best solution to our problem statement.

A more sophisticated method of replicating the heart developed by Wyss Institute for Biologically Inspired Engineering uses Pneumatic Artificial Muscles (PAM). Wyss had been able to recreate the Left Ventricle Twist, or Cardiac Rotation, that occurs in healthy and diseased hearts. Through soft robotics, the team at Wyss has replicated the striated muscles in the heart with "silicone elastomer and an embedded braided mesh" [2]. The soft material was used to mimic the epicardium, the outer most layer of the heart, due to its influence on the twisting motion of the heart.

2.3. Patent Search

Below is a brief list of patents related to anticipated development for this project.

Table 1: Patents relevant to this project.

Patent	Description	Reference
Motion/Force Simulators with Six or Three Degrees of Freedom	Parallel actuating robot comprising of 6 serial sub chains and a platform end-effector with certain configurations allowing for 3 or 6 degrees of motion.	[3]
Modular Suspended Manipulator	An actuating robot utilizing cables with a drive mechanism to create 6 degrees of motion.	[4]
Light Weight Parallel Manipulators Using Active/Passive Cables	A robot that uses a parallel configuration and cables to provide a lightweight embodiment with 6 degrees of motion through passive and active drive mechanisms.	[5]
Hybrid Serial/Parallel Manipulator	An actuating robot that utilizes both parallel and serial mechanism (a five-bar linkages and rigid platform end-effectors) to create 6 degrees of motion.	[6]

Our focus during the patent search revolved around the use of parallel and serial robots due to their ability to meet the strict motion requirements needed for simulation. The locations of potential anchor placement all exhibit unique motion that require multiple degrees of freedom to replicate. Stewart Platforms are known for achieving motion to six degrees of freedom, but the linkages and mechanisms used can vary significantly.

The first patent [3] details a variation of a Stewart Platform with three pairs of two-bar serial linkages that form a parallel link between the end-effector and base. The benefit to this design idea stems from the flexibility of achieving three or six degrees of freedom based on design requirements. The second patent [4] takes a different approach to parallel robotics, using cables and pulleys connected to a set of servo motors to provide functionality. The third patent [5] uses cables and winches in conjunction with a telescoping post and a gyroscopic base that moves in all six degrees of freedom. The final patent researched [6] utilizes both serial and parallel linkages with rigid end effectors to obtain the necessary degrees of motion.

2.4. Technical Literature Review

Tricuspid regurgitation is a disease that is caused when the tricuspid valve is enlarged preventing it from closing as it should, leaving gaps that allow blood to flow backward into the right atrium. [7]. As of now, tricuspid regurgitation is not treated in most cases, and patients are forced to live with the symptoms. Edwards plans to treat this disorder with a product delivered to the patient's heart via catheter. The device will fill the gaps in the tricuspid valve, so regurgitation no longer occurs. To keep this device secure, it will include a rail that will be anchored to the right ventricle apex. [8].

Most technical literature on the heart is focused on the main pumping chamber, the Left Ventricle. Like the right ventricle, the LV has a very dynamic movement, the left ventricular twist, that dominates motion on both sides of the heart [9]. A correlation between the right and left ventricular motion has been shown to exist, with the LV providing the source of motion [10]. Through a combination of MRI tagging, endiocardiographic tracking, and kinematics, the layers of the heart can be modeled and developed into a three-dimensional model for testing. [11] & [12].

Research into motion of the right ventricle has revealed that many groups have successfully determined the motion of the heart from radiology imaging. However, most reports do not include positional data for all degrees of freedom, or only report calculated stress. The method most commonly used by these groups to determine motion of the right ventricle is to produce 3D models of the right ventricle with CT scans of the heart and with software assistance. Once a 3D model is created, measurements can be made to determine the orientation of planes tangent to locations of interest, to provide rotational data. A point of interest can be selected to determine translational data [13] & [14].

2.5. Applicable Standards and Protocols

This section provides information on standards, protocols, and controls that will be useful in conducting and evaluating development results of the dynamic RV model.

- **Waterproofing**: To quantify satisfactory waterproofing of our finished product the IEC 60529 standard can be implemented. This standard is for ingress protection and is denoted by IP*AB,* IP stands for Ingress Protection, A is a number quantifying protection against solids, and B is a number quantifying protection against liquids. As these numbers increase in value, so does the level of protection. For our device an IPX8 rating will likely be necessary. This rating is for continuous submersion, adherence to any particular dust rating is omitted. Verification testing to meet this rating is determined by the manufacturer [15].
- **FDA Controls**: The FDA defines Medical Device Development Tools (MDDT) as devices or methods used to assess aspects of a medical device such as performance. A dynamic RV model would fall into the MDDT subcategory of a Non-Clinical Assessment Model (NAM), as it will be used to predict the function of medical devices. While having a device approved as an MDDT is a voluntary process, thorough documentation of our devices clinical relevance will provide Edwards this option if they choose to pursue it [16].

- **CT Imaging Protocol**: The following recommendations are provided by Bernd Ohnesorge, PhD, for CT imaging of the heart. It is recommended that to achieve a 4D representation (spatial and time) of the heart, between 10 to 12 data sets should be collected for every cardiac cycle. Spatial resolution for multi-planar reconstruction should be between 1 and 2 mm. Analysis based on more data or higher resolution data provides a negligible improvement in usable information [17].

3. Objectives

This section covers details of project scope and deliverables to our sponsor.

3.1. Problem Statement

Edwards Lifesciences is a medical device company specializing in the repair and replacement of heart valves. To advance treatments available, Edwards engineers need a way to accurately simulate motion of the right ventricle to develop and perfect the anchoring mechanism used by Edwards medical equipment to attach to the heart. Because of the right ventricle's complex motion, a device is needed to simulate its motion at specified locations where anchors will be attached. A device capable of this will allow the Edwards team to develop anchors with greater confidence, ultimately providing safer and more reliable treatments for its customers.

3.2. Boundary Diagram

The boundary diagram in figure 2 below shows potential locations the device may interact with, and the space our device can fill. The device interacts with the tissue sample that the anchor attaches to, the device can fill the area around the sample.

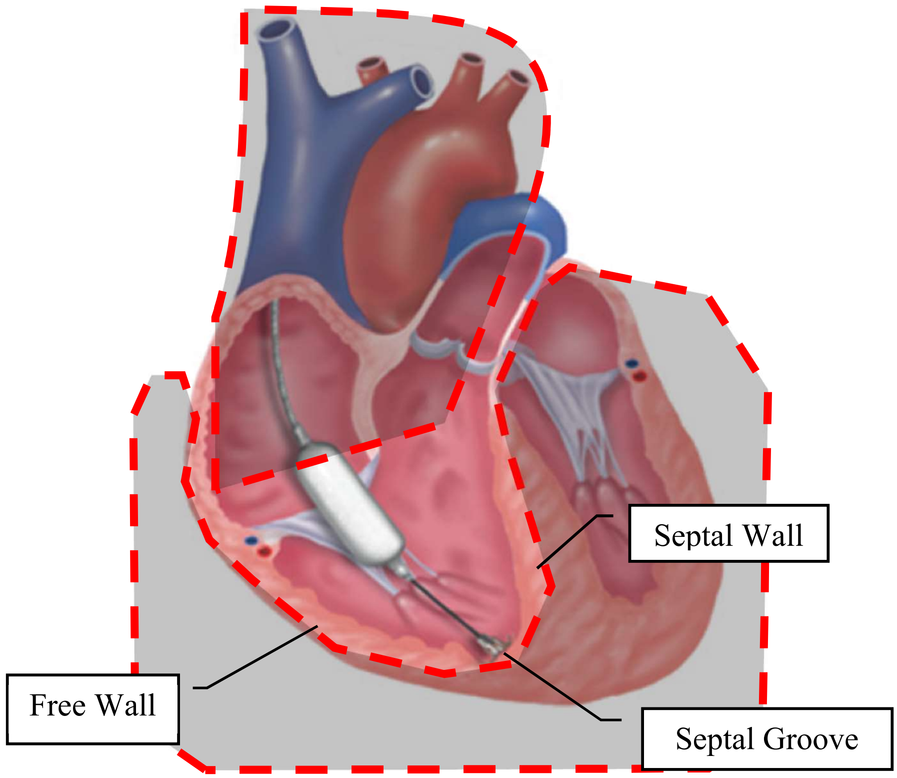


Figure 2. Boundary diagram depicting what our device can interact with in the right ventricle, along with an example of anchor installation. Image Source: [2]

3.3. Summary of Needs / Wants

The most important aspect of the dynamic RV model to Edwards is that it produces clinically relevant motion and conditions. All tradeoffs and assumptions made that may impact clinical relevance must be justified and documented.

To produce the desired motion, a 6 DOF system is desired to simulate motion of the septal wall, septal groove, and free wall. Motion at these locations will be determined from radiology imaging. The motion must be produced onto tissue samples that can easily be attached and removed. To increase clinical relevance, the tissue sample must be submerged during device operation.

All necessary tools, fixtures, and software required to use the device for testing must be provided. Operation and setup of this device must be safe and easy so that it can be done by a single operator. It is also necessary that the device be easily used with a tabletop setup.

All development costs must not exceed $3,000.

3.4. Quality Function Deployment

Quality Function Deployment (QFD) has been implemented to further define and quantify sponsor and user needs. Through QFD, the importance of each need was quantified for our sponsor, the overall Edwards anchor engineering team, and the device operators. Once needs and wants of each user were addressed, these needs and wants were translated into measurable engineering specifications. Finally, QFD allowed for existing methods or potential solutions of anchor testing to be quantified, according to the needs determined. Specifications found in table 2 below are taken from the full QFD chart attached in Appendix A.

3.5. Engineering Specification Table

In the table below, risk is labeled as high (H), medium (M), or Low (L), and compliance will be check by inspection (I), analysis (A), or test (T). These specifications were defined before any design took place. See table #5 for verification of these specifications.

Table 2. Specification Table

Spec #	Parameter Description	Requirement or Target (Units)	Tolerance	Risk	Compliance
1	Translation Positional Accuracy	.05” Translation	.05”	M	T
2	Submersion Depth of Tissue (Lowest Point)	Full Device	Min	H	T
3	Tissue Submersion Time	8 (Hours)	Min	H	T
4	6 DOF	3 Linear, 3 Rotational	N/A	L	I
5	Modular Design	Separate Electronics and Hardware	N/A	M	I
6	Different Patient Profiles	More Than One	N/A	M	I
7	Variable Heart Rate	30-140(BPM)	N/A	L	T
8	Overall Dimensions	1 (FT^3)	Max	L	T
9	Weight	20 (LBS)	Max	L	T
10	Software Setup with Minimal Effort	10 (Mins)	Max	L	T
11	Current Between Modules	10 A	N/A	L	T
12	Surface Temperature	100 (F)	Max	L	T
13	Reproduce Motion of Septal Wall, Septal Groove, and Free Wall	3 Locations	Min	M	A
14	Development Cost	$3,000	Max	M	I
15	Tissue Replacement Time	10 (Mins)	Max	L	T
16	Rotational Accuracy	1^{o} Rotation Accuracy	1^{o}	M	T

3.6. Specification Measurement

This section is to demonstrate that each specification can be measured using available equipment.

Many specifications can be verified by dimensional measurements. The simplest, submersion depth and overall product dimensions can be checked with a ruler. Higher tolerance position accuracy requirements can be measured directly for translational with calipers and rotation with an inertial measurement unit.

Other specifications require basic equipment such as a timer for time requirements, a scale for weight, and an infrared thermometer for max temperature. The remaining specifications will be confirmed by inspection.

3.7. High Risk Specifications

High risk specifications are related to submersion capability, due to the risk liquids pose to electromechanical equipment. Because this risk is unavoidable without limiting the usability of the device; it will be reduced when possible through consideration of equipment layout and ingress protection methods during development.

4. Concept Design Development

This section covers the ideation process and a thorough description of the selected concept.

4.1. Concept Development Process & Results

The two main challenges that solutions need to develop for are the clinically relevant movement of the tissue and the attachment of the tissue to our device. During ideation sessions, many solutions were developed for these functions through brainstorming and brainwriting. Next, concept models were made to visualize these ideas and to see if they were feasible. Sketches or pictures of these concepts are below in figures 3-8.

4.1.1. Creating the Motion

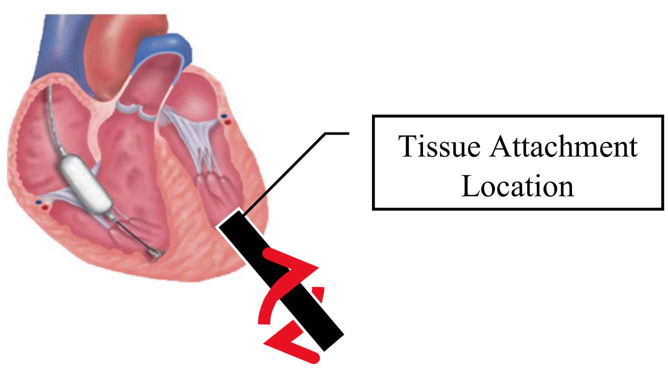


Figure 3. Diagram of a rotating shaft to create motion. The shaft will be attached to the heart through the left ventricle, and a twist along with translation will be applied to cause motion in the right ventricle.

Figure 3 is a diagram of the Rotating Shaft, one of the three final concept ideas analyzed with the weighted decision matrix. Pros associated with this design include the ease of integration with an actual heart, as well as robustness. Cons include a lack of precision when trying to simulate the three key locations.

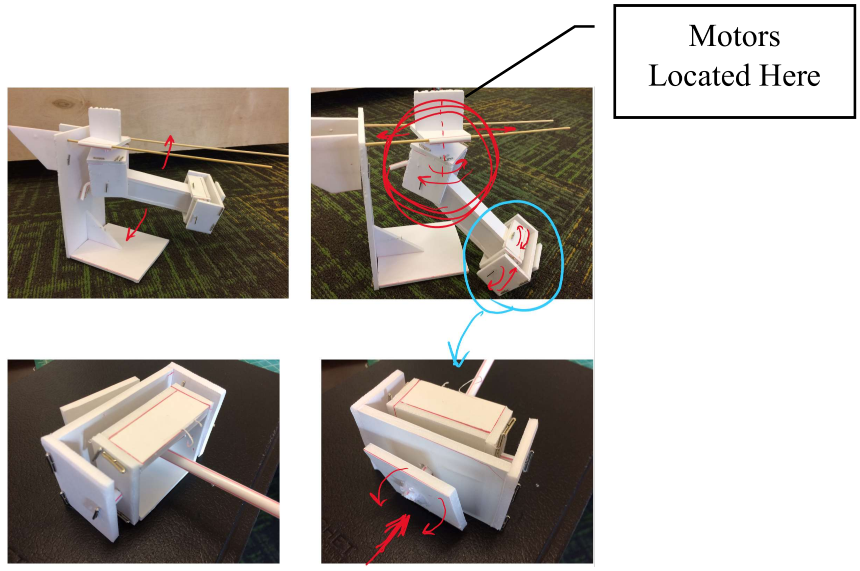


Figure 4. Concept model of a robotic arm designed to create motion on a tissue sample. The arm would be above a tank of water with the platform holding the tissue sample hanging down into the water.

Figure 4 documents the Robotic Arm design. This design provides 6 DOF while keeping all electronics away from the water in the tank. The size and multitude of components provide negatives for this design, ultimately leading to a non-robust device.

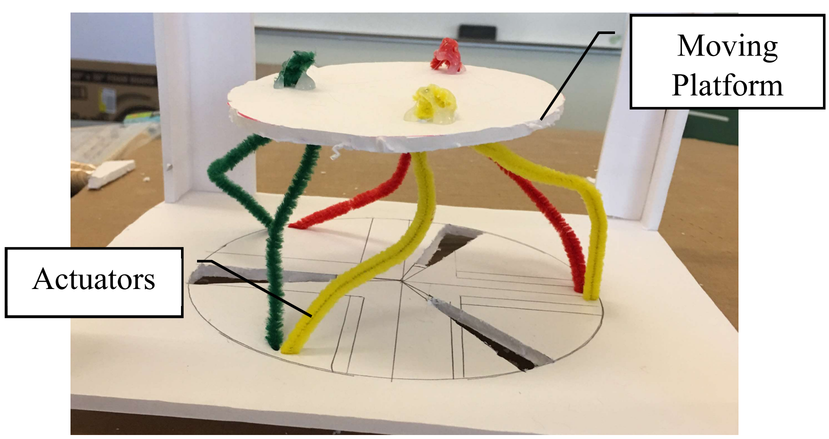


Figure 5. Concept model of a Stewart platform. The colored, fuzzy wires above will lengthen and shorten causing movement with six degrees of freedom at the top platform where a tissue sample would be located.

Figure 5 is an initial concept model of a Stewart Platform design. The benefits of this design include precise motion with minimal components necessary for manufacturing. A negative of this design stems from synchronizing the motion of 6 actuators. This can lead to complex motion design and a need for efficient software development.

4.1.2. Tissue Attachment

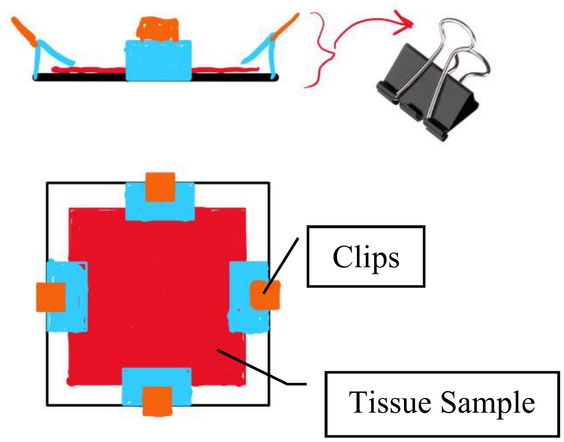


Figure 6. Sketch of the four-clip method of clamping down a tissue sample. A small, square tissue sample will be secured by four clips, that will then be attached to our movement device.

Figure 6 is a rough sketch of the Four-Clip design. The benefits of using this design include low cost and an easy manufacturing process. The negatives arise when using this design with x-ray imaging, seeing that the clips would likely be made of metal.

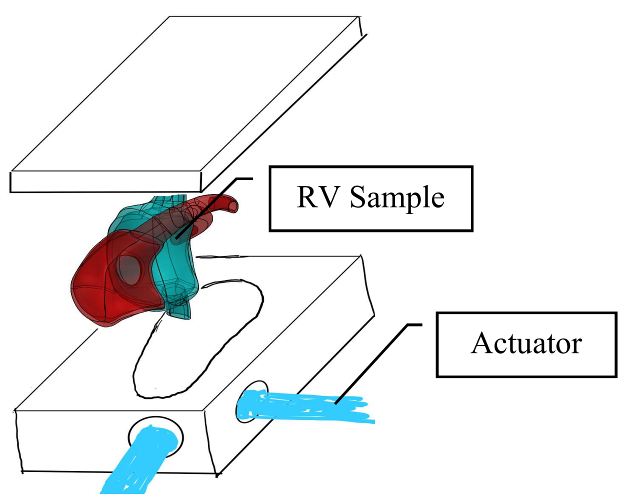
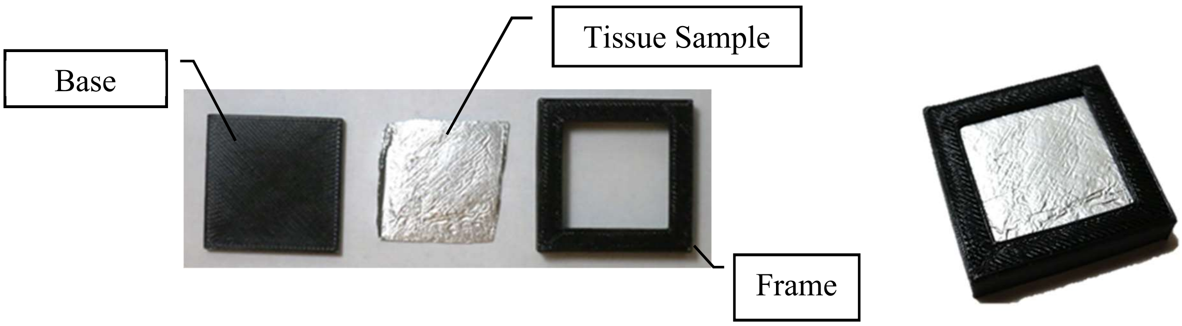


Figure 7. Sketch of a shaped container to hold a heart or right ventricle while motion is being applied to it.

Figure 7 details the Shaped Container design. This design is meant for simulating motion with animal hearts and right ventricles, providing a location to put a large tissue sample that can then be used to simulate motion. While this design would work for modeling the whole heart more accurately, problems may arise with heart samples that vary in size as well as when trying to acquire precise motion.



(a) Clamp Frame Components (b) Mockup Assembly

Figure 8. 3-D printed prototype of a clamp frame to hold a rectangular tissue sample. The tissue sample will be placed between the two parts of the clamp which will snap together.

Figure 8 details the Clamp Frame design. This design provides the largest benefit when it comes to security and preventing the tissue sample from undesired motion. The most significant negative is that the tissue sample must be a certain size to be secured to the motion device.

4.2. Concept Selection Process & Results

Initial ideas that were found to not be feasible were discarded. The remaining ideas from each function were then analyzed in a Pugh matrix. Each function was evaluated based on the criteria found to be most significant to each function. For the movement function, the criteria the solutions were judged on was the capability of 6 degrees of freedom, C-arm clearance, x-ray compatibility, fitting on the operating table, an easy setup, safety, submersion, and repeatability. For the tissue type, the criteria were cost, set-up time, easy to move and attach, similarity to actual procedure, and amount of waste. Finally, the attachment method criteria were setup time, minimal damage to tissue, waste, ability to be cleaned, x-ray compatible, and tissue security. Lastly, each solution was compared to a datum and scored with a plus, minus, or same for each criterion. The top solutions from each function became a part of a morphological matrix that mixed and matched each function. After discarding a couple of the non-feasible combinations, we added the rest to a weighted decision matrix.

The weighted decision matrix consisted of combinations of the ideas sketched above. For a full list of the items on the matrix see appendix B. The ideas were scored on new, weighted criteria which allowed us to converge on a solution to move forward with. In descending order, the criteria we found to be most crucial to the design were precision of motion, tissue replacement time, tissue submergibility, robustness, cost, size, and simplicity of creating motion. The Stewart Platform, tissue sample, and clamp frame was the combination that scored the highest on our matrix, and this confirmed what our intuition told us was the best idea. All the afore-mentioned matrices may be found in appendices F, G, and H.

4.3. Concept Model

To better visualize how to produce motion using a Stewart platform, a mockup design was created for the concept model. The model was actuated using six levers located at the base of the platform. This made it possible to visualize and physically actuate the device to produce different motions. The model was sized approximately the same as the final design is expected to be. In addition to visualizing the motion and control necessary for a Stewart platform, the proposed seal method was included (discussed in section 4.4.3.). For the prototype, the seal was constructed of a plastic bag, which allowed for all six degrees of freedom to be expressed without significant interference to motion.

(a) Prototype of a finger-actuated Stewart platform

(b) Prototype in Use

Figure 9. Mockup finger actuated Stewart platform used to visualize how motion is created with a Stewart platform, and how a seal may be created around the platform.

4.4. Selected Concept

The selected concept for producing motion of the right ventricle to test anchoring systems is intended to be broken down into several modular subsystems. An advantage of this method is faster system development by having fewer dependencies between systems; reduced dependencies also make it possible to improve and modify the system in the future. In this way, the scope of the project can be narrow enough to provide reasonable confidence that the project will be completed on time, but future work can easily be done to expand device capabilities.

The proposed concept consists of a custom Stewart platform which produces the desired motion. To transmit this motion to the appropriate location in space, custom tissue adapters will be made for each target location. To accurately represent the conditions the anchor system experiences, a model of the pathway the catheter takes to the target locations is included. All these systems are built within a tank that can be filled with water to better represent the environment of the heart. The complete system is anticipated to fit within a cubic foot. A simplistic CAD model showing the approximate layout of each of these systems is shown in figure 10 below. The following discussion details the various subsystems, and how they interact together to produce a realistic and expandable RV model.

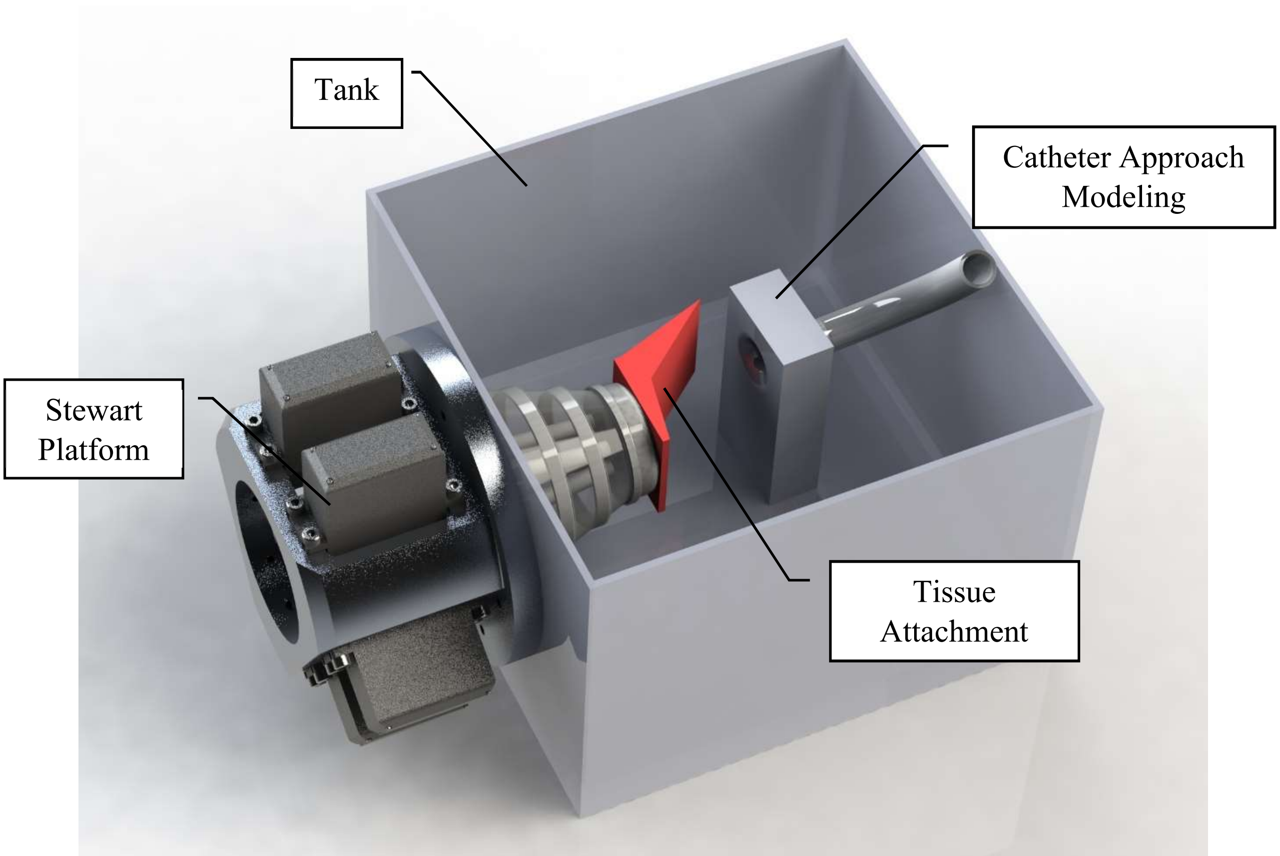


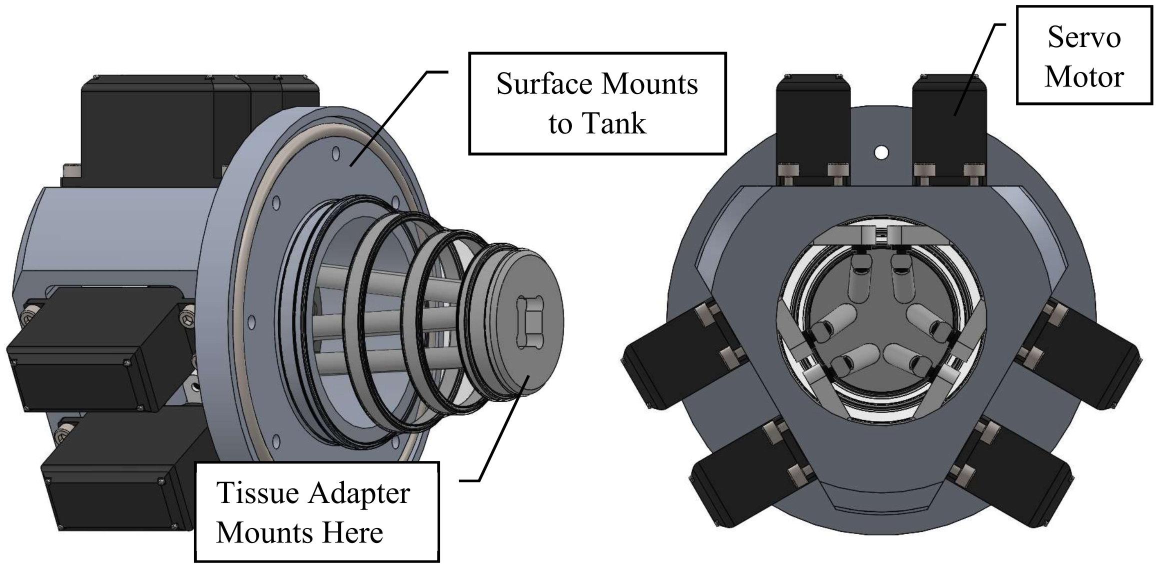
Figure 10. Mockup of design solution for modeling motion of right ventricle to test anchoring systems. Shown: Simplistic models of catheter approach, an example of a tissue attachment device, and the Stewart platform.

4.4.1 Tank

Subsystems used to model the right ventricle and relevant features of the heart are combined by attaching to a large tank. To setup the test, the tank is placed onto the operating table and filled with water to an indicated height. Clear materials can be used to construct the tank, so operators can see the anchors interaction with the target wall location throughout the cardiac cycle (when appropriate tissue adapters are used). To reduce manufacturing time, it may be adequate to modify an acrylic fish tank. The Stewart platform will be mounted to one side of the tank through a circular hole. The catheter approach modeling will be fixed in place at the opposite end of the tank

4.4.2 Stewart Platform

To produce motion of the target locations in the right ventricle, a Stewart platform like that shown in figure 11 below will be used. The Stewart platform assembly shown here is assumed to use six servos to move rods that connect to the platform where the tissue adapter attaches. However, other actuation methods are possible. The Stewart platform will be screwed onto the tank with a backing plate located inside the tank to distribute pressure from the screws, if necessary.



(a) Front of Stewart Platform (b) Rear of Stewart Platform

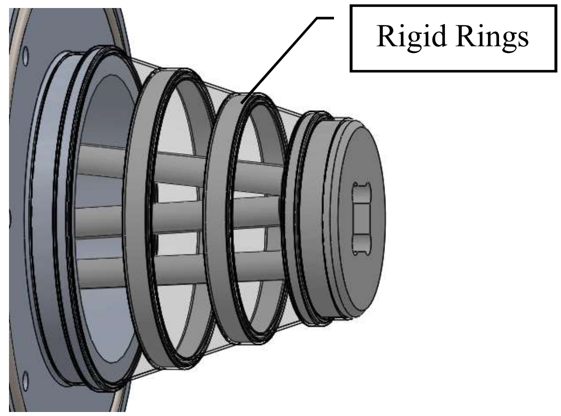
Figure 11. Concept Stewart platform design.

One goal of the Stewart platform design is to separate difficult to waterproof electrical components from the water, this is discussed in detail in the following section. Another consideration is to keep all electrical and metal components away from the tissue attachment site, so x-ray imaging of the anchor while testing is possible. This was accomplished by cantilevering the tissue adapter attachment location into the tank; all components extending into the tank will be metal free. While the design shown above is not production ready, it was designed with manufacturing in mind. The Major housing that holds the servos can be manufactured by hand using a combination of lathe and mill.

4.4.3. Stewart Platform Seals

To successfully execute this design, sealing is needed where the Stewart platform mates to the tank, for all fasteners used to attach the Stewart platform to the tank, and across the gap between the tank wall and the tissue adapter attachment location. Sealing where this module mates to the tank can easily be accomplished through soft, medium to large diameter, O-rings or a soft rubber gasket. The advantage of using an O-ring is that the gland requirements for the seal are well documented, and the rings are readily available. Assuming machine screws are the fasteners used to mount this module to the tank either threading the screws into blind holes or using Teflon tape on the threads will be sufficient. The seal spanning between the mounting location and the tissue adapter location, shown in figure 12 below, is the most technically challenging seal as it must be able to move with the end of the Stewart platform which will be both translating and twisting (including axially).

(a) Prototype Seal



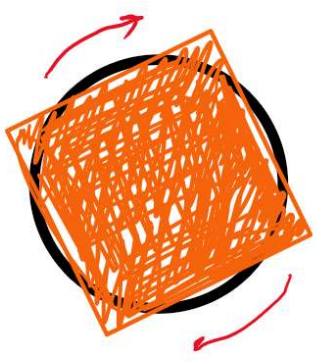
(b) Mockup Seal Design

Figure 12. Proposed design for the seal that extends from the base to the end of the Stewart platform.

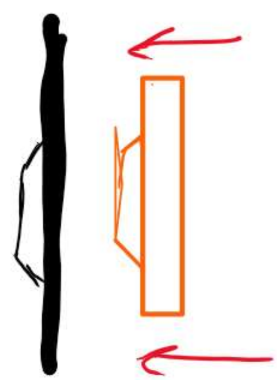
This seal must not significantly impede motion of the platform while remaining water tight. The proposed solution to this problem is to use a flexible and/or baggy design that can be used to bridge the gap between these two components. Because it is anticipated that water pressure surrounding the seal will push it inwards towards moving components where it may interfere or get worn prematurely, the inclusion of rigid rings placed intermittently along the seal is proposed to keep the seal from resting against other components.

4.4.4 Tissue Adapter

At the end of the Stewart platform is where the tissue adapter used to model different target locations within the heart attaches. The concept is that a tissue sample can be loaded into the adapters off the machine, so that the operator does not have to struggle to insert the tissue underwater and at what may be an unusual angle. Once the tissue is loaded onto the adapter, the adapter is connected to the end of the Stewart platform. Examples of how this may take place are shown in figure 13 below.



(a) Twist On

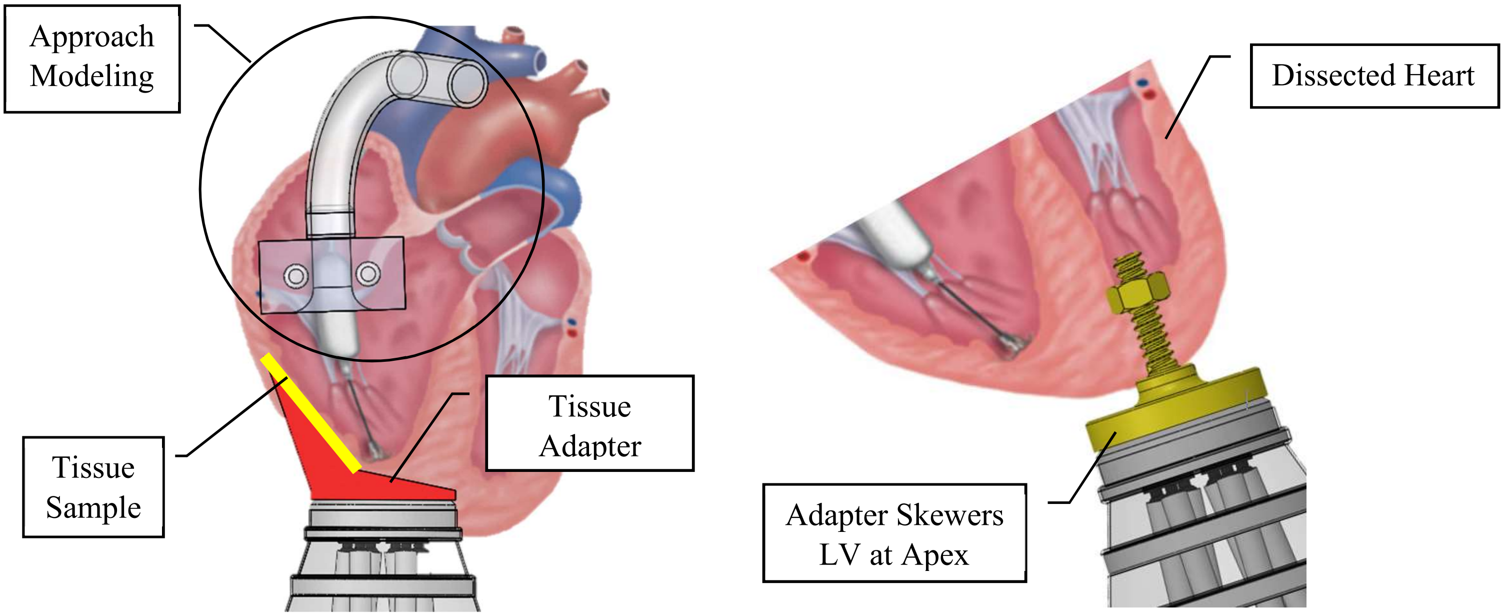


(b) Snap On

Figure 13. Example of how the tissue adapters could connect to the Stewart platform. Black represents the platform while orange represents the tissue adapter.

Tissue adapter installation could be further simplified by using software to tilt the end of the platform up when installing the adapter. The adapters could be indexed to ensure correct orientation when installed. By using adapters to install tissue samples onto the Stewart platform, new adapters can be created in the future if needed.

Because different target locations need to be modeled with this device, and the model must be oriented as a patient would be on the operating table; it is necessary to either move the device for each target location or produce unique tissue adapters for each location. In the interest of repeatability, and setup simplicity, it was decided to exchange tissue adapters. The motion profile generated by the Stewart platform will be adjusted to account for the unique offset of the tissue sample from the end of the Stewart platform for each adapter. Two adapter styles were selected to move forward with in the design, these are shown in in figure 14 below.



(a) Flat Tissue Adapter at Free Wall (b) Dissected Heart Adapter

Figure 14. The above represents the two tissue adapters selected to move forward with in the design. The flat tissue adapter uses a small square of tissue, custom adapters are constructed for each target location. The dissected heart adapter uses a sample containing both the RV and LV from an animal. These are mockups of how the adapters function, not a final design.

The first tissue adapter is designed to work with a small tissue sample using the clamp frame method first shown in section 4.1.2. It is anticipated that having a solid surface behind the tissue sample could make anchoring to this sample unrealistic. To remedy this problem, a cavity can be included behind the tissue sample once it is on the adapter, shown below in figure 15.

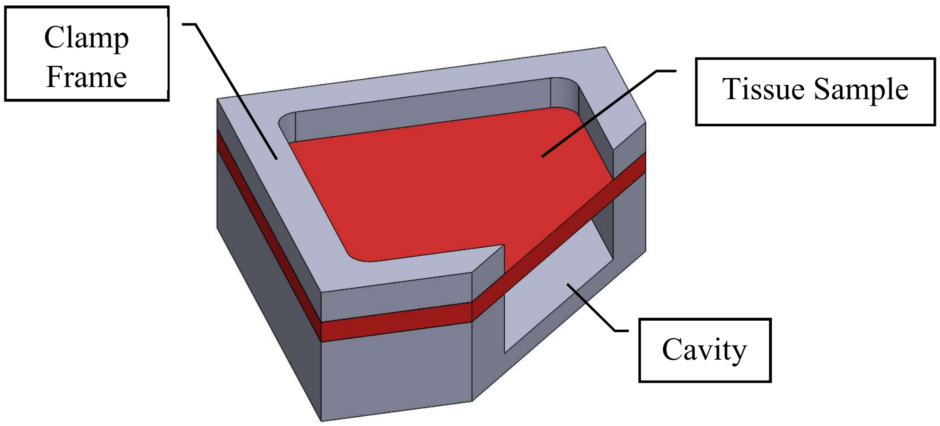


Figure 15. Mockup of how the tissue can be installed onto the flat tissue adapter. Cutaway shows how a cavity can be incorporated under the tissue sample to better model actual heart.

The flat tissue adapter would come in three different orientations for modeling the different target locations. The space between the modeled tricuspid valve (discussed in section 4.4.5) and the flat tissue adapter will be left open. This will provide the benefit to the engineering team that they can directly observe, photograph, and videotape the anchoring system interacting with the tissue sample.

The second tissue adapter that will be developed operates by skewering the apex of the left ventricle. This method has the advantage of leaving the right ventricle intact, creating a more realistic environment for the anchor.

For X-ray compatibility, these adapters will need to be plastic. As a result, it will be feasible to 3D print the adapters, allowing for quicker prototyping and reduced manufacturing time for the final design.

4.4.5. Catheter Approach Modeling

Catheter approach modeling deals with guiding the anchor system to the tissue sample in a way that represents the actual procedure and locating the FROMA spacer as it would be in a real heart. Without this, exerting motion on the tissue sample would not cause the same forces to develop on the anchor as occur in a real heart. To accomplish this, a static model of the subclavian vein leading to the right atrium, the right atrium, and the tricuspid valve will be created. The regions to be modeled are outlined in figure 16 below.

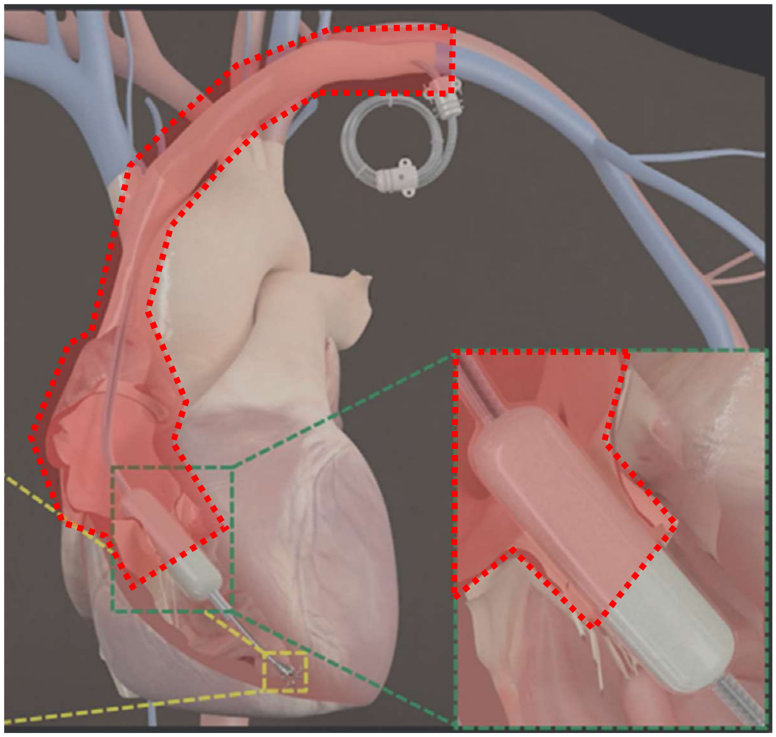


Figure 16. The area outlined in red contains the features that are to be produced using plastics and soft materials such as silicon to reproduce the catheters approach to the tissue sample.

4.4.6 Components Not Shown

While this CAD mockup demonstrates many of the subsystems needed to accurately represent the environment within the right ventricle from the perspective of the anchoring system, there are several aspects of the design that have been omitted. While software and electronics must be developed to utilize the functionality of the Stewart platform, these components will be largely influenced by the selection of actuators and any sensors deemed necessary on the device. As a result, these aspects of the device will be fully defined later.

4.5. Selected Concept Functionality

Through the early design phase, our project sponsor has brought up many great ideas to create the most relevant model possible for anchor testing. While we attempted to address as many of these needs as possible, the above proposal was crafted with consideration for the time available to complete this already ambitious project. We believe the above design will produce a relevant and valuable tool for testing anchoring systems. Furthermore, we believe pursuing the above design direction with our sponsors suggestions that we are not able to implement in mind, will make the addition of these features in the future feasible, perhaps by another senior project team.

While we find it necessary to keep the scope of our project narrow to deliver a functioning and useful product to our sponsor, the selected design direction meets the needs for evaluating anchoring systems.

To create motion, the Stewart platform provides the 6 degrees of freedom that will make it possible to recreate the motion of any single area at a time on the right ventricle. Two different tissue adapter styles allow for different tissue types to be used, and new adapters can be made in the future for different tissue types, and target locations. In addition, the Stewart Platform can be updated with new motion profiles in the future.

Modeling of the catheter approach to the tissue sample is the other critical aspect to realistically creating a model of the right ventricle, from the perspective of the anchoring system. This will be accomplished in our model using a combination of tubing and more complex models of key features such as the right atrium and the tricuspid valve that the anchor system passes through on its way to the target location. To best represent the environment of the heart, the catheter approach model, as well as the tissue sample will be submerged in water.

Along with creating a realistic environment for the anchor system, our device satisfies the needs of the testing environment at Edwards. To do this, components located nearest the tissue sample have been designed so that they can be manufactured out of low density materials such as plastic. This allows for x-ray imaging of the anchor while it interacts with our model. The device has also been sized small enough to easily fit on an operating table and clear the C-arm.

4.6. Risks & Unknowns

The current risks we are aware of and need to assess further are our ability to seal the device to prevent water from interacting with the electronics, and allowing for x-ray compatibility.

While the design of the seal has been discussed (see section 4.4.3.) in detail, testing will need to be performed early in the process to ensure the design works. The constant movement occurring within the sealed area must not be able to displace the seal and or create a hole in the material chosen.

Materials with higher densities appear darker in x-rays than materials with lower densities. With that in mind, a plastic tissue adapter with a density close to 1300 kg/m^3 and a nitinol anchor with a density of 9000 kg/m^3 would ideally contrast well with water in an x-ray machine.

Once actuators have been selected for the Stewart platform it is desired to produce a rapid prototyped (3D printed) version of the Stewart platform module that can be used to begin writing, testing, and debugging code to operate the platform as early as possible.

We will also need to develop a basic tissue attachment device and send to Edwards to get feedback on how well it works.

Lastly, a design hazard checklist has been attached in Appendix I.

5. Final Design

The next section focuses on the final design and the steps taken to determine this design.

5.1. System Modeling

To reproduce motion of the right ventricle, it is necessary to first determine this motion. This was done in two main steps. First, CT scans of the right ventricle were segmented through various points in time using ITK SNAP as seen in figure 17. These segmentations were then analyzed using a custom MATLAB script to determine motion.

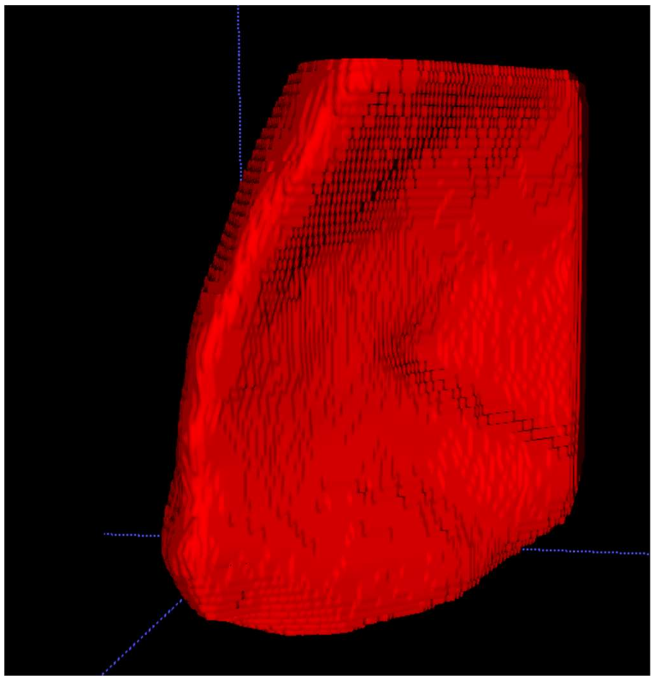


Figure 17. Example of right ventricle segmentation shown inside ITK SNAP. The septal wall is visible along with the apex.

To produce the segmented right ventricle within ITK SNAP, the user identifies the general region of interest and the segmentation is auto generated from there. This approach is both faster, and more repeatable than manually segmenting each image. For images where the scan resolution exceeded the recommendations discussed in section 2.5, resolution was reduced improving repeatability and reducing errors when producing segmented right ventricle models.

After creating a set of segmentations for one cardiac cycle, the segmentations are loaded into custom MATLAB code to determine motion. First, a point cloud of each segmentation is generated, followed by the identifications of general regions within the right ventricle (free wall, septal wall, front edge) as shown below.

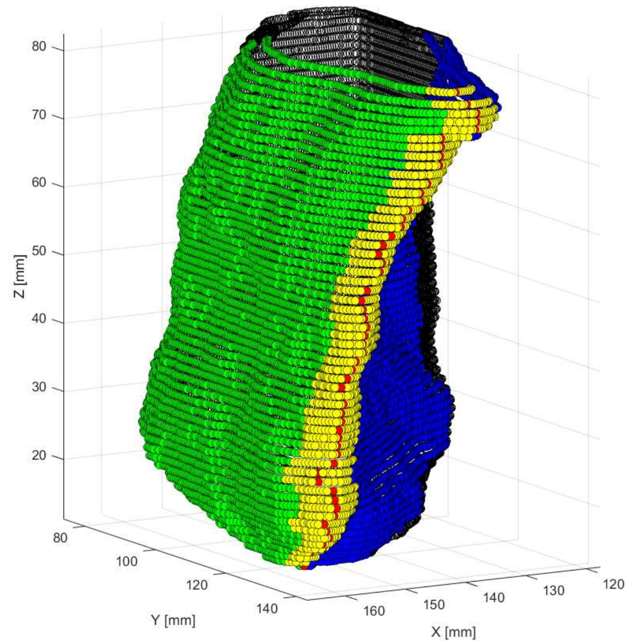


Figure 18. General region identification of right ventricle by MATLAB script. Green: Free Wall, Yellow/Red: Front Edge, Blue: Septal Wall, Black: N/A

Several user variables can be used to adjust how each region is defined. From here the apex location of the right ventricle is identified, followed by a target location on both the free and septal wall. Because there is no way to track a given location within the free or septal walls on their own, the location of the apex through time is used to guide the selected locations on these walls through time. Again, the user can adjust parameters of the selection. An example of identified target locations is shown below.

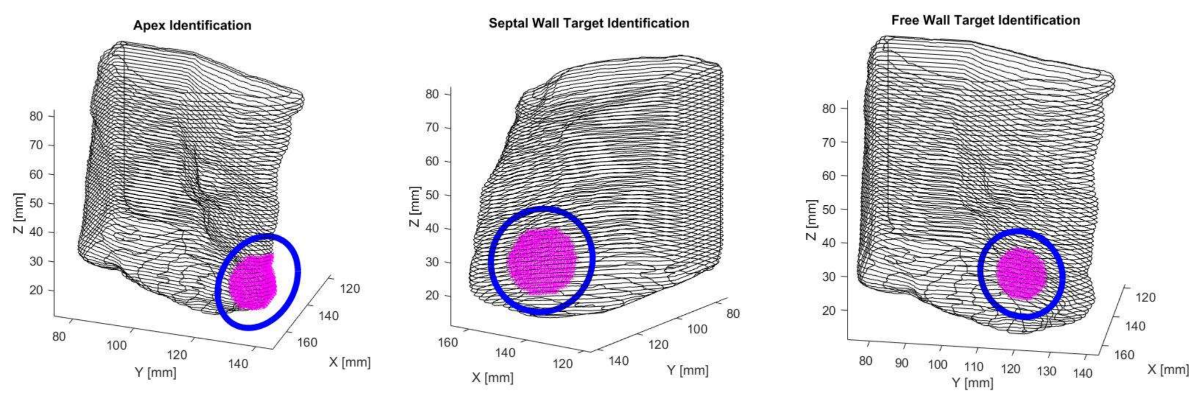


Figure 19. Example of identified target locations at one point in time. The shape constructed of black lines is the segmented right ventricle. The magenta portion represents the points selected within the target region, while the blue circle is on a plane normal to, and through the center of the magenta region.

While target locations are identified as a single point initially, noise in the source images and segmentation can cause any given point to shift substantially from one point in time to another. To resolve this, a sphere of a user defined radius is drawn around the anticipated target location point. All points in the point cloud within the target locations general region (i.e. a septal wall target and the septal wall general region) that fall within this sphere are identified and the average location of these points is treated as the location of that target point, for that instance in time. This collection of points is also used to draw a vector normal to them to determine orientation of this target location at the instance in time they are being analyzed. This method allows for less noise in the resulting motion, along with better visualization of where motion is being determined. One drawback of this approach is that rotation about the axis normal to a given surface cannot be determined. However, without physical points to track along a surface of the right ventricle, it is unlikely that this motion could be determined, even with a different analyses method.

As of CDR, the above analysis method has been completed for one CT scan. To make the raw motion data useful for continuous motion simulation, the beginning and end motion locations are made equal, and interpolation is used to increase the number of data points, as shown below.

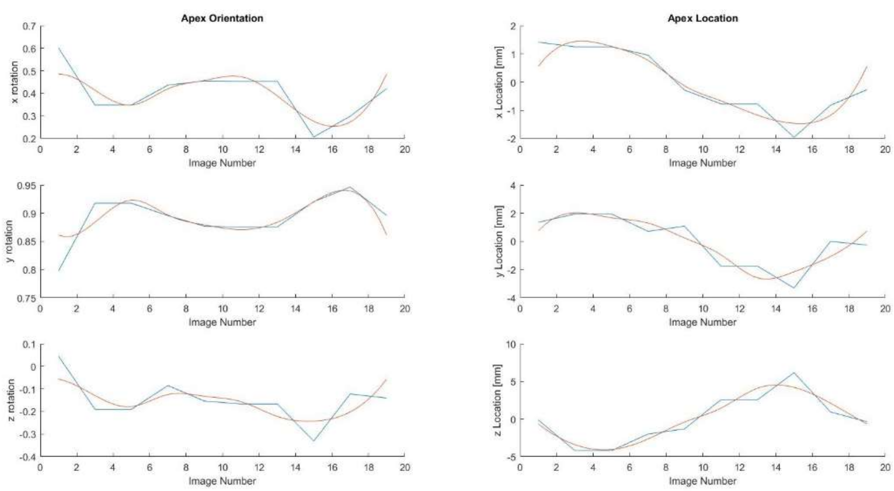


Figure 20. Example of output data from the motion analysis of the Apex for one set of right ventricle segmentations through time. Apex orientation is shown here as the components along each axis of a vector drawn normal to the apex target location. Motion is the translation of the apex target location. Keep in mind the axis have not been oriented in a meaningful way at this point. The blue line represents raw data, while the orange line has been interpolated.

After successfully determining motion, the above modeling was expanded to include a model of a tissue adapter and that of a Stewart platform as shown below. This made it possible to simulate the test system discussed during PDR, before developing a functional CAD model.

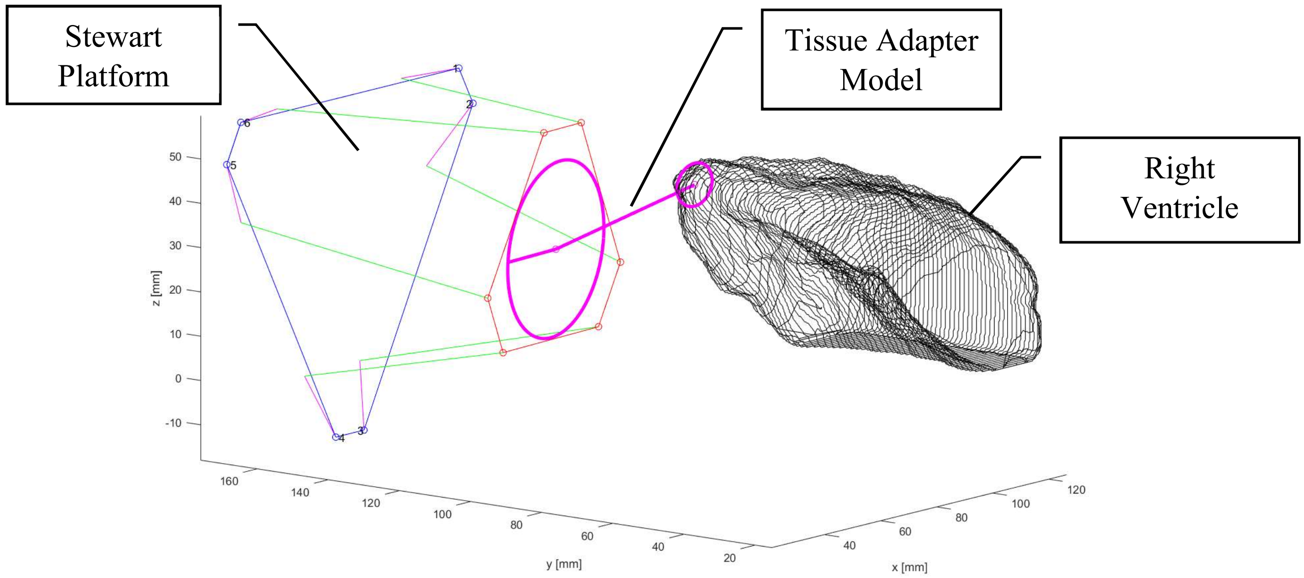


Figure 21. MATLAB Model of motion system at one instance in time. The model incorporates the right ventricle, as well as a mathematical model for a tissue adapter and a Stewart platform.

The model is created by first using transformation matrices to place all components in an orientation as close as possible to how they would be within an actual patient on an operating table. The Stewart platform is initialized at a neutral 'home' position, and the tissue adapter is generated as attaching from there to the average location of a given target location on the right ventricle. After initialization, the tissue adapter model acts as a rigid body, rotating to the orientation of the target location for each point in time. Because the tissue adapter is modeled as a rigid body, as one end rotates to match the current orientation and position of a target location, the rest of the model must pivot about and translate with the target location. Because of this, the motion and orientation of the end of the tissue adapter model that mates with the Stewart platform is greater than that of the target location.

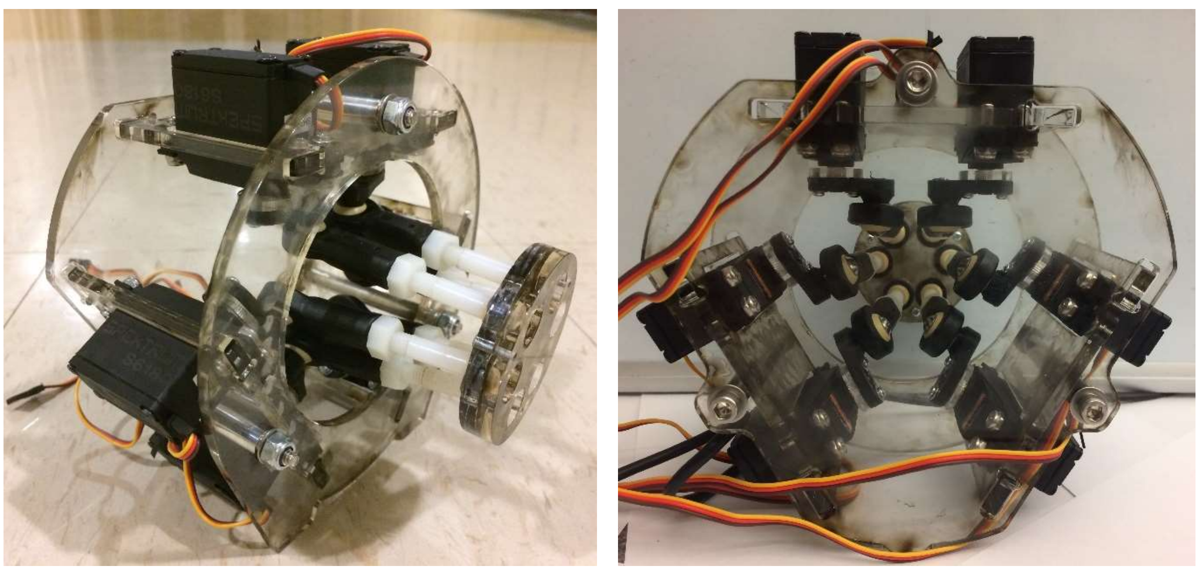
The Stewart platform model takes translation and rotation parameters at the end effector and converts it into servo angels as a result of user defined geometry. This code is based on modified code provided by Rama Adajian, another Cal Poly student. Modifications to this model allow it to report parameters such as swivel on spherical bearings and rod ends used in the model, as well as servo speed requirements and the range of servo angles utilized for a given motion profile, among other measurements.

Ultimately, this model was used to determine appropriate platform geometry for this project. This was done by running the model for motion profiles of all three target locations. Because the motion data available all originated from the same CT scan, a multiplier of 1.5 was added to exaggerate the motion and ensure future motion profiles will be compatible. When determining platform geometry, the goal was to use 100 degrees of servo motion and keep max servo speeds within the range of most available servos. While most servos can travel 120 degrees stop to stop, only utilizing 100 degrees allows for any calibration that may be necessary to occur without reducing the range of motion that can be produced.

A quick calculation of anticipated force on the end effector due to water pressure found that any given servo has several times the torque needed to support the platform on its own. Because six servos will be operating in unison, it is believed that forces would be both very difficult to determine for this platform, and unnecessary. In addition to this, many of the components such as rod ends, and spherical bearings were purchased based on the smallest sizes readily available, which were still oversized for our purposes, so again the main design challenge for the platform was one of kinematics.

5.2. Design Considerations and Structural Prototype

The structural prototype was used to test manufacturing methods, components, and geometry determined from the MATLAB model. The assembled structural prototype can be seen below, followed by a discussion of what was learned from its creation.



(a) Front View (b) Back View

Figure 22. Structural Prototype manufactured primarily out of laser cut acrylic. The scorched edges were caused by debris in the base of the laser cutter igniting while cutting the acrylic. This issue will be resolved in the future by using tape or something similar on the bottom face of the acrylic when cutting.

The structural prototype was designed to both implement the appropriate platform geometry, as well as make manufacturing and assembly as easy as possible. One method used to achieve this was to design the main housing that holds all the components out of acrylic sheets that fit together like puzzle pieces using three main bolts. By laser cutting the acrylic panels, manufacturing of the housing can take place in a matter of minutes. By leveraging additional rapid prototype methods such as 3D printing when possible, the entire structural prototype can be constructed in approximately five hours.

In addition to being used to construct the housing, laser cutting was tested as a means of producing custom servo spline adapters. While initially it was unclear if the laser could produce the detail necessary, after iteration of several sized parts a fit was found, as shown below.

Figure 23. Laser cut servo spline adapter. Holes on sides are threaded so that the laser cut portion can be used with more complex 3D printed parts that wouldn't be able to incorporate a strong or detailed enough spline.

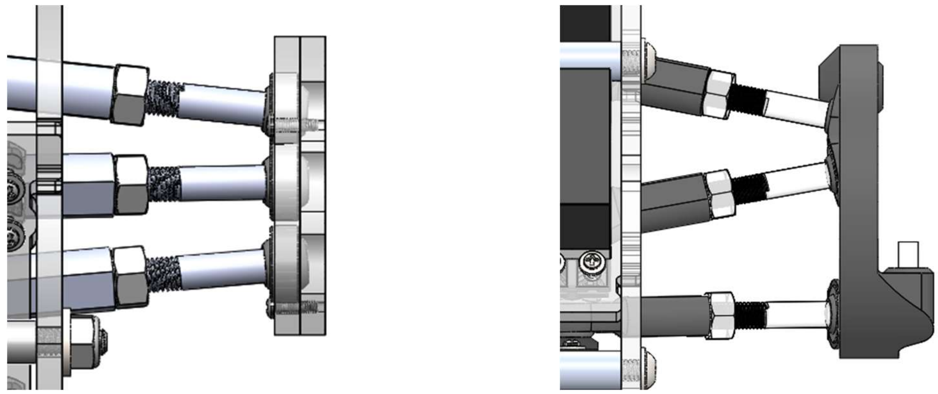
While the structural prototype demonstrated that most components can be manufactured and assembled in a matter of hours with the resources available at Cal Poly, it did raise the need to redesign platform geometry.

It was found on this prototype that significant motion of the end effector was possible without changing any servo angles. While the potential for this problem was known, it was hoped that by making the diameter of the base of the Stewart platform larger than that of the end effector, triangulation between any given connecting rod and the opposing rod would mitigate free motion. Unfortunately, this approach was not successful, and a redesign was needed.

5.3. Current Motion System Design

While the structural prototype validated many of the components and manufacturing methods intended for the final motion system hardware design, it did not address waterproofing. Additionally, it raised the issue of inadequate platform geometry.

To address the issue of platform geometry, the approach was shifted from trying to create triangulation by having the connecting rods produce a cone from the larger diameter base to the end effector; to instead make both components similar diameters and produce the triangulation between opposing connecting rods, as visualized below.



(a) Structural Prototype Geometry (b) Updated Geometry

Figure 24. Side view of connecting rods leading to end effector. The updated geometry produces greater triangulation between rods compared to that of the structural prototype, which is expected to eliminate unintended movement of the end effector.

The updated geometry now matches that used by commercially available Stewart platforms. To help facilitate this new geometry, the end effector of the platform was redesigned to be a 3D printed part, which allows for the spherical bearings to be inserted at an angle, so their rotation limits are not reached as quickly. 3D printing also allows for a method of attaching the tissue adapter to be incorporated into the end effector, along with part of the seal (discussed more in section 5.4 & 5.5).

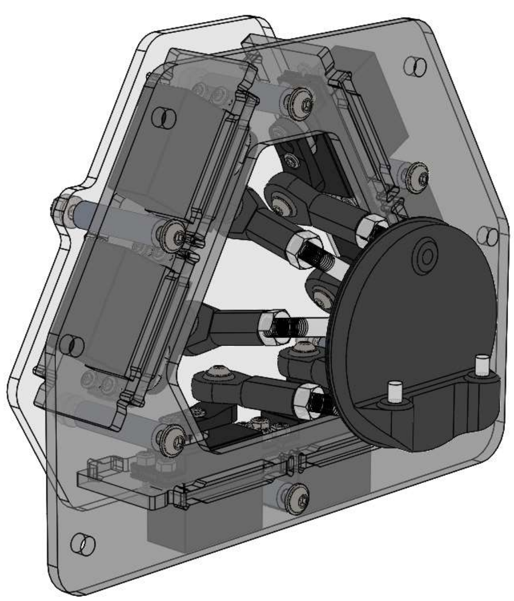


Figure 25. Updated core motion system design. Shares many components and manufacturing methods that were successfully tested with the structural prototype, but overall geometry has changed.

Along with increased rigidity, this updated geometry allows for the servos to be rotated towards each other, significantly reducing the overall length of the assembly. Because the entire assembly will be built into a waterproof enclosure, this reduced depth allows for better packaging and reduces the issue of having to counteract buoyancy on the device when under water.

The method being pursued to make the above hardware waterproof is demonstrated below.

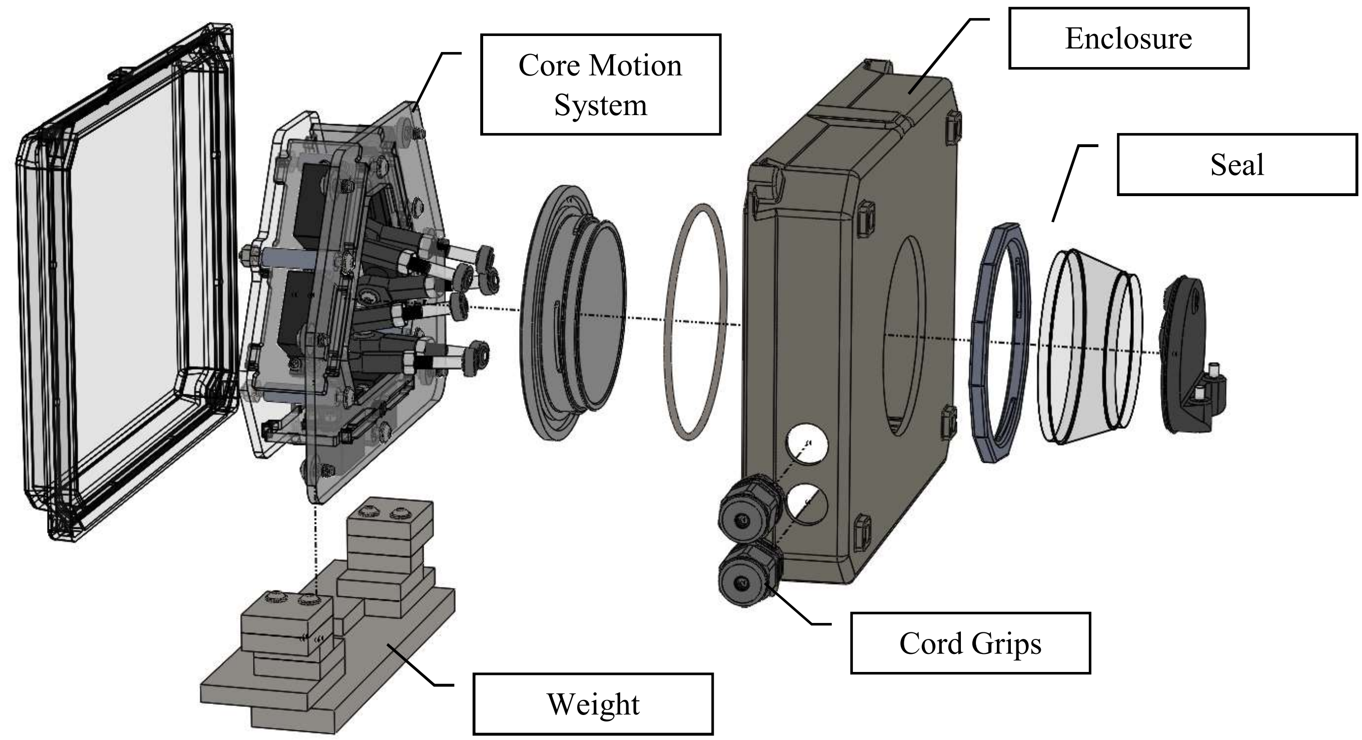
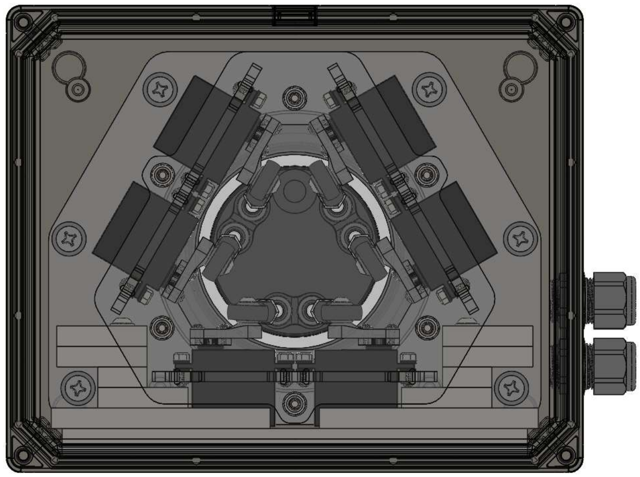
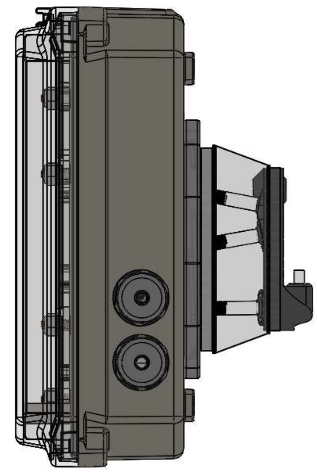


Figure 26. Assembly of motion system into waterproof enclosure. The flexible seal is mounted through a hole cut into the back of the enclosure. Watertight cord grips are used to allow for power and data cables to reach the servos while it is submerged. A steel weight is placed towards the bottom to help counteract buoyancy.

As discussed, the motion system will be built within a modified commercial waterproof enclosure to ensure it can be used underwater. The modifications necessary to the box include cutting a hole for the end effector to go through, and then incorporating a seal around this hole. In addition, cord grips are used for power and data cables to be supplied to the servos, along with a large weight to counteract buoyancy. This system fully assembled is shown below, followed by a discussion of the seal.



(a) Motion System Rear View



(b) Motion System Side View

Figure 27. Assembled motion system enclosure. Images shown with end effector at its neutral home position. All components extending beyond the face of the tank are plastic as to not interfere with x-ray imaging.

5.4. Seal

The seal will prevent all water from entering the enclosure while still allowing the Stewart platform to move through its full range of motion. This will be done by a combination of a hard, internal seal with an O-ring and a thin, flexible seal membrane outside the enclosure. As seen in the overall layout in figure 28, the internal seal will have an O-ring in it on the inside of the box, and it will extend through the hole in the box. The seal lock ring will be placed around the internal seal on the outside of the enclosure. They both have notches on them that allow them to tighten with a clockwise turn. This will create the force necessary for the O-ring to be effective. Lastly, the flexible seal will be secured from the end of the internal seal to the end effector which both have lips to accommodate the seal membrane.

For the final design, both the internal seal and the seal's locknut will be 3D printed using one of Cal Poly's 3D printers. The O-ring will be ordered off McMaster and is made from Buna-N Rubber. Finally, the materials for the flexible seal will be determined after testing. Materials and items to be included in testing include rubber heat shrink tubing, various thin plastics, silicone, glue, waterproof tape, hose clamps, and zip ties. More information on how this seal will be manufactured and tested, in the following sections.

(a) Assembled Seal (b) Exploded View

Figure 28. Two views of the seal. The seal consists of various parts which will prevent all water from entering the enclosure containing servos, and it will allow the Stewart platform to move through its full range of motion without interference.

5.5. Tissue Adapter

The purpose of the tissue adapter is to ultimately translate the motion created from the Stewart platform to the Right Ventricle apex. As seen in figure 29 below, the main tissue adapter part will slide onto the end effector and will be fastened with a nylon screw. The thin tip of the main tissue adapter part will skewer the bottom of the left ventricle. Since the heart will be dissected we will have access to the inside of the left ventricle. From the inside of the left ventricle, a flat, washer-like object will be placed over the thin part that skewers the left ventricle. Finally, to fasten this together and secure the left ventricle to our tissue adapter, a screw will be placed through the washer from the inside of the left ventricle, and will screw through the inside, threaded hole in the main tissue adapter part.

The motion of our Stewart platform accounts for the translation of motion from the end effector to the left ventricle over the rigid tissue adapter. The location of the attachment in the left ventricle is very close to the target location of the right ventricle apex. Because of this we can safely assume that the motion will be effectively translated to the right ventricle. See section 5.9.11 for all changes made to the tissue adapter.

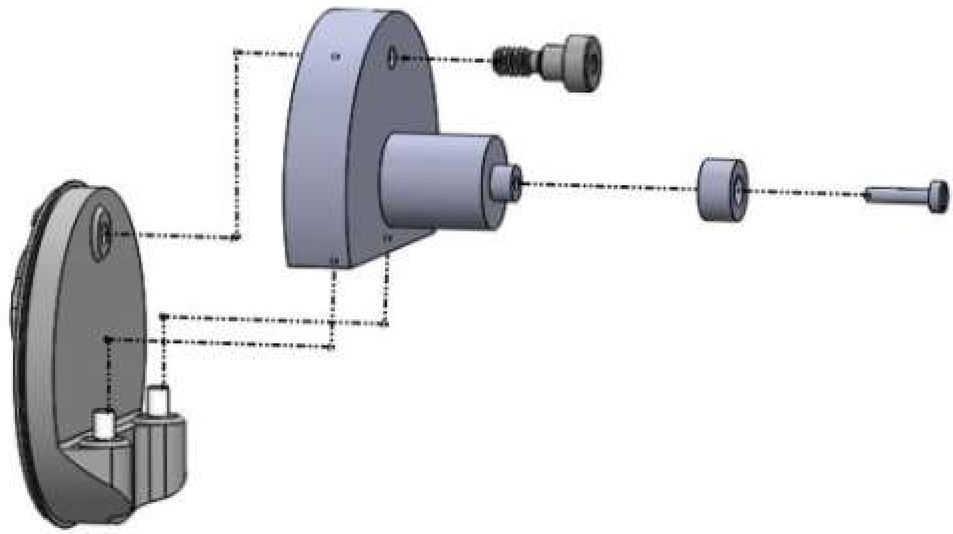


Figure 29. Exploded view of the tissue adapter assembly. The main tissue adapter part will skewer the left ventricle. As motion is directly applied to the left ventricle, the desired movement will result at the right ventricle.

5.6. Overall Layout

Another change to our design since our Preliminary Design Review is how the motion system is oriented compared to the water tank. Originally, the motion system was going to be outside the tank with the Stewart platform extending into the box. Now, our entire system can be placed inside of any water tank large enough to fit it. Figure 30 below is a very preliminary idea of what the layout will look like with all the parts together on one platform. This platform and approach will not be included in sections 6 or 7 because we do not have a manufacturing plan for them yet. We are including them here to give an idea of what the finished product will theoretically look like. The platform is a new development which is why we have no manufacturing plans for it, but we will have a properly dimensioned part and a manufacturing plan for it by the end of winter quarter. See section 5.9.12 for a refinement to the overall layout.

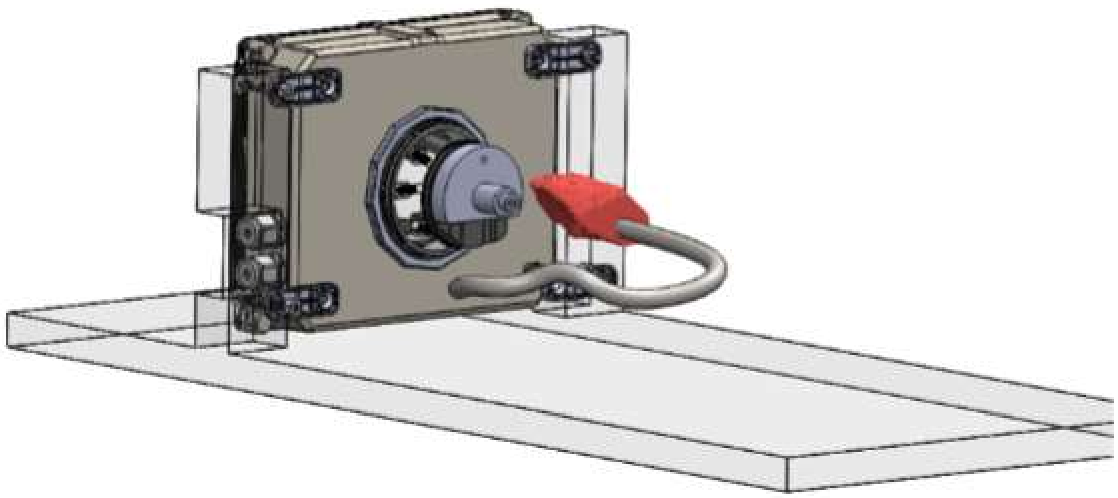


Figure 30. Theoretical layout of final product. This is a preliminary idea to convey an idea of what the final product could look like. The idea is to have the motion system, approach, and heart sample all fixed to one platform that could then be placed into any tank large enough to contain it.

5.7. Structural Prototype Electronics

The servos chosen for use in the final prototype are the Spektrum S6180 Digital Surface Servos. These servos are rated for use at two voltage levels: 6.0 and 4.8 Volts. Both voltage levels allow for different torque and speed values. The torque values at the high and low voltage levels are 100 and 80 oz.-in, respectively, while the speed values are .14 and .18 seconds. These servos were compared with the Spektrum Low Profile HV Digital Surface Servo series. The differences between these two servo models range from an increase in speed, torque, voltage levels, and price. During prototyping, we will be using the cheaper model to verify our geometries and code architecture. If, however, we discover that the speed and quality of the S6180 is found to be insufficient for a final product, we will purchase the Low-Profile series and, due to the uniform geometry of servos, easily swap them out. Both types of servo can be seen in figure 31.

Figure 31. The image on the left is the Spektrum S6180 Digital Surface Servo. The image on the right is the Spektrum Low Profile HV Digital Surface Servo. The left model is the cheaper of the two and what is currently used in the Structural Prototype [18]. The right model is the more expensive but higher quality version that may need to be purchased if the S6180 does not meet project requirements [19].

These servos run through a system of electronics that consist of an ATxmega 256A3BU development kit, an Atmel ICE debugger, a solderless breadboard, micro and mini USB cables, a PC, two 1000 µF capacitors, and a benchtop power supply. The PC deposits the software onto the development kit through the USB cables and the debugger. The kit communicates with the servos through the breadboard, where power and ground lines are distributed. Additionally, the capacitors help regulate the electron flow and prevent current draw spikes. A picture of the complete structural prototype setup can be seen in figure 32.

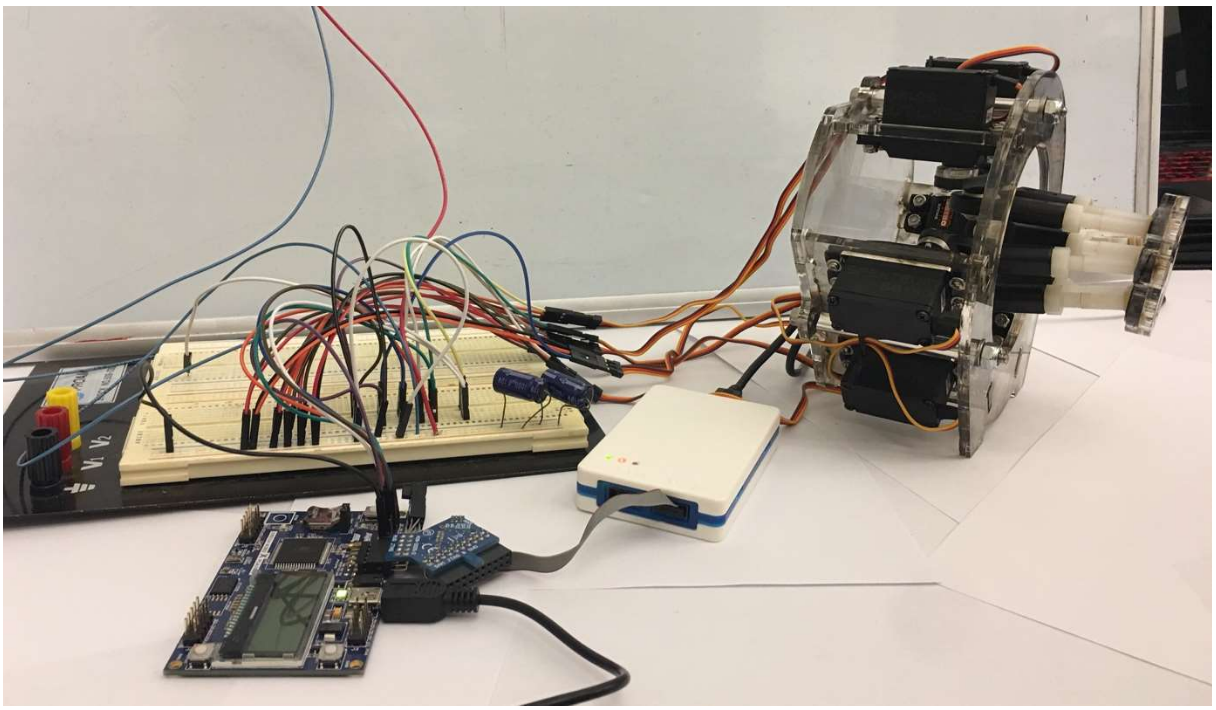


Figure 32. The setup used to run the structural prototype demo. Pictured are the ATxmega 256A3BU Development Kit, the Atmel ICE Debugger, six Spektrum S6180 Digital Surface Servos, and a solderless breadboard.

The ATxmega 256A3BU, seen in figure 33, is a development kit used to prototype and test systems that will eventually have a specific printed circuit board created that caters to the final product's needs. While the functionality is beyond what is needed for the final Stewart platform, the development kit enables the geometry and firmware to be tested at no cost since we already had the microcontroller. While testing is being performed, a printed circuit board will be designed through EAGLE that more specifically suits the project requirements.

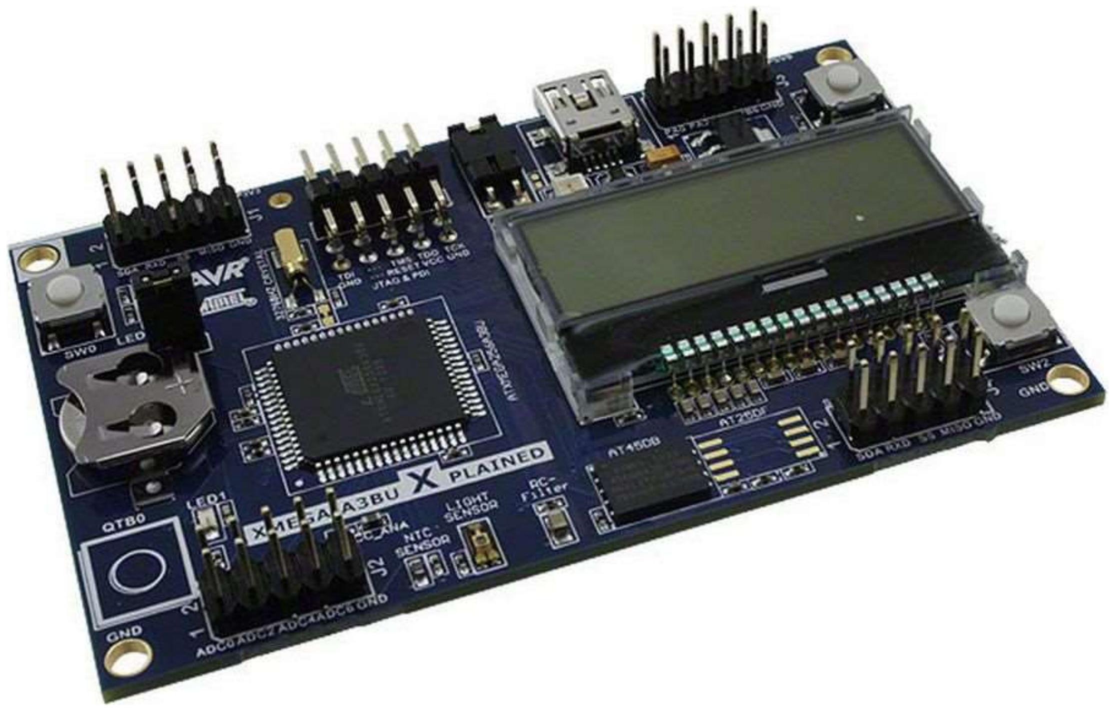


Figure 33. The ATxmega256 A3BU development kit is show above. This is an all-purpose circuit board that is intended for prototyping and learning situations [20].

Benchtop power will not be used to drive the system in the final iteration. Instead, a 5V AC to DC converter will act as the power supply. The converter takes 120V of AC power and converts it to 5V DC power. This power can then be distributed to two sets of electronics: the six servos and the microcontroller. The microcontroller needs a voltage input between 3.3V and 5V to operate, while the servos need 6V to operate at the speed needed for our application. While this issue has still not been addressed, there are a few options to disperse the correct amount of power to the right locations. One idea is to increase to an AC/DC converter with an output of 6V and then step down to the microcontroller voltage while sending 6V to the servos. The second idea is to use the 5V AC/DC converter and conversely step up to the 6V for servo operation. Further testing and analysis will be done to conclude what is the best method moving forward.

In the final iteration, the electronics will be interacting with a body of water, so precautions must be taken to prevent damage to the electronic hardware and the user. The microcontroller and the power supply will be removed from the water and operating at a safe distance away from Stewart platform. The power supply with be placed within a box to prevent the user from touching both the high and low side of the power lines. This, along with the microcontroller, will be connected to the Stewart platform by wires that connect to the Stewart platform through sealed and secured entry ways.

5.8. System Software

The firmware design can be broken into three categories: servo control, serial communication, and a graphical user interface. For the structural prototype, only servo control was developed, leaving both USART protocol and graphical user interface design for the next steps.

Servo control was established through oscilloscope analysis and microcontroller programming. Pulse width modulation, the primary method of servo control, is a form of digital signaling used in junction with high resolution counters. A pulse width is a percentage based on the duty cycle of a signal, over the duration of the period. Most microcontrollers contain functionality built in that manipulates different types of pulse width modulations. On the ATxmega 256A3BU, the pins used that have pulse width modulation and timer functionality are pins C0 through C5. Pins C0-C3 run on timer channel zero (TC0), while pins C4 and C5 run on timer channel one (TC1). Both timers must be adjusted to run based on the system's CPU speed, which in the case of the ATxmega 256 is 2 MHz.

Servos in general need a 20 ms period to function properly. The duty cycle; however, varies from servo to servo. After the timers were adjusted properly and the timer pins were configured to output pulse width modulation, we connected the servo and microcontroller to the oscilloscope to define the limits of the duty cycle for a full range of motion. The complete range of motion for the S6180 is 120°, where the position perpendicular to the ground is 60°. In terms of duty cycle, .88 ms corresponds to 0° and 2.88 ms corresponds to 120°. With this information, we found that 1.2 ms, or 1200 μs, covers the full range of motion; a 10 μs increase in duty cycle is needed for every 1° of motion desired. Likewise, a 1 μs increase in duty cycle leads to a 1° of motion increase. This resolution allows for precise movement from position to position.

The firmware for the structural prototype was designed to test the geometry as well as the angle-to-pulse width algorithm. Angles were hard coded into to a script and ran through a loop demonstrating translational movement of the end effector. With this accomplished, steps were taken to plan firmware development moving forward.

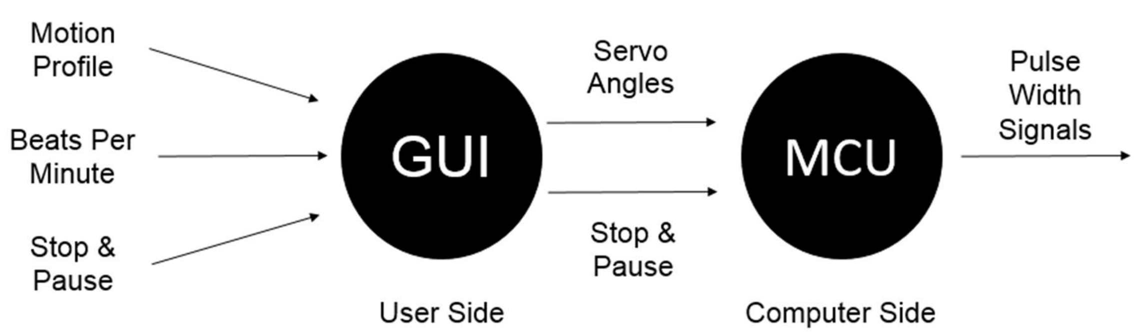


Figure 34. Software Flowchart that shows the inputs and outputs of the two subsystems: GUI and MCU.

The flowchart in figure 34 shows the complete process of user interaction to machine operation, detailing what inputs are required to certain parts of the system, and the outputs those parts generate. There are two subsystems within the process: the user and the computer subsystems. The user subsystem consists of a graphical user interface (GUI) that the user interacts with. This interface will be made with the python coding language. The user will input a motion profile, consisting of x, y, z, roll, pitch, and yaw data, along with a beats per minute (BPM) that dictates how fast the machine will be moving. Within the GUI, the python software will take the data and produce servo angles that can be read by the MCU. Additionally, the user will have access to a stop and pause command. The stop command shuts down the current sequence and sets the system up to wait for new commands while the pause command halts the current sequence and waits for either a stop or resume command. This functionality is intended to allow the user to stop the current sequence in case of an emergency or other testing reasons.

The link between the GUI and the MCU is the Universal Synchronous and Asynchronous Receiver and Transmitter (USART), a type of serial communication protocol. USART allows for reliable communication between the GUI and MCU subsystems, transferring data and information through a USB to TTL converter on the computer side, to the corresponding pins on the MCU side. This communication is time critical and will also need a Real-Time Operating System (RTOS) to properly schedule tasks and prevent data corruption.

Finally, the computer side will consist of firmware that is located on the MCU. Majority of the MCU subsystem has already been created during the structural prototype process. The remaining features consist of RTOS implementation, task creation, and servo and serial driver classes, all written in C++. Driver classes are created to help organize code and add a modular design component to the firmware.

5.9. Cost

Table 3 shows the costs associated with this project. The cost represented here includes all prototypes, tools, and components both used and not used in the final hardware. This said, many components used for structural prototypes were reused in the final hardware, reducing total cost.

Table 3: Project Cost

Category	Cost ($)
Budget	3,000
Spent	2,180.85 (73%)
Remaining	819.15 (27%)

More detailed cost data is available in appendix G.

5.9. Post CDR Changes

Due to the complexity of this project and the relatively fast manufacturing processes utilized many changes were made after CDR to improve the design. In an effort to preserve the documentation leading up to CDR these changes will be discussed in detail in this section.

5.9.1. Second Structural Prototype

Immediately following CDR a second prototype was constructed to determine if the geometry changes made fixed the problems observed in the initial prototype. In addition, the settings used for laser cutting the acrylic components were refined to reduce burning that ruins the acrylics surface finish.

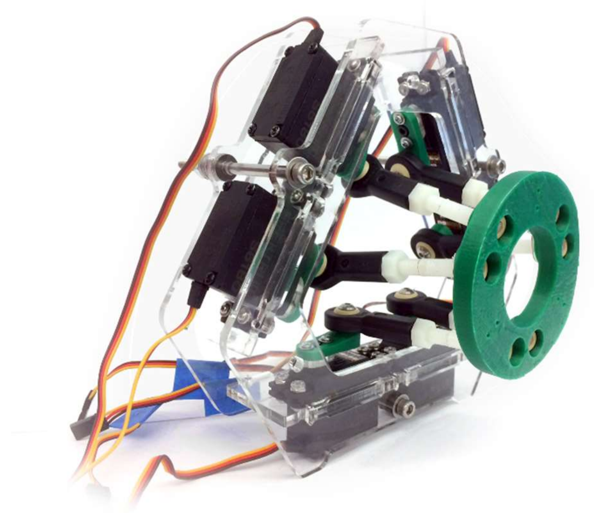


Figure 35. Second structural prototype used to validate design changes made for CDR to improve upon the first structural prototype design.

The second structural prototype had encouraging results, but some play in the system was still present at the end effector. After observing the system this, play was determined to be primarily originating from backlash and flexing in the servo output shaft.

5.9.2. Changes to Improve Motion Accuracy

As discussed, the second prototype made major improvements to motion accuracy, but several changes were made for both the third and final prototypes to further improve.

The addition of springs added preload to the system and made the backlash and deflection in the system more predictable, so that it could be accounted for in software.

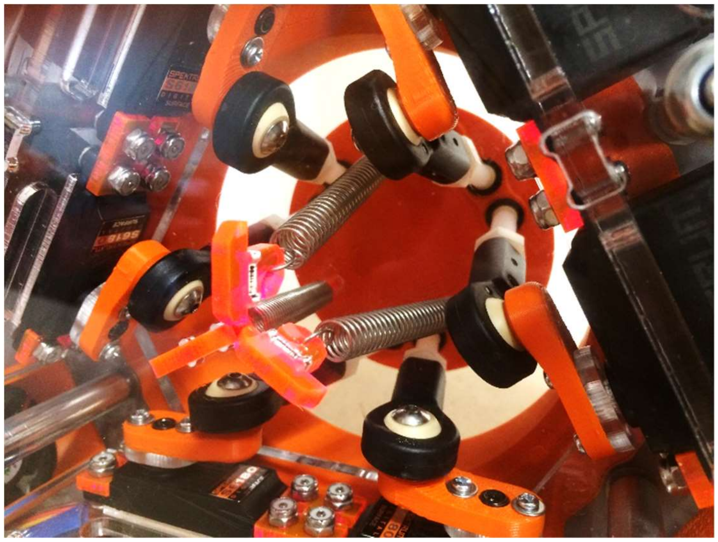


Figure 36. Springs used to reduce play in system shown on third structural prototype.

Additionally, it was observed that the rubber bushings that come with the servos were allowing for the entire servo to move relative to the housing. To eliminate this the bushings were removed, and acrylic tabs were used to secure the servos into place. The tabs also allowed for the slots the servos fit into to be made wider than the servos so that the servo wires can fit through the slot, and then their location can be fixed by the colored plastic tabs used to mount the servos as shown below.

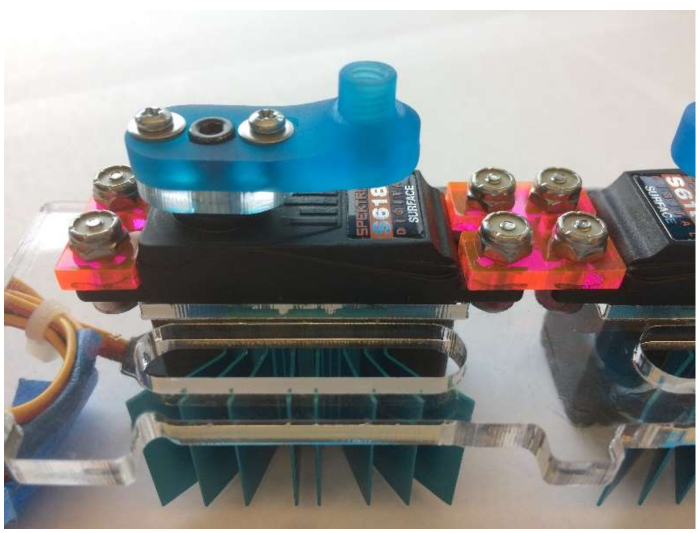


Figure 37. Updated servo mounting mechanism used to reduce motion of servos relative to housing, and to allow for easier servo installation.

One final change to address motion accuracy was the use of smaller spherical bearings in the end effector made possible by finding a supplier outside McMaster. The incorporation of smaller bearings allowed for the triangulation between connecting rods going from the servos to the end effector to be further increased, helping with overall rigidity of the system.

5.9.3. Changes to Improve the seal system

Since CDR the seal has been designed to increase in diameter at its base to allow for better clearance of the servo arms and connecting rods. In addition, a large chamfer was added on the inside of the seal component that contains the O-ring so that the servos could be moved closer without interference. Additional changes include tapering faces that glue to the flexible seal. The angle selected for these faces produces a cone slightly longer than what is needed. This slight increase in length helps prevent it from restraining end effector motion.

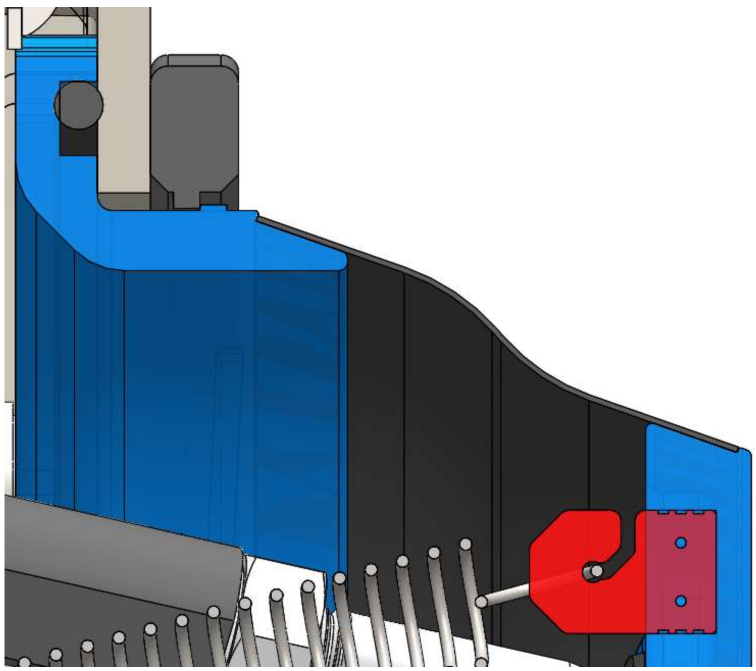


Figure 38. Section view of the updated seal assembly.

The force required to compress the O-ring must be supplied by tightening the locknut on the outside of the enclosure. To ensure that these components are strong enough to handle this force data for compression force based on seal length was found for the selected O-ring cross sectional diameter and durometer [21]. To determine if the seal's strength would be adequate it was necessary to select a manufacturing process.

Due to the complex geometry of the end effector and seal components stereolithography prints were selected for their high resolution and solid non-porous prints. After looking into the materials prints could easily be ordered in Formlabs tough resin was selected for its strength, relatively high modulus of elasticity, and resistance to cracking, along with being compatible with water.

Using the above information, it was possible to create an FEA model of the seal base and ensure all dimensions were adequate to compress the O-ring. The results of this modeling are shown below. It was found that material could be removed which was highly desirable as it reduced print costs.

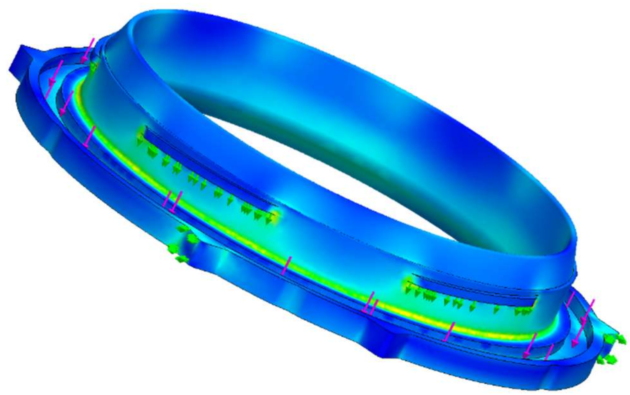


Figure 39. FEA performed on a portion of the seal system to ensure adequate strength.

Since the seal system is assembled with glue, which will be discussed below, once the seal is assembled it cannot be separated from the internal housing containing the servos. As a result, once the seal is placed into the waterproof enclosure it is impossible reach the seal while installing the locknut. To adequately tighten the lock ring onto the seal a means of preventing rotation of the seal was necessary. To do this, small tabs were added to the seal. These tabs rested against tabs protruding from the acrylic servo mounts. As a result, the seal is correctly positioned and held in place from the inside, so that the lock ring can easily be installed.

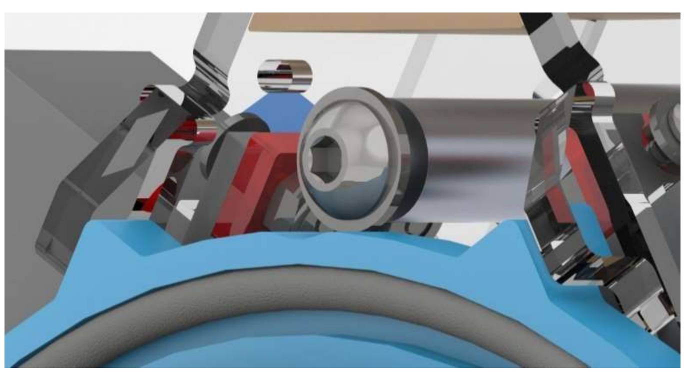


Figure 40. Locking mechanism between seal system and the internal housing within the waterproof enclosure.

A detail that had not been determined from CDR was how the flexible portion of the seal would be constructed. Initially it was desired to find a product that could be modified to produce a continuous seal with no seams. The idea of using things such as rubber gloves was explored, however there were no readily available options that aligned well with our desired dimensions. As a result, it was determined that it would be best to construct a custom seal that met our design needs. After researching several material options nitrile rubber was selected for its resistance to water, flexibility, high strength, and durability [22]. To construct the seal a nitrile sheet was cut into the shape of a cone with a small overlap for gluing. To reduce the risk of leaks the seam was specified to be oriented towards the top of the device.

In addition to selecting an appropriate rubber for the application, it was necessary to select an appropriate adhesive. After researching several adhesives, 3M 847 was selected. The standout characteristics of this sealant were its ability to adhere nitrile to itself as well as many other plastics, both of which were necessary for the construction of the seal. Additionally, this sealant could be easily painted onto the surfaces to be glued and provided 15 minutes for positioning and realignment before it began to set, which was critical for installation.

When testing the seal on the final prototype it was found that an increase in system temperature could cause the air within the waterproof enclosure to expand to the point where the seal prevented free motion of the end effector. To remedy this problem a last-minute design change was made in incorporate the snorkel shown below.

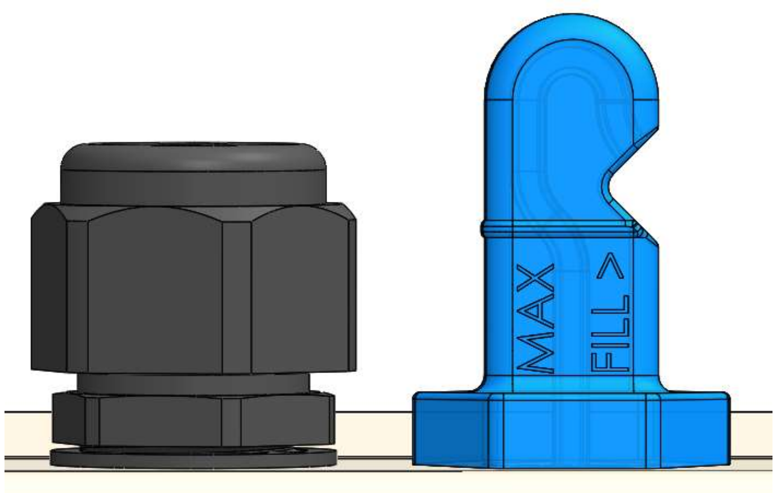


Figure 41. Addition of a snorkel on the top of the waterproof enclosure allows for air to flow in and out of the system.

The snorkel allows for air to freely move in and out of the enclosure. In addition to removing the problem of thermal expansion of air within the system, it also allows air to flow as the end effector moves, putting less strain on the flexible portion of the seal.

A final change to the seal system included coating the faces that contact the O-ring with a small amount of rubber and plastic compatible waterproof grease to prevent slow leaks. For the final build of the system that will be provided to our sponsor White Lightning High Performance Clear Grease was used, but others could be substituted in the future.

5.9.4. Addition of Cooling system

One concern with running the system for long periods of time was keeping the servos from overheating. While we were not able to collect any temperature data from the various prototypes, with the knowledge that overheating is a common cause of servo failure and based on the recommendation of our sponsor a cooling system was proactively integrated into the system.

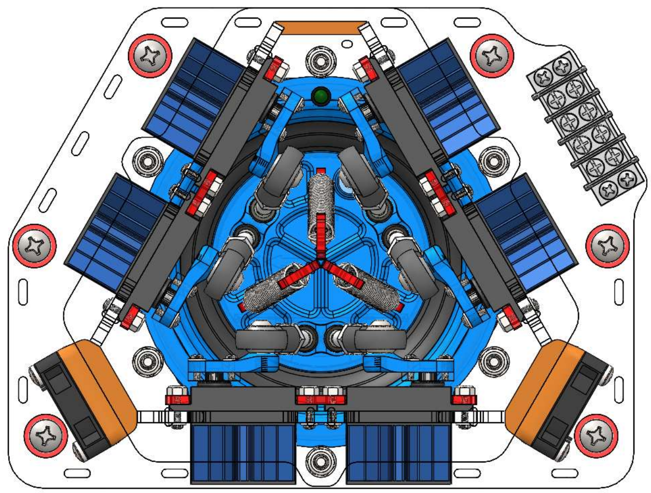


Figure 42. Addition of two fans and a barrier so that air is blown into the internal cavity and out over the servos.

The basic premise of the system is that air is blown into the internal cavity of the motion system and is then allowed to escape through slots cut on the sides of the servos. On one face of the servos adhesive heatsinks were installed to extract as much heat as possible. However, because of the internal layout of the servos and servo material it is not evident if the heatsinks will have a large impact on cooling.

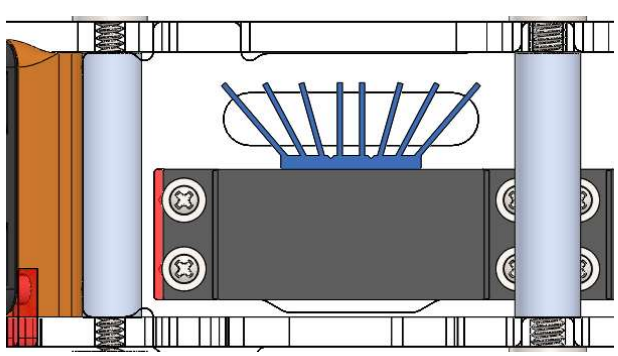


Figure 43. Slots above the servos allow air to pass over them.

Once the heat is removed from the servos it can be conducted through the system walls and to a lesser extend transferred by the airflow through the snorkel.

5.9.5. Additional Motion System Changes

While changes to improve motion accuracy and changes to the seal system were the most significant changes since CDR there were also several smaller changes that will be discussed here.

In the proposed CDR design steel was added to weigh down the system and prevent it from floating when submerged. In the final design these weights have been removed per the request of the project sponsor, and the system will be constrained externally to prevent flotation.

To reduce the risk of water entering the system and make it easier to install the system into a test setup, the cord grips that pass power and data cables into the system have been moved from a bottom corner to the top of the device, where they are at most submerged within an inch of water.

To further increase the safety of the system a stop button was added to the top of the system so that an operator can stop motion even if additional controls are not within reach. This button is IP68 rated so that it can be submerged continuously if necessary. This button stops the system through software, so in an emergency the emergency stop button remains the first course of action.

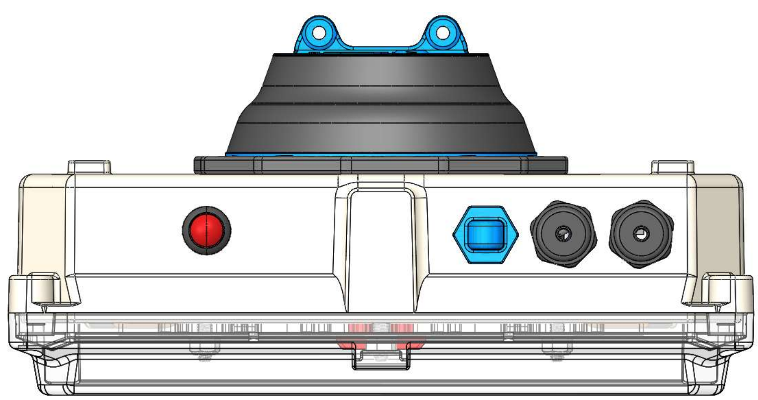
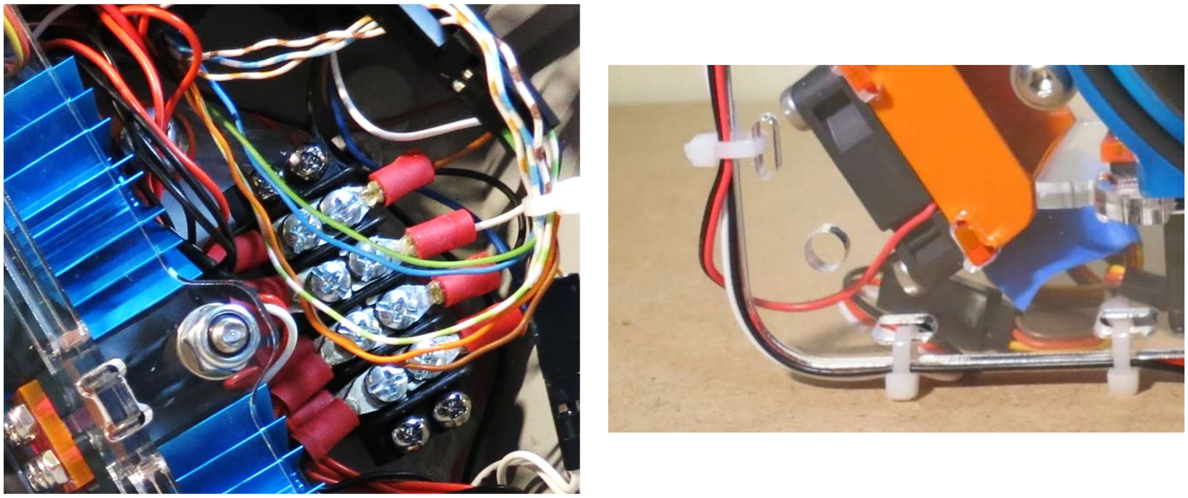


Figure 44. Top view of final design with stop button, snorkel, and cord grips all located on the top of the waterproof enclosure.

For easier wire management a barrier block was placed inside the enclosure so that power could be connected and disconnected easily between the power cable and the servos. Additionally, slots for zip ties were placed around the perimeter of the internal housing to secure wires.



(a) Barrier Block (b) Zip Tie Locations

Figure 45. Both the Barrier Block and Zip Tie locations are used for better cable management within the waterproof enclosure.

Finally, using FEA as needed, material was removed from several parts that were to be printed so that the overall print cost was reduced. And the coordinate system was added to the end effector as shown below for easier orientation when producing new motion profiles.

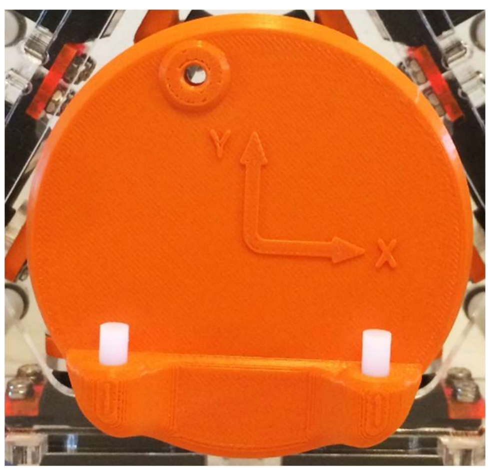


Figure 46. End effector prototype with coordinate system included in print.

5.9.6. Electronics Enclosure

In addition to producing the motion system that is submerged and connects to the tissue adapter, electronics for power and control are needed to have a fully functioning system. To reduce the risk of electric shock or of having difficult to replace components damaged by water, it was decided to position many of the electronics in a separate enclosure.

The electrical enclosure houses the main system 50W 5V power supply (adjusted to 5.8V) along with a low wattage 12V supply used to run the cooling system fans. The AC, 5V, and 12V lines each have individual and externally replaceable fuses in the event of a short in the system. Throughout the system power/signal inputs have exposed contacts while power/signal outputs have shrouded contacts to prevents an operator from accidentally touching a live power line if all cables are not connected.

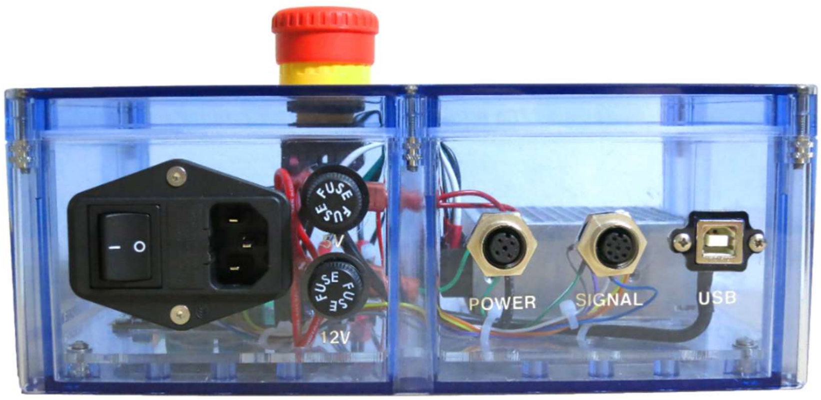


Figure 47. Dedicated electronics enclosure that is kept separate from water.

The electrical enclosure also features a USB port for connecting to the microcontroller, a power switch so it does not have to be unplugged to be turned off, and an emergency stop connected to the AC line input. Labeling indicates what each connector is for.

The enclosure floor is constructed out of laser cut acrylic which incorporates mounting points for each component along with locations to secure wiring with zip ties.

Figure 48. Top view of electric enclosure. The main power supply can be seen on the left, with a custom PCB located on the right under the emergency stop button.

5.9.7. Third Prototype

Many of the changes discussed above were implemented into the third prototype or made from observation of the third prototype. Several images from this hardware iteration are shown below.

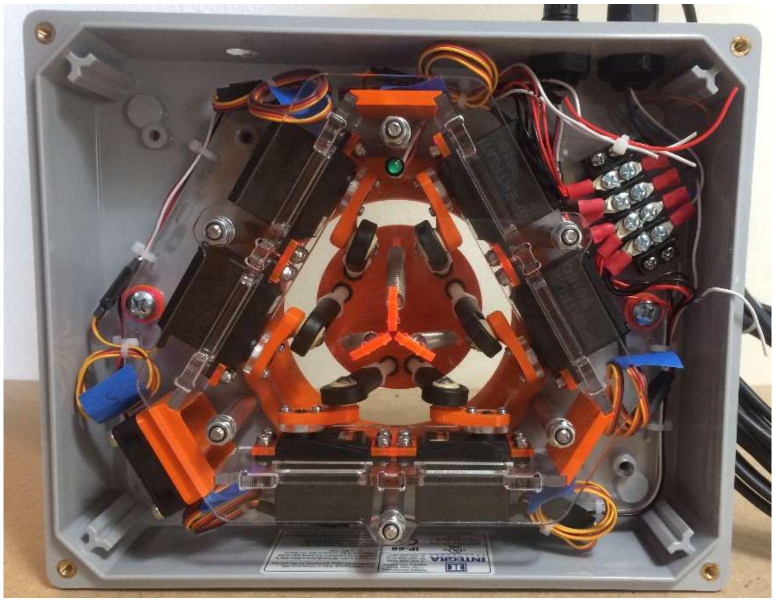


Figure 49. Rear view of third prototype mounted into waterproof enclosure to check fit.

Figure 50. Test of the seal assembly without adhesive.

5.9.8. Addition of a Custom PCB

A Printed Circuit Board (PCB) was designed to interface between the user and the servos. While previously we used a development kit supplied by Atmel, the capabilities of the premade board surpassed what was needed for the final design. Additionally, the development kit required the use of external breadboards and jumper cables that created disorder. Setting up the device with an external breadboard took away from time that could have been spent furthering the software and firmware development. An external breadboard also added to risk when a wire may have disconnected from the system with an unorganized array of wires hindering hardware solutions.

The software used for PCB design was EAGLE by Autodesk. The design process underwent three stages of iteration. The final design served a few primary purposes. The first being data reception. The microcontroller (MCU) receives data from the user inputs on the graphical user interface (GUI). This data transfer takes place across USB-B type cables. To receive this data, a FT 232 integrated circuit was needed. This device takes USB and RX as inputs and transmits TX as an output. The TX data line is sent to the MCU and read. The MCU then responds by sending data across the RX line, into the FT 232, and out to the user on the GUI. While this data transfer is happening, two LED's were placed on the PCB. An orange light indicates that data is being transferred from the user, to the MCU. The green LED indicates the opposite. Additionally, the FT 232 powers the MCU. Instead of stepping down voltage from the 5.8V power supply operating the servos, the USB-B connection powers the MCU, stepping down the computer's 5V to the 3.3V's needed to operate the MCU.

The next primary purpose of the PCB is to control the six servos. When working with the development kit, the wires connected between the kit, the breadboard, and the servos created clutter. The PCB served to eliminate this clutter, prevent wire malfunction, and increase the portability of the system. This was accomplished with a series of Phoenix Screw Terminals. With the servos being controlled by two timers, additional MCU pins were connected to screw terminals in case of future use.

The final purpose of the PCB was to establish a manual software reset. In the case that the machine needs to be stopped for an emergency, there are three possible solutions. The first being a hard disconnect between the computer and the device. The second being the emergency stop located on the electronics enclosure. The final stop is located on the housing that holds the stewart platform. This reset works by grounding a signal between the power supply and the MCU. The PCB provides a path for a signal from the power supply to be established on board. This signal is then put through a voltage divider of 1kOhm and 750 Ohm before entering the MCU, preventing any internal damage from occurring. When this signal is grounded, the firmware notices that a signal was dropped, thus issuing a software reset.

5.9.10. Development of System Software

The system software works through three tasks, that consist of state machines, running on a Real-Time Operating System (RTOS). The three tasks include a Reboot Task, a Servo Task, and a User Task.

The simplest of these three is the Reboot Task. This task contains two states. State 0 constantly checks for an input pin to go low. When the input pin, normally high, is read low, a flag is raised that send the Reboot Task into State 1. State 1 utilizes the Watch Dog Timer (WDT), a series of commands that activates an internal safety mechanism that prevents MCU stalling. This state sets the WDT for 120ms and proceeds to enter an infinite for loop, causing the MCU to stall. By manually causing the MCU to stall, the WDT is triggered and causes a soft reset.

The second task used is a Servo Task. This task consists of five states that directly interface with the six servos. In State 0, the task is waiting for a user command. From State 0, the firmware will either enter the Zero Position State, the Go State, or the Sort State. If the user zeros the device, the firmware will transition to State 1. In State 1, each servo is sent their respective neutral home positions. The servos have differing home positions based on the placement of the 3D printed servo adapters. These positions were found via visual inspection and signal adjustment. After the servo home-position signals have been transmitted, the firmware exits State 1 and returns to State 0. The second pathway out of State 0 is through State 2, the Sort State. The Sort State manipulates the data received via transfer from the user. The form the data is in when transferred initially prevents reusability. Instead, during the Sort State, the data is converted into arrays that can be reused upon the completion of one cardiac cycle. This gives the device the capability to run through an unlimited number of cycles. Once both State 0 and State 1 have been completed, the firmware can enter the Go State. Here, the firmware communicates directly with the servos through the timer registers. The data sorted in State 2 is cycled through during the Go State at a rate that corresponds with the Beats Per Minute entered by the user. From this state, the firmware can pause which is accomplished through State 3 which has two exit points. One path is State 4, where the firmware resumes the previous profile, while the other is to return to State 1 to return each servo to the neutral home position.

The User task has 16 states that are used for interfacing directly with the GUI. State 0 is where the user can decide whether to enter Command Mode or to stay in Start Up Mode and perform a soft reboot. State 1 is the waiting state that responds to specific inputs from the GUI including the Start, Stop, Resume, and Zero commands in addition to the Data Transfer Initialization command. State 1 serves as the mastermind state that controls all aspects of the user interaction. States 2 through 8 are involved directly with data communication from the GUI to the Firmware. State 2 serves as the central hub for the data transfer, choosing which servo gets which set of data. Likewise, states 3 though 8 correspond to servos 1 through 6. The data comes across the communication line bit by bit and must be decoded and then reassembled before use. States 9 through 16 are used to raise certain flags or markers that tell the firmware's other tasks what to do next.

5.9.11. Development of Graphical User Interface

In addition to the firmware placed on the board, a GUI is used to assist the user in operation. This interface was developed using Python on the PYQT application. The interface has a few key modules with specific controls within each.

The first module contains all aspects that focus on Data Importation. Here, the GUI can search through the current directory with the Import button. Whatever .csv file is found in the current directory will then be added to the drop-down list to the right. Once a file has been selected, the Select button converts the motion profile into data that can be manipulated prior to data transfer.

The next module is the Communication Port Module. This module is used to connect with the computer via USB-B. On initialization, the Connect button is red, but after a Communications Port is selected from the drop-down menu and connected with, the button will turn green. This signals that a line of communication has been established.

The Data Transfer Module contains two buttons that work with the data that being transferred across the communication lines. The Transfer button begins the data transfer process. This process sends data bit by bit and takes a longer period based on the size of the data. When the transfer is complete, a message will be displayed in the Communication Window. From there, the Sort button is pressed next, organizing the data in a way that can be reused for multiple cardiac cycles.

The Beats Per Minute Module contains a spin box and a Select button. Whatever value is inputted, between 5 and 140 Beats Per Minute, will be converted into clock ticks that are used to run the Go State in the Servo Task.

The Operation Module holds the four buttons that directly control the servos, Start, Stop, Resume, and Zero. Before Start is pressed, Zero must be pressed to bring the servos back to the home position. After Start is pressed, the current motion profile will run until told to stop. The Stop command paused the current motion profile and gives the user two options for control. The first option is Resume, returning the servos to the last command they received and resuming the motion profile. The second option is Zero, ending the current run and bring the servos to the home position.

The last two modules contain commands that dictate higher-level software structure. Within Command Mode, all the previous controls are operational. When in Start Up Mode, the only command accessible is the System Reset button, which enables a soft reboot.

5.9.12. Refinement of Tissue Adapter

Since the CDR, the tissue adapter has had design changes that allow it to work more efficiently and to lower manufacturing costs. The skewer is now a constant diameter that is long enough to reach from the apex of the heart, through the left ventricle, and just through the mitral valve into the left atrium. Also, instead of a small nut going inside the heart to tighten on, a long cap will be placed into the left atrium over the skewer creating a pinch point at the bottom of the left ventricle. The tissue adapter material on either side of the pinch point has been designed to be sharply ridged so that the tissue being pinched will not slide around when motion is applied. Finally, on the part of the tissue adapter that connects to the end effector, unnecessary material was removed which greatly lowered the cost of 3D printing this part.

Figure 51. The tissue adapter including the skewer which attaches to the end effector, the cap which runs over the skewer, and the screw which tightens the cap.

5.9.13. Refinement of Overall System Layout

Figure 30 shows a preliminary design of what the overall layout should look like. The purpose of the overall layout is to mount the motion system vertically to keep it table while it runs. This layout is also used to attach the access path that the catheter will run through during the operation. The access path will be able to slide back and forth on the layout base in order for the heart to be easily attached to it. As seen below in figure 52, the layout is one piece of equipment that secures the motion system and approach and allows the heart to be secured as well. All parts of this layout will not interfere with x-ray.

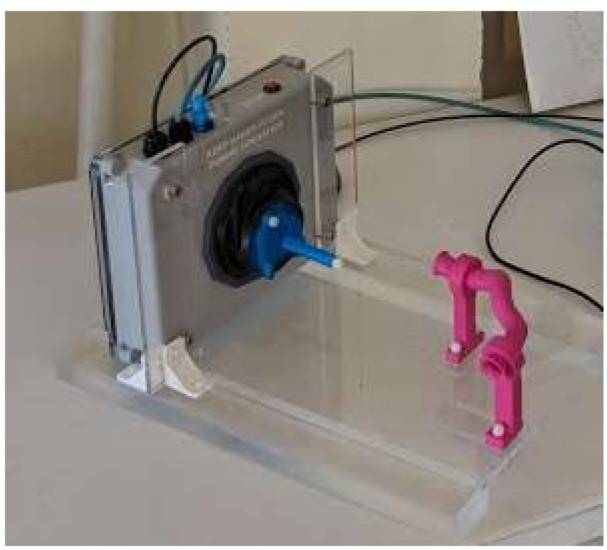


Figure 52. The overall layout is shown above. It is made of clear acrylic which provides support to the motion system and the pink access path. This whole assembly may be submerged into water.

5.9.14. Motion Profile Data Format

To increase flexibility of the system, in addition to easily being able to install new adapters onto the end effector, new motion profiles can be generated and run through the system software.

These files should be created as commas separated variable (CSV) files, something that can easily be done in excel. The data necessary is stored in 9 columns of data as shown below:

X	Y	Z	Roll	Pitch	Yaw	X Off	Y Off	Z Off

The first six columns contain position and orientation data, the last three columns are used to specify the location of that motion, units are millimeters and degrees. By specifying the location of the motion, a coordinate frame with identical orientation to that of the overall system is placed in space relative to the end effectors neutral position.

For instance, if the last three columns are zero the prescribed motion will happen about the end effector. If a Z Off value of 15 is given the prescribed motion will be produced at a location 15mm from the surface of the end effector. So, if a roll value of 10º were specified with a positive Z Off value, all other values being zero, the end effector would roll 10º along with translating so that the location of Z Off is unchanged.

It is recommended that all motion profiles be limited to no more than 200 data points, as this may cause the microcontroller to run out of memory. Motion profiles should be cyclic with the initial and final position being similar if not identical.

5.9.15. Final Hardware

The final hardware was a continuation of the third prototype, with major changes being updated prints of various components primarily for waterproofing and slight dimensions changes.

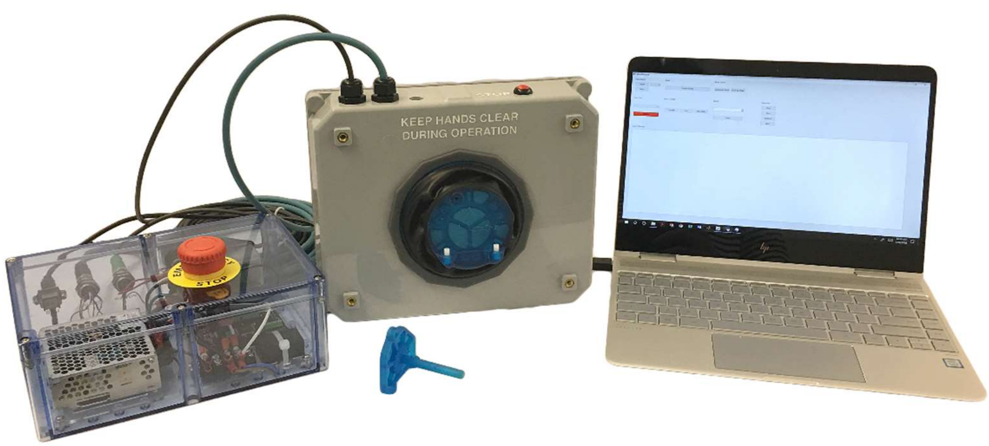


Figure 53. From left to right the electronics enclosure, motion system (snorkel not yet installed), and the system software GUI running on a laptop. Below the motion system is a portion of the tissue adapter for connecting an animal heart to the system.

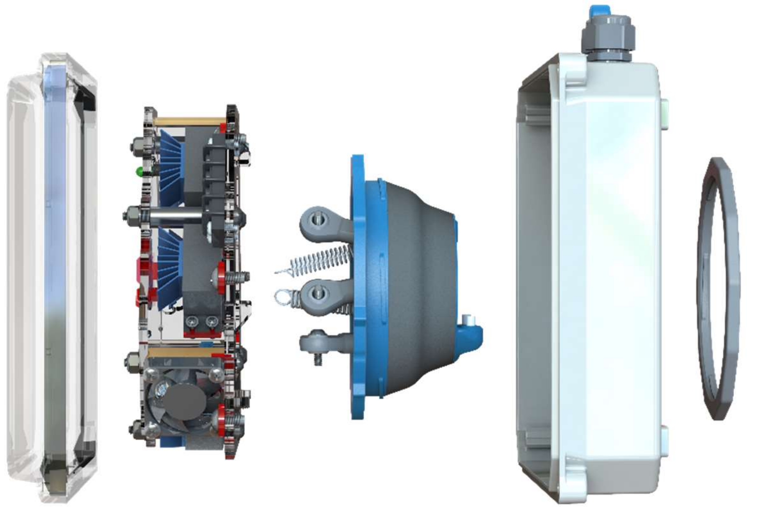


Figure 54. Exploded view of final motion system design. The internal housing can be removed from the waterproof enclosure for easier maintenance.

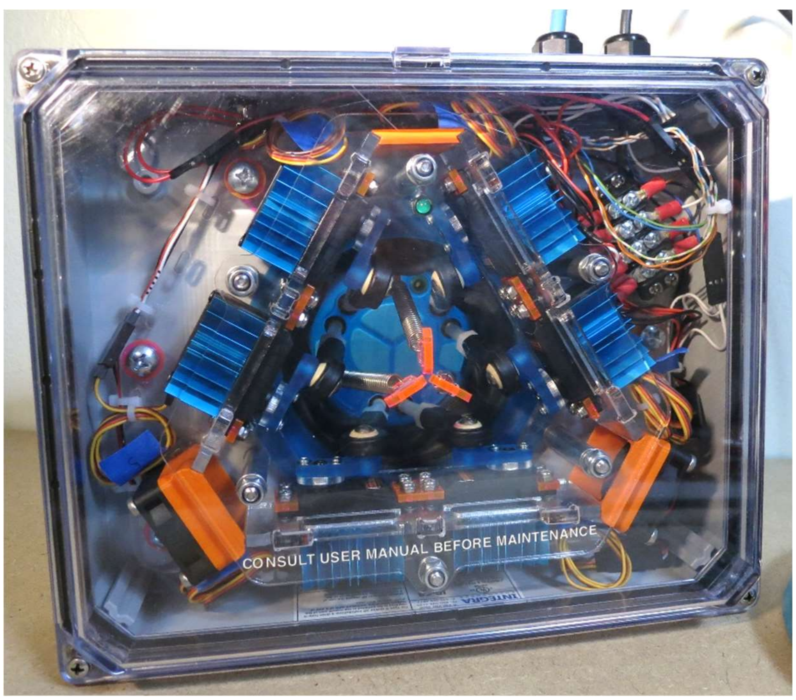


Figure 55. Rear view of fully assembled (sans snorkel) motion system.

Figure 56. Fully assembled seal and end effector on motion system.

6. Manufacturing Plan

This section describes the manufacturing that went into assembling the final prototype.

6.1. Material Procurement

Whenever possible materials were ordered through McMaster or Digikey. This reduced the number of orders necessary and shipping costs. However, some of the more unique components such as the waterproof enclosure, spherical bearings, and 3D prints had to be ordered from other sources. For components that would be needed in very small quantities (for instance one bolt) it was best to purchase these from the local Ace Hardware to avoid having to order in bulk from McMaster.

6.2. Manufacturing Process

This section provides detailed information on the complex manufacturing process necessary for producing the final product.

Table 4: Description of custom made parts.

Part Description	Material	Manufacturing Process
Servo Spline Adapter	Acrylic	Laser Cut
Servo Adapter	Plastic	3D Print
Locknut	Plastic	3D Print
End Effector	Plastic	3D Print
Connecting Rod	Nylon	Lathe/Tap
Internal Housing	Acrylic	Laser Cut
Internal Seal	Plastic	3D Print
Seal Locknut	Plastic	3D Print
Tissue Adapter	Plastic	3D Print/Tap
Overall Layout	Acrylic	Laser Cut

6.2.1. Laser Cut Components

A large quantity of manufacturing was done via laser cutting. This process was desirable for its speed, ability to create complex shapes, and tight tolerances. An example of laser cut parts before being removed from the laser cutter is shown below.

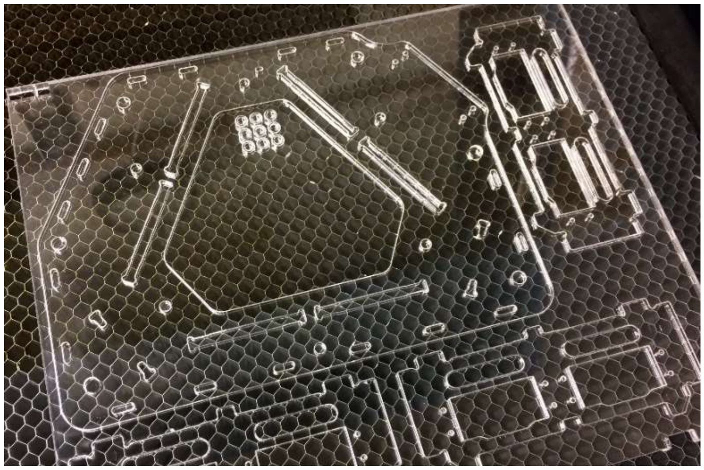


Figure 57. Laser cut acrylic housing components sitting in the bed of the laser cutter. Some test cuts used to adjust laser setting can be seen in the top left corner.

A primary challenge with using the laser cutter was getting the laser power setting correct for the material and its thickness. While the software used to run the laser would estimate power based on material and thickness, it was necessary to make a few test cuts, usually of a small square or circle, and adjust power so it was set just high enough to make the cut. If the power was set too high burning would occur, ruining the finish of the acrylic, and creating a tapered cut like what occurs with a water jet cut. Some acrylic sheets came with a paper coating on each side that could be left on during cutting, helping to reduce these problems.

6.2.2. 3D Printing

For the final 3D prints it was necessary to have a stereolithography process with a durable resin. After comparing several suppliers, 3D hubs was selected to produce the prints. Three batches of prints were ordered for the final build and the quality, speed, and price were very reasonable each time. An example of a printed part received through this service is shown below.

Figure 58. Stereolithography print using Formlabs tough resin. Print ordered through 3D Hubs.

While the resolution of this print method was enough to include threads in the prints, it was often necessary to use a tap to get a better fit.

6.2.3. Mill Parts

Both the motion system and the electronics enclosure were built around purchased polycarbonate enclosures. To adjust these components for their intended use it was necessary to use a mill to drill various holes and to mill slots in the electric enclosure as necessary. In general polycarbonate is very easy to mill, and all that had to be done to prepare was wrap the parts in masking tape before placing them in a vice or fixturing them, so that they did not get scratched.

The one unusual cut was a 4.5” hole that had to be cut in the motion systems waterproof enclosure to allow the end effector to go through. To do this, the cover was removed from the enclosure, and the enclosure was fixtured directly to the mill’s table. After verifying the correct location, a centering drill was used at the holes origin. Next a new 4.5” hole saw was used at low speeds to cut the hole. For large cuts such as this it is important to make the cut by pecking, and not one motion, to avoid melting the surrounding plastic.

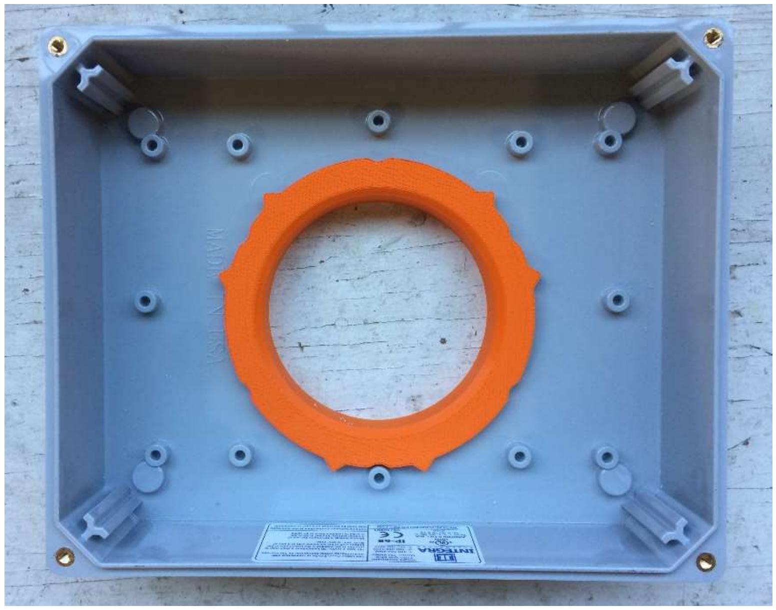


Figure 59. 3D printed seal prototype installed in waterproof enclosure after cutting 4.5” hole with hole saw.

In addition to drilling holes in this enclosure, it was necessary to use an endmill to reduce the height of one of the mounting points below the seal, so that there was clearance for a bolt head at that location.

Note that the inside surface has extruded letters saying “MADE IN USA” along with additional text under the seal, and extrusions from the molds ejector pins. It was necessary to remove these, so the seal’s O-ring had a smooth surface to rest on. This is discussed in section 6.2.5.

6.2.4. Lathe Parts

The nylon connecting rods for this project were produced using a mill. Because these parts had a small diameter it was not possible to manufacture these parts in a standard lathe chuck. As a result, the parts were made on a miniature lathe. Unfortunately, this lathe less precise than a full-size mill so producing the desired tolerances was difficult. To cope with this, when making a set of connecting rods it was best to cut the nylon stock into significantly more sections than should be needed to produce the finished parts. From here, it was best to setup the mill for one cut and adjust until the dimensions were correct, then perform that operation on all parts (checking dimensions along the way) before moving to the next operation.

Additional tips include placing the part as far into the lathe chuck as possible for each cut to reduce part deflection when making a cut. Also, even though nylon is a relatively soft material, it is recommended to use new lathe tools to avoid heat generation that could melt the nylon.

Figure 60. Finished Nylon connecting rod next to a sharpie for scale.

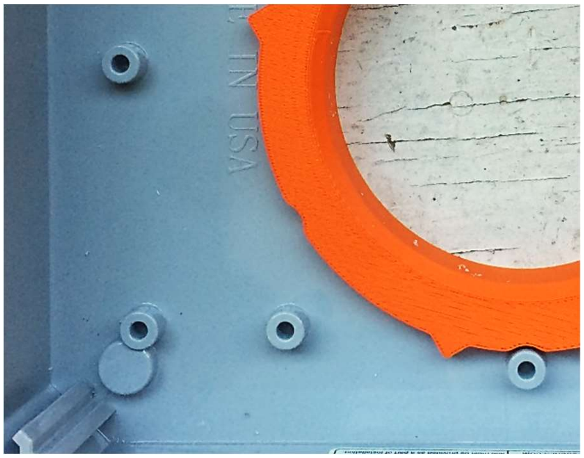
One challenge that repeatedly arose with this component was producing the threads. Originally this was done in a traditional way of placing the part in a lathe vice and resting a die against the lathe tailstock while threading. However, it was easy to get misalignment especially when using a rather dull die from the shops, and the rod would often shear when removing the die.

To remedy this a new die was purchased and placed into a vice. Then the connecting rods were placed into the chuck of a cordless drill set to its lowest speed and slowly advanced through the die. This method brought the threading process form approximately 50% yield rate to 100%.

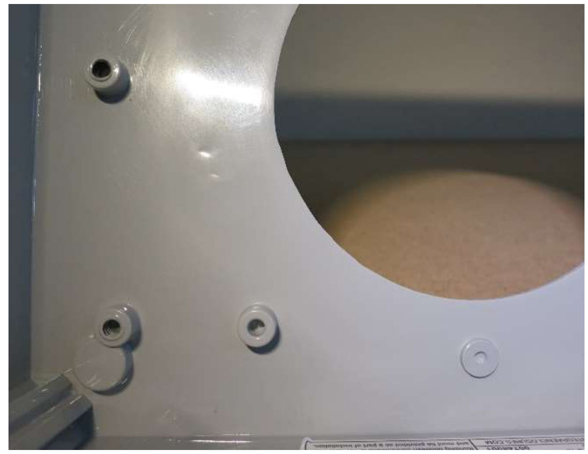
6.2.5. Surface Finishing

As mentioned in section 6.2.3. the waterproof enclosure for the motion system had several extruded markings in the location where the seal's O-ring was supposed to sit. To make this surface smooth a Dremel with a lightly abrasive polishing tool was used to reduce the extruded text to approximately the same height as the surrounding surface. Next, all areas where the O-ring would sit were wet sanded beginning with 400 grit and working up to 1500 grit until the surface was uniform. A flashlight was used to check for any surface markings.

Once satisfactorily sanded a polishing wheel attached to a drill and a polishing compound was used to shine the previously sanded area. The results of this process are shown below.



(a) Before



(b) After

Figure 61. Example of waterproof enclosure before and after removing all extruded text and ejector pin markings.

A similar process was performed at other locations on the enclosure where the surface finish was not adequate for the use of an O-ring or gasket.

6.3. Assembly Process

The drawing package in appendix E can be used as a general reference for constructing and assembling this device. Because many of the components contain complex features made with 3D printers or a laser cutter, their drawings exist as a reference and are not intended to have final parts produced from them. For these parts the CAD files should be used directly. The following subsections include information on several of the more challenging aspects of assembly.

6.3.1. Seal & End Effector Assembly

Begin preparing the end effector by pressing in the two front dowel pins into the end effector. Glue can be used but should not be necessary for this step.

The remaining Seal and end effector assembly steps are highly reliant on adhesives to produce the finished assembly, as a result time must be taken between steps to allow the adhesives to dry fully. Also note that denatured alcohol is recommended for preparing surfaces, do not use acetone on any surfaces or components.

To begin the spring hooks must be installed into the end effector. These should be prepared by lightly sanding the portion of the spring hook that will be glued and using a knife to mark the walls of the slot they will be glued into. Next, denatured alcohol can be used to clean surfaces on both the spring hook and the end effector. Place the hooks into their corresponding slots and use masking tape to tape around the hooks. After these preparations mix a small batch of Loctite 1C epoxy and use a knife edge to coat the walls of the end effector slots before inserting the spring hooks. Firmly press each hook in. Before the epoxy begins to set the masking tape can be removed and denatured alcohol along with paper towels can be used to remove any excess epoxy.

(a) Hooks Prepared for Installation (b) Installed Hook

Figure 62. Installation process of spring hooks into end effector.

While the epoxy used to secure the spring hooks is curing, preparations for installing the seal can be made. The first step is to produce the initial nitrile cone from a nitrile sheet. To help produce this shape a template was laser cut out of MDF. The template could then be pressed onto the nitrile sheet and a knife run around the edge to cut out the exact shape desired. It is recommended that several cones be made at this stage, so the best one can be selected for the final assembly.

Once several copies have been cut out of the nitrile sheet, they must be washed with water to remove any surface coatings. Additionally, the overlapping portion that will be glued to produce the cone shape should be cleaned with denatured alcohol. At this point a paintbrush can be used to paint 3M 847 onto the two overlapping portions of material and they can then be pressed together to form the seal and left to cure for at least a day.

Once the seals cone shapes have dried, the best one should be selected for installation with the remaining components of the seal. Again, clean all surfaces with denatured alcohol before gluing. First the seal should be glued to the larger diameter portion of the seal. Coat both the nitrile and the 3D print with sealant and stick them together. Ensure the seam is oriented so it will be at the top of the device once fully assembled. After waiting ~30 minutes a similar process can be repeated for the end effector. On both printed components use masking tape to protect the prints in areas that are not to be glued.

Figure 63. Flexible seal installed and curing.

The plastic cover that goes on the back side of the end effector can also be installed using 3M 847 at this time.

While this assembly is curing, combine the rod ends and spherical bearings with the connecting rods and nylon nuts to produce a complete connecting rod assembly and size to length. The connecting rod should form a press fit with the spherical bearing, however if this fit is not adequate Loctite 1C epoxy can be used with appropriate surface preparations.

Finally, the connecting rods can be installed into the end effector. To do this prepare both the spherical bearings and end effector in the manor discussed for the spring hooks. Mix a small batch of Loctite 1C epoxy and using a knife coat the walls of the end effector with a thin coating and press in the spherical bearing. Once all connecting rods have been glued into place periodically rotate them to ensure no epoxy got onto the spherical bearings when they were being pressed into place.

Figure 64. Assembled connecting rods after being glued into end effector.

6.3.2. Motion System Housing
It is recommended that all seals be tested before installing the electromechanical components into the system. However, it is necessary to build up the motion system housing to install the seal for testing. In this section how to construct the housing is discussed, a later section will cover how to complete the assembly after testing the seals.

To begin three sets of the servo mounts must be constructed. Once complete they should look like that shown below. Remember to indicate servo number in some way. It is recommended that the servo cables be wrapped up and zip tied. Connectors will later be routed up to each servo, so that the each set of servos can be easily removed without having to undo wiring.

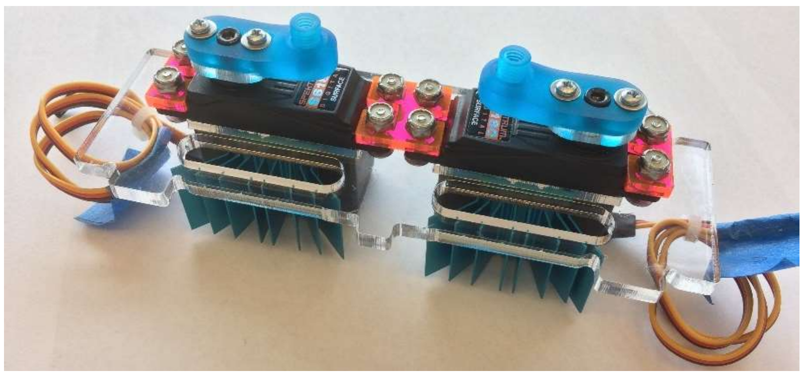


Figure 65. Servos fully assembled onto acrylic servo mount.

To install the servo arms the servos must be set to their neutral positions. This can be done using the systems software and electrical enclosure.

When installing the heatsinks slide a thick card between the acrylic and the heatsink to keep them from resting directly on the acrylic.

Next sandwich the assembled servo mounts between the two walls of the housing and install all six bolts and spacers.

6.3.3. Preparing the Waterproof Enclosure
It is recommended that before assembling the full system into the waterproof enclosure all components that must be sealed be installed and the system tested to avoid damaging electromechanical components.

To do this begin by installing all the components that go onto the top of the enclosure as shown below. Note that the snorkel was being shipped at the time this photo was taken so packing tape was used to waterproof the hole.

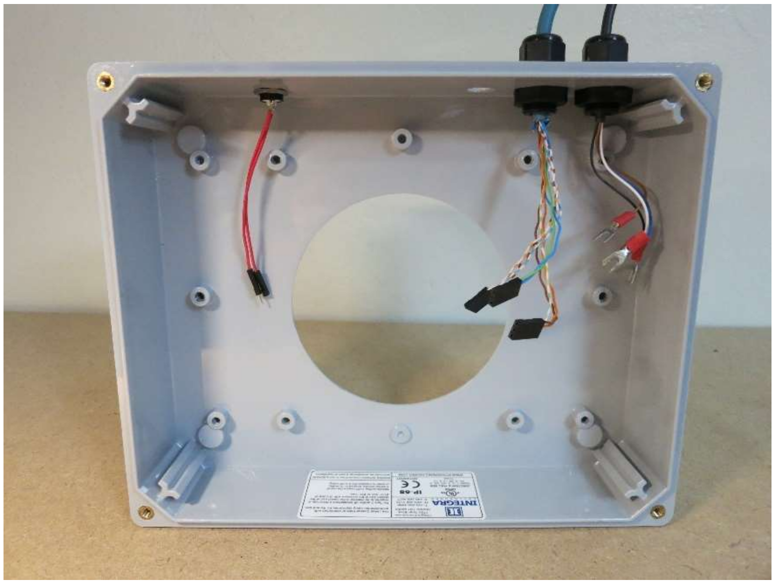
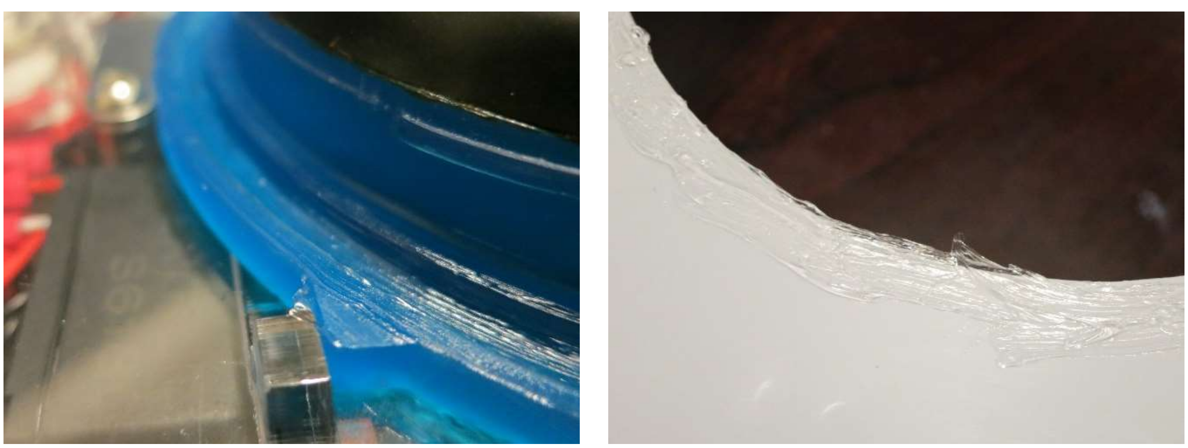


Figure 66. Cord grips and stop button installed into waterproof enclosure in preparation for submersion test.

Next it is necessary to install the seal for testing. Because the seal relies on the internal housing to hold in place while the locknut is installed, the internal housing must also be temporarily installed. Do not at this point connect the rod ends to the servos.

To prepare the seal apply waterproof grease to the O-ring gland and waterproof enclosure surface as shown below.



(a) Grease in O-ring Gland (b) Grease on Waterproof Enclosure

Figure 67. Waterproof grease is used along with the O-ring to produce a reliable seal.

If the waterproof enclosure is new there will be no threads present in any of the mounting points. The recommended screws for these locations are self-threading and will produce the threads on their first use.

Once the internal housing and seal are in place, install a small amount of waterproof rubber friendly grease to the seal lock ring and tighten. At this point the internal housing can be removed leaving the seal in place.

Before installing the cover onto the enclosure use a washable marker to draw lines around various components that could potentially leak. This way if water is visible after submerging the system it will be easier to find the source. The marker can be washed off before assembling the final system.

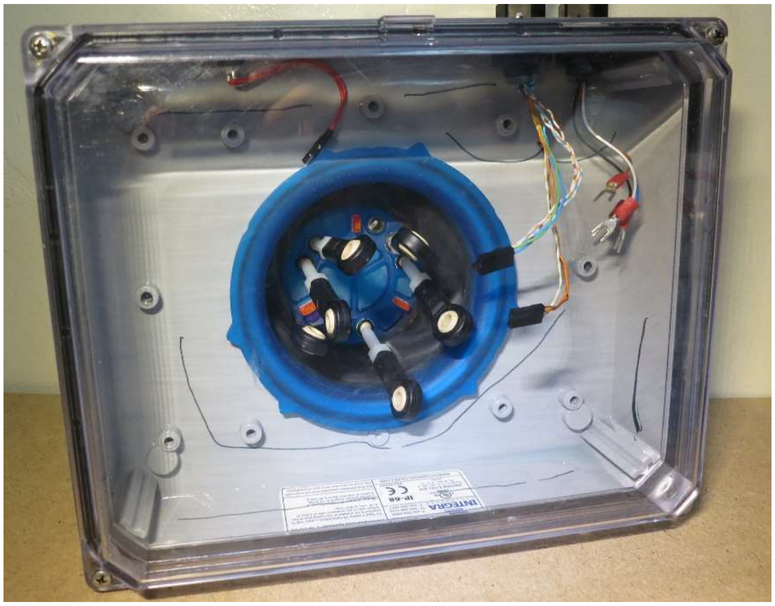


Figure 68. System after an early submersion test.

Before installing the rear cover make sure the foam seal built into the cover overlaps at its beginning/end, otherwise leaks will occur. Once the system is shown to be waterproof the system can be safely assembled.

6.3.4. Final Motion System Assembly

To fully assemble the system some patience will be required. This section will outline the general procedure and what various stages should look like.

To begin the internal housing must be partially disassembled so that the connecting rods can be installed. A good way to do this is to elevate the system on something such as cups while installing various components as shown below.

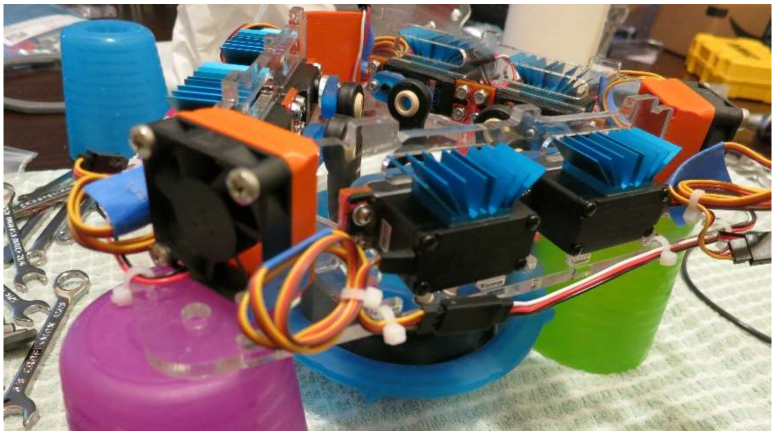


Figure 69. System elevated during installation of end effector/seal assembly.

Once all connecting rods are fully installed place the housings spring hooks through the rear acrylic panel and hook on the springs. With all components in place reassemble the housing using the appropriate bolts, spacers, and washers. If not done already setup wiring following all necessary wiring information in appendix E and zip tie the wires so they are out of the way.

Now the springs can be stretched and connecting to the spring hooks of the end effector. Once this step is done and all wiring is complete the system can be installed back into the waterproof enclosure. At this point the system should look like the picture below.

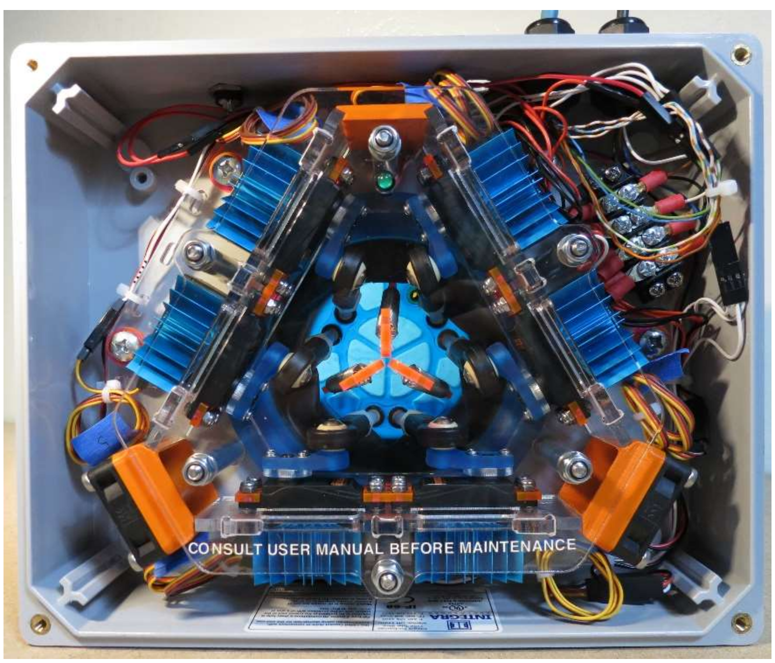


Figure 70. Assembled motion system inside waterproof enclosure prior to having rear cover installed.

At this point the rear cover can be installed along with the seal lock ring and the system is ready for testing.

6.3.5 Assembling Motion System to Overall Layout

The components of the layout include the base, two legs, two uprights, two fastening plates, 4 corner brackets and 24 screws. All cuts and custom features on the base such as holes and slots were made with a laser cutter, and holes were tapped by hand if necessary. The first step is to screw the motion system and the two uprights together. Next, the brackets are to be screwed into the base. The uprights are then attached to the brackets and all screws are tightened to secure the motion system. Next, the access path is screwed through the base into the fastening plates which will sit underneath the base. Finally, to allow the base to sit flat and slightly elevated, the two legs will be glued to the bottom of the base. See figure 70 for a picture of the overall layout.

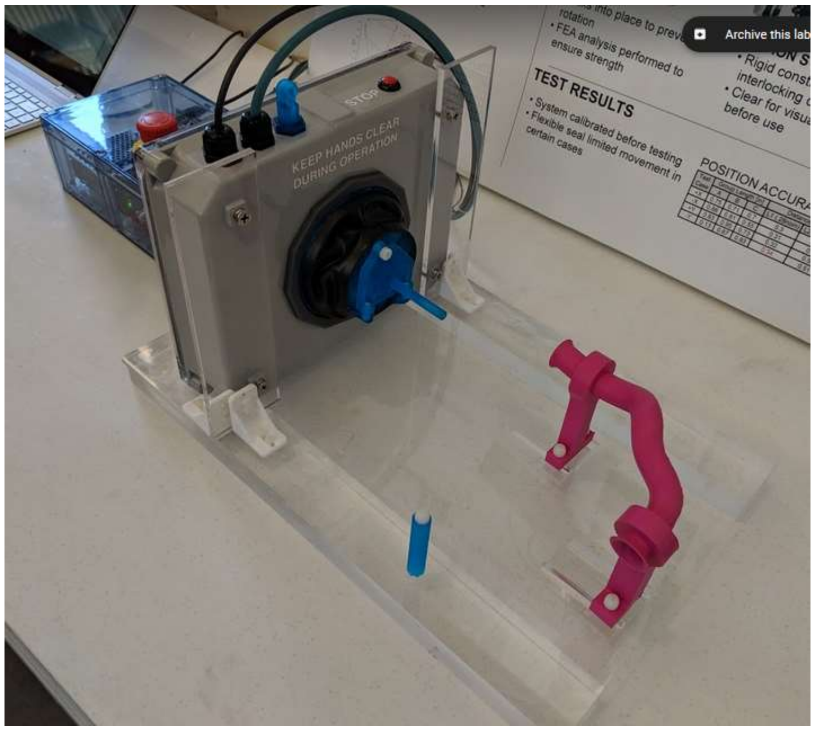


Figure 71. Assembled motion system attached to the base which keeps it steady while it is run. A pink access path is also on the layout.

6.4. Calibration

Once the system is assembled it will be necessary to calibrate it. If the system had previously been calibrated those calibrations must be removed before beginning.

To calibrate the performance of the X, Y, and Z axis along with Roll, Pitch, and Yaw must be independently quantified.

For example, if the X axis is to be calibrated motion profiles can be generated and executed one at a time from a negative X axis value and slowly progressing to a positive X value. The actual end effector position can then be measured and plotted against the programmed position yielding results like what is shown below.

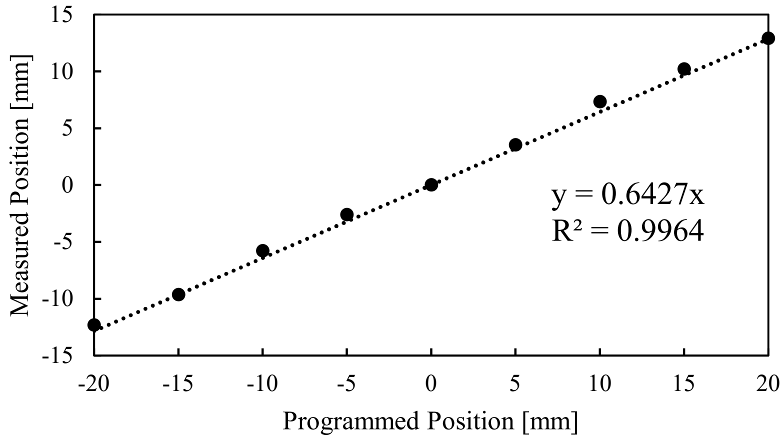


Figure 72. Example calibration curve for X axis.

This information can then be used to modify the PlatformModel.py file as shown below.

```
'convert input orientation into translation and rotation arrays'
x_translation = (1/.6427)*orientation[0] # [mm]
y_translation = (1/.6317)*orientation[1] # [mm]
z_translation = (1/.9512)*orientation[2] # [mm]
x_rotation = (1/.7896)*math.radians(orientation[3]) # [rad]
y_rotation = (1/.7801)*math.radians(orientation[4]) # [rad]
z_rotation = (1/.5844)*math.radians(orientation[5]) # [rad]
```

Figure 73. Example of calibration data input into PlatformModel Python file.

6.5. Recommendations for Future Manufacturing

The manufacturing process is generally straightforward for this device. Using the final design of each component and the recommendations included above a high yield rate can be expected when producing individual components, and a successful overall build.

That said, the assembly can be a time-consuming process as many of the components require time for adhesives to cure and have small features that are difficult to assemble. Because the device will never be produced in large quantities however, it is reasonable to expect some level of craftsmanship necessary with each device to work around constraints found on a device to device basis.

The best advice for building another would be to select a timeline that allows for lots of patience when working through some of the more detailed aspect of construction.

7. Design Verification Plan

The following section discusses the testing plan for this device. Because of development delays many of the specifications were not formally tested, those that were qualitatively demonstrated are noted below. Formal tests that were conducted are discussed in greater detail below.

Table 5. Design Verification Plan and Report

Date: 2/9/18		Team: DyHeart	Sponsor: Aric Stone			Description of System: Replicating the Dynamic Motion of the Right Ventricle						DVP&R Engineer:	
TEST PLAN										TEST REPORT			
Item No	Specification #	Test Description	Acceptance Criteria	Test Responsibility	Test Stage	SAMPLES TESTED		TIMING		TEST RESULTS			NOTES
						Quantity	Type	Start date	Finish date	Test Result	Quantity Pass	Quantity Fail	
1	1,4,16	Translational/Rotational Position Accuracy: Use test adapters to verify performance of final hardware	.05” Translation and 1^{o} Rotation Accuracy	Sam	FP	1	Sub	2/19/2018	6/29/18	FAIL	20	6	Seal limited yaw. Y axis had small deviation in negative direction.
2	2,3	Submersion: Submerge waterproof portion of system as specified and inspect for leaks	No leaks for 1 hour at max depth	Sam	FP	1	Sub	2/26/2018	6/29/18	PASS	1hr	0	No evidence of water ingression. Assumed ability to last >1hr.
3	7	Variable Heart Rate: Be able to adjust the speed of simulation	30 – 140 PBM	John	FP	1	Sub	2/19/2018	-	NC	-	-	Implemented in software but not tested.
4	10	Software Usability: Time a friend or colleague how quickly they can set up and start the software with GUI instructions	10 minutes	John	FP	1	C	2/26/2018	-	NC	-	-	Initial installation can be time consuming.
5	11	Current Testing: Max system current	10A total	John	SP	1	Sub	2/12/2018	-	Pass	-	-	50W Power Supply at >5V Used
6	5	Modular Design	Easily Changed Motion Profiles and Adapters	Sam		1	-	-	-	Pass	-	-	System meets requirement.
7	6	Different Patient Profiles	Analysis of Multiple CT Scans	Sam		-	-	-	-	Fail	-		Only had access to one scan capable of being analyzed.
8	8	Overall Dimensions	<1ft^3	-		1	-	-	-	NC	-	-	Criteria no longer relevant.
9	9	Weight	20lbs Max	-		1	-	-	-	NC			Criteria no longer relevant.
10	12	Surface Temperature	<100^{o}F	-		1	-	-	-	NC	-	-	High temperatures not observed.
11	13	Reproduce RV Motion	Free Wall, Septal Wall, Apex	Sam		1	-	-	-	Pass	3	3	From MATLAB
12	14	Development Cost	<$3,000	Sam		1	-	-	-	Pass	-	-	
13	15	Tissue Replacement Time	<10 min	Brian		1	-	-	-	NC	-	-	Unofficial tests took less than 10mins

7.1. Translational/Rotational Position Accuracy

The translational/rotational position accuracy test was performed on the fully assembled final hardware after it had been calibrated. This test consisted of loading a motion profile that stepped one axis of translation or rotation at a time from zero to an intermediate value, to an extreme value, back to the intermediate and back to zero before repeating. For each degree of freedom being measured this profile would be repeated ten times to demonstrate repeatability. The intermediate value is approached form two direction to demonstrate overall accuracy.

For rotational accuracy a custom adapter holding a BNO055 IMU was used in conjunction with an Arduino to record orientation of the end effector as it moves. This setup is shown below.

Figure 74. BNO055 IMU mounted onto custom adapter for determining end effector orientation.

Once rotational data was collected, the data was analyzed in excel to determine the angles reached in comparison to the target values.

For positional accuracy a custom adapter that had a flat surface which 2x2" pieces of paper could be attached was used in conjunction with a marker held in space in front of the end effector (generally taped to another object). The motion profiles would move the end effector slightly in the Z axis, so the marker would place a dot at the three locations of interest for each test. These markings could then be measured to determine overall performance.

A result of this testing showed that translation occurred accurately across all axis except -Y. this error could have been a result of an imperfect test setup, as the marker tip would make inconsistent mark sizes, or a result of a device calibration that could be improved. Rotational results were strong for all tests except Yaw. During Yaw tests the flexible seal would limit the overall motion of the system, reducing its accuracy.

Despite this 99% confidence that translation will be within .034" of the target value and rotation will be within .331º was found.

7.2. Submersion Time

The submersible motion system is designed using IP68 rated components, which will allow for indefinite submersion. However, our modifications to these components require that we test the overall system again.

To determine if the system is waterproof the final build was submerged at max depth for one hour, checking for leaks at intermediate times throughout. At the end of the test no evidence of water ingression was found. An image of this test setup is shown below.

Figure 75. Submersion test setup used to hold device underwater for one hour.

8. Project Management

The overall project timeline along with a discussion of how well the project timeline was executed.

8.1. Project Timeline

Project activities will be structured around reaching the milestones listed in table 6 below. These major deliverables act as a guide for determining lower-level project activities and timelines.

Table 6: Major Project Deliverables

Date	Deliverable	Description
10/13/17	Scope of Work	A document addressed to a specific person that outlines a solution to a specific problem statement as well as details the steps needed to accomplish the goal.
11/14/17	Preliminary Design Review	The PDR supplements the SOW with an added section focused on the design process and how the lead concepts were developed and chosen.
1/16/18	Interim Design Review	The IDR is a presentation that ties up any loose ends presented in the PDR. While no formal document is created, a final idea should be chosen by this point.
2/06/18	Critical Design Review	The CDR is an updated version of the previous two documents (SOW and PDR) that can be used as a guide by anyone to completely build a finished product, including components, prices, and CAD models.
3/13/18	Manufacturing & TEST Review	The Manufacturing and Test Review is a presentation that lists the current manufacturing status of the final design along with test procedures and safety guidelines.
4/26/18	Hardware / Safety Demo	The Hardware/Safety Demonstration is performed post prototype development and used to demonstrate that all safety precautions have been met.
6/01/18	Project Conclusion / Final Design Review	The FDR is the final document that will be updated from the CDR, listing any changes that may have been made during construction and will be submitted to the Library.

8.2. Notes on Project Management

The complexity of this project made it a continuous challenge to meet project deadlines and coordinate work between members. Beginning as early as the critical design review it was clear that many details of the project were not being completed on time. This problem accumulated as the project progressed and while the vast majority of details were eventually worked out to deliver a final product, other activities such as testing, and documentation were pushed back as a result.

The team would have benefited from taking extensive time to plan the project timeline and implementing meaningful consequences for work not completed on time or at an acceptable quality. This lack of planning also made it difficult to distribute the workload. The packaging requirements of the final hardware required that each component be both functional and fit within restricted spaces, something that could not easily be communicated across team members with our level of management.

9. Conclusion & Recommendations

This project began with a concise problem, determine right ventricle motion from CT scans, and reproduce that motion. From early concept and prototypes to the final device there has been a huge quantity of development and revision as detailed in this document. And this document does not even touch on the near weekly iterations of individual components necessary to produce a functioning final product.

The final hardware that will be delivered to the sponsor allows for a motion profile extracted from CT scans to be produced onto an actual animal heart. However, at its core the system developed can take any motion profile, not just that of the right ventricle, and reproduce it. The ability to generate and use new motion profiles in the future, along with the ability to install different adapters onto the device, provides the possibility to further improve the devices clinical relevance for its designed use, or to completely repurpose the device.

Although at the devices extremes some motions are not reproduces as accurately as desired, the hardware makes a significant advancement towards the sponsors goal and will allow them to at a minimum evaluate the concept before investing more time or money into such endeavors. With this in mind the following section provides some recommendations for any future development of this concept.

9.1. Future Development Recommendations

- Increase functionality with new motion profiles and adapters.
    - This system was designed for these changes to be made easily, expanding and improving functionality.
- Upgrade Servos
    - To achieve faster performance and greater force at the end effector the servos can be replaced with higher performance models.
    - Higher performance servos will also reduce play in the system caused by the servos.
    - This upgrade would require a replacement of the system power supply, power cable, and depending on the servos slight changes to software.
    - It would be recommended to stick within the Spektrum family of servos.
- Upgrade MCU
    - For motion profiles with many data points the microprocessor clock speed can limit how fast the profile can run. This could be resolved by using a faster microprocessor.
- Increase Length of the Flexible Seal
    - This would prevent the seal from constraining yaw motion at angles greater than ±10º as observed during testing.
- Design system for greater range of motion
    - Some of the systems designed motion range was not achievable after calibration. A factor of safety was applied to the original design which made this acceptable, but a redesign should expand on the current systems range of motion.
- Make the threaded through hole on the end effector blind to reduce potential sources of leaks.
    - This hole was made blind on the prototype, so it could be tapped if needed.
- Add a heatsink to the MCU for additional cooling if necessary.

9. Works Cited

[1] "Emerging Transcatheter Therapies For TR." *American College of Cardiology*, www.acc.org/latest-in-cardiology/articles/2017/01/31/13/08/emerging-transcatheter-therapies-for-tr.

[2] *ScienceDaily*, ScienceDaily, www.sciencedaily.com/releases/2014/02/140226110840.htm.

[3] "US5752834A - Motion/force Simulators with Six or Three Degrees of Freedom." *Google Patents*. Google, n.d. Web.

[4] "US6566834B1 - Modular Suspended Manipulator." *Google Patents*. Google, n.d. Web.

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Appendix

A. QFD House of Quality
B. Decision Matrices
C. Preliminary analyses
D. Concept layout drawing
E. Drawing package
F. Purchased Parts Details
G. Budget
H. Test Results
I. Safety Hazard Checklist, FMEA, Risk Assessment
J. User Manual
K. Gantt Chart
L. Motion Analysis Documentation

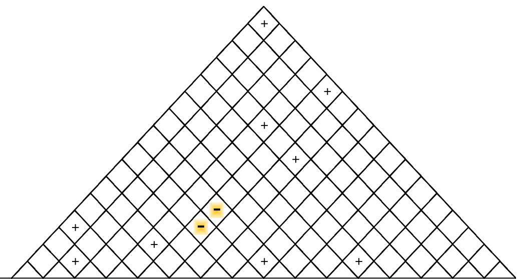
APPENDIX A

QFD HOUSE OF QUALITY

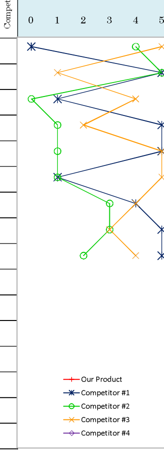
Correlations	
Positive	+
Negative	−
No Correlation	

Relationships	
Strong	●
Moderate	○
Weak	▽

Direction of Improvement	
Maximize	▲
Target	◇
Minimize	▼



								Column #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16							
	WHO: Customers							Direction of Improvement	▲	▲	▲	◇	◇	◇	◇	▼	▼	◇	▼	▼	◇	◇	▼		NOW: Current Product Assessment - Customer Requirements						
Row #	Weight Chart	Relative Weight	Aric Stone (Sponsor)	Lab Technicians	Design Team		Maximum Relationship	WHAT: Customer Requirements (explicit & implicit) / HOW: Engineering Specifications	Translation Positional Accuracy	Submersion Depth of Tissue	Tissue Submersion Time	6 DOF	Modular Design	Different Patient Profiles	Variable Heart Rate	Overall Dimensions	Weight	Software Setup with Minimal Computer Knowledge	Current Between Modules	Temperature	Reproduce Motion of Septal Wall, Septal Groove, and Free Wall	Development Cost	Tissue Replacement Time	Rotational Position Accuracy	Our Current Product	Competitor #1: *Static Tissue Sample*	Competitor #2: Live Animal Testing	Competitor #3: 6DOF Robotic Arm	Competitor #4:	0 1 2 3 4 5	Row #
1		12%	5	2	5		9	Clinically Relevant Right Ventricle Motion	●			●		○	○						●			●		0	4	5			1
2		10%	5	1	4		9	Submersible		●	●								▽	▽						5	5	1			2
3		8%	3	1	4		9	Future Adjustability					●										▽			1	0	4			3
4		7%	5	1	1		9	Budget														●				5	1	2			4
5		12%	3	5	3		9	Easy Attachment of Tissue					○										●			5	1	5			5
6		10%	5	2	3		9	Covers Large Patient Population						●	○						▽					1	1	5			6
7		16%	5	5	5		9	Safe Operation									▽		●	○						4	3	4			7
8		14%	5	5	3		9	Table Top Setup					▽			●										5	3	3			8
9		11%	2	5	3		9	Single Operator								○	●	○					▽			5	2	4			9
10		0%																														10
11		0%																														11
12		0%																														12
13		0%																														13
14		0%																														14
15		0%																														15
16		0%																														16
								HOW MUCH: Target	TBD	1 Foot from Tissue Surface	8 Hours in Motion	3 Linear 3 Rotational	Separate Electronics and Hardware	Amount of Categories TBD	30-160 BPM	1 FT^3	20 LBS	Less than 10 Minutes of Software Setup	TBD	<100 F	3 Locations	<$3,000	<10 Minutes	TBD							
								Max Relationship	9	9	9	9	9	9	3	9	9	3	9	3	9	9	9	9							
								Technical Importance Rating	110.08	89.294	89.294	110.08	123.38	127.42	66.937	157.52	116.31	33.459	153.34	57.727	120.16	60.262	127.59	110.08							
								Relative Weight	7%	5%	5%	7%	7%	8%	4%	10%	7%	2%	9%	3%	7%	4%	8%	7%							
								Weight Chart																							



APPENDIX B

DECISION MATRICES

Motion Mechanism					
Criteria	Baseline	Alternative Solution			
	Rotating Shaft	Robotic Arm	Stewart Platform	Silicone Heart with Linear Actuators	Multi-Platform Motion
6 DOF	0	1	1	0	1
Attaching Tissue	0	1	1	0	-1
X-Ray Compatible	0	0	0	0	-1
Size	0	0	1	1	0
Easy Setup	0	1	1	0	-1
Safety	0	0	0	0	0
Submersability of Tissue	0	1	1	0	0
Repeatability	0	1	1	0	0
Sum of Positives	-	5	6	2	3
Sum of Negatives	-	0	0	0	2
Sum of Neutrals	-	3	2	6	3
Sum	-	5	6	1	-2

Motion Mechanisms:

Rotating Shaft, Robotic Arm, Stewart Platform: See Weighted Decision Matrix for description

Silicone Heart: Rigid heart with softer, moveable material at target locations where linear actuators are attached

Multi-Platform Motion: Platform where a heart or right ventricle is starpped in and twisted and moved linearly

Tissue Type			
Criteria	Baseline	Alternative Solutions	
	Full Heart	RV Sample	Tissue Sample
Cost/Affordability	0	0	1
Uniformity	0	0	1
Setup Time	0	1	1
Easy to Move	0	0	1
Easy to Attach	0	1	1
Similar to Procedure	0	0	-1
Tissue Waste	0	0	1
Sum of Positives	-	2	6
Sum of Negatives	-	0	1
Sum of Neutrals	-	5	0
Sum	-	2	5

See Weighted Decision Matrix for Descriptions.

Tissue Attachment						
Criteria	Baseline	Alternative Solutions				
	Needles	Magnets	4 Clips	2 Clips	Large Clamp Frame	Heart Shaped Container
Setup Time	0	0	0	0	1	1
Minimal Damage	0	1	1	1	1	1
Tissue Waste	0	0	0	0	0	-1
Ability to Clean	0	1	0	0	0	0
X-Ray Compatible	0	-1	1	1	1	0
Tissue Security	0	0	1	1	1	0
Sum of Positives	-	2	3	3	4	2
Sum of Negatives	-	1	0	0	0	1
Sum of Neutrals	-	3	3	3	2	3
Sum	-	1	3	3	4	1

Tissue Attachment:

4 clips, Clamp Frame, Heart Shaped Container: See Weighted Decision Matrix for description.

Needles: Tissue will be pierced by needles which will secure it to a platform.

2 Clips: Two clips similar to binder clips around the edge of a square/rectangle used to secure the tissue sample.

Magnets: Tissue will remain undamaged and will be held in place with magnets.

	Ideas			
Functions	1	2	3	4
Movement	Rotating Shaft	Robotic Arm	Stewart Platform	
Tissue Type	Tissue Sample	RV Sample		
Attachment	4-Clip	2-Clip	Clamp Frame	Shaped Container

				Feasible?	Continue?
1	Rotating Shaft	Tissue Sample	4-Clip	Y	Y
2	Rotating Shaft	Tissue Sample	2-Clip	Y	N
3	Rotating Shaft	Tissue Sample	Clamp Frame	Y	Y
4	Rotating Shaft	Tissue Sample	Shaped Container	N	N
5	Rotating Shaft	RV Sample	4-Clip	N	N
6	Rotating Shaft	RV Sample	2-Clip	N	N
7	Rotating Shaft	RV Sample	Clamp Frame	N	N
8	Rotating Shaft	RV Sample	Shaped Container	Y	Y
9	Robotic Arm	Tissue Sample	4-Clip	Y	Y
10	Robotic Arm	Tissue Sample	2-Clip	Y	N
11	Robotic Arm	Tissue Sample	Clamp Frame	Y	Y
12	Robotic Arm	Tissue Sample	Shaped Container	N	N
13	Robotic Arm	RV Sample	4-Clip	N	N
14	Robotic Arm	RV Sample	2-Clip	N	N
15	Robotic Arm	RV Sample	Clamp Frame	N	N
16	Robotic Arm	RV Sample	Shaped Container	Y	Y
17	Stewart Platform	Tissue Sample	4-Clip	Y	Y
18	Stewart Platform	Tissue Sample	2-Clip	Y	N
19	Stewart Platform	Tissue Sample	Clamp Frame	Y	Y
20	Stewart Platform	Tissue Sample	Shaped Container	N	N
21	Stewart Platform	RV Sample	4-Clip	N	N
22	Stewart Platform	RV Sample	2-Clip	N	N
23	Stewart Platform	RV Sample	Clamp Frame	N	N
24	Stewart Platform	RV Sample	Shaped Container	Y	Y

Weighted Decision Matrix											
Potential Design Solutions			#	Factors							Total
				Anticipated Cost	System Size	Tissue Replacement Time	Tissue Submersibility	Simplicity of Creating Motion	Precision	Robustness	
Movement	Tissue Type	Attachment	Weight	4	3	6	5	1	7	5	-
Rotating Shaft	Tissue Sample	4-Clip	1	**5**	**5**	**5**	**5**	**7**	**3**	**6**	148
Rotating Shaft	Tissue Sample	Clamp Frame	2	**5**	**5**	**7**	**5**	**7**	**3**	**6**	160
Rotating Shaft	RV Sample	Shaped Container	3	**3**	**5**	**3**	**5**	**7**	**2**	**6**	121
Robotic Arm	Tissue Sample	4-Clip	4	**4**	**4**	**5**	**4**	**5**	**7**	**4**	152
Robotic Arm	Tissue Sample	Clamp Frame	5	**4**	**4**	**7**	**4**	**5**	**7**	**4**	164
Robotic Arm	RV Sample	Shaped Container	6	**1**	**4**	**3**	**4**	**5**	**6**	**4**	121
Stewart Platform	Tissue Sample	4-Clip	7	**4**	**5**	**5**	**3**	**5**	**8**	**5**	162
Stewart Platform	Tissue Sample	Clamp Frame	8	**4**	**5**	**7**	**3**	**5**	**8**	**5**	174
Stewart Platform	RV Sample	Shaped Container	9	**2**	**5**	**3**	**3**	**5**	**7**	**5**	135

About the Matrix:

Potential design solutions originated from a series of brainstorming activites, pugh matricies to determine the best solutions for each function, and using a morphological matrix to produce the various combinations of function solutions shown here. Each potential design solution is rated from 1-10 (10 being best) on its anticipated ability to fulfill each factor. The factors are given weights of relative importance used to calculate each potential solutions overall score, higher being best.

Movement Types:

Rotating Shaft: This is similar to a method currently used by Edwards. A shaft is inserted into the heart and attached to the tissue location of interest. Inducing motion on the shaft produces motion at the desired location. Similar to the robotic arm idea.

Robotic Arm: A 6DOF robotic arm with all electrical components housed above the test area, with the arm descending into water (if any) and attaching to the tissue sample.

Stewart Platform: A standard Stewart Platform used to induce motion onto the tissue sample.

Tissue Types:

Tissue Sample: A flat likely rectangular sample of tissue.

RV Sample: A full right ventricle sample.

Attachment Types:

4-Clip: Four clips similar to binder clips around the edge of a square/rectangle used to secure the tissue sample.

Clamp Frame: A tissue sample is placed onto a surface approximatley the same size. A retainer that is open in the center (similar to a picture frame) is brought down and secured onto the sample.

Shaped Container: This would be a container likely 3D printed that could fully or partially incapsulate and support the sample (most likely an RV sample).

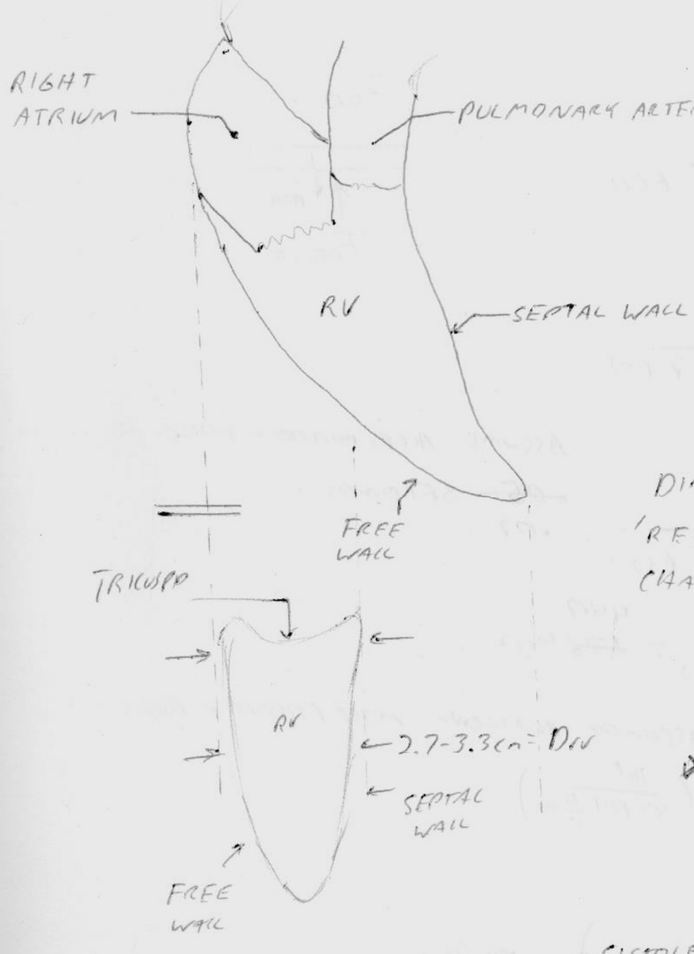
APPENDIX C

PRELIMINARY ANALYSIS

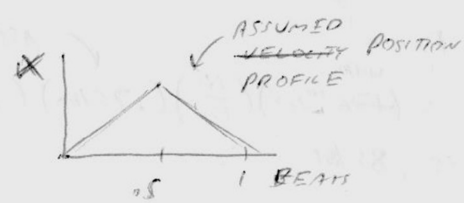
ROUGH APPROXIMATION OF DEVICE SPEEDS AND FORCES

VERY ROUGH DETERMINATION OF ANTICIPATED MOTION PARAMETERS.

CALCULATED BY ASSUMING FREE AND SEPTAL WALL COME TOGETHER ONCE PER CARDIAC CYCLE.



DIMENSIONS FROM 'RECOMMENDATIONS FOR CHAMBER QUANTIFICATION' 1, MARCH, 2016



$$V_{wall} = \frac{D_{RV}}{\text{CONTRACTION}} \cdot \frac{\text{CONTRACTION}}{\text{min}} \cdot 2$$

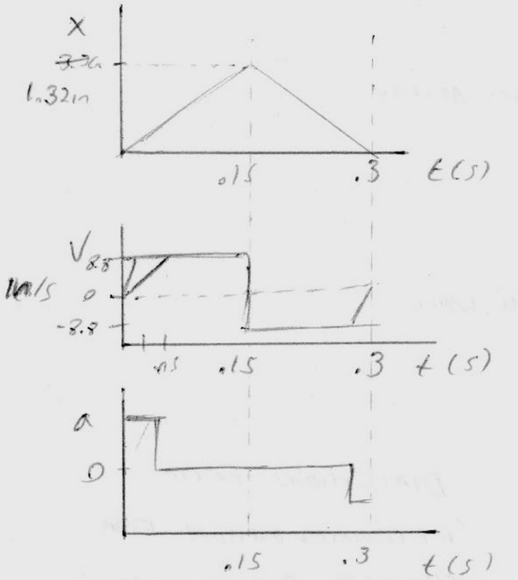
D_{RV}/CONTRACTION = RV DIAMETER; CONTRACTION/min = HEART RATE; 2 ← SISTOLE + DIASTOLE

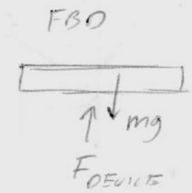
$$= \frac{3.3\text{cm}}{\text{Contraction}} \cdot \frac{300\text{ contraction}}{\text{min}} \cdot \frac{1\text{min}}{60\text{s}} \cdot \frac{.4\text{in}}{1\text{cm}} \cdot 2$$ ← WORST CASE (300 BPM UNLIKELY)

$= 8.8$ in/s ← ASSUME THIS WOULD BE VERTICLE MOTION OF TISSUE PLANE ON FREE WALL

AT 200 BPM

$$\left(\frac{200\ \text{CYCLES}}{\text{min}} \cdot \frac{1\ \text{min}}{60\ \text{s}}\right)^{-1} = .3\ \text{s/CYCLE}$$





ASSUME ACCELERATION TAKES PLACE IN ~~.05~~ .02 SECONDS

SO $a_{max} = \left(\frac{8.8\text{in}}{s}\right) / \ \text{~~.05~~}\ .02(s) = \text{~~176~~}\ 440\ \text{in/s}^2$

$F = ma$ ← ASSUMED PLATFORM MASS (TISSUE + DEVICE)

$= (\text{~~176~~}\ 440\ \text{in/s}^2)\left(\frac{1\text{ft}}{12\text{in}}\right)(.75\ \text{lbm})\left(\frac{1\text{lbf}}{32.174\ \frac{\text{ft}}{\text{s}^2}\ \text{lbm}}\right)$

$= .85\ \text{lbf}$

PLATFORM WEIGHT

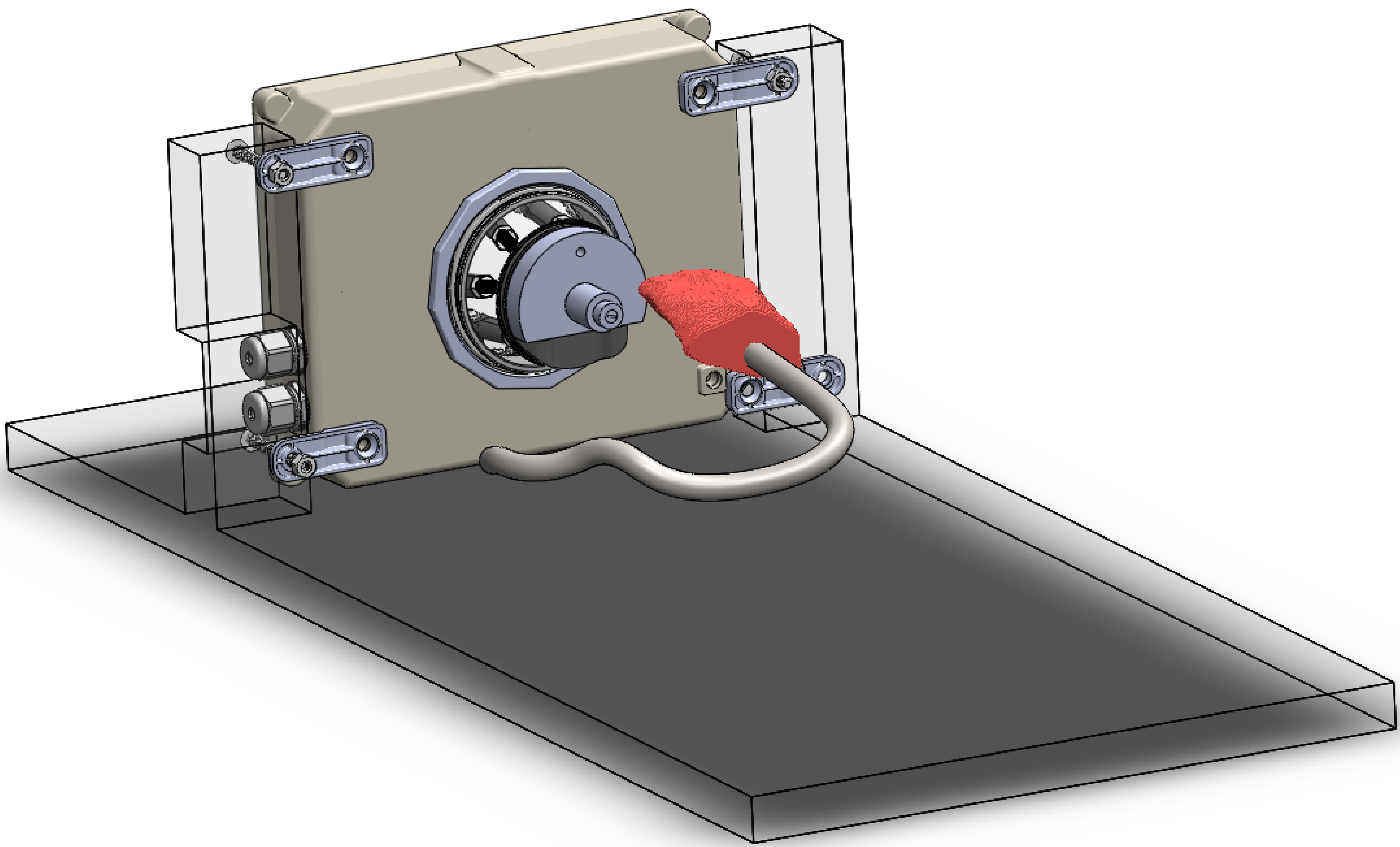
$(.75\text{lbm})(32.174\ \text{ft/s}^2)\left(\frac{1\text{lbf}}{32.174\ \frac{\text{ft}}{\text{s}^2}\ \text{lbm}}\right) = .75\ \text{lbf}$

WORST CASE FORCE NEGLECTING DRAG ON PLATE

$F = 1.6\ \text{lbf}$ \
$V = 8.8\ \text{in/s}$ } ROUGH ESTIMATE OF DEVICE PERFORMANCE.

APPENDIX D

CONCEPT LAYOUT DRAWING



APPENDIX E

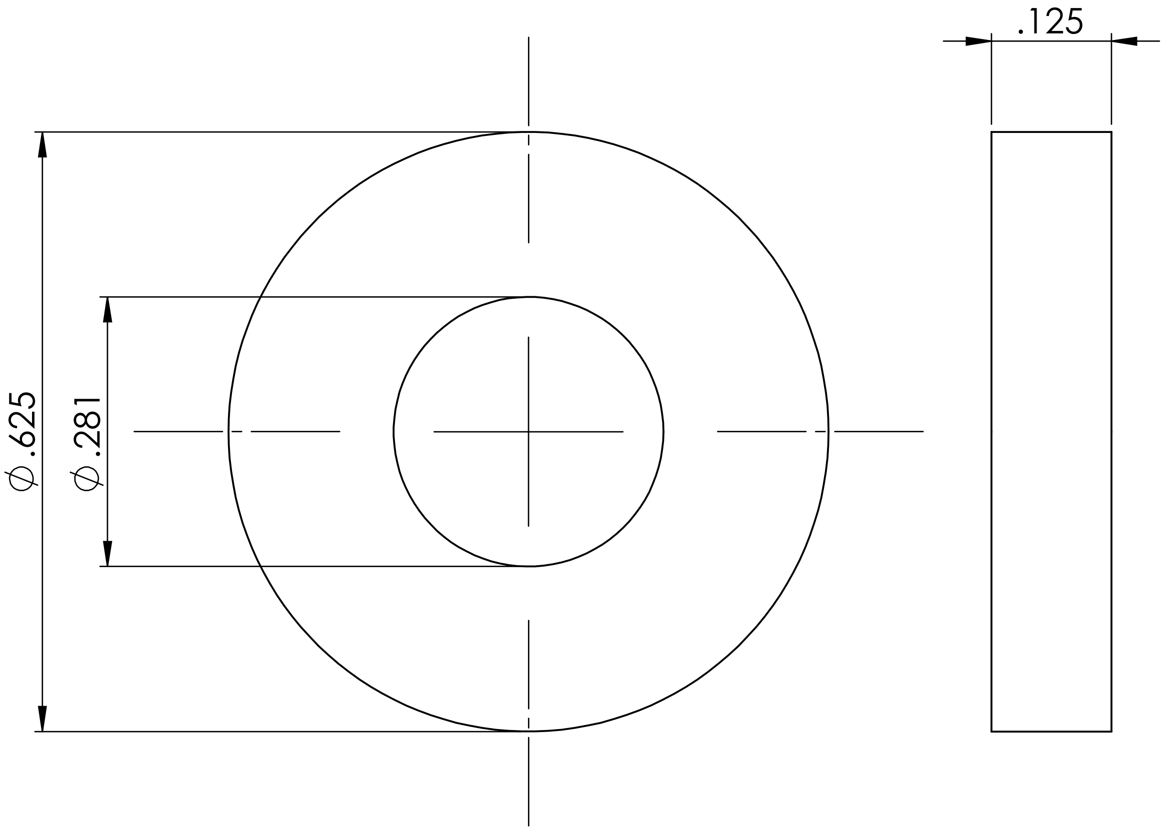
DRAWING PACKAGE

Indented Bill of Material (BOM)
Dynamic RV Simulator

Assembly Level	Part Number	Lvl0	Lvl1	Lvl2	Lvl3	Lvl4	Lvl5	Material	Qty	Total Qty
0	00000	FULL SYSTEM							1	1
1	00001		WATERPROOF ENCLOSURE ASSY					-	1	1
2	00002			WATERPROOF ENCLOSURE				Polycarbonate	1	1
2	00003			CORD GRIP				Plastic	2	2
2	00004			SNORKEL				Resin	1	1
2	00005			SNORKEL NUT				Resin	1	1
2	00006			STOP BUTTON				-	1	1
2	00007			SEAL NUT				Plastic	1	1
2	00008			MOTION SYSTEM CORE				-	1	1
3	00009				SERVO MOUNT ASSY			-	3	3
4	00010					SERVO		-	2	6
4	00011					HEATSINK		Aluminum	2	6
4	00012					SERVO CLIP FULL		Acrylic	1	3
4	00013					SERVO CLIP HALF		Acyrlic	2	6
4	00014					2-56 Locknut		Stainless Steel	8	24
4	00015					N0. 2 WASHER		Stainless Steel	8	24
4	00016					2-56 9/16" Philips Screw		Stainless Steel	8	24
4	00017					SERVO MOUNT		Acrylic	1	3
4	00018					SERVO SCREW		Stainless Steel	2	6
4	00019					SERVO ADAPTER ASSY		-	2	6
5	00020						SERVO SPLINE ADAPTER	Acrylic	1	6
5	00021						SERVO ADAPTER	Resin	1	6
5	00022						N0. 2 WASHER	Stainless Steel	1	6
5	00023						2-56 5/16" Philips Screw	Stainless Steel	1	6
3	00024				SEAL ASSY			-	1	1
4	00025					FLEXIBLE SEAL		Nitrile	1	1
4	00026					SEAL BASE		Resin	1	1
4	00027					END EFFECTOR ASSY		-	1	1
5	00028						END EFFECTOR	Resin	1	1
5	00029						END EFFECTOR SPRING HOOK	Acrylic	3	3
5	00030						3/16 X 1/2 DOWEL PIN	Nylon	2	2
5	00031						THREAD COVER	Acrylic	1	1
4	00032					CONNECTING ROD ASSY		-	6	6
5	00033						CONNECTING ROD	Nylon	1	6
5	00034						SPHERICAL BEARING	Plastic	1	6
5	00035						1/4-20 NUT	Nylon	1	6
5	00036						ROD END	Plastic	1	6
4	00037					249 O-RING		Nitrile	1	1
3	00038				Fan Assy			-	2	2
4	00039					FAN		-	1	2
4	00040					FAN DUCT		ABS	1	2
4	00041					M4 SCREW		Stainless Steel	4	8
4	00042					FAN CLIP		Acrylic	2	4
3	00043				HOUSING SPRING HOOK			Acrylic	3	3
3	00044				10-24 Locknut			Stainless Steel	6	6
3	00045				N0. 10 Washer			Stainless Steel	6	6
3	00046				LED Indicator			-	1	1
3	00047				HOUSING END			Acrylic	1	1
3	00048				AIR BLOCK			ABS	1	1
3	00049				BARRIER BLOCK			-	1	1
3	00050				BARRIER BLOCK SCREW			Stainless Steel	4	4
3	00051				SPACERS			Aluminum	6	6
3	00052				SPRINGS			Stainless Steel	3	3
3	00053				SERVO ADAPTER SCREW			Stainless Steel	6	6
3	00054				HOUSING SEAL END			Acrylic	1	1
3	00055				10-24 2-1/4" Hex Head Screw			Stainless Steel	6	6
2	00056			ACRYLIC WASHER				Acrylic	6	6
2	00057			1/4-20 SELF THREADING SCREW				Stainless Steel	6	6
2	00058			SERVO CABLE EXTENSIONS				-	6	6
2	00059			CAPACITORS				Aluminum	2	2
2	00060			POWER CABLE				-	1	1
2	00061			SIGNAL CABLE				-	1	1

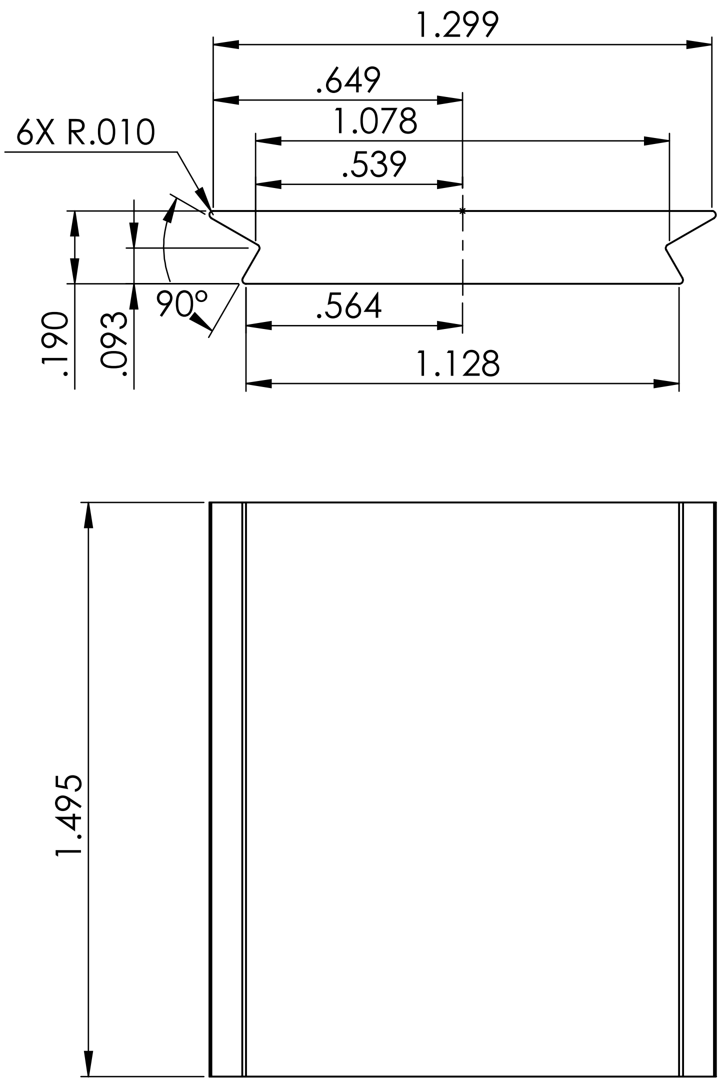
Assembly Level	Part Number	Lvl0	Lvl1	Lvl2	Lvl3	Lvl4	Lvl5	Material	Qty	Total Qty
1	00062		ELECTRICAL ENCLOSURE					-	1	1
2	00063			FLOOR				Acrylic	1	1
2	00064			5V POWER SUPPLY				-	1	1
2	00065			12V POWER SUPPLY				-	1	1
2	00066			FUSE HOLDER				-	2	2
2	00067			5V FUSE				-	1	1
2	00068			12V FUSE				-	1	1
2	00069			AC FUSE				-	2	2
2	00070			Barrier Block Screws				-	1	1
2	00071			BARRIER BLOCK SCREWS				-	4	4
2	00072			ZIP TIE				Nylon	-	-
2	00073			RED 18G WIRE				-	-	-
2	00074			BLACK 18G WIRE				-	-	-
2	00075			GREEN 18G WIRE				-	-	-
2	00076			WHITE 18G WIRE				-	-	-
2	00077			EMERGENCY STOP				-	1	1
2	00078			ENCLOSURE				Polycarbonate	1	1
2	00079			POWER RECEPTICLE				-	1	1
2	00080			POWER CABLE CONNECTOR				-	1	1
2	00081			SIGNAL CABLE CONNECTOR				-	1	1
2	00082			USB CONNECTOR				-	1	1
2	00083			PCB ASSY				-	1	1
3	00084				PCB			-	1	1
3	00085				MCU			-	1	1
3	00086				USB/Volt Regulator			-	1	1
3	00087				Phoenix 6 connector			-	3	3
3	00088				Phoenix 4 connector			-	1	1
3	00089				100000 PF Cap			-	1	1
3	00090				4.7 uf Tantalum Cap			-	1	1
3	00091				.1 uf Cap			-	9	9
3	00092				Ferrite Bead			-	3	3
3	00093				Green LED			-	1	1
3	00094				Orange LED			-	1	1
3	00095				Reset Switch			-	1	1
3	00096				10 kOhm Resistor			-	1	1
3	00097				1 kOhm Resistor			-	1	1
3	00098				750 Ohm Resistor			-	1	1
3	00099				270 Ohm Resistor			-	2	2
1	00100		TISSUE ADAPTER					-	1	1
2	00101			TISSUE ADAPTER				Resin	1	1
2	00102			TISSUE ADAPTER CAP				Resin	1	1
2	00103			CAP SCREW				Nylon	1	1
2	00104			ADAPTER SCREW				Nylon	1	1
1	00105		SYSTEM LAYOUT ASSY					-	1	1
2	00106			BASE				Acrylic	1	1
2	00107			THREADED BAR				Acrylic	2	2
2	00108			UPRIGHT				Acrylic	2	2
2	00109			RAILS				Acrylic	2	2
2	00110			Corner Bracket				Nylon	4	4
2	00111			Nylon Screws, 8-32 3/8"				Nylon	12	12
									Total:	352

MOTION SYSTEM COMPONENTS

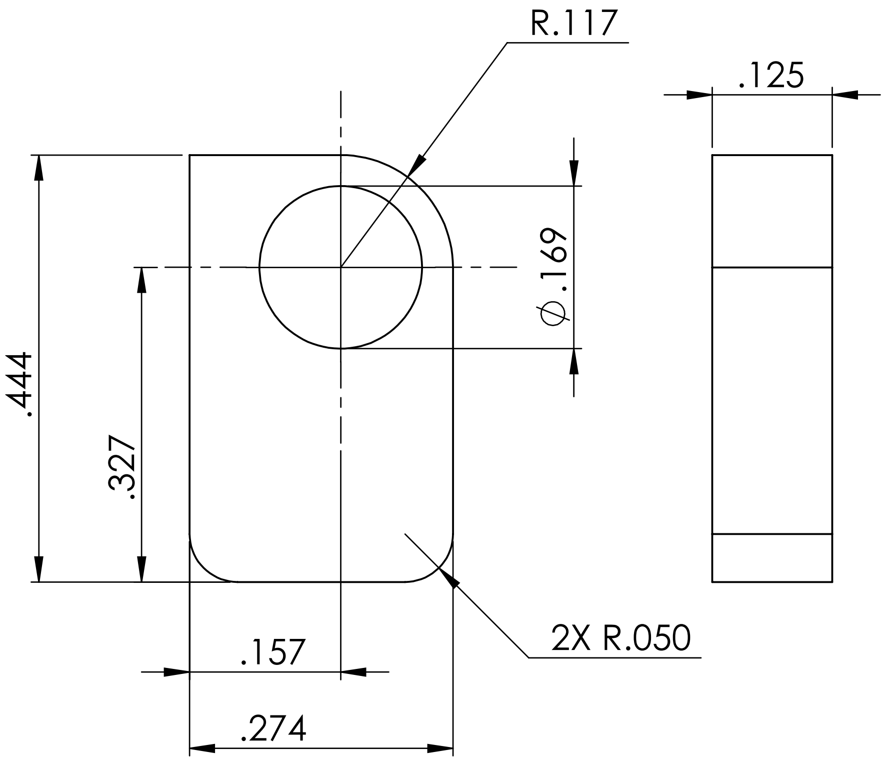


PART NAME: ACRYLIC WASHER
PART NUMBER: 00056
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES
- X.XXX = ±.005
- X.XX = ± .01
- ANGLES = ±1°

DATE: 6/6/18
DRAWN BY: SAM PORTER



PART NAME: AIR BLOCK
PART NUMBER: 00048
MATERIAL: PLASTIC (NO REQUIREMENT)
MANUFACTURING METHOD: 3D PRINT (ANY METHOD)
ALL DIMENSIONS IN INCHES
SCALE 2:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1 °
DATE: 6/6/18
DRAWN BY: SAM PORTER



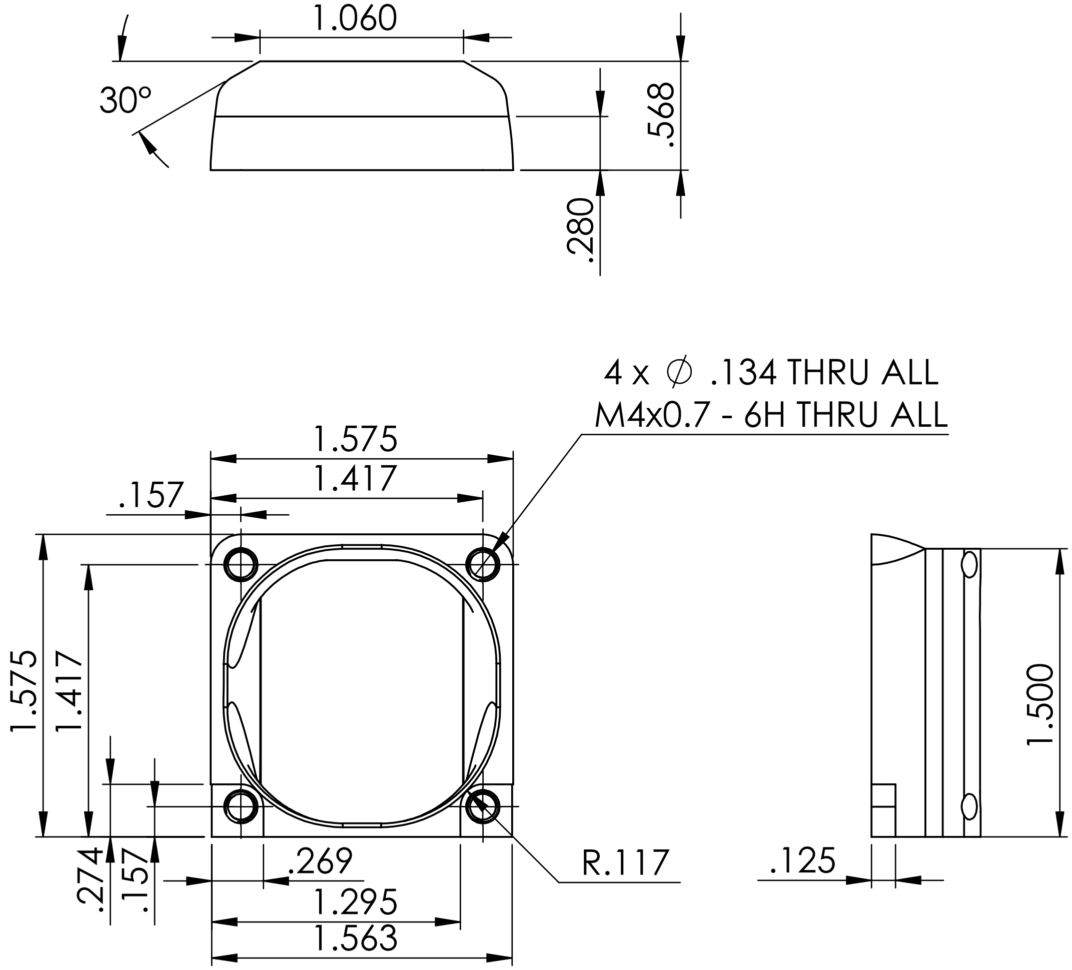
PART NAME: FAN CLIP
PART NUMBER: 00042
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES

X.XXX = ±.005

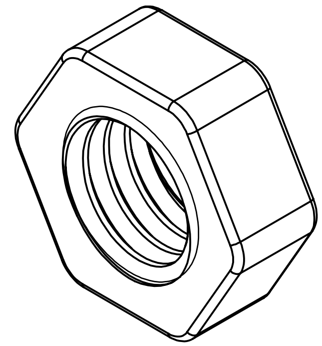
X.XX = ± .01

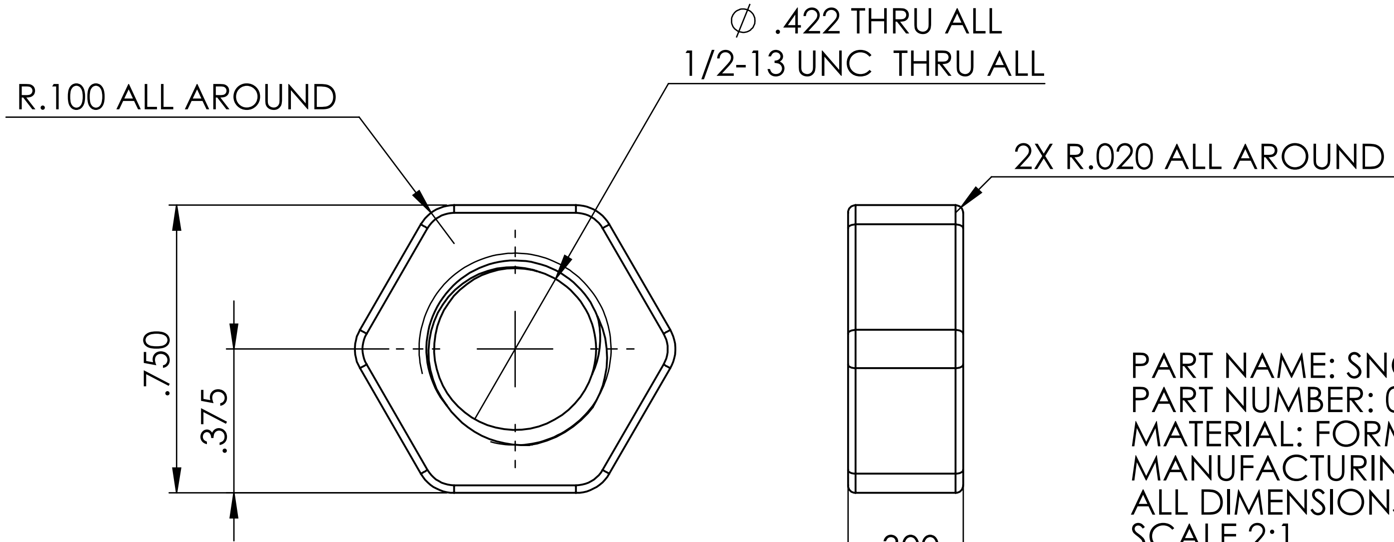
ANGLES = ±1°

DATE: 6/6/18
DRAWN BY: SAM PORTER

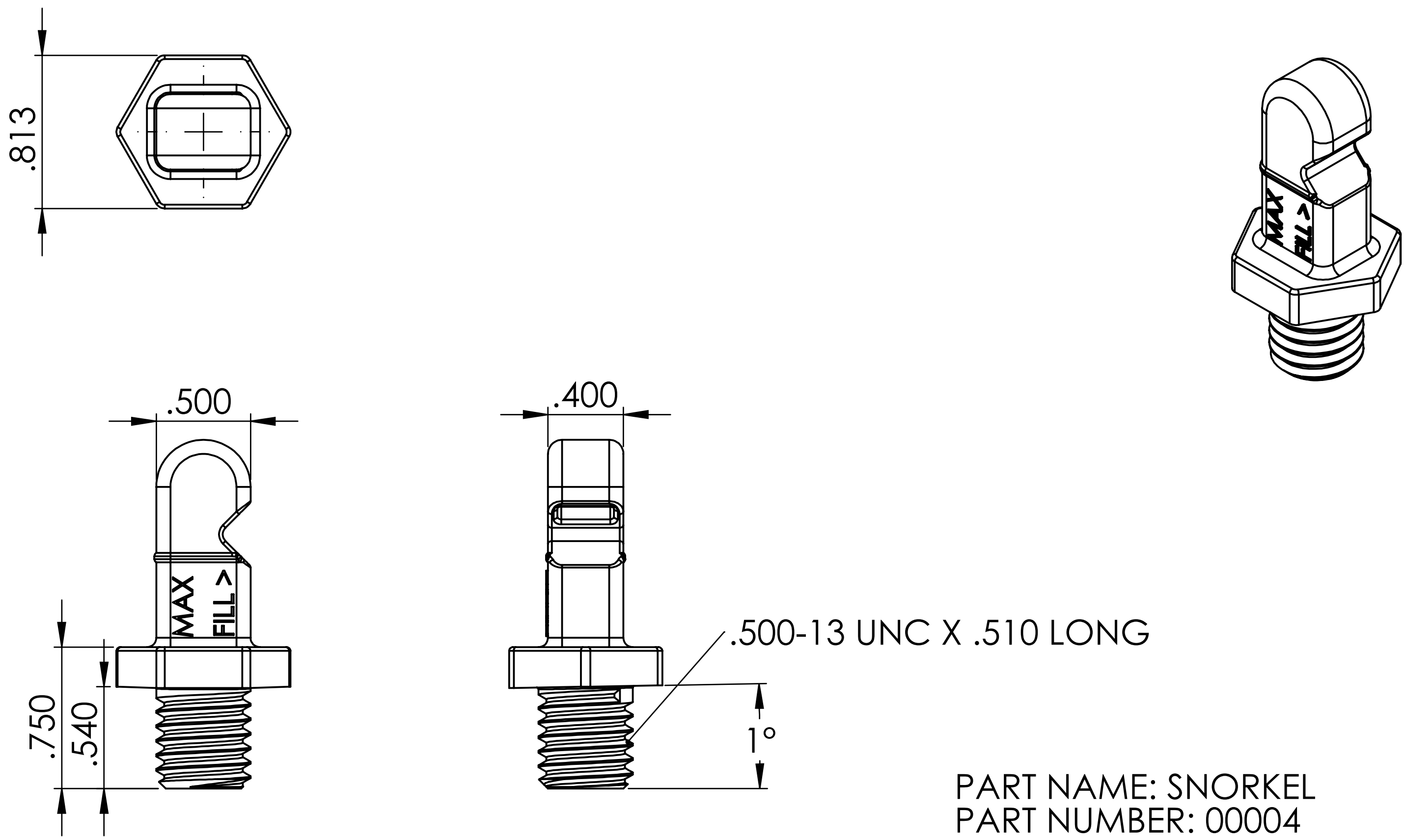


PART NAME: FAN DUCT
PART NUMBER: 00040
MATERIAL: PLASTIC (UNSPECIFIED)
MANUFACTURING METHOD: 3D PRINT
ALL DIMENSIONS IN INCHES
SCALE 1:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER

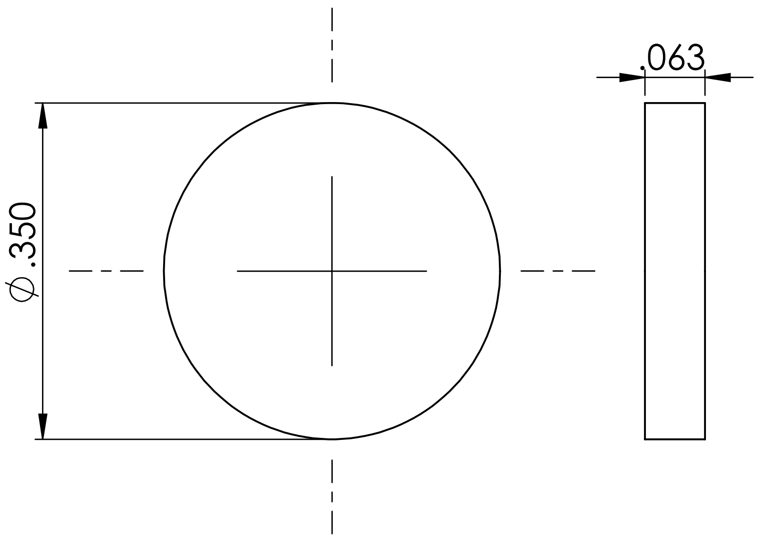




PART NAME: SNORKEL NUT
PART NUMBER: 00005
MATERIAL: FORMLABS TOUGH RESIN
MANUFACTURING METHOD: SLA PRINT
ALL DIMENSIONS IN INCHES
SCALE 2:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER

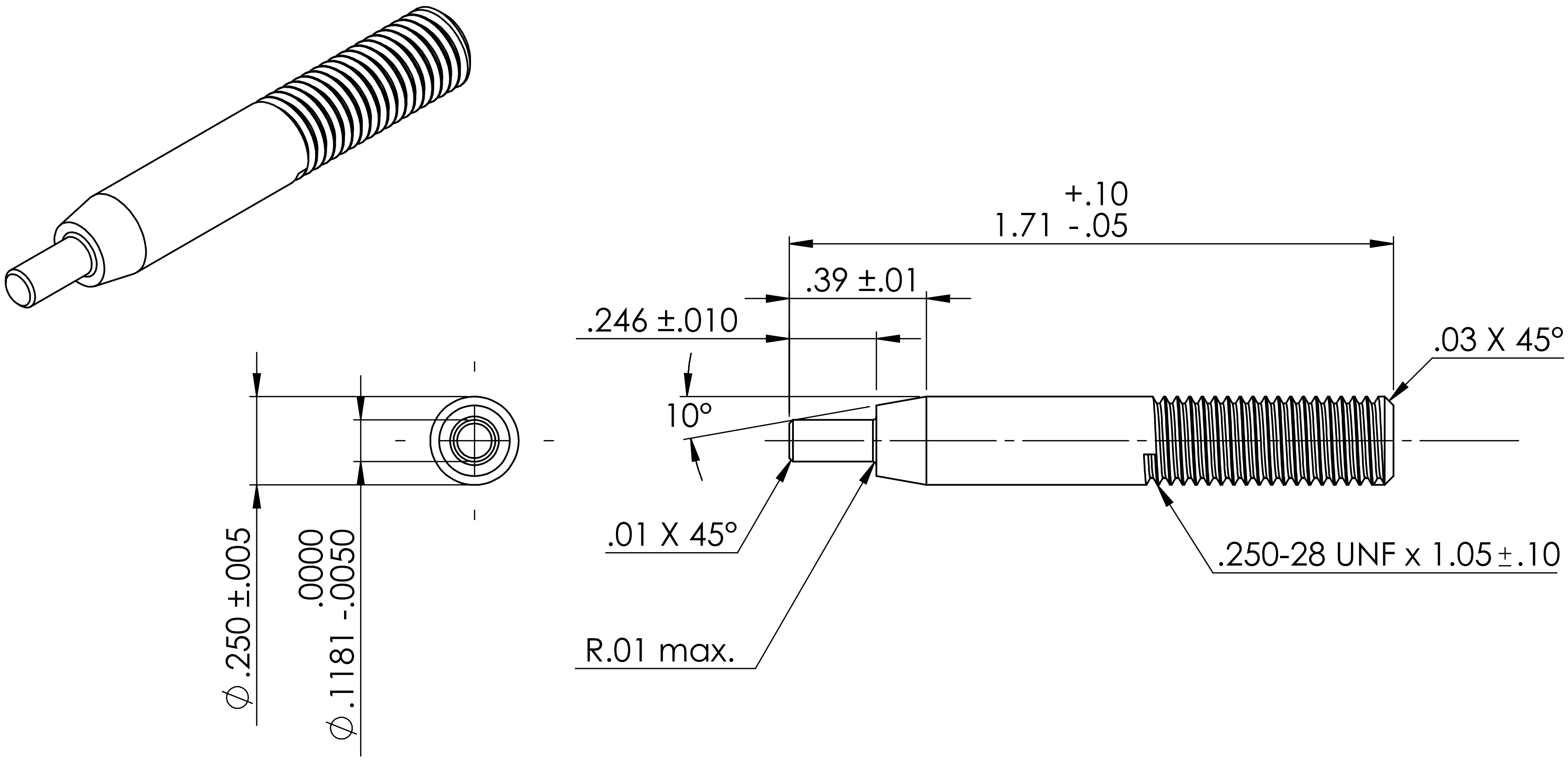


PART NAME: SNORKEL
PART NUMBER: 00004
MATERIAL: FORMLABS TOUGH RESIN
MANUFACTURING METHOD: SLA PRINT
ALL DIMENSIONS IN INCHES
SCALE 1:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER

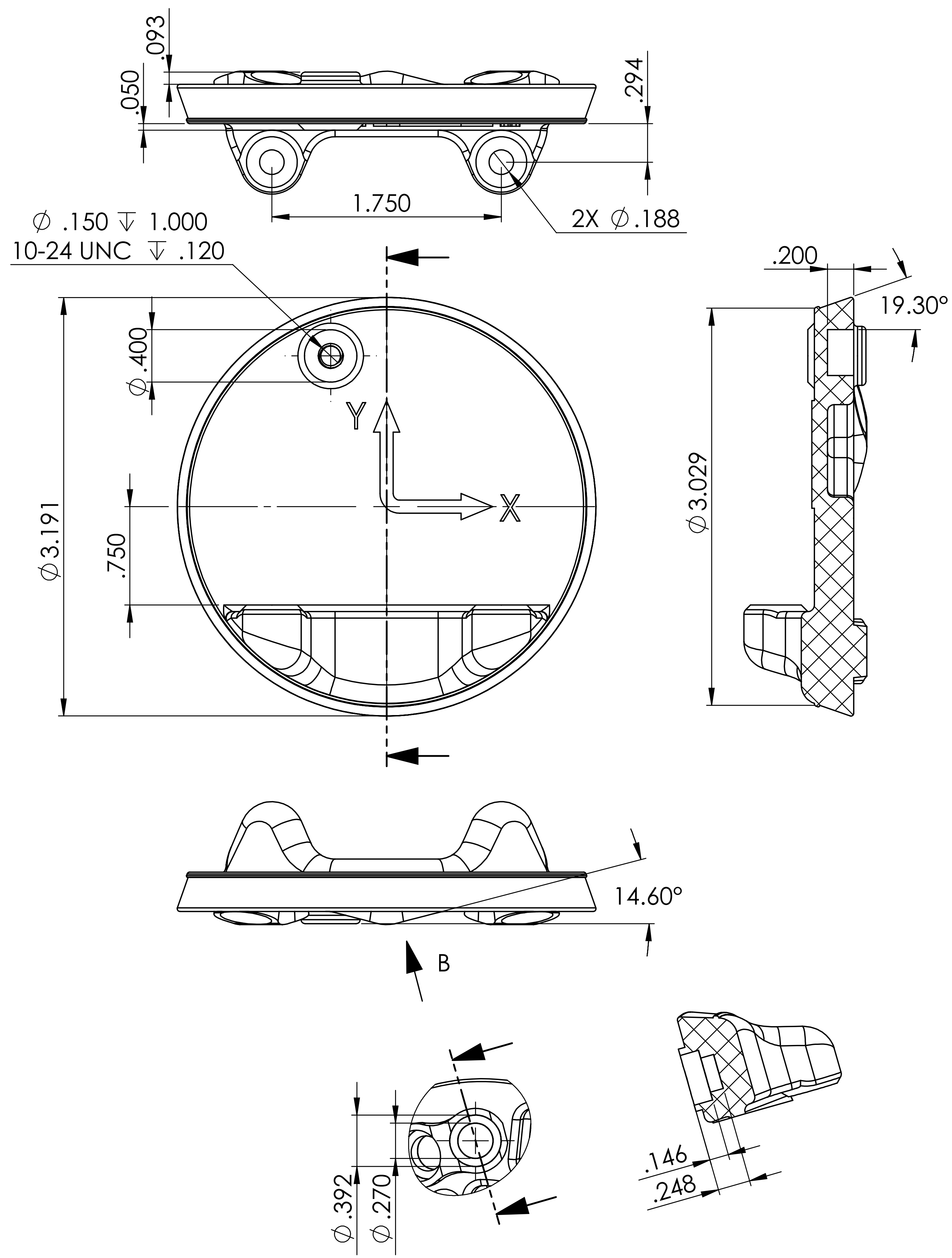


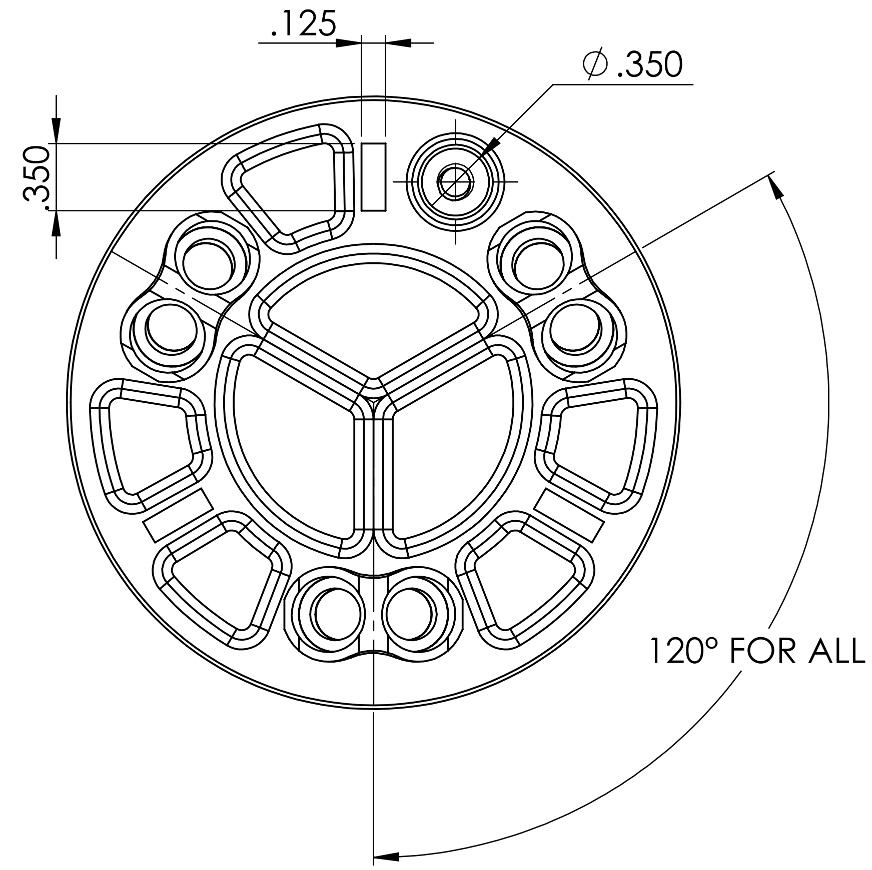
PART NAME: THREAD COVER
PART NUMBER: 00031
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES
- X.XXX = ±.005
- X.XX = ± .01
- ANGLES = ±1°

DATE: 6/6/18
DRAWN BY: SAM PORTER

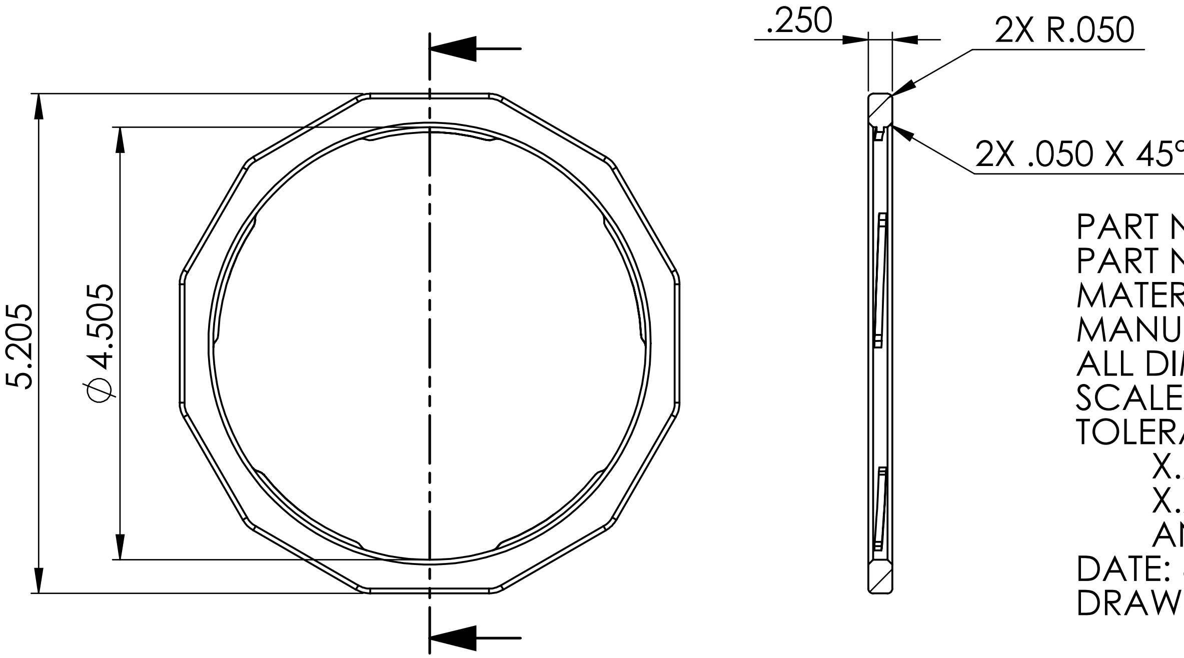


PART NAME: CONNECTING ROD
PART NUMBER: 00033
MATERIAL: NYLON
MANUFACTURING METHOD: LATHE
ALL DIMENSIONS IN INCHES
SCALE 2:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1 °
DATE: 6/6/18
DRAWN BY: SAM PORTER





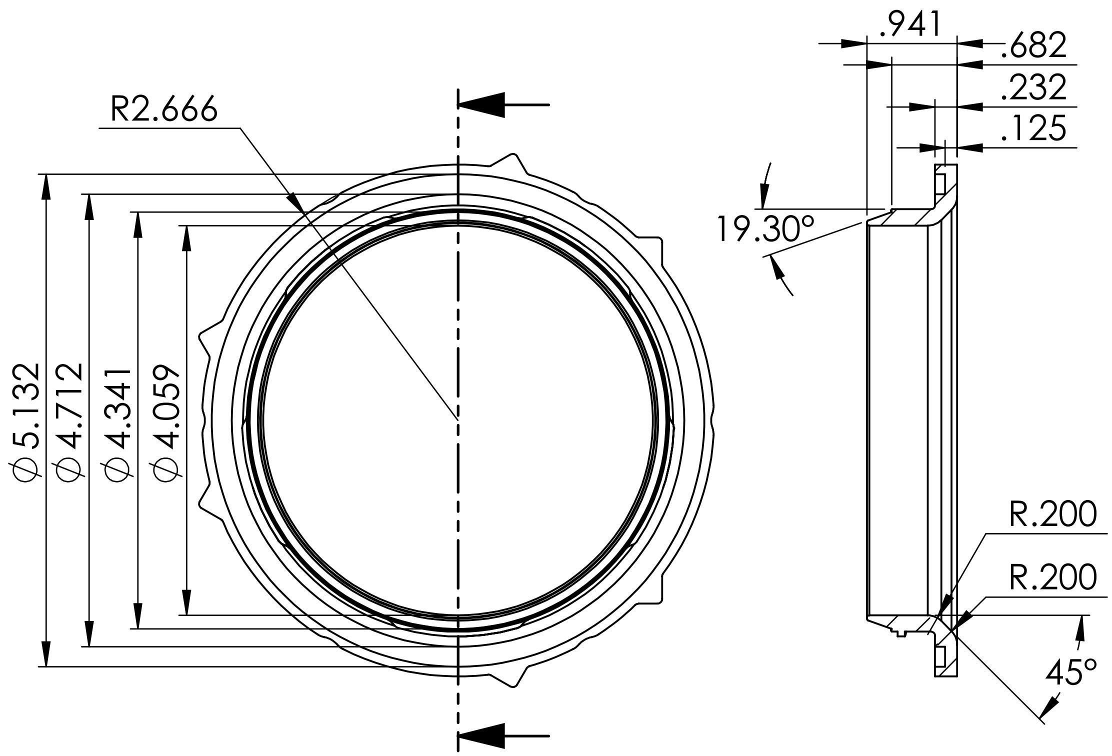
PART NAME: END EFFECTOR
PART NUMBER: 00028
MATERIAL: FORMLABS TOUGH RESIN
MANUFACTURING METHOD: SLA PRING
ALL DIMENSIONS IN INCHES
SCALE 1:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER

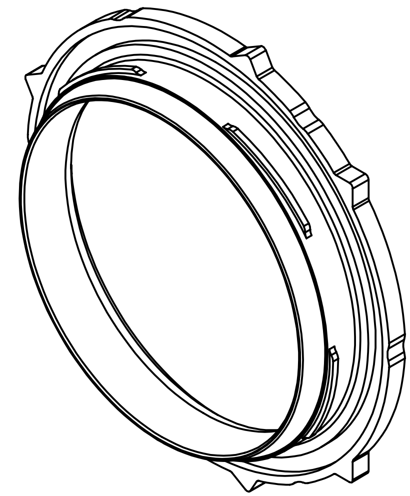


PART NAME: SEAL NUT
PART NUMBER: 00007
MATERIAL: FORMLABS TOUGH RESIN
MANUFACTURING METHOD: SLA PRINT
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES

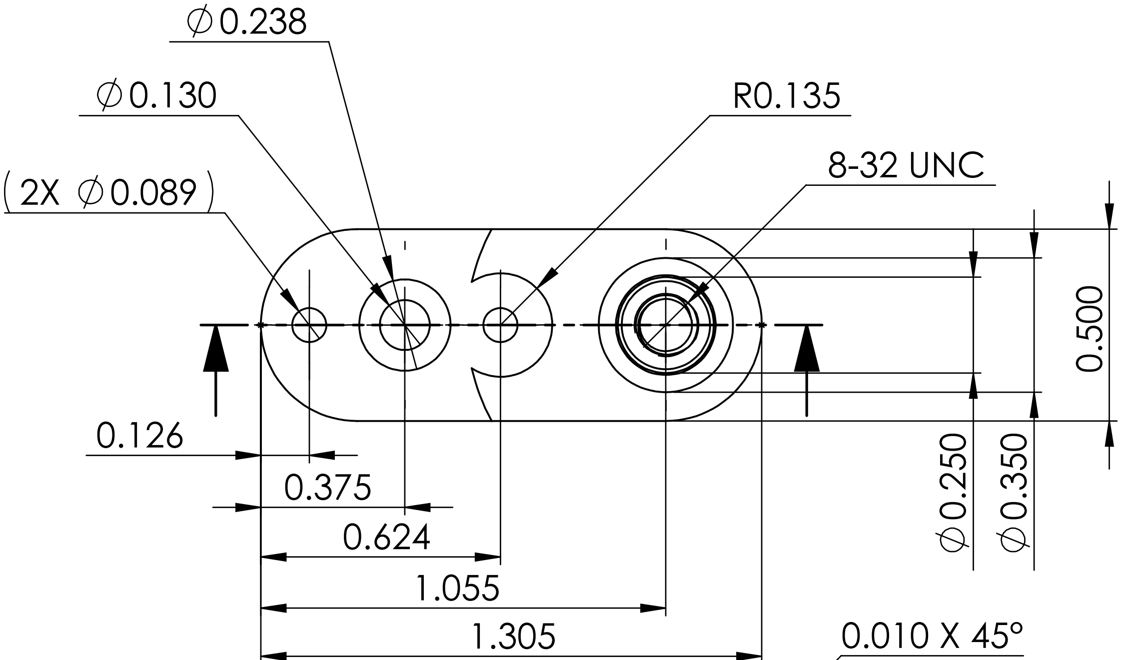
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°

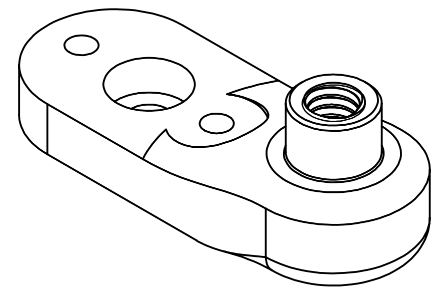
DATE: 6/6/18
DRAWN BY: SAM PORTER

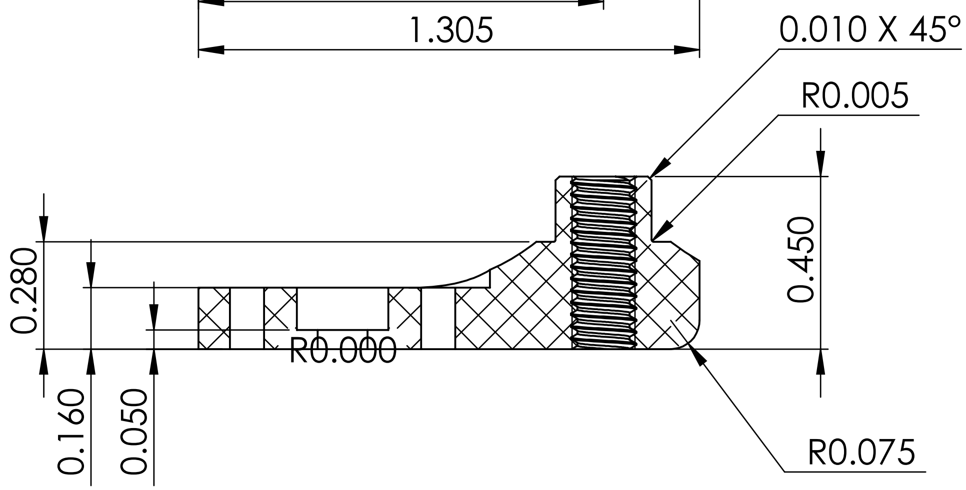




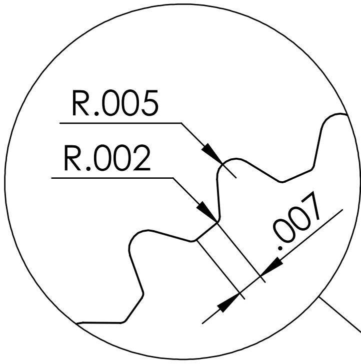
PART NAME: SEAL BASE
PART NUMBER: 00026
MATERIAL: FORMLABS TOUGH RESIN
MANUFACTURING METHOD: SLA PRINT
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



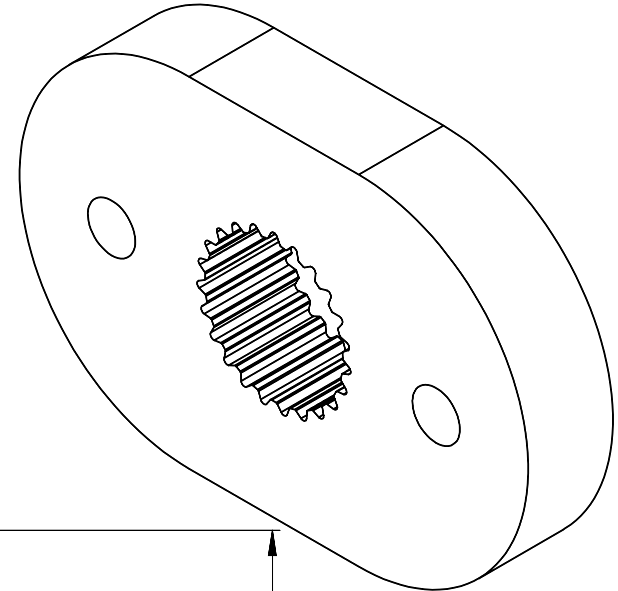


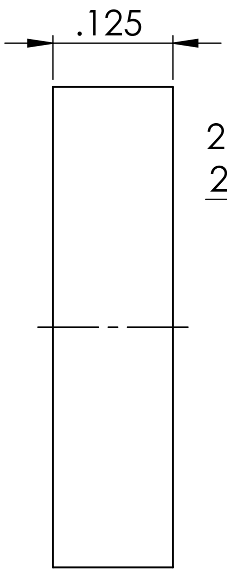


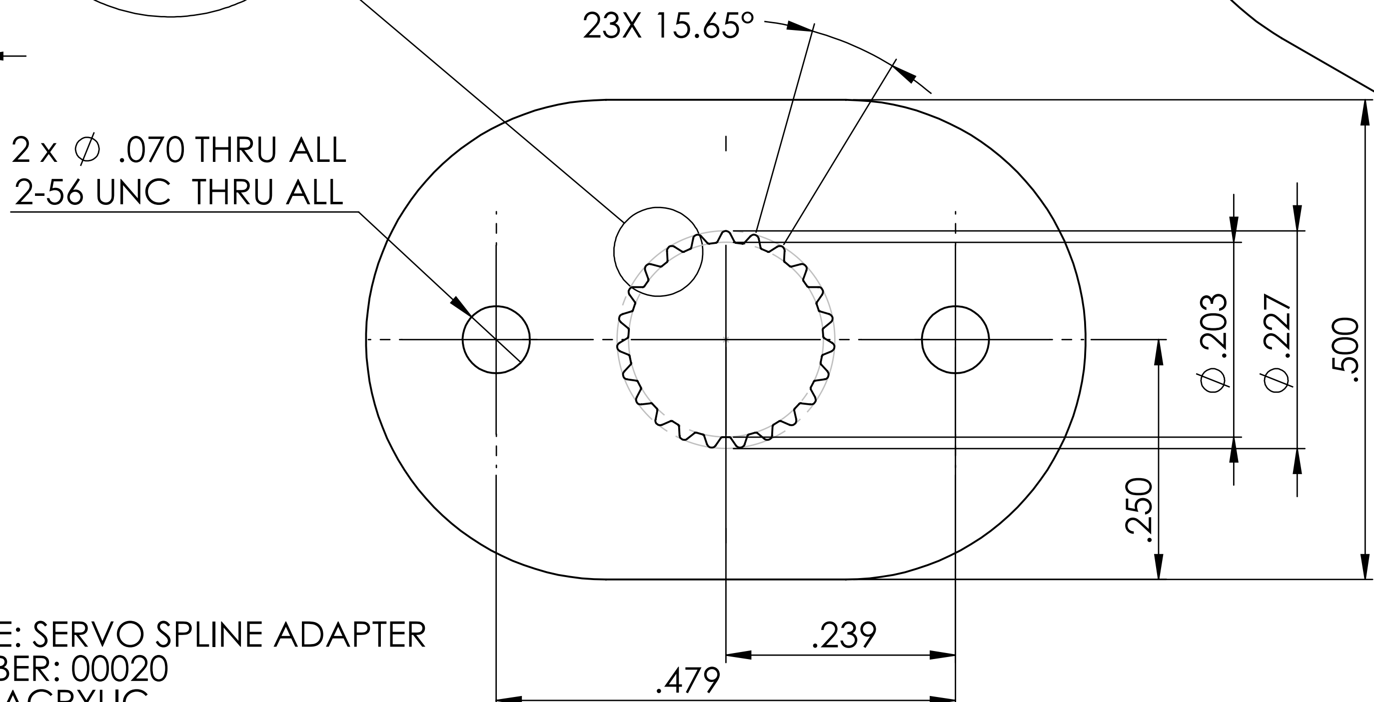
PART NAME: SERVO ADAPTER
PART NUMBER: 00021
MATERIAL: FORMLABS TOUGH RESIN
MANUFACTURING METHOD: SLA PRINT
ALL DIMENSIONS IN INCHES
SCALE 2:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1 °
DATE: 6/6/18
DRAWN BY: SAM PORTER



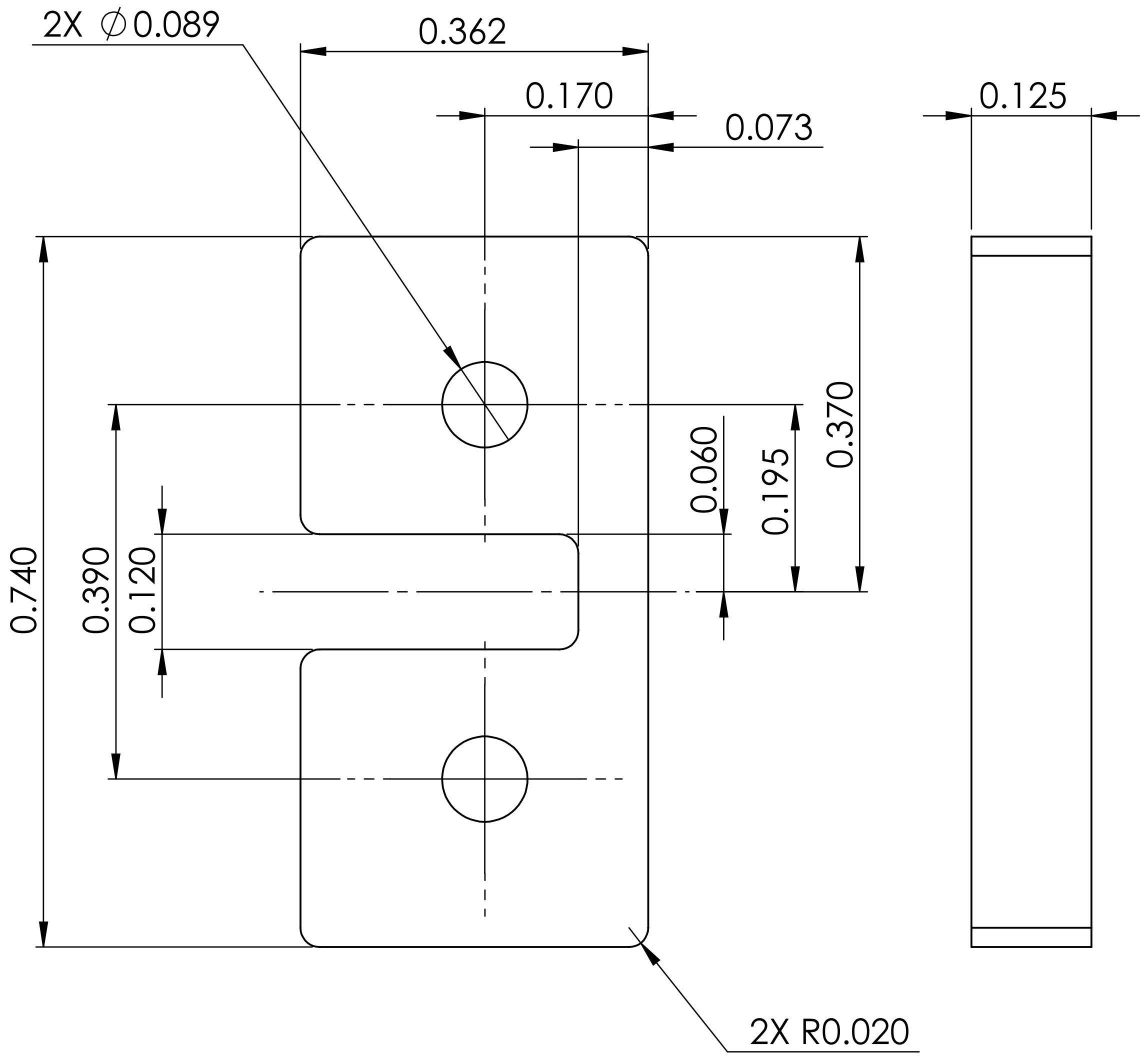
PART TO BE LASER CUT.
SPLINE SIZED FOR APPROPRIATE FIT
WHEN LASER CUT USING CAD MODEL.
DIMENSIONS LISTED HERE MAY BE
SMALLER THAN THAT OF FINAL PRODUCT.



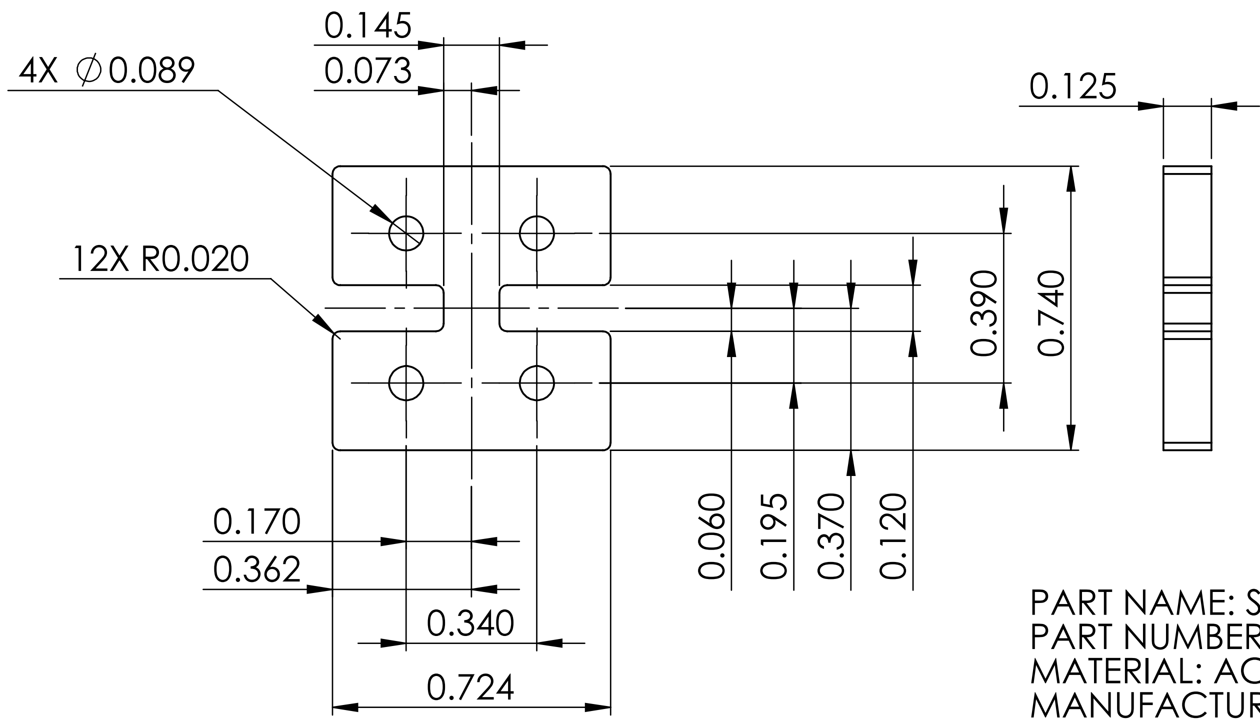




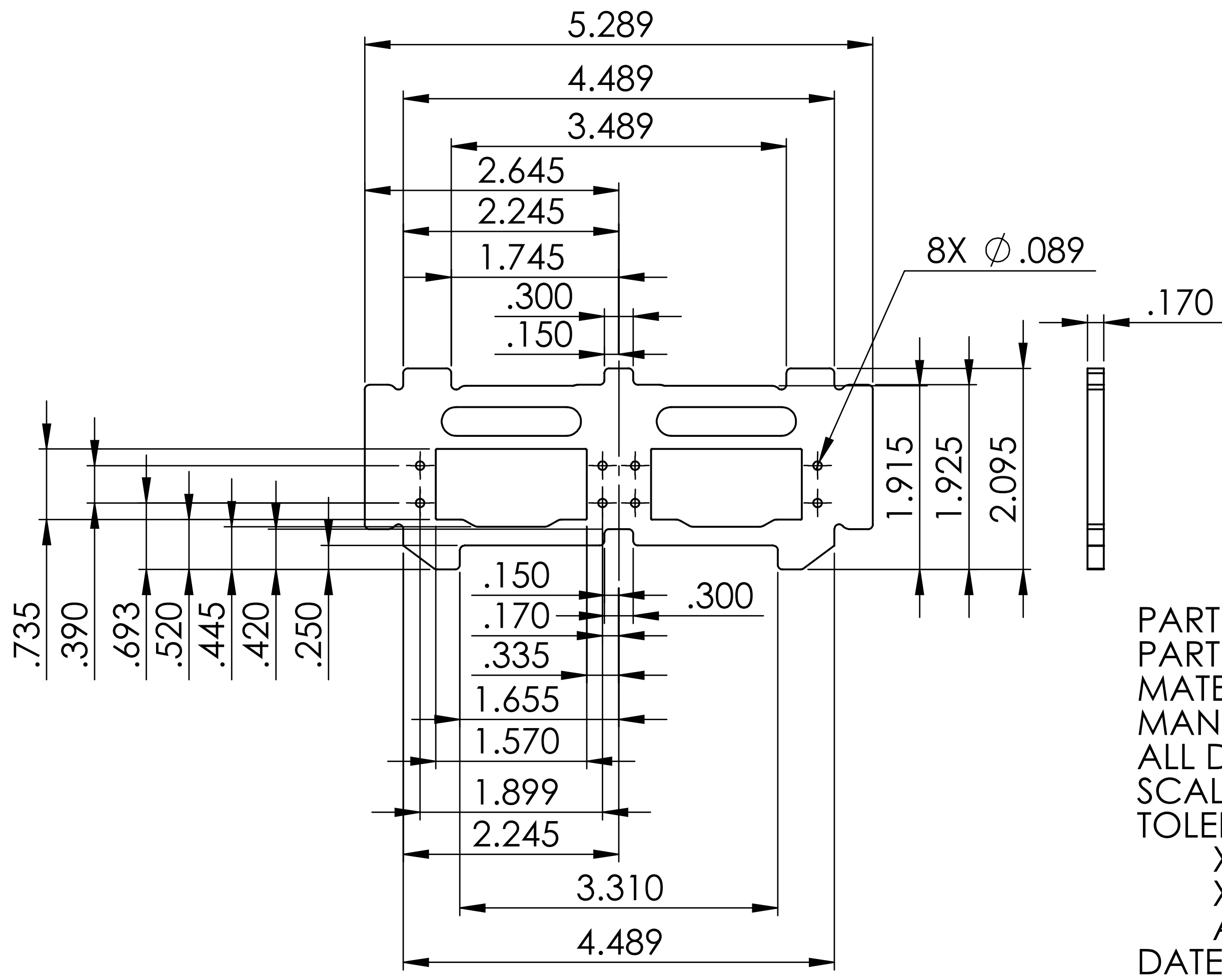
PART NAME: SERVO SPLINE ADAPTER
PART NUMBER: 00020
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1 °
DATE: 6/6/18
DRAWN BY: SAM PORTER



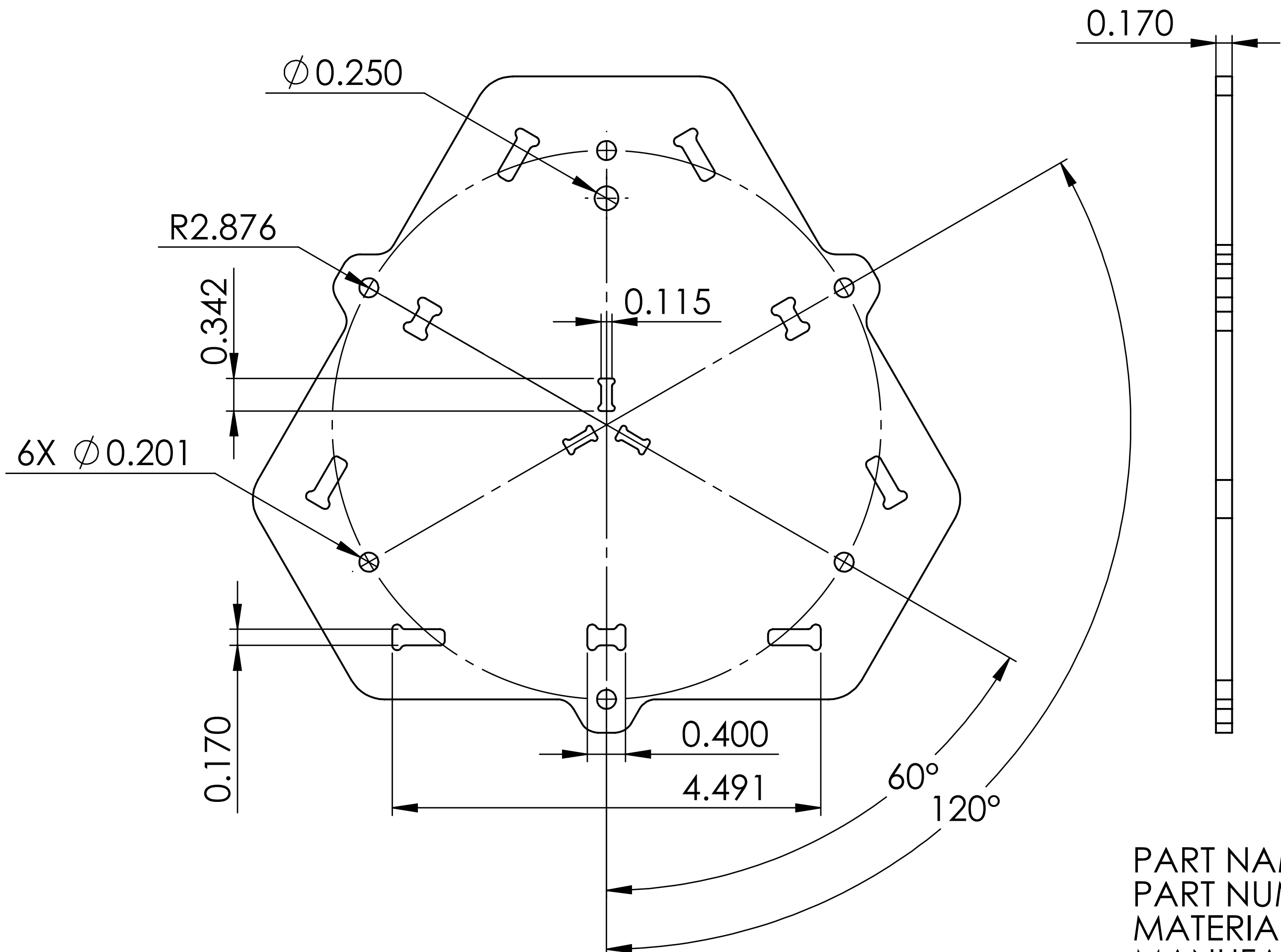
PART NAME: SERVO CLIP HALF
PART NUMBER: 00013
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



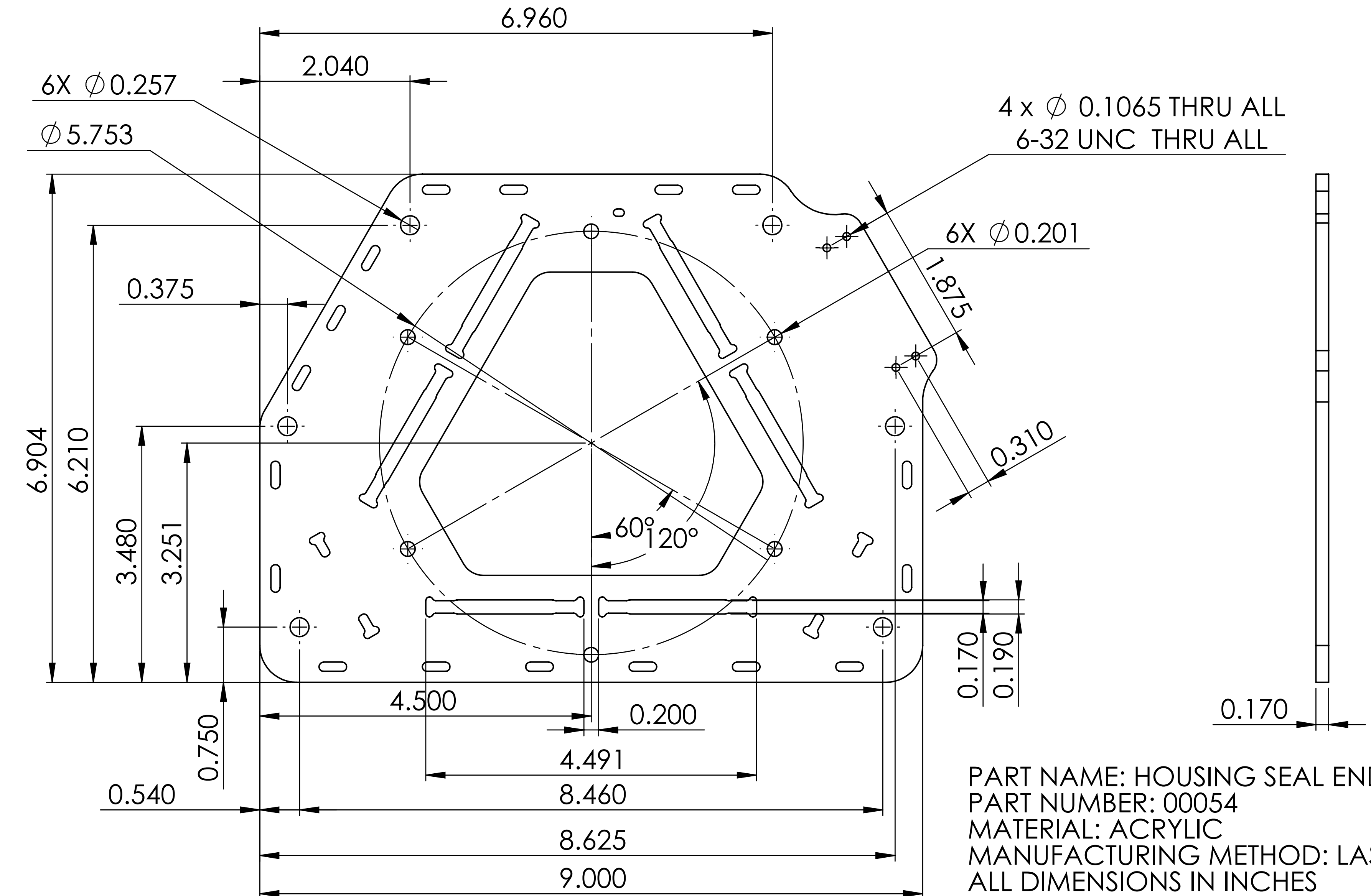
PART NAME: SERVO CLIP FULL
PART NUMBER: 00012
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 2:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



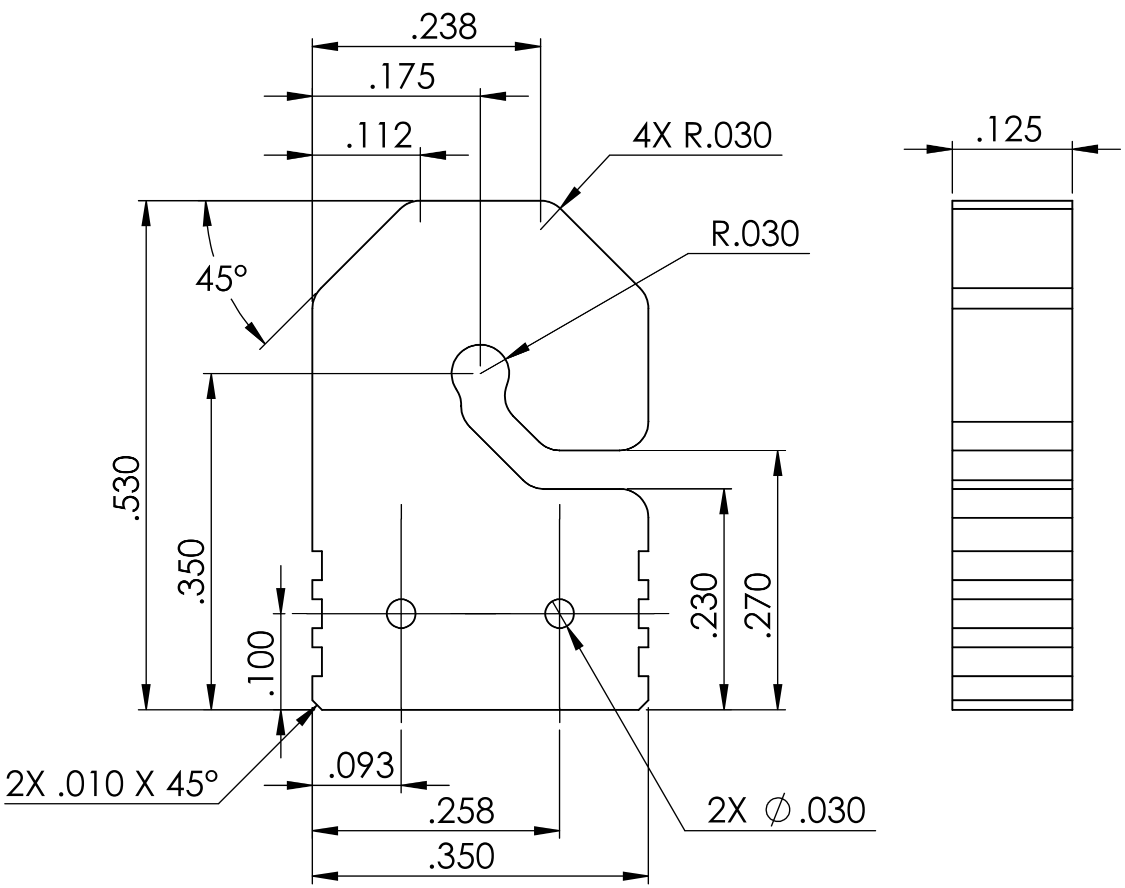
PART NAME: SERVO MOUNT
PART NUMBER: 00017
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



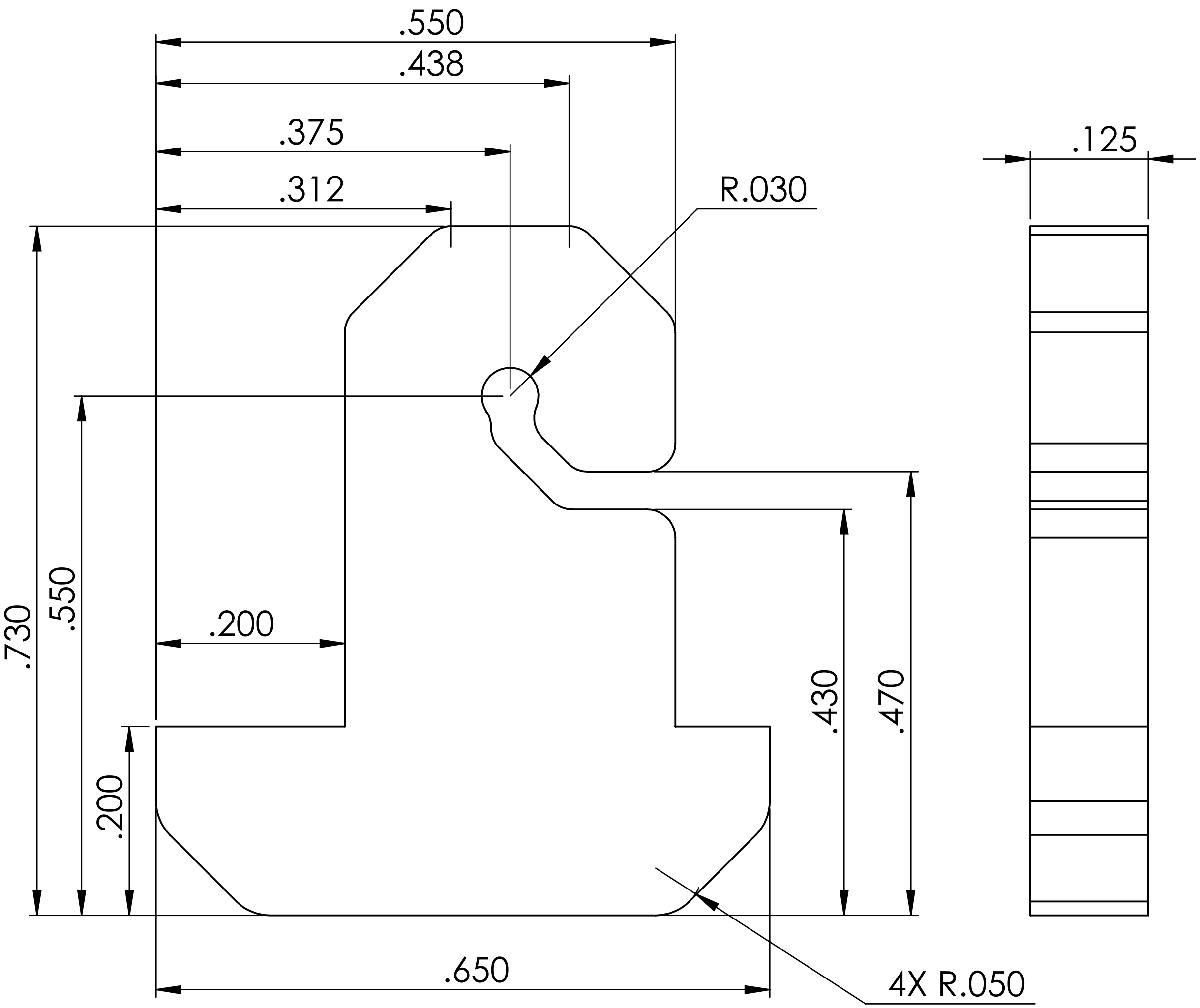
PART NAME: HOUSING END
PART NUMBER: 00047
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



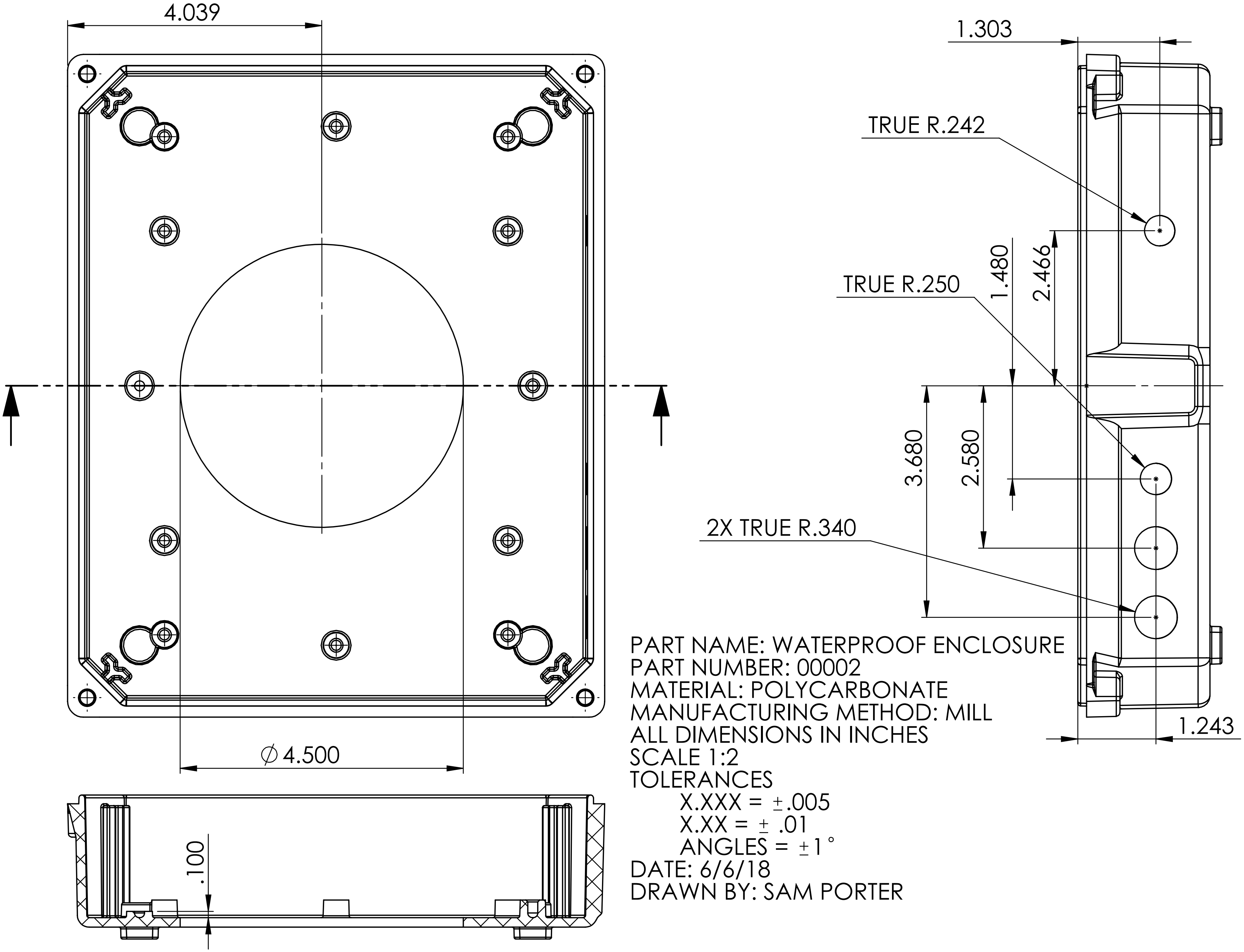
PART NAME: HOUSING SEAL END
PART NUMBER: 00054
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



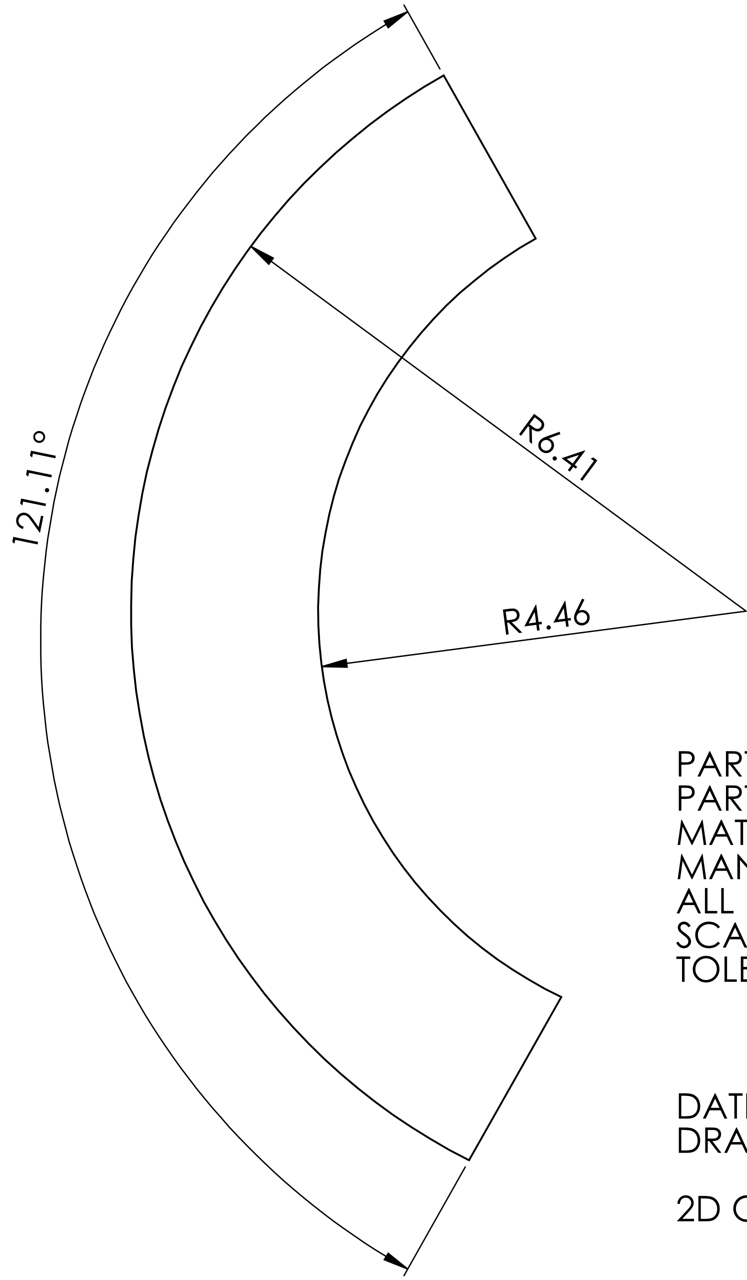
PART NAME: END EFFECTOR SPRING HOOK
PART NUMBER: 00029
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1 °
DATE: 6/6/18
DRAWN BY: SAM PORTER



PART NAME: HOUSING SPRING HOOK
PART NUMBER: 00043
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 5:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



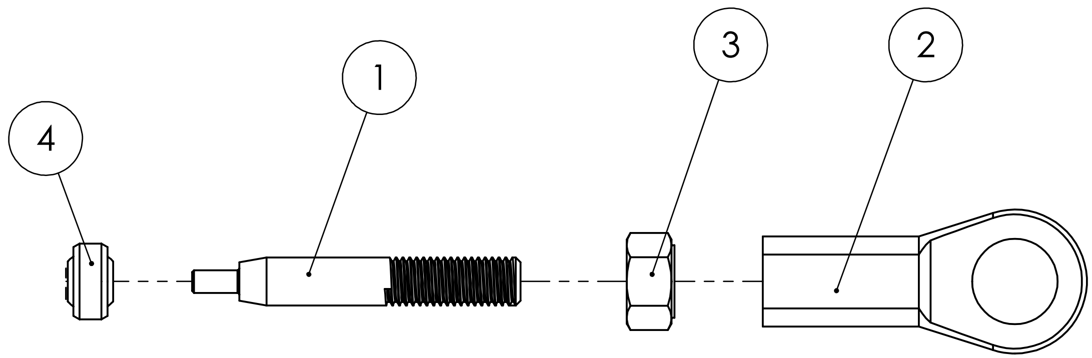
PART NAME: WATERPROOF ENCLOSURE
PART NUMBER: 00002
MATERIAL: POLYCARBONATE
MANUFACTURING METHOD: MILL
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER



PART NAME: FLEXIBLE SEAL
PART NUMBER: 00025
MATERIAL: 1/64" NITRILE
MANUFACTURING METHOD: MANUAL CUT
ALL DIMENSIONS IN INCHES
SCALE 2:1
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1 °
DATE: 6/6/18
DRAWN BY: SAM PORTER

2D OUTLINE OF FLEXIBLE SEAL ASSUMING .3" OVERLAP AT SEAM

MOTION SYSTEM ASSEMBLIES

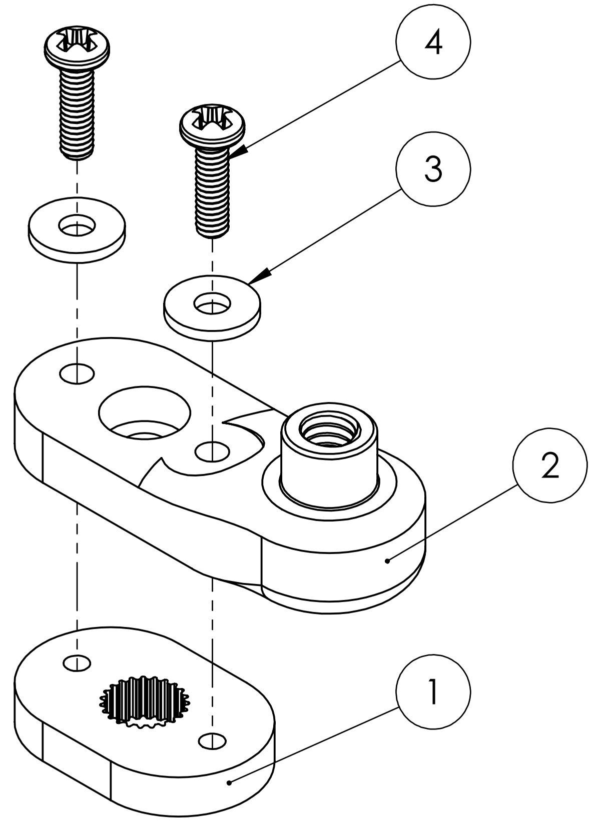


ASSY NAME: SERVO CONNECTING ROD ASSY
PART NUMBER: 00032
SCALE 1:1
DATE: 6/6/18
DRAWN BY: SAM PORTER

ITEM NO.	PART NUMBER	DESCRIPTION	FOR DRAWING/QTY.
1	33	CONNECTING ROD	1
2	36	ROD END	1
3	35	1/4-28 NYLON NUT	1
4	34	SPHERICAL BEARING	1

2 1

B B

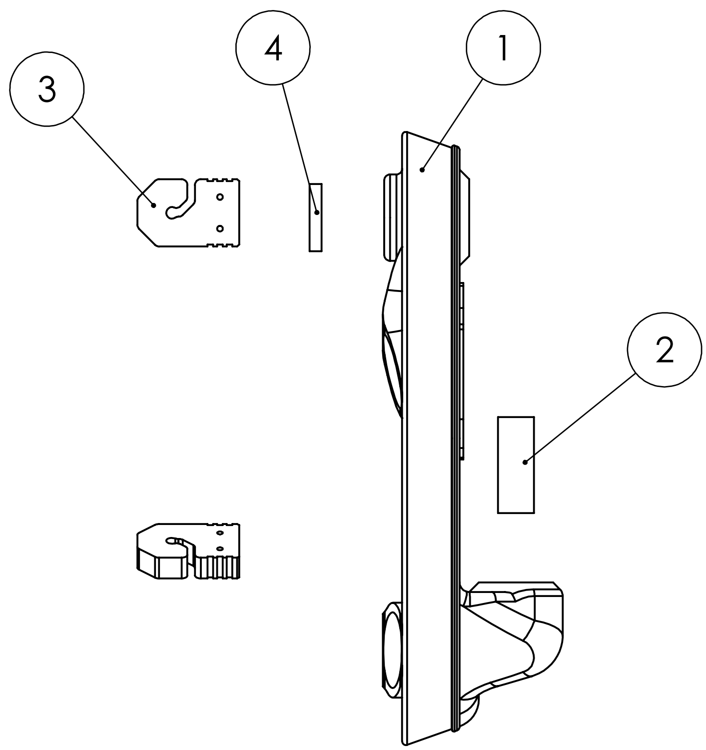


A A

ASSY NAME: SERVO ADAPTER ASSY
PART NUMBER: 00019
SCALE 2:1
DATE: 6/6/18
DRAWN BY: SAM PORTER

ITEM NO.	PART NUMBER	DESCRIPTION	FOR DRAWING/QTY.
1	20	SERVO SPLINE ADAPTER	1
2	21	SERVO ADAPTER	1
3	22	NO 2 WASHER	2
4	23	2-56 5/16" SCREW	2

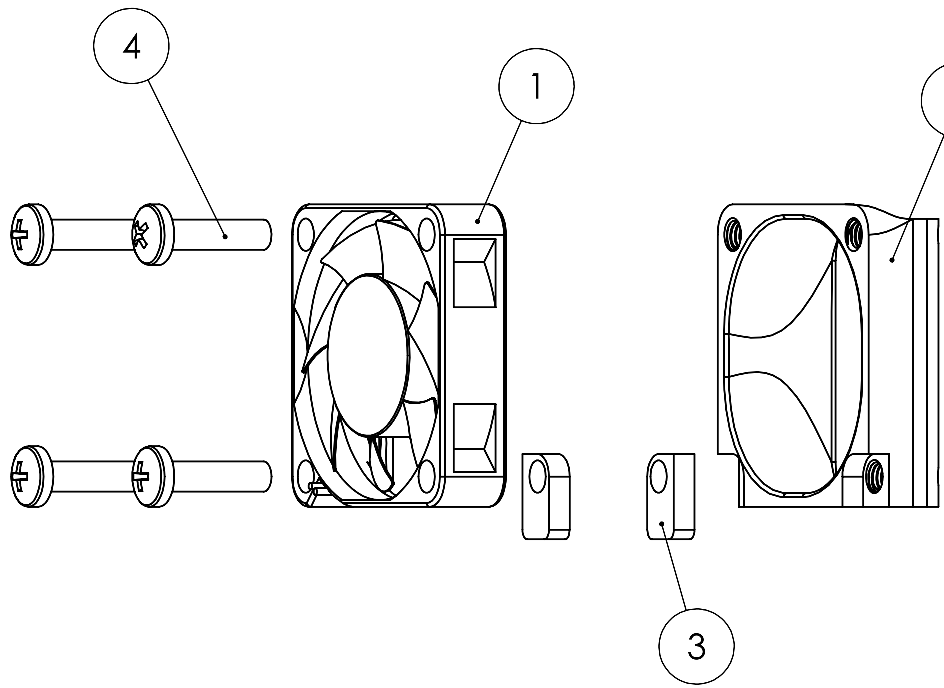
2 1



ASSY NAME: END EFFECTOR ASSY
PART NUMBER: 00027
SCALE 1:1
DATE: 6/6/18
DRAWN BY: SAM PORTER

ITEM NO.	PART NUMBER	DESCRIPTION	FOR DRAWING/QTY.
1	28	END EFFECTOR	1
2	30	3/16 X 1/2" DOWEL PIN	2
3	29	END EFFECTOR SPRING HOOK	3
4	31	THREAD COVER	1

B B

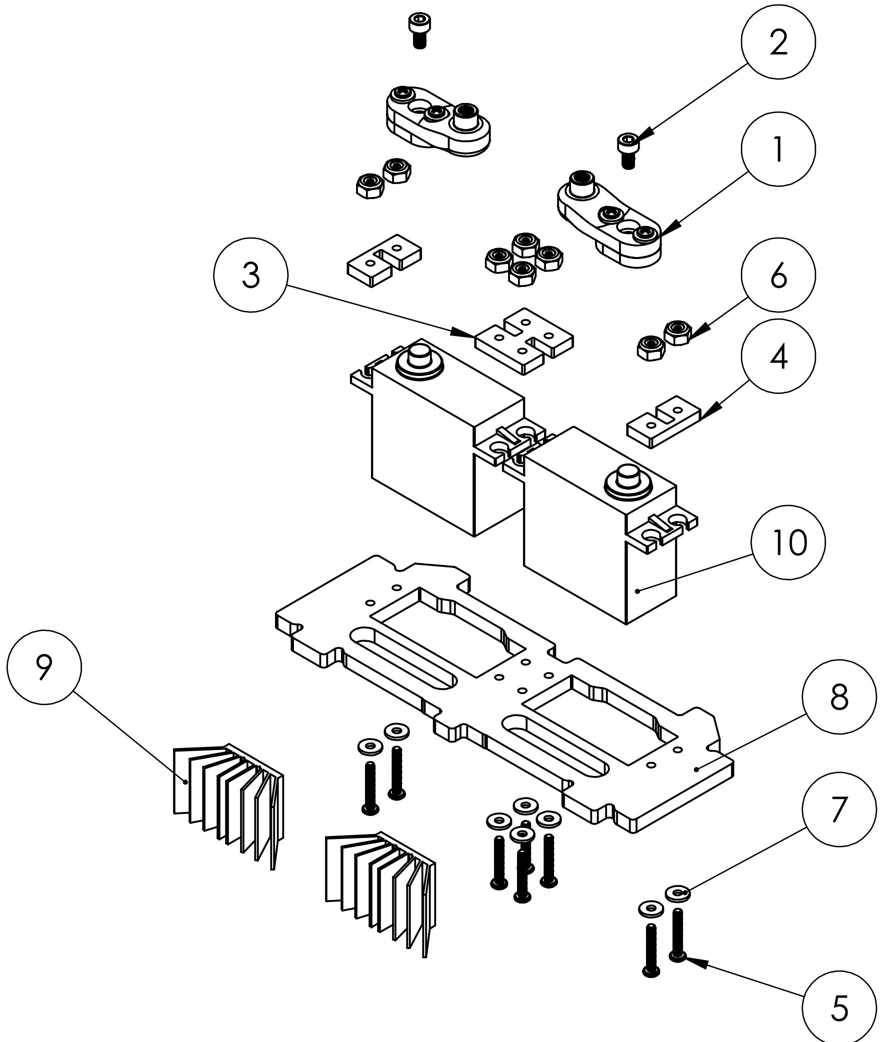


A A

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	39	FAN	1
2	40	FAN DUCT	1
3	42	FAN CLIP	2
4	41	M4 X 16 SCREW	4

ASSY NAME: FAN ASSY
PART NUMBER: 00038
SCALE 1:1
DATE: 6/6/18
DRAWN BY: SAM PORTER

B B



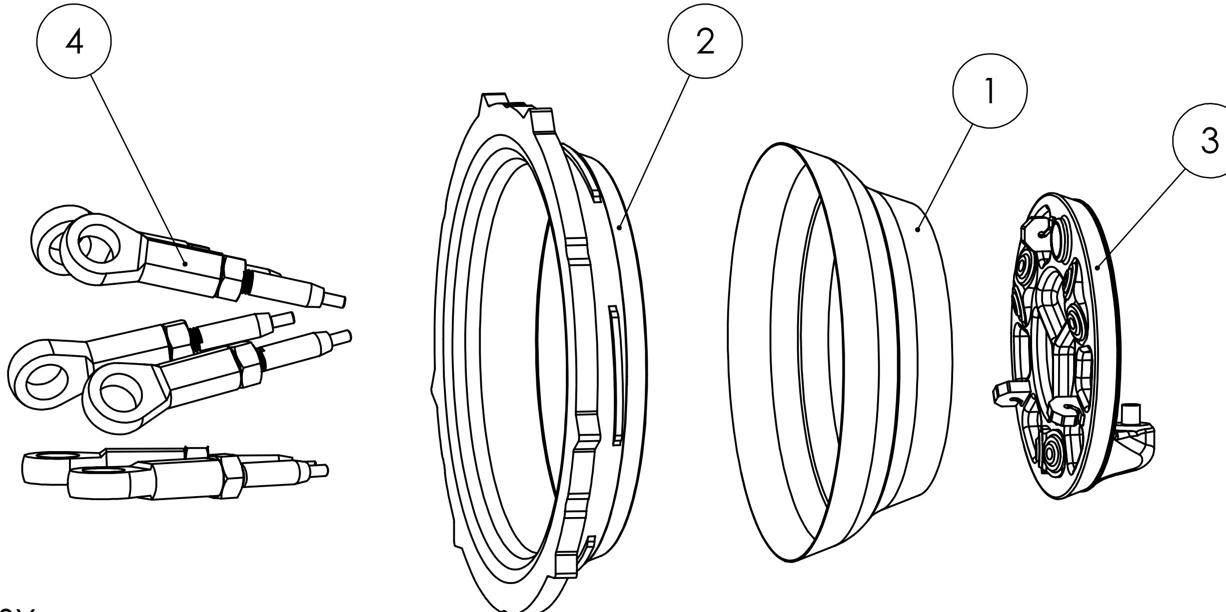
ASSY NAME: SERVO MOUNT ASSY
PART NUMBER: 00009
SCALE 1:2
DATE: 6/6/18
DRAWN BY: SAM PORTER

A A

ITEM NO.	PART NUMBER	DESCRIPTION	Servo Mount/QTY.
1	19	SERVO ADAPTER ASSY	2
2	18	SERVO SCREW	2
3	12	SERVO CLIP FULL	1
4	13	SERVO CLIP HALF	2
5	16	2-56 9/16" SCREW	8
6	14	2-56 LOCKNUT	8
7	15	NO 2 WASHER	8
8	17	SERVO MOUNT	1
9	11	HEATSINK	2
10	10	SERVO	2

2 1

B B



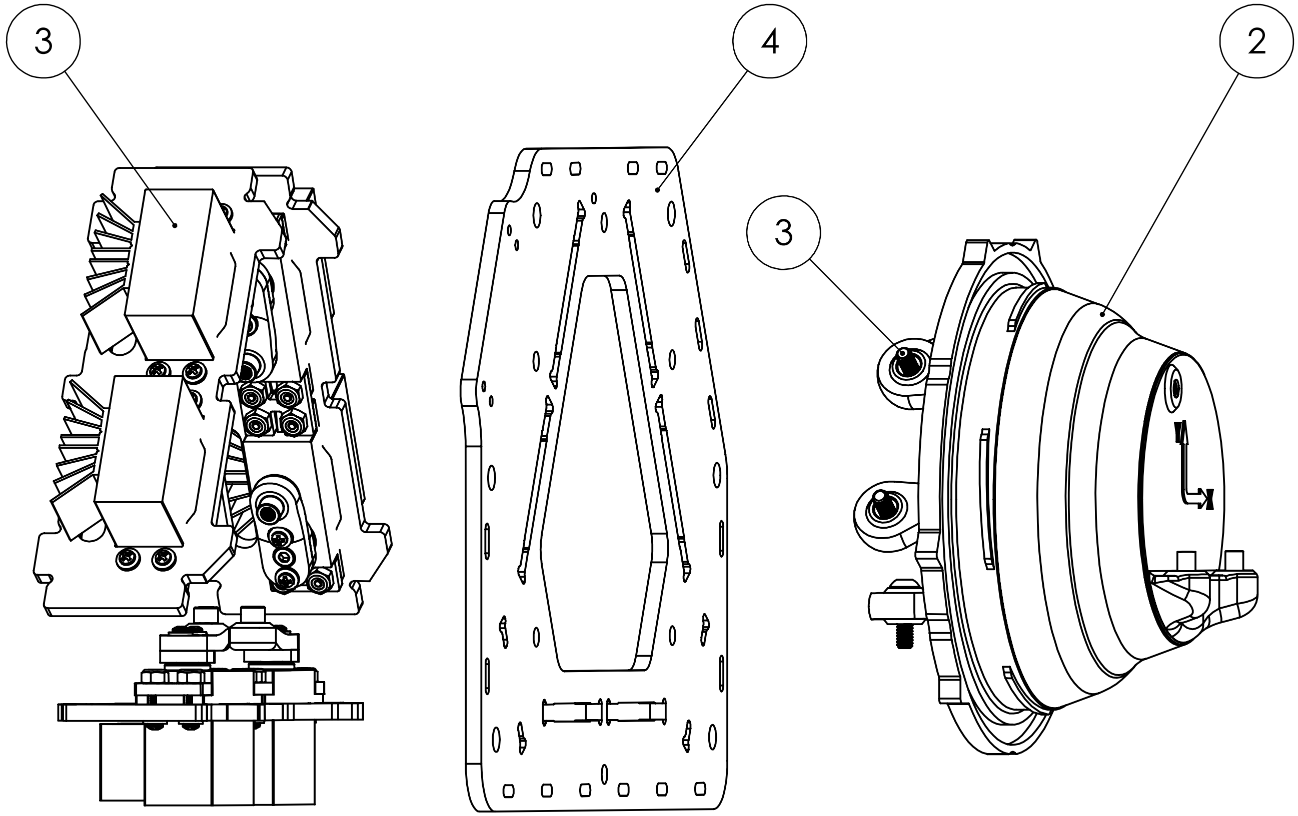
ASSY NAME: SEAL ASSY
PART NUMBER: 00025
SCALE 1:2
DATE: 6/6/18
DRAWN BY: SAM PORTER

*O-RING NOT SHOWN

A A

ITEM NO.	PART NUMBER	DESCRIPTION	Seal Assy/QTY.
1	25	FLEXIBLE SEAL	1
2	26	SEAL BASE	1
3	27	END EFFECTOR ASSY	1
4	32	CONNECTING ROD ASSY	6
5	37	249 O-RING	1

2 1

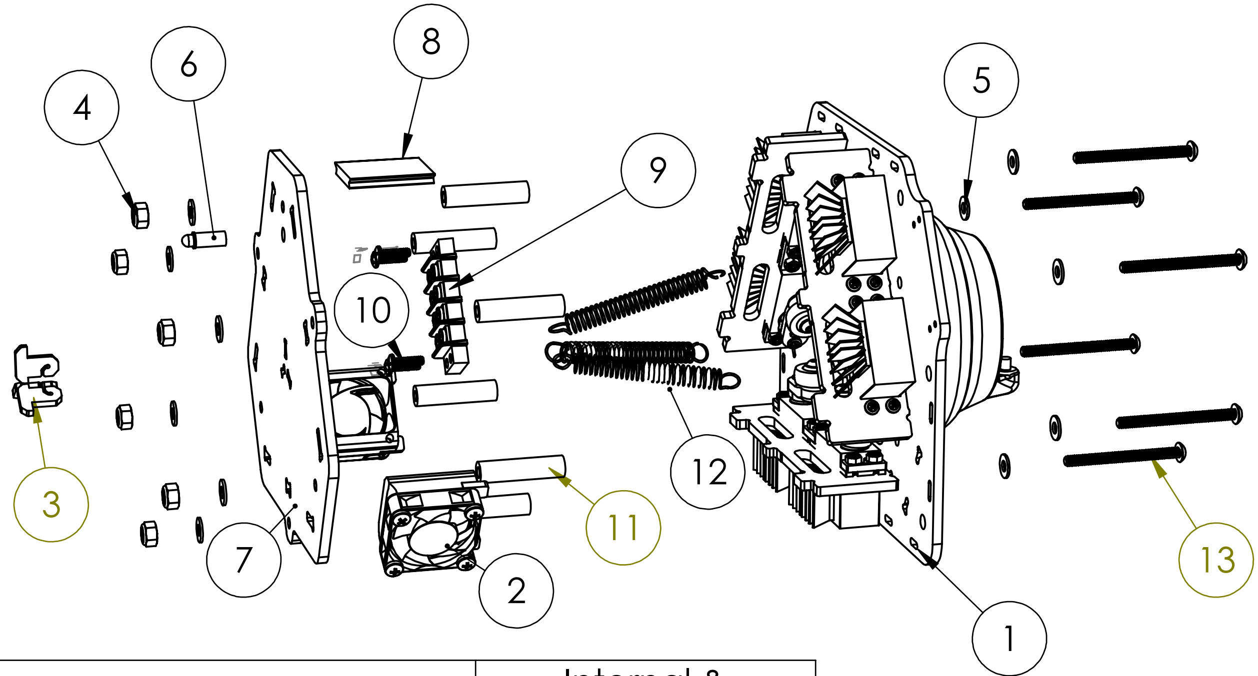


ASSY NAME: PARTIAL CORE ASSY
PART NUMBER: NA
SCALE 1:2
DATE: 6/6/18
DRAWN BY: SAM PORTER

ITEM NO.	PART NUMBER	DESCRIPTION	Servo Mounts & Seal/QTY.
1	9	SERVO MOUNT ASSY	3
2	24	SEAL ASSY	1
3	53	8-32 5/8" SCREW	1
4	54	HOUSING SEAL END	1

2 1

B B



ASSY NAME: MOTION SYSTEM CORE
PART NUMBER: 00008
SCALE 1:3
DATE: 6/6/18
DRAWN BY: SAM PORTER

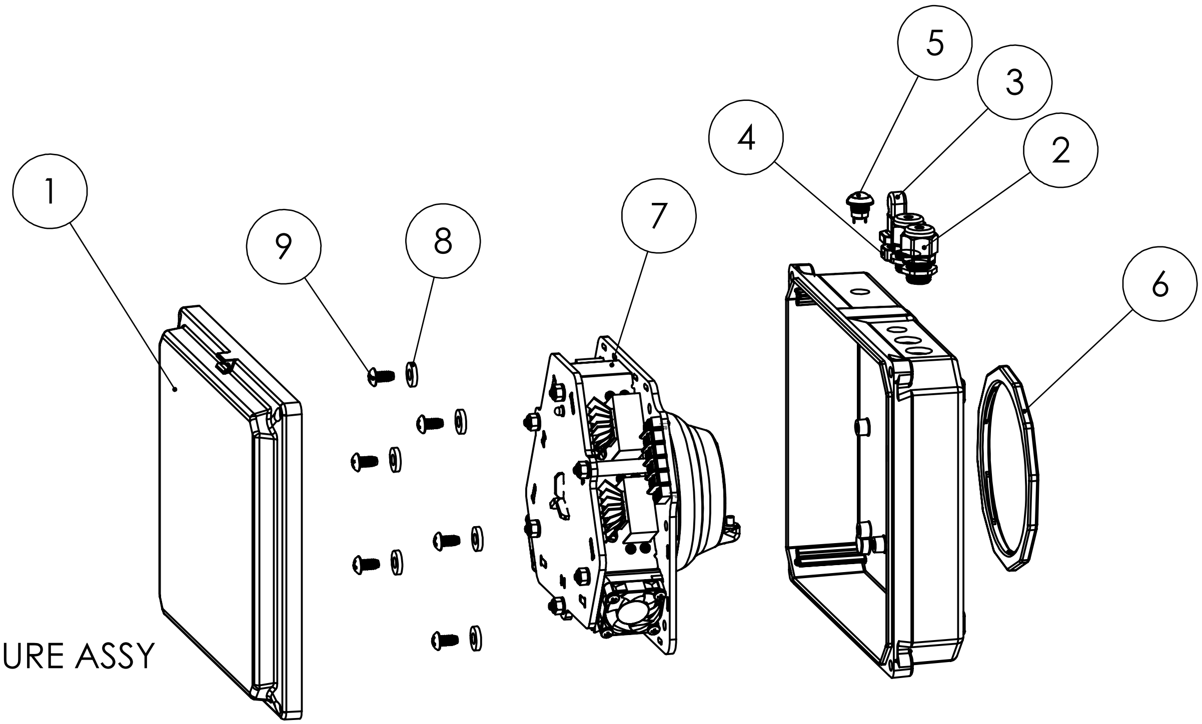
ITEM NO.	PART NUMBER	DESCRIPTION	Internal & Seal/QTY.
1	NA	PARTIAL CORE ASSY	1
2	38	FAN ASSY	2
3	43	HOUSING SPRING HOOK	3
4	44	10-24 LOCKNUT	6
5	45	NO10 WASHER	6
6	46	LED INDICATOR	1
7	47	HOUSING END	1
8	48	AIR BLOCK	1
9	49	BARRIER BLOCK	1
10	50	BARRIER BLOCK SCREW	4
11	51	SPACER	6
12	52	SPRING	3
13	55	10-24 2-1/4" SCREW	6

A A

2 1

2 1

B B



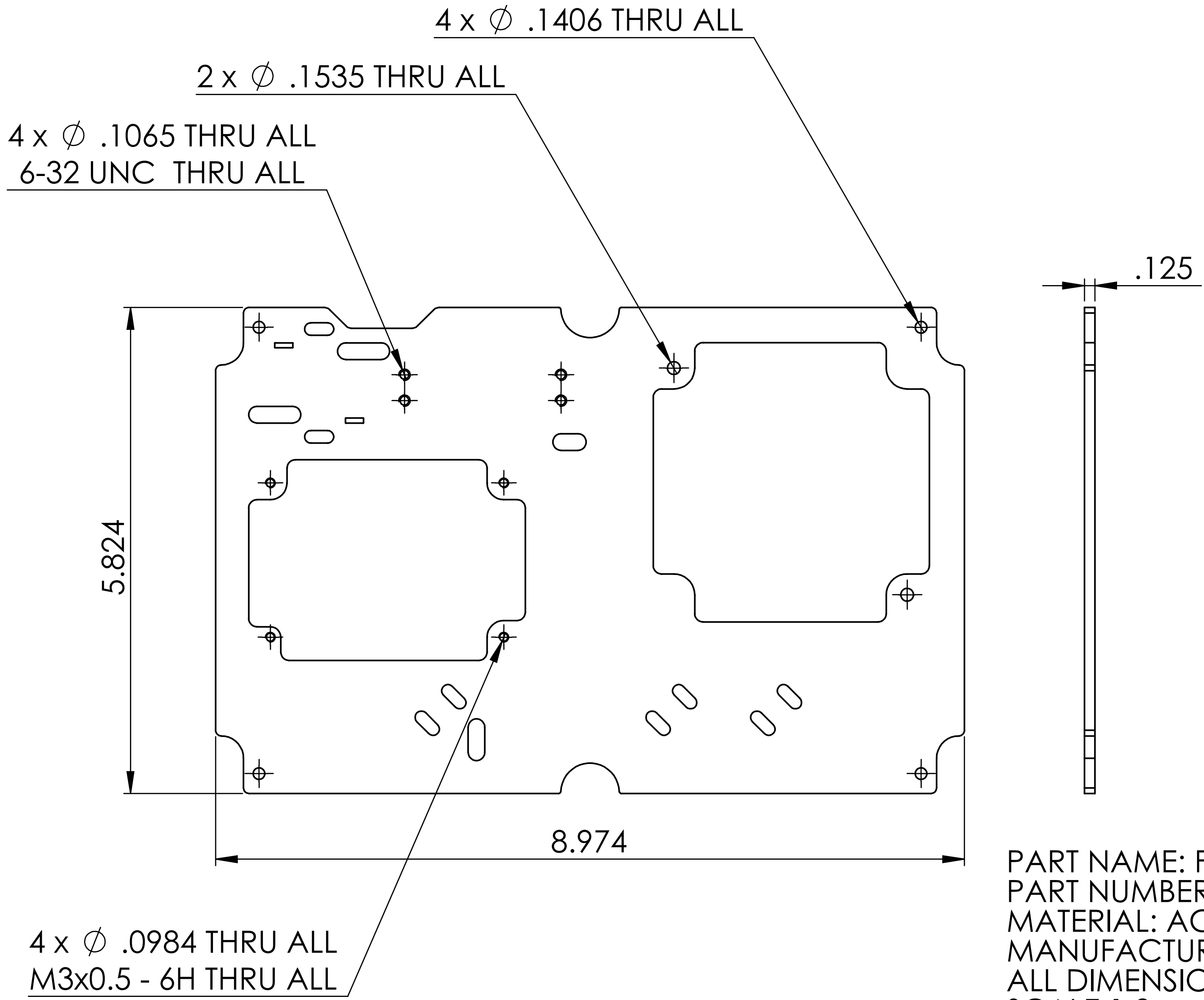
ASSY NAME: WATERPROOF ENCLOSURE ASSY
PART NUMBER: 00001
SCALE 1:5
DATE: 6/6/18
DRAWN BY: SAM PORTER

A A

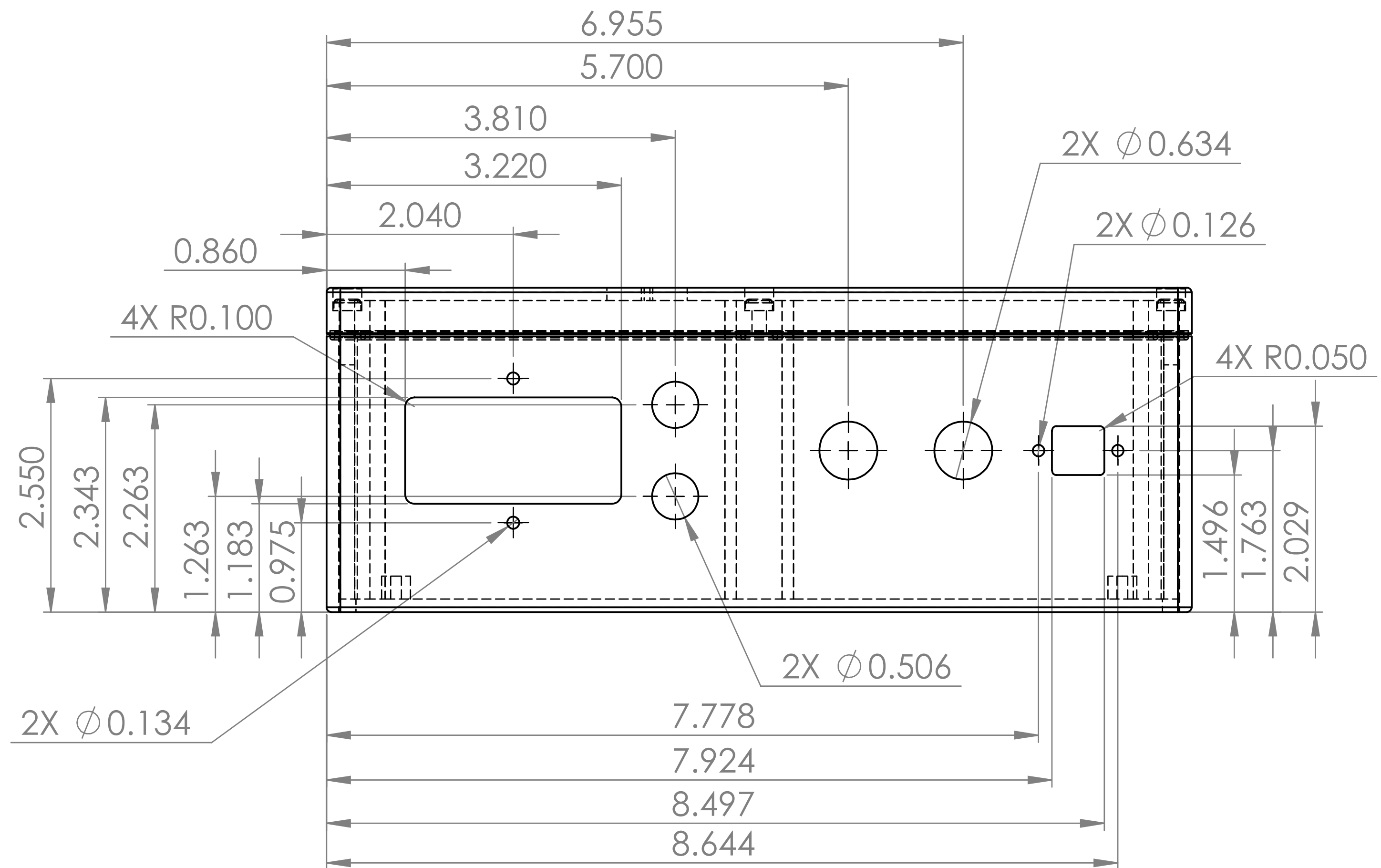
ITEM NO.	PART NUMBER	DESCRIPTION	Default/ QTY.
1	2	WATERPROOF ENCLOSURE	1
2	3	CORD GRIP	2
3	4	SNORKEL	1
4	5	SNORKEL NUT	1
5	6	STOP BUTTON	1
6	7	SEAL NUT	1
7	8	MOTION SYSTEM CORE	1
8	56	ACRYLIC WASHER	6
9	57	1/4-20'' SELF THREADIGN SCREW	6

2 1

ELECTRICAL ENCLOSURE COMPONENTS



PART NAME: FLOOR
PART NUMBER: 00063
MATERIAL: ACRYLIC
MANUFACTURING METHOD: LASER CUT
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°
DATE: 6/6/18
DRAWN BY: SAM PORTER

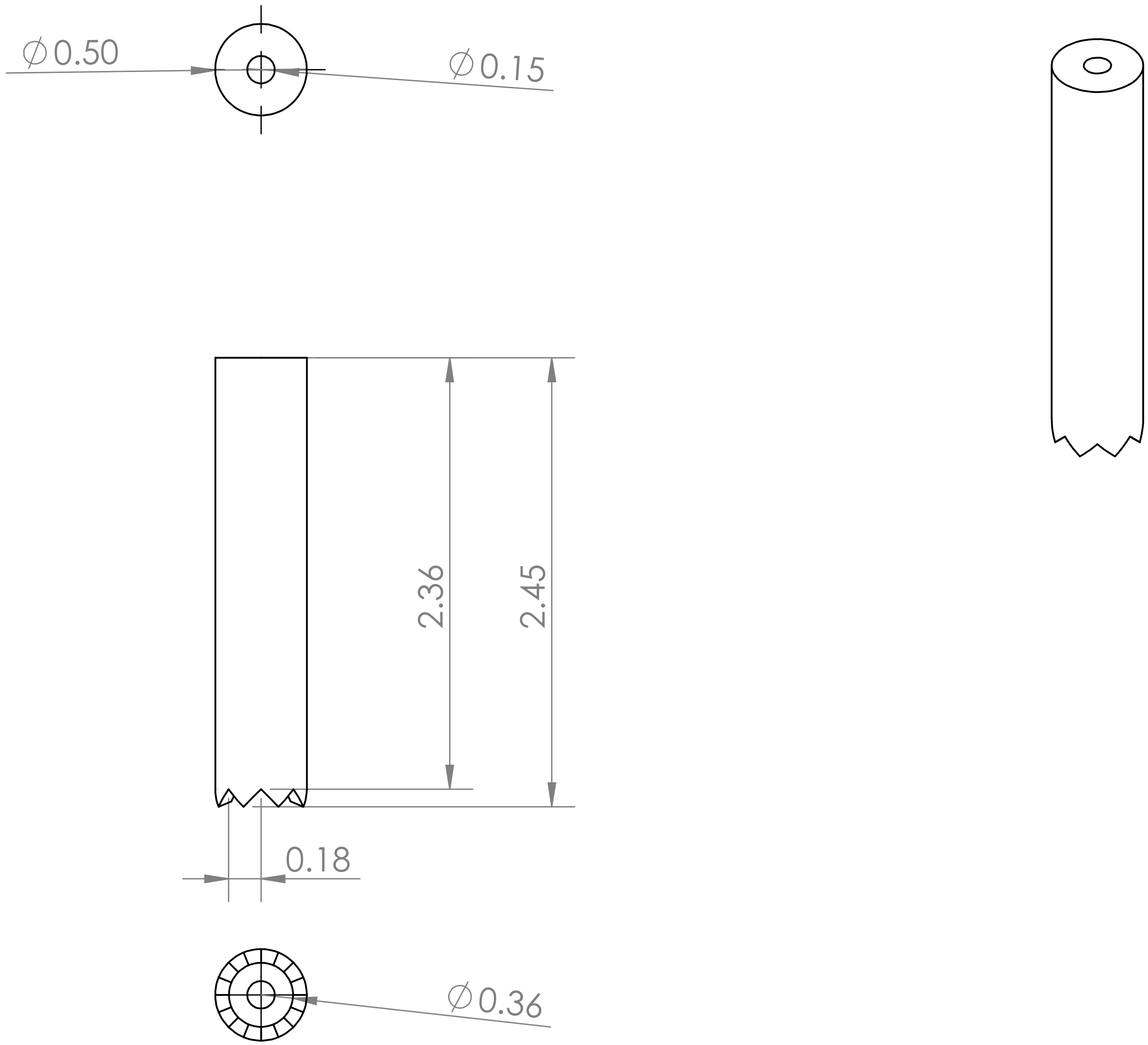


PART NAME: ELECTRICAL ENCLOSURE
PART NUMBER: 00078
MATERIAL: POLYCARBONATE
MANUFACTURING METHOD: MILL
ALL DIMENSIONS IN INCHES
SCALE 1:2
TOLERANCES

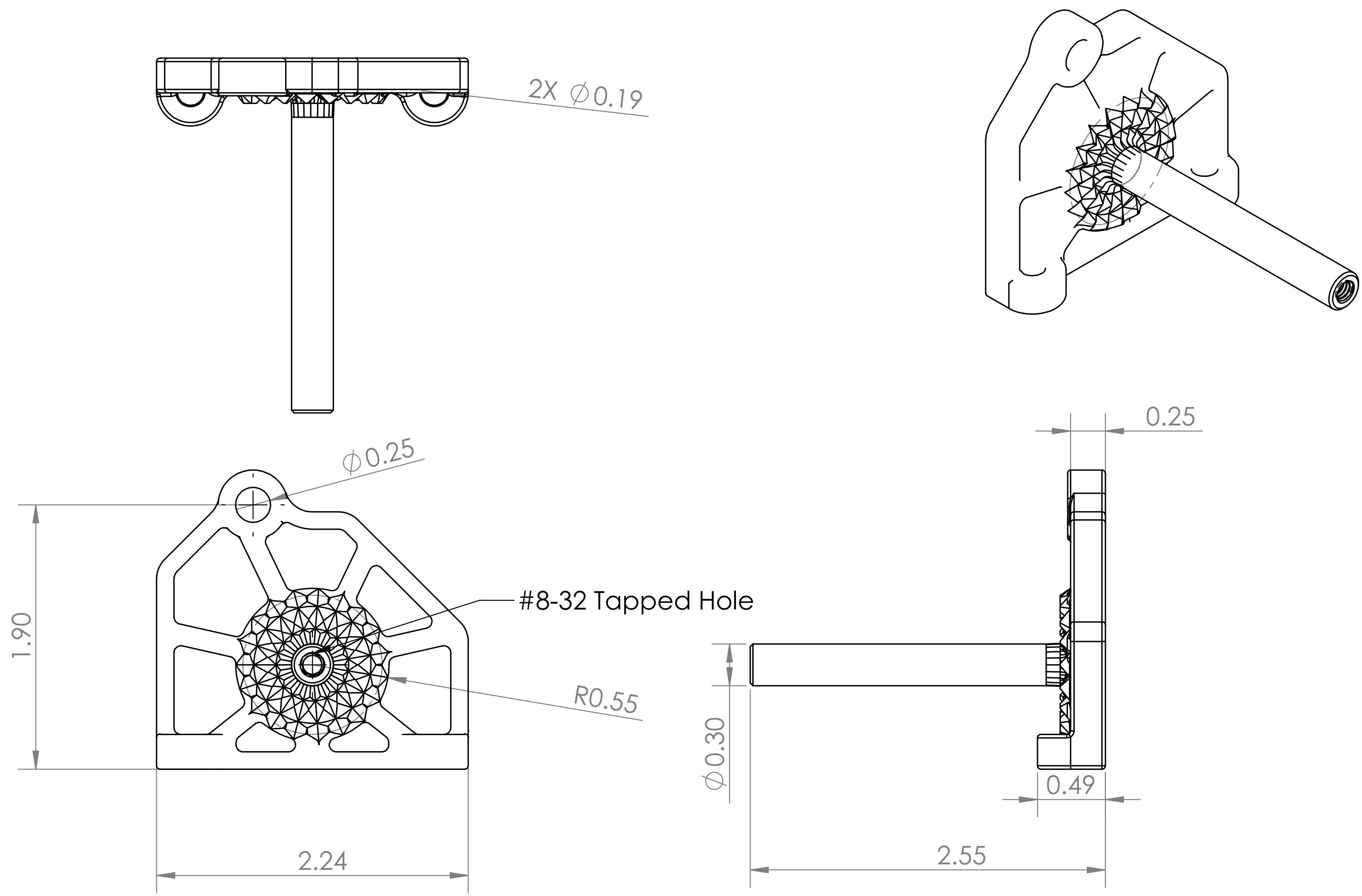
X.XXX = ±.005
X.XX = ± .01
ANGLES = ±1°

DATE: 6/6/18
DRAWN BY: SAM PORTER

TISSUE ADAPTER COMPONENTS

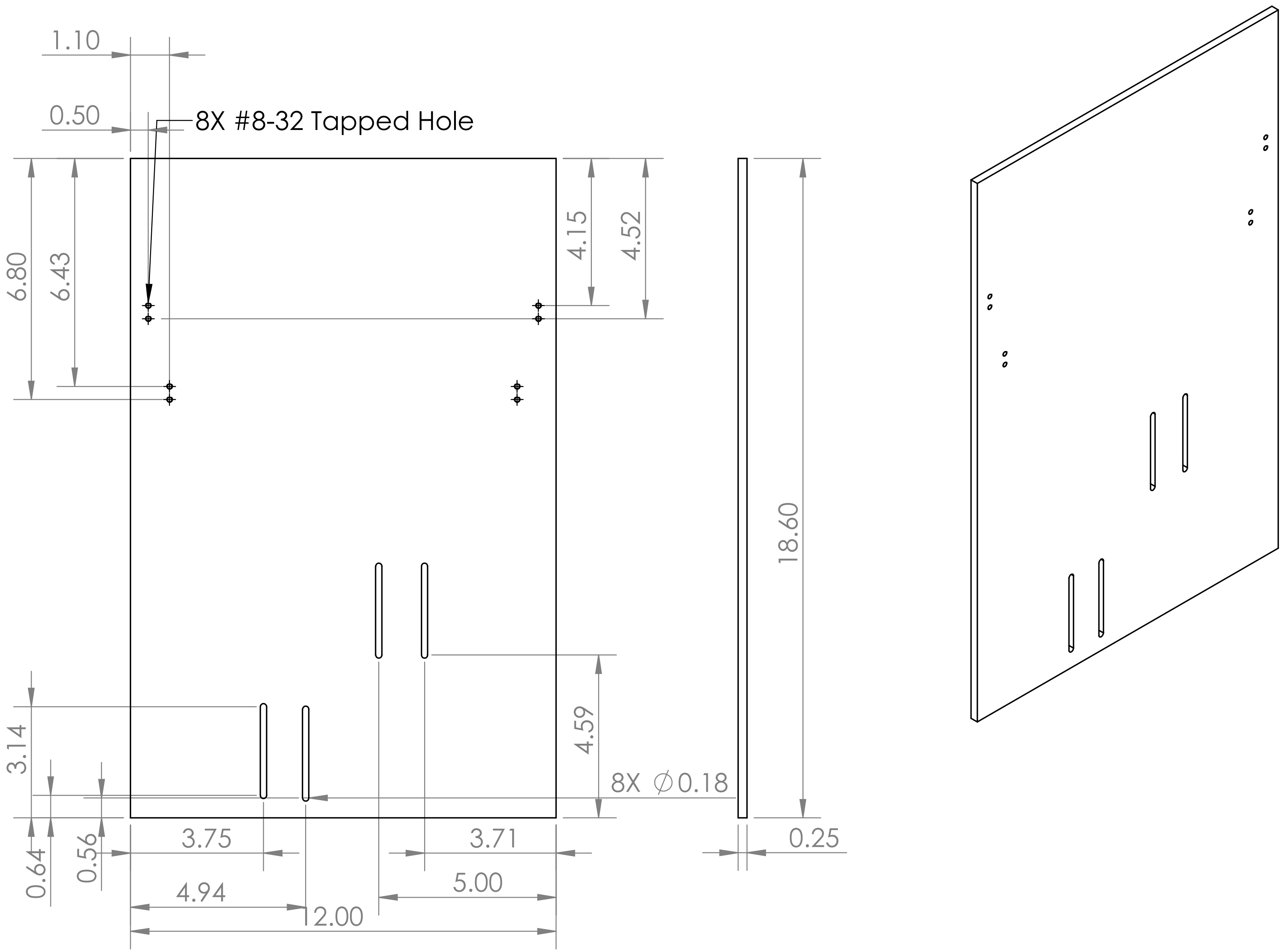


Cal Poly Mechanical Engineering	Lab Section:	Assignment #	Title:SKEWER CAP	Drwn. By:BRIAN LARSEN
	Dwg. #:	MATERIAL: RESIN	Date:6/4/2018 Scale:1:1	Chkd. By: ME STAFF

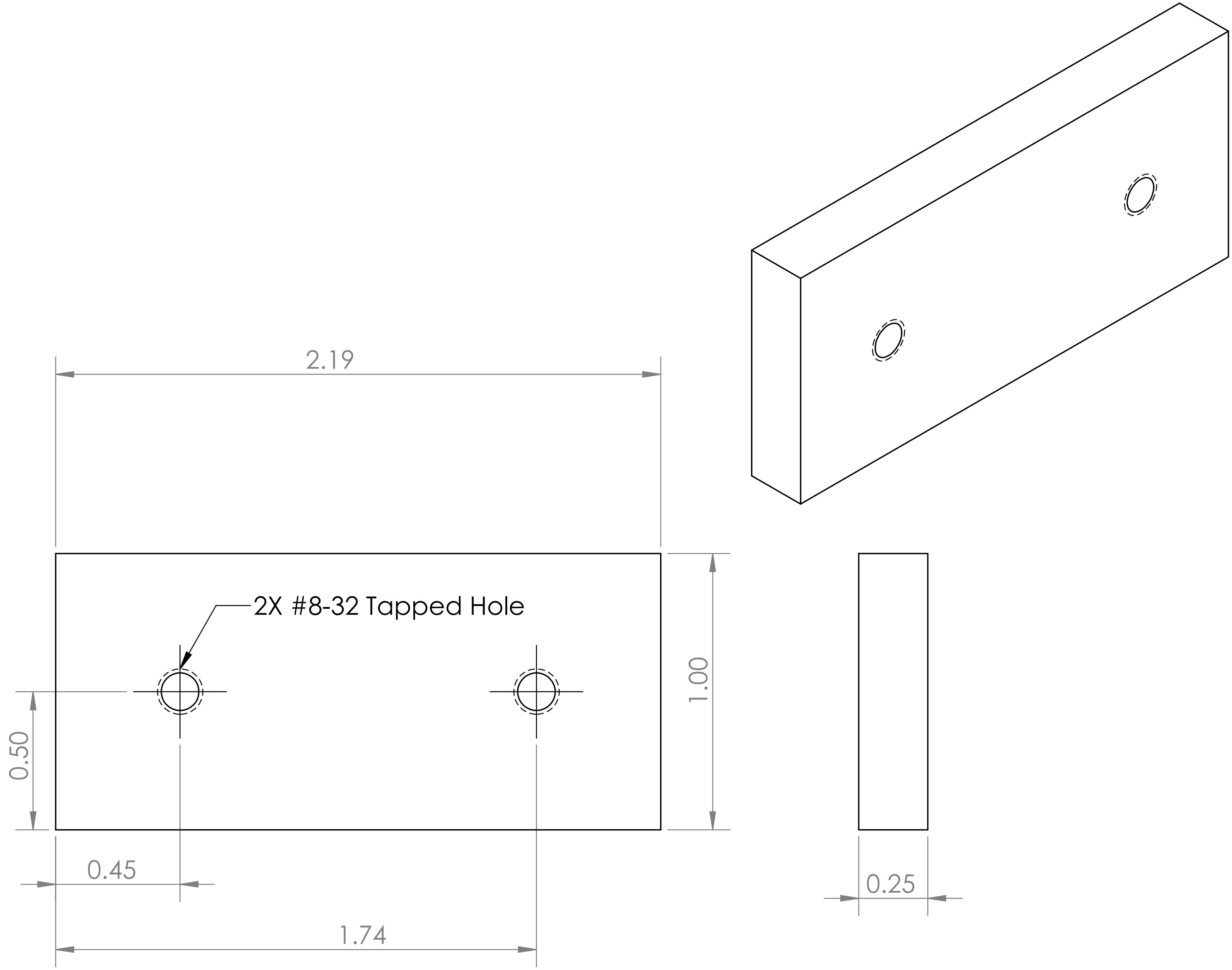


Cal Poly Mechanical Engineering	Lab Section:	Assignment #	Title:TISSUE ADAPTER SKEWER		Drwn. By:BRIAN LARSEN
	Dwg. #:	MATERIAL: RESIN	Date:6/4/2018	Scale:1:1	Chkd. By: ME STAFF

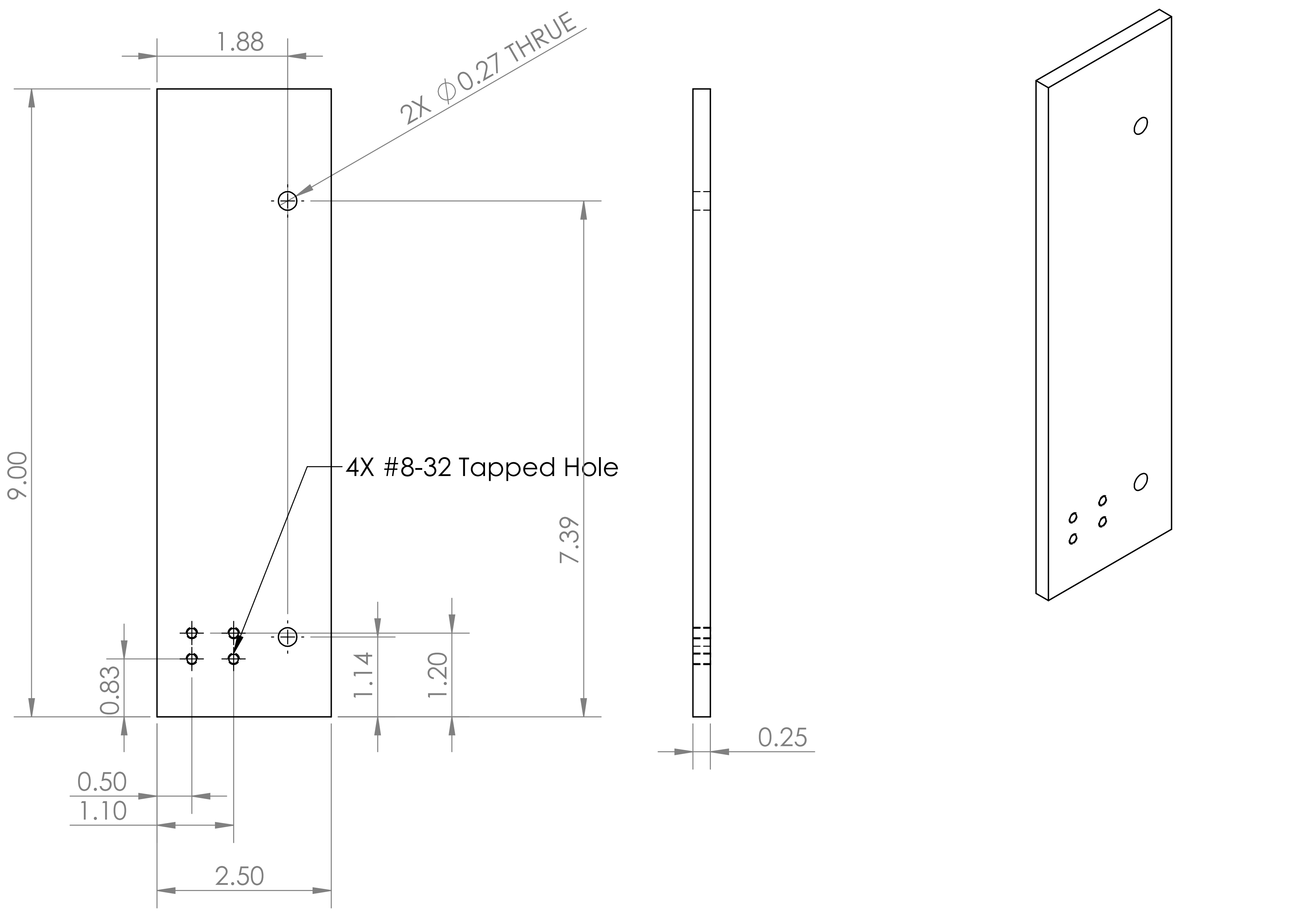
LAYOUT COMPONENTS



Cal Poly Mechanical Engineering	Lab Section:	Assignment #	Title:BASE		Drwn. By:BRIAN LARSEN
	Dwg. #:	MATERIAL: ACRYLIC	Date:6/4/2018	Scale:1:4	Chkd. By: ME STAFF



Cal Poly Mechanical Engineering	Lab Section:	Assignment #	Title:THREADED BAR	Drwn. By:BRIAN LARSEN
	Dwg. #:	MATERIAL: ACRYLIC	Date:6/4/2018 Scale:2:1	Chkd. By: ME STAFF



Cal Poly Mechanical Engineering	Lab Section:	Assignment #	Title:UPRIGHT	Drwn. By:BRIAN LARSEN
	Dwg. #:	MATERIAL: ACRYLIC	Date:6/4/2018 Scale:1:2	Chkd. By: ME STAFF

SYSTEM WIRING

SYSTEM WIRING

POWER			
Pin	Signal	Cable Wire Color	Housing Wire Color
1	5.75V	Bn	RED
2	gnd	Wh	BLACK
3	gnd	Bu	BLACK
4	5.75V	Bk	RED

SIGNAL					
Pin	Signal	Cable Wire Color	Housing Wire Color	Sub Connector	Pin
1	Servo 1	WH/BU	White	A	1
2	Servo 2	WH/BN	Brown	A	2
3	Servo 3	BN	Orange	B	1
4	Servo 4	OG	Yellow	B	2
5	Servo 5	WH/GN	Blue	B	3
6	Servo 6	WH/OG	Grey	A	3
7	Stop Button	BU	Purple	C	2
8	12V	GN	Green	C	1

APPENDIX F

PURCHASED PARTS DETAILS

NOTE:

This document has not been updated since critical design review. Many of the components have carried over. However, always check assembly drawings or CAD for specific part information.

Part Number	Description	URL to Specs
4615T91	Acrylic for Servo Spline Adapter	https://www.mcmaster.com/
92141A003	N0. 2 Stailness Steel Washer	https://www.mcmaster.com/
90272A078	2-56 5/16" Philips Pan Head Screw	https://www.mcmaster.com/
98164A450	8-32 5/8" Button Head Hex Screw	https://www.mcmaster.com/
8538K14	Nylon for Connecting Rod	https://www.mcmaster.com/
1071K110	Plastic Rod End	https://www.mcmaster.com/#10
1064K721	Plastic Spherical Bearing	https://www.mcmaster.com/#cadin
94812A800	1/4-28 Hex Nut	https://www.mcmaster.com/#9481
97155A529	3/16 X 1/2" Dowel Pin	https://www.mcmaster.com/#9
92141A011	N0. 10 Stainless Steel Washer	https://www.mcmaster.com/#9
92510A651	Unthreaded Spacer	https://www.mcmaster.com/#
92949A825	10-24 2-1/4" Hex Head Screw	https://www.mcmaster.com/#
90631A011	10-24 Locknut	https://www.mcmaster.com/#9
91831A002	2-56 Locknut	https://www.mcmaster.com/#9183
91772A265	2-56 9/16" Philips Pan Head Screw	https://www.mcmaster.com/#
8589K61	Acrylic for Internal Housing	https://www.mcmaster.com/#8
H10082SC	Polycarbonate Enclosure	https://www.integraenclosures
8910K946	Metal for Weight Shape A	https://www.mcmaster.com/
8910K663	Metal for Weight Shape B	https://www.mcmaster.com/
8910K653	Metal for Weight Shape C & D	https://www.mcmaster.com/
93878A536	1/4-20 Self Threading Screw	https://www.mcmaster.com/
98370A028	Oversized Flat Washer	https://www.mcmaster.com/
2418T195	O-Ring	https://www.mcmaster.com/
69915K540	Cord Grip	https://www.mcmaster.com/
285-1817-ND	Power Supply	cas-inc/LS150-5/285-1817- N
839-1184-ND	Wall Power Cable	https://www.digikey.com/
277-15696-ND	Device Power Cable	https://www.digikey.com/
277-9872-ND	Data Cable	https://www.digikey.com/
94320A399	Plastic Fastener	https://www.mcmaster.com/
93897A403	Shoulder Screw	https://www.mcmaster.com/

APPENDIX G

BUDGET

Part Number	Vendor	Vendor Part Number	Description	Qty Needed	Qty Package	Packages Needed	Price / Package	Total Price
20	McMaster	4615T91	Acrylic for Servo Spline Adapter	1	1	1	2.14	2.14
40	Cal Poly	(3D Printing)	Servo Adapter, Seal, Cooling, End Effector	1	1	1	175	0
15, 22	McMaster	92141A003	N0. 2 Stailness Steel Washer	36	100	1	1.4	1.4
23	McMaster	90272A078	2-56 5/16" Philips Pan Head Screw	12	100	1	3.28	3.28
	McMaster	98164A450	8-32 5/8" Button Head Hex Screw	6	50	1	7	7
33	McMaster	8538K14	Nylon for Connecting Rod	3	1	3	0.47	1.41
	McMaster	1071K110	Plastic Rod End	6	1	6	5.14	30.84
	McMaster	1064K721	Plastic Spherical Bearing	6	1	6	3.87	23.22
35	McMaster	94812A800	1/4-28 Hex Nut	6	100	1	6.47	6.47
	McMaster	92141A011	N0. 10 Stainless Steel Washer	10	100	1	2.33	2.33
	McMaster	92949A825	10-24 2-1/4" Hex Head Screw	10	10	1	3.09	3.09
	McMaster	90631A011	10-24 Locknut	6	100	1	3.18	3.18
14	McMaster	91831A002	2-56 Locknut	24	50	1	3.8	3.8
16	McMaster	91772A265	2-56 9/16" Philips Pan Head Screw	24	100	1	3.1	3.1
	McMaster	8589K61	Acrylic for Internal Housing	2	1	2	7.19	14.38
10,18	Horizon Hobby	----	Spektrum S6180 Servo	6	1	6	36.095	216.57
2	Integra Enclosures	H10082SC	Polycarbonate Enclosure	1	1	1	161.92	161.92
	Digikey	285-1817-ND	Power Supply	1	1	1	40.3	40.3
	Digikey	839-1184-ND	Wall Power Cable	1	1	1	2.82	2.82
	Digikey	277-15696-ND	Device Power Cable	1	1	1	39.3	39.3
	Digikey	277-9872-ND	Data Cable	1	1	1	24.27	24.27
	Digikey	----	XMEGA 128A4U	1	1	1	4.24	4.24
	Digikey	----	USB to Serial	1	1	1	9	9
	Microchip Direct	----	Atmel ICE	1	1	1	76.82	76.82
	McMaster	94320A399	Plastic Fastener	1	100	1	7.17	$7.17
	McMaster	93897A403	Shoulder Screw	1	25	1	6.72	$6.72
	McMaster	8589K61	Clear Acrylic Sheet 12"x12"x3/16"	----	----	4	7.19	28.76
	McMaster	92510A556	Aluminum Unthreaded Spacer 5/16" OD, 2-1/2" Long, for Number 10 Screw Size	----	----	3	2.47	7.41
	McMaster	92185A218	Super-Corrosion-Resistant 316 Stainless Steel Socket Head Screw 10-24 Thread Size, 3-1/4" Long	----	----	1	6.96	6.96
	McMaster	4615T91	Clear High-Strength UV-Resistant Acrylic 6"x6"x1/8"	----	----	1	2.14	2.14
	Digikey	MC78L05BP-APMSCT-ND	5V Linear Regulator	----	----	2	0.49	0.98
	Digikey	1528-1154-ND	JUMPER WIRE M/M 40X6" 150MM	----	----	1	3.95	3.95
	Digikey	1528-1162-ND	JUMPER WIRE F/M 40X6" 150MM	----	----	1	3.95	3.95
	Digikey	1528-1379-ND	FEMALE/FEMALE JUMPER WIRES 40X6	----	----	1	3.95	3.95
	McMaster	5306T99	29 mil Gloves	1	2	1	3.57	3.57
	McMaster	5330T3	Thicker Gloves	1	2	1	3.14	3.14
	McMaster	7425A51	Silicone Sealant	3	1	3	4.56	13.68
	McMaster	9920T17	Heat Shrink Tubing	1	1	1	9.15	9.15
	McMaster	80005K46	Nylon Cable Ties	10	10	1	5.48	5.48
	McMaster	2418T195	O-Ring	1	5	1	9	9
	Flex Seal Products	--------	Waterproof Tape	1	1	1	12.99	12.99
	DigiKey	285-2362-ND	5V 10A AC-DC Converter	1	1	1	39	39
	DigiKey	679-3758-ND	Emergency Stop Button	1	1	1	34.62	34.62
	DigiKey	L10025-ND	LED Panel Indicator Green	2	1	2	1.92	3.84
	DigiKey	1144-1009-ND	Power Cord Recepticle	1	1	1	13.39	13.39
	DigiKey	839-1180-ND	Power Cable	1	1	1	4.55	4.55
	DigiKey	283-2711-ND	Fuse Holder	1	1	1	2.98	2.98
	DigiKey	F6242-ND	DC Side Fuse - Slow	2	2	2	0.94	1.88
00067	DigiKey	F1763-ND	DC Side Fuse - Fast	2	2	2	0.37	0.74
00069	DigiKey	507-2002-ND	AC Side Fuse	2	2	2	0.26	0.52
	DigiKey	1754-1025-ND	Signal Connector	1	1	1	9.24	9.24
	DigiKey	1754-1002-ND	Power Connector	1	1	1	6.87	6.87
00061	DigiKey	277-9869-ND	Signal Cable	1	1	1	46.29	46.29
00060	DigiKey	277-4455-ND	Motion System Power Cable	1	1	1	21.38	21.38
	DigiKey	1175-1265-ND	Female A USB	2	1	2	0.84	1.68
	DigiKey	MUSBD11130-ND	Female B USB	1	1	1	8.76	8.76
	DigiKey	AE10618-ND	USB Cable	1	1	1	2.77	2.77
00070	DigiKey	WM5761-ND	Barrier Block	1	1	1	3.39	3.39
	DigiKey	277-15446-ND	Quick Disconnects	10	10	10	0.17	1.7
	DigiKey	679-1363-ND	Emergency Stop Labeling	1	1	1	2.97	2.97
	McMaster	6363K211	Heatshrink	1	1	1	4.15	4.15
00075	McMaster	8054T25	Green 18 Wire	1	1	1	5.56	5.56
00073	McMaster	8054T25	Red 18 Wire	1	1	1	5.56	5.56
00074	McMaster	8054T25	Black 18 Wire	1	1	1	5.56	5.56

Part Number	Vendor	Vendor Part Number	Description	Qty Needed	Qty Package	Packages Needed	Price / Package	Total Price
	Amazon	B016HLJHAE	Servo Adapter Wire	1	1	1	6.99	6.99
	McMaster	7092K14	Electrical Enclosure	1	1	1	25.94	25.94
00063	McMaster	8589K41	Acrylic For Enclosure	1	1	1	5.4	5.4
	McMaster	8589K61	3/16 Housing Acrylic	2	1	2	7.19	14.38
	McMaster	85635K421	1/8 Colored Acrylic	1	1	1	8.31	8.31
	McMaster	8560K178	1/16 Acrylic	1	1	1	2.75	2.75
	McMaster	94135K12	High K Spring Option	6	6	1	8.97	8.97
00052	McMaster	94135K9	Low K Spring Option	6	6	1	6.92	6.92
	McMaster	1813A221	Structural Epoxy	1	1	1	11.17	11.17
	McMaster	7509A65	3M 847 Gasket Adhesive	1	1	1	19.3	19.3
00025	McMaster	86715K629	1/64" Buna-N Sheet	1	1	1	7.77	7.77
	McMaster	8635K641	1/32" Buna-N Sheet	1	1	1	7.92	7.92
	McMaster	93897A236	End Effector Shoulder Screw	1	25	1	6.34	6.34
00030	McMaster	97155A529	3/16 X 1/2" Dowel Pin	2	50	1	3.46	3.46
	McMaster	92510A651	Unthreaded Spacer	6	1	6	1.66	9.96
	IGUS	KGLM-03	Smaller Spherical Bearings	14	1	14	2.07	28.98
	McMaster	93878A536	1/4-20 Self Threading Screw	6	25	1	8.75	8.75
50, 71	McMaster	94836A256	Barrier Block Screws	4	10	1	3.1	3.1
	McMaster	69915K51	Cord Grip	2	1	2	2.82	5.64
	McMaster	4066A61	4.5" Hole Saw	1	1	1	24.45	24.45
	McMaster	4066A79	Hole Saw Arbor	1	1	1	10.88	10.88
	McMaster	8888A23	3/32" Endmill	1	11	1	17.06	17.06
	McMaster	94320A399	Brians Screw	1	100	1	7.17	7.17
00011	Digikey	ATS1116-ND	Heatsinks	6	1	6	7.32	43.92
00039	Digikey	259-1547-ND	Fans	2	1	2	6.04	12.08
	Digikey	945-2212-ND	12V AC-DC Converter	1	1	1	14.35	14.35
49, 70	Digikey	WM5761-ND	Barrier Block	1	1	1	3.39	3.39
00006	Digikey	CKN10761-ND	Waterproof Button	1	1	1	7.98	7.98
	Digikey	283-2711-ND	Fuse Holder	1	1	1	2.98	2.98
	Digikey	F4803-ND	Fan Fuse	2	1	2	1.27	2.54
)6, 107, 1	McMaster	8560K355	Clear Cast Acrylic Sheet, 12" x 24" x 1/4"	1	1	1	29.77	29.77
00109	McMaster	1227T639	Clear Cast Acrylic Bar, 1-1/2" x 1" x 2'	2	1	2	20.52	41.04
00110	McMaster	13135A61	Corner Bracket	8	1	8	0.5	4
00111	McMaster	95868A342	Nylon Screws, 8-32 3/8"	16	100	1	6.12	6.12
00037	McMaster	4464T286	O-Ring	1	5	1	12.38	12.38
	McMaster	3367A121	Right hand lathe tool	1	1	1	4.56	4.56
	McMaster	3367A131	Left hand lathe tool	1	1	1	4.56	4.56
	McMaster	8092K16	Larger Electrical Enclosure	1	1	1	35.52	35.52
00076	McMaster	8054T25	White 18 Wire	1	1	1	5.56	5.56
00041	McMaster	90116A213	M4 Screws	8	50	1	7.7	7.7
	3D Hubs	----	Seal, End Effector, Servo Arm	1	1	1	203.49	203.49
00007	3D Hubs	----	Seal Locknut	1	1	1	56.23	56.23
4, 5	3D Hubs	----	Snorkel	1	1	1	60.92	60.92
	McMaster	----	Shipping and Tax for Order on 5/22/18	1	1	1	17.19	17.19
	McMaster	----	Shipping and Tax for Order on 2/22/18	1	1	1	9.21	9.21
	McMaster	----	Shipping and Tax for Order on 5/22/18	1	1	1	6.71	6.71
	McMaster	----	Shipping and Tax for Order on 4/23/18	1	1	1	11.98	11.98
	McMaster	----	Shipping and Tax for Order on 4/12/18	1	1	1	24.92	24.92
	Digikey	----	Shipping and Tax for Order on 4/20/18	1	1	1	14.61	14.61
	Digikey	----	Shipping and Tax for Order on 4/11/18	1	1	1	25.99	25.99
	Digikey	----	Shipping and Tax for Order on 1/23/18	1	1	1	10.98	10.98
00085	Mouser	556-ATXMEGA256A3BUAU	MCU order 2	1	1	3	8.39	25.17
	Microchip Direct	----	MCU order 1	1	1	2	6.74	13.48
00086	Digikey	768-1007-1-ND	USB/Volt Regulator	1	1	2	4.5	9
00087	Digikey	277-1277-ND	Phoenix 6 connector	3	3	6	4.5	27
00088	Digikey	277-1275-ND	Phoenix 4 connector	1	1	3	3.14	9.42
00089	Digikey	399-6741-1-ND	100000 PF Cap	1	1	3	0.29	0.87
00090	Digikey	478-8125-1-ND	4.7 uf Tantalum Cap	1	1	3	0.36	1.08
00091	Digikey	478-10836-1-ND	.1 uf Cap	9	9	30	0.144	4.32
00092	Digikey	490-4001-1-ND	Ferrite Bead	3	3	10	0.145	1.45
00093	Digikey	475-1410-1-ND	Green LED	1	1	3	0.33	0.99
00094	Digikey	475-2488-1-ND	Orange LED	1	1	3	0.35	1.05
00095	Digikey	SW400-ND	Reset Switch	1	1	3	0.3	0.9
00096	Digikey	RR12P10.0KDCT-ND	10 kOhm Resistor	1	1	3	0.11	0.33
00097	Digikey	P1.0KDACT-ND	1 kOhm Resistor	1	1	3	0.36	1.08
00098	Digikey	RNCP0805FTD750RCT-ND	750 Ohm Resistor	1	1	3	0.1	0.3
00099	OshPark	k7p2Hc2d	Printed Circuit Boards	1	3	1	67.2	67.2
00100	Digikey	RHM270KCT-ND	270 Ohm Resistor	2	2	6	0.1	0.6
	Microchip Direct	----	Tax and Ship	1	1	1	7.82	7.82
	OshPark	----	Tax and Ship	1	1	1	24.7	24.7
	Digikey	----	Tax and Ship	1	1	1	14.52	14.52
							Total spent:	2180.85

APPENDIX H

TEST RESULTS

Motion System Accuracy Testing Procedures.

Background:

All test procedures within this document are intended to demonstrate that the motion system (software and hardware together) can position the end effector correctly in space. Because the motion system is known to have a small amount of play in the system, each test will record data for different positions and orientations when approached from opposing directions. The resulting information will be used to demonstrate overall performance.

Test #1: Translation

Test Description:

This test is used to evaluate the motion systems ability to correctly translate to various positions relative to its home position. The overall test structure is to attach the paper holder to the end effector and tape on a test card. A fine-tip marker will then be positioned along the z axis of the system (when at its neutral position) and touching the card. Various motion files can then be run to move the end effector and mark the card at locations determined in the motion file. The resulting data can then be measured to determine overall system translational performance. Because translations along the z axis require all servos to move in unison, this test will not be performed as it would require additional test hardware, and it is assumed the performance along this axis will be better than the more complex coordinated motions on the XY plane.

Test Hardware:

Table 1: Test #1 Hardware

Hardware	Version/Serial Number	Notes
Motion System	Final	
Electronics Enclosure	Final	
Card Adapter	1	
Fine Point Marker		Felt Tip
Scotch Tape		Used Double Sided
6 2”x2” Cards		Printer Paper

Table 2: Test #1 Motion Files

File Name	Version/Serial Number	Notes
+X	7mm & 14mm	
-X	7mm & 14mm	
+Y	7mm & 14mm	
-Y	7mm & 14mm	

Test Setup:

1. Setup the motion system with associated electronics and software.
2. Ensure motion system is level.
3. Install card adapter onto end effector.

Test procedure:

1. Tape card onto card adapter with top right corner aligned with top right edge of adapter.
2. Position marker so that it is touching the center of the end effector and oriented normal to it, when the end effector is in its home position. Securely attach marker to a solid object in this position.
3. Load first motion file as described in table 3 below.
4. Set motion speed as specified.
5. If possible set motion file to run the cycle number specified below, otherwise manually observe test and stop test or remove marker when the cycle number is reached.
6. Begin motion.
7. At completion of test remove card from card adapter and record the following information on back of card:
    i. Date and time of test.
    ii. Motion File Used.
    iii. Number of Cycles.
    iv. Cycles Per Minute
8. Record any additional notes in the space provided at the bottom of this procedure.
9. Repeat procedure for remaining tests as detailed in table 3 below.

Table 3: Test Procedure

File Name	Cycles/Min	Cycles
+X	10	10
-X	10	10
+Y	10	10
-Y	10	10

Analysis:

After completing each test case above, fill in table 4 below following the directions below. Each motion file will produce 3 groups of points. The outermost groups are approached from only one direction each time and contain as many points as cycles run of the test. The center group contains twice as many points as it is approached from both directions.

- Group Length:
    - The group at the origin of the end effector is group A, while the outermost group is group C.
    - Using calipers measure greatest distance between any two points in a given group and record in table.
- Distances
    - L1 is the distance between the center of group A and the center of group B. Measure this distance using calipers and record.
    - L2 is the distance between the center of group A and the center of group C. Measure this distance using calipers and record.

Table 4: Translation Test Results

Test Case	Group Length [in]			Distances [in]		Pass/Fail	
	A	B	C	L1	L2	Group Lengths	Distances
+X	.75	.71	.7	.3	.51	Pass	Pass
-X	.86	.81	.55	.31	.53	Pass	Pass
+Y	.83	.95	.73	.32	.56	Pass	Pass
-Y	.13	.67	.93	.34	.51	Pass	Fail

PASS/FAIL Criteria:

To pass, the largest group length of any test must be less than .1”. Distances L1 must be within .226 and .326in. Distance L2 must be within .501 and .601in.

The overall test is considered a pass if all trials passed based on the above requirements.

Test Results: PASS / FAIL

Date: 5/30/18

Tested By: SAM PORTER

Notes: FAILED IN -Y DIRECTION, OFF BY .02”. LIKELY A RESULT OF TEST SETUP OR DEVICE CALIBRATION.

Test #2: Rotation

Test Description:

This test is used to evaluate the motion systems ability to correctly rotate to various positions relative to its home position. Similar to the translation test certain orientation values will be approached from both directions to better represent overall system performance.

Test Hardware:

Table 5: Test #2 Hardware

Hardware	Version/Serial Number	Notes
Motion System	Final	
Electronics Enclosure	Final	
IMU Adapter	1	
IMU	BNO055	
Arduino	Uno	
Arduino Software	Adafruit BNO055 Examples	
Laptop	-	

Test Setup:

1. Setup the motion system with associated electronics and software.
2. Ensure motion system is level.
3. Install IMU adapter with IMU onto end effector.
4. Connect Arduino to both IMU and computer.

Test procedure:

1. Load first motion file as described in table 6 below.
2. Set motion speed as specified.
3. If possible set motion file to run the cycle number specified below, otherwise manually observe test and stop test when the cycle number is reached.
4. Setup Arduino to acquire orientation of axis being tested by the current file, and to print this data to the terminal.
5. Begin motion and data acquisition with Arduino.
6. At completion of test copy angle values printed in the terminal to an excel file. Include in the excel file the following information:
    i. Date and time of test.
    ii. Motion File Used.
    iii. Number of Cycles.
    iv. Cycles Per Minute
7. Record any additional notes in the space provided at the bottom of this procedure.
8. Repeat procedure for remaining tests as detailed in table 6 below.

Table 6: Test Procedure

File Name	Cycles/Min	Cycles
+Roll	10	10
-Roll	10	10
+Pitch	10	10
-Pitch	10	10
+Yaw	10	10
-Yaw	10	10

Analysis:

After completing each test case above, fill in table 7 below following the directions below. Each motion file will rotate the designated axis from its neutral position to an angle of 10º hold at this position briefly, then to an angle of 20º back to 10º and finally returning to 0º holding briefly at each value. Apply color formatting to each set of acquired data and ensure that all of these angles are within ±1º of their designated value. It is acceptable to zero the data by subtracting the IMUs initial readings from the entire data set.

Table 7: Rotational Test Results

Test Case	0º		10º		20º		Pass/Fail		
	Max	Min	Max	Min	Max	Min	0º	10º	20º
+Roll	0	-.37	10.32	9.75	19.82	19.5	Pass	Pass	Pass
-Roll	.88	-.37	10.32	9.69	19.82	19.44	Pass	Pass	Pass
+Pitch	.06	-.32	10.68	9.68	19.81	19.62	Pass	Pass	Pass
-Pitch	1	-.07	10.87	9.81	20.18	19.75	Pass	Pass	Pass
+Yaw	.18	-.94	10.56	8.43	-	-	Pass	Fail	Fail
-Yaw	1.69	-.5	11.62	8.56	-	-	Fail	Fail	Fail

PASS/FAIL Criteria:

The results from each test case are considered a pass if the max and min values for each angle are within 1º of the desired value.

The overall test is considered a pass if all test cases passed.

Test Results: PASS / FAIL

Date: 5/30/18

Tested By: SAM PORTER

Notes: THE FLEXIBLE SEAL LIMITED THE MOTION OF THE DEVICE IN THE YAW AXIS.

Overall Testing Results:

The overall testing can be considered a pass if all above tests are marked as a **PASS**.

Test Results: PASS / FAIL

Date: 6/30/18

Tested By: SAM PORTER

Notes:

System performed as desired for majority of testing. The flexible seal interfered with yaw motion of the device. Translation in the -Y direction was out of tolerance at one point, but may be a result of the test setup.

APPENDIX I

SAFETY HAZARD CHECKLIST

FMEA

RISK ASSESSMENT

NOTE:

The license to design safe used when generating a portion of these documents expired before they could be updated. All safety concerns found using the design safe software have been addressed in the manor initially described in the design safe report.

DESIGN HAZARD CHECKLIST

Team: DyHeart Advisor: Professor Schuster Date: 11/9/17

Y	N	
☐	☑	1. Will the system include hazardous revolving, running, rolling, or mixing actions?
☐	☑	2. Will the system include hazardous reciprocating, shearing, punching, pressing, squeezing, drawing, or cutting actions?
☐	☑	3. Will any part of the design undergo high accelerations/decelerations?
☐	☑	4. Will the system have any large (>5 kg) moving masses or large (>250 N) forces?
☐	☑	5. Could the system produce a projectile?
☐	☑	6. Could the system fall (due to gravity), creating injury?
☐	☑	7. Will a user be exposed to overhanging weights as part of the design?
☑	☐	8. Will the system have any burrs, sharp edges, shear points, or pinch points?
☐	☑	9. Will any part of the electrical systems not be grounded?
☐	☑	10. Will there be any large batteries (over 30 V)?
☐	☑	11. Will there be any exposed electrical connections in the system (over 40 V)?
☐	☑	12. Will there be any stored energy in the system such as flywheels, hanging weights or pressurized fluids/gases?
☐	☑	13. Will there be any explosive or flammable liquids, gases, or small particle fuel as part of the system?
☐	☑	14. Will the user be required to exert any abnormal effort or experience any abnormal physical posture during the use of the design?
☐	☑	15. Will there be any materials known to be hazardous to humans involved in either the design or its manufacturing?
☐	☑	16. Could the system generate high levels (>90 dBA) of noise?
☐	☑	17. Will the device/system be exposed to extreme environmental conditions such as fog, humidity, or cold/high temperatures, during normal use?
☐	☑	18. Is it possible for the system to be used in an unsafe manner?
☑	☐	19. For powered systems, is there an emergency stop button?
☐	☑	20. Will there be any other potential hazards not listed above? If yes, please explain on reverse.

For any "Y" responses, add (1) a complete description, (2) a list of corrective actions to be taken, and (3) date to be completed on the reverse side.

Description of Hazard	Planned Corrective Action	Planned Date	Actual Date
Our design will include a Stewart platform which will include pinch points while the device is being used.	The moving components that will have pinch points will be covered and not able to be touched. The front end will be cantilevered into a water tank and covered with a seal, and the back end will be covered because we will mount the controller at the opening. Also we will have an E-stop.	03/13/18	

designsafe Report

Application:	RV Motion Simulator	Analyst Name(s):	Sam Porter
Description:	Risk assesment of the 6DOF right ventricle motion simulation system for edwards lifesiences.	Company:	
Product Identifier:		Facility Location:	
Assessment Type:	Detailed		
Limits:			
Sources:			
Risk Scoring System:	ANSI B11.0 (TR3) Two Factor		

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment Severity Probability	Risk Level	Risk Reduction Methods /Control System	Final Assessment Severity Probability	Risk Level	Status / Responsible /Comments /Reference
1-1-1	operator normal operation	mechanical : pinch point Finger caught between back of end effector and seal.	Moderate Unlikely	Low	warning label(s), instruction manuals	Moderate Unlikely	Low	
1-1-2	operator normal operation	mechanical : unexpected start Software Glitch | Unintended User Input	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
1-1-3	operator normal operation	electrical / electronic : water / wet locations Servos operate in waterproof enclosure that could fail.	Minor Likely	Low	Implement fuses if power at dangerous levels.	Minor Likely	Low	
1-1-4	operator normal operation	electrical / electronic : power supply interruption Unintended disconnect of power cable.	Minor Unlikely	Negligible		Minor Unlikely	Negligible	
1-1-5	operator normal operation	slips / trips / falls : slip System splashes water out of its tank.	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
1-1-6	operator normal operation	slips / trips / falls : trip Power/data cables routed across walkway.	Moderate Likely	Medium	Determine cable length that allows for easy routing.	Moderate Unlikely	Low	Action Item [3/31/2018] Sam Porter
1-2-1	operator clean up	mechanical : unexpected start Software Glitch | Unintended User Input	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment Severity Probability	Risk Level	Risk Reduction Methods /Control System	Final Assessment Severity Probability	Risk Level	Status / Responsible /Comments /Reference
1-3-1	operator basic trouble shooting / problem solving	mechanical : pinch point Finger caught between back of end effector and seal.	Moderate Unlikely	Low	warning label(s), instruction manuals	Moderate Unlikely	Low	
1-3-2	operator basic trouble shooting / problem solving	mechanical : unexpected start Software Glitch | Unintended User Input	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
1-4-1	operator load / unload materials	electrical / electronic : unexpected start up / motion Software Glitch | Unintended User Input	Minor Unlikely	Negligible		Minor Unlikely	Negligible	
2-1-1	maintenance technician parts replacement	mechanical : pinch point Catch finger in exposed mechanical linkage.	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
2-1-2	maintenance technician parts replacement	mechanical : break up during operation Part replacement performed without checking calibration after.	Serious Unlikely	Medium	special procedures, warning label(s)	Serious Unlikely	Medium	Action Item [4/30/2018] Sam Porter
2-1-3	maintenance technician parts replacement	electrical / electronic : energized equipment / live parts Device not properly disconnected.	Serious Likely	High	warning label(s), instruction manuals	Serious Unlikely	Medium	Action Item [3/31/2018] John D'Ambrosio
2-1-4	maintenance technician parts replacement	electrical / electronic : water / wet locations Device not properly dried before performing maintenance.	Moderate Remote	Negligible		Moderate Remote	Negligible	
2-2-1	maintenance technician periodic maintenance	mechanical : break up during operation Maintenance performed without checking calibration after.	Serious Likely	High	special procedures, warning label(s)	Serious Unlikely	Medium	Action Item [4/30/2018] Sam Porter

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment Severity Probability	Risk Level	Risk Reduction Methods /Control System	Final Assessment Severity Probability	Risk Level	Status / Responsible /Comments /Reference
2-2-2	maintenance technician periodic maintenance	electrical / electronic : water / wet locations Device not properly dried before maintenance.	Serious Remote	Low	instruction manuals	Serious Remote	Low	
2-3-1	maintenance technician trouble-shooting / problem solving	mechanical : unexpected start Software Glitch | Unintended User Input	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
3-1-1	passer by / non-user work next to / near machinery	slips / trips / falls : slip System splashes water out of its tank.	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
3-1-2	passer by / non-user work next to / near machinery	slips / trips / falls : trip Power/data cables routed across walkway.	Moderate Likely	Medium	Determine cable length that allows for easy routing.	Moderate Unlikely	Low	Action Item [4/30/2018] Sam Porter
3-2-1	passer by / non-user walk near machinery	slips / trips / falls : slip System splashes water out of its tank.	Moderate Unlikely	Low	instruction manuals	Moderate Unlikely	Low	
3-2-2	passer by / non-user walk near machinery	slips / trips / falls : trip Power/data cables routed across walkway.	Moderate Likely	Medium	Determine cable length that allows for easy routing.	Moderate Unlikely	Low	Action Item [4/30/2018] Sam Porter

Design Failure Mode and Effects Analysis

Product: RV Motion Simulator

Team: DyHeart

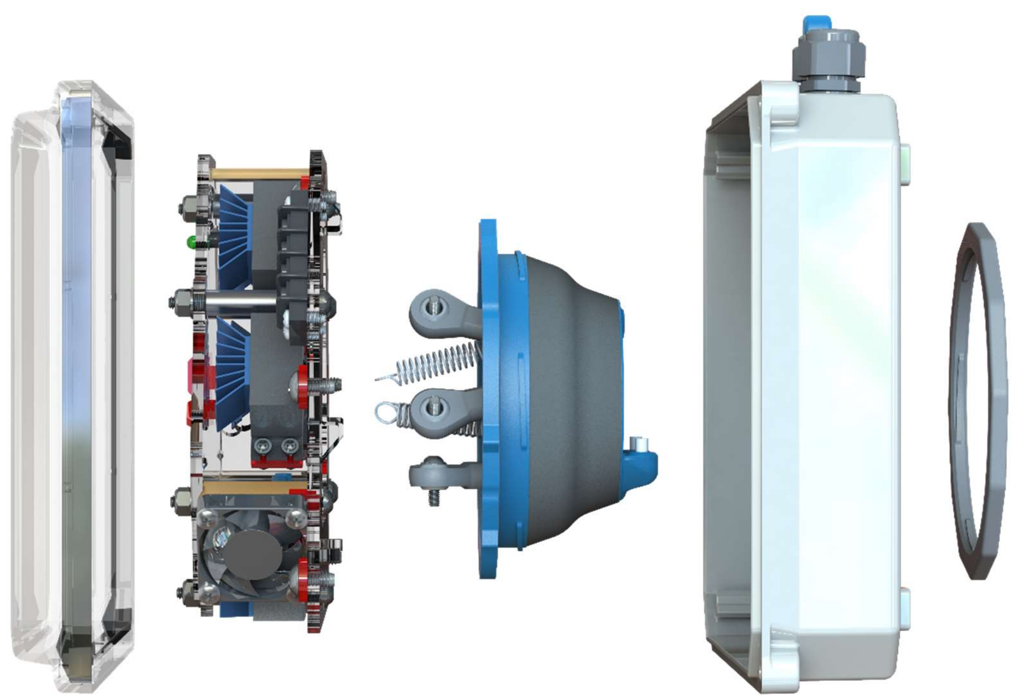
System / Function	Potential Failure Mode	Potential Effects of the Failure Mode	Severity	Potential Causes of the Failure Mode	Current Preventative Activities	Occurence	Current Detection Activities	Detection	Priority	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken	Action Results: Severity	Action Results: Occurence	Action Results: Criticality
Motion System/ Accurately Simulates Target Location Motion	Definied Motion Incorrect	Recreated motion not relevant	6	1) Motion Research Conducted Incorrectly	1) Justify technique for determing motion 2) Document assumptions and anticipated errors of defined motion	2	Compare motion of device with motion of heart scans	7	84	Take a new approach for converting the CT Scan motion into numbers	Sam 6/1/18	Documented motion analysis technique in report to sponsor. Verified code was mathmatically correct.			
	System Cannot Produce Motion	Device incapable of modeling motion	9	1) Software incapable of accounting for tissue location relative to end effector. 2) Insufficient Power to move end effector	1) Incorporate Factor of Safety Into Actuator Selection	3	Measure System Performance to Ensure it Exceeds Minimum Requirements	2	54	Determine source of failure (software/hardware). Have entire team brainstorm and agree on fix.	John 4/25/18	Ran tests of motion and system can produce motion.			
Motion System/ Connects to Tissue Adapter	Unable to Connect	System cannot produce test environment	9	1) Connection Designed Incorrectly 2) Manufacturing inadequate	1) Prototype Connector Method	2	Demonstrate Connector Capability	1	18	Redesign Tissue Adapter	Brian 5/15/18				
	Unable to Stay Connected	Tissue Adapter Disconnects During Use	7	1) Connection Designed Incorrectly	1) Prototype Connector Method	3	Test Tissue Adapter With Motion System	1	21	Redesign Tissue Adapter	Brian 5/15/18				
	Adapter Orientation not Fixed	Motion of Tissue Sample Incorrect	6	1) Connector works in multiple orientations 2) Too much movement present once connected	1) Prototype Connector Method	2	Measure Movement Allowed by Connector	1	12	Redesign Tissue Adapter	Brian 5/15/18				
Motion System/ Seperates Electronics from Water	Electronics Get Wet	Damage to Electronics	8	1) Failure of a sealing method 2) Water is able to splash onto electronics.	1) Separate from Water 2) Add Splashguard	3	Test	2	48	Re-design sealing technique	Brian 5/15/18				
Approach/ Models Procedure	innacurately represents human heart	use of device is not clinically relevant	6	1) approach components are modeled incorrectly 2) Approach positioned incorrectly	1) Verify model with proessionals before manufacuring 2) Position according to sponsor	2	Inspection by Sponsor	1	12	Consult with Sponsor for new approach	Brian 5/15/18				
Secure approach and motion system	Approach and motion system are not secured and move	the precise motion of the RV is no longer relevant	5	1) Approach and motion system are not adequately fastened	1) Build fixtures to hold approach and motion system in place	2	Test: Attempt to move them	2	20	Re-design fixture setup	Brian 6/05/18				
Tissue Adapter/ Connects Tissue to Motion System	Tissue Sample Not Secure	4	5	1) Sample not held with enough pressure/force.	1) Prototype Adapter Method	4	Test tissue adapter prototype	3	60	increase pressure produced by connector onto tissue sample. If failure persists change connector form	Brian 4/30/2018	Prototype Tissue Adapter was tested and worked sufficiently.			

APPENDIX J

USER MANUAL

Dynamic Right Ventricle Model

Operators Manual



Prepared For: Aric Stone, Edwards Lifesciences

Prepared By: John D'Ambrosio

Brian Larsen

Sam Porter

NOTE: Do not clean system using acetone. Denatured alcohol or water is acceptable.

Contents

1. Overview

The dynamic right ventricle model is a system capable of taking motion profiles generated from CT scans or other means and reproducing the motion.

The system can move in six degrees of freedom. From the home position translations of ±14mm are possible in any direction with an accuracy of 1.5mm or better. Also, from the home position roll and pitch rotations of ±20º with an accuracy of 1º or better are possible. Yaw has a range of ±10º at a reduced accuracy.

In general, motion profiles can be run at over 100 cycles per minute.

1.1. Components

The complete system is shown below along with a brief description of what each component does.

Figure 1. From left to right the electronics enclosure, motion system (snorkel not yet installed), and the system software GUI running on a laptop. Below the motion system is a portion of the tissue adapter for connecting an animal heart to the system.

1.1.1. Electronics Enclosure

The electronics enclosure houses the systems power supply as well as the microcontroller used to control the motion system. Additionally, the system emergency stop is located on this enclosure. The enclosure is splash proof but should remain a safe distance from water.

1.1.2. Motion System

The motion system is the submersible portion of the system which various adapters can connect to. For instance, the tissue adapter discussed below.

1.1.3. GUI

The GUI is used to control the motion system. Motion files can be selected along with a corresponding speed, additionally the system can be paused and resumed.

1.1.4. Tissue Adapter

The Tissue adapter secures the heart to the motion system in a way that accurately translates the motion of the end effector to the target location in the right ventricle.

2. Safety

The following sections discuss safety concerns when operating the device and when repairing, as well as the safety features designed into the system.

2.1. Standard Use

The primary safety feature of this system is the emergency stop button located on the electrical enclosure. This button will disconnect AC power from the system and should be pushed as a first step in an emergency.

If the primary emergency stop button is not within reach a software implemented stop button is located on the motion system. This button must be held down until the system stops, but it will not disconnect power from the system.

Before each use inspect the system for water, frayed cables, damaged components, or other obvious signs of excessive wear or part failure. Follow all warning labels and keep hands away from end effector while the device is moving. Be aware that sudden and unexpected motion can occur when the system is powered. Be aware that shielding may be necessary to prevent water from being splashed from the container the motion system is submerged in.

2.2. Repair Precautions

Before attempting any repairs ensure all power cables are disconnected from the system. During the repair process, be aware that incorrect assembly could cause acrylic components to shatter. After making repairs to the waterproof enclosure submerge it without power connected to ensure the enclosure lid has formed an appropriate seal. If operating device with the cover removed keep hands clear of moving parts.

3. Setup

This section covers the typical steps necessary to begin using the system.

3.1. Hardware

To setup the system hardware simply put the motion system into its desired location along with any necessary fixturing to secure it. Next, the motion systems power cable (black) and signal cable (blue) can be connected to the electronics enclosure. The connectors are different so there is only one way to do this.

Next, connect an AC power cable to the electronics enclosure and a USB cable to the computer that will be used for testing. Place the electronics enclosure in a dry area that leaves the emergency stop button accessible and zip tie any extra cable out of the way.

When submerging the motion system, it is recommended that the operator periodically check the enclosure for leaks.

3.2. Software

To operate the software a specific order of steps must be taken for proper use as described below. Reference figure 2 for button locations.

1. First press the red “Import” button. This action populates the drop-down window to the right with motion profiles in the same directory as the program.
2. Choose a motion profile from this list and press the orange “Select” button. If the motion profile is not compatible with the system an error will be generated.
3. Next, choose a serial port connection from the drop-down menu in the “Com Port” section and press “Connect” which then turns the button green.
4. From here, press the green “Command Mode” button, putting the system into a state that can communicate with the servos.
5. Once in Command Mode, press the yellow “Transfer” button to begin transferring the data previously selected. The PCB contains an orange LED used to flash only when data is being transferred. When the LED stops flashing, data transfer has been successful.
6. With the data transferred, press the light green “Sort” button to organize the data into reusable arrays found within the memory on the Microcontroller.
7. Following the sorting process, press the dark blue “Select” button under the Beats Per Minute category once the chosen BPM is selected.
8. Finally, press the black “Zero” button to return the end-effector to the neutral home position.
9. From here, the user can press the purple “Start” button to begin motion.

While running, the brown “Stop” button to pause a run. The user can then either resume the run with the grey “Resume” button, or zero the platform with the black “Zero” button. When the user wants to begin a new motion profile, the light blue “Start Up Mode” button must be pressed followed by the “System Reset” button. Then follow the steps above.

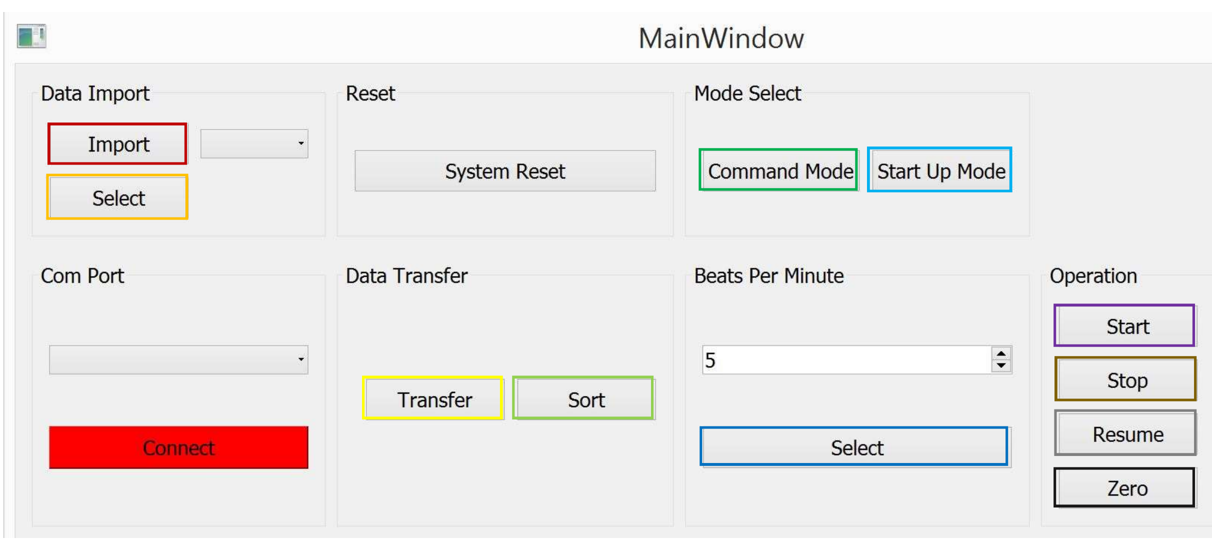


Figure 2. Color coordinated picture of the control section on the Graphical User Interface

Commands are also displayed in the Communications Window that assist in operation.

3.3. Heart Attachment

This section will explain the steps to take when fixturing a heart to the device. Below are the primary components that will be used.

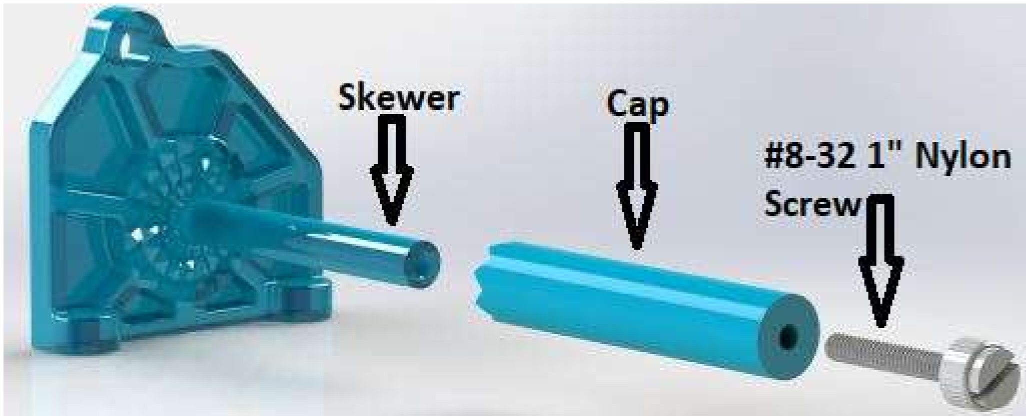


Figure 3. These three components make up the tissue adapter. The tissue adapter attaches to the end effector and to the heart. The movements created by the motion system are translated to the heart through the tissue adapter.

Be sure to wear gloves during this entire process. First, create a very small incision in the bottom of the left ventricle as close to the apex as possible. Completely insert the tissue adapter skewer through the incision.

Figure 4. After a small incision is made in the bottom of the left ventricle very close to the apex, the blue skewer is placed completely into the heart. Verify that that bottom flat part and the back side of the heart are both facing the ground during this point in the procedure.

From the top side of the heart, place the cap into the top left atrium and completely over the skewer. Use the #8-32 screw and screw it through the cap into the skewer by hand until there is no slipping between the heart tissue and the skewer base.

Figure 5. This top view of the heart shows the blue cap which has been placed into the left atrium and over the skewer. Also shown is the white #8-32 1" screw that screws through the cap into the skewer. When this screw is tightened, there is a pinch point created that fastens the heart to the tissue adapter at the location where the motion will be translated to the heart.

Verify that the top of the skewer base is facing the same direction as the front side of the heart. Next, loosen the screws at the base of the access path so it can freely slide back and forth. Insert the end of the access path closest to the motion system into the superior vena cava and fasten down with a zip-tie.

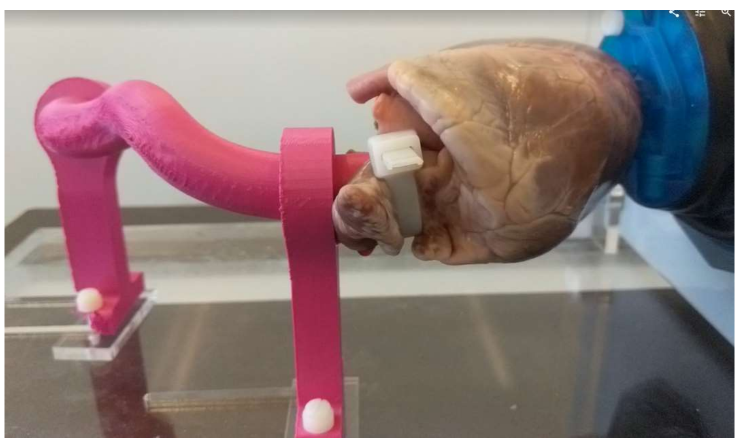


Figure 6 The access path is inserted into the superior vena cava and tightened with a zip tie. During this step, the screws at the base of the access path should be loose enough for the pink access path to be able to freely slide back and forth.

Hold the skewer base and slide the heart and access path towards the motion system until the skewer base can slide over the two pins on the end effector. Finally, insert the #10-24 nylon shoulder screw into the end effector and tighten the screws on the access path base until it cannot slide.

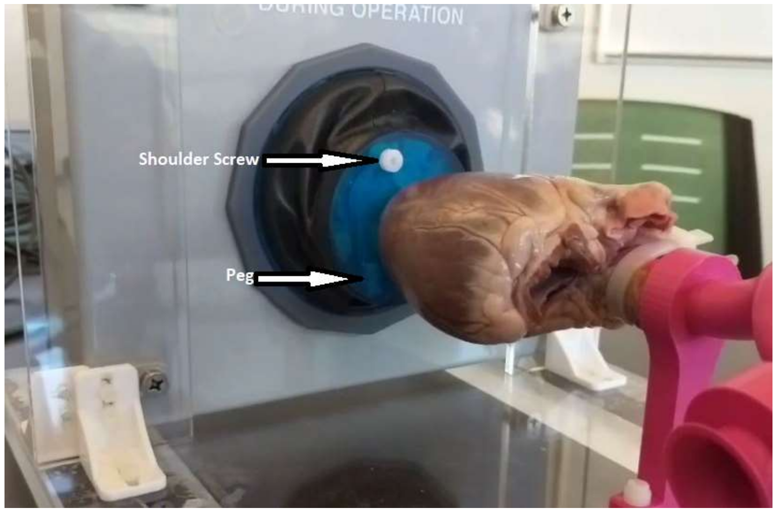


Figure 7. After the heart is zip-tied to the access path, the tissue adapter should be placed over the pins on the end effector, and finally the shoulder screw is screwed in to fasten the tissue adapter.

5. Customization

The functionality of the system can be expanded by creating custom motion profiles and adapters. Information to help in this process if found below.

5.1. Creating Motion Files

To increase flexibility of the system, in addition to easily being able to install new adapters onto the end effector, new motion profiles can be generated and run through the system software.

These files should be created as commas separated variable (CSV) files, something that can easily be done in excel. The data necessary is stored in 9 columns of data as shown below:

X	Y	Z	Roll	Pitch	Yaw	X Off	Y Off	Z Off

The first six columns contain position and orientation data, the last three columns are used to specify the location of that motion, units are millimeters and degrees. By specifying the location of the motion, a coordinate frame with identical orientation to that of the overall system is placed in space relative to the end effectors neutral position.

For instance, if the last three columns are zero the prescribed motion will happen about the end effector. If a Z Off value of 15 is given the prescribed motion will be produced at a location 15mm from the surface of the end effector. So, if a roll value of 10º were specified with a positive Z Off value, all other values being zero, the end effector would roll 10º along with translating so that the location of Z Off is unchanged.

It is recommended that all motion profiles be limited to no more than 200 data points, as this may cause the microcontroller to run out of memory.

5.2. Creating Tissue Adapters

System functionality can be expanded by creating new adapters that connect to the end effector. General requirements for this are shown below.

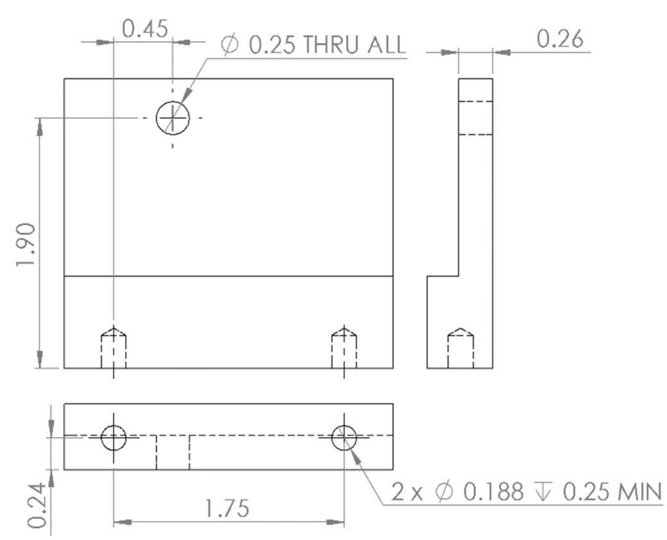


Figure 8. General dimensional requirements for custom adapters.

6. Upgrading & Repairing

6.1. Servos

For better overall performance, including power draw and noise reduction, higher quality Spektrum servos can be purchased and substituted into the design. If a servo upgrade is required, an upgrade will be warranted from the power supply and power cable due to current limitations.

When installing new servos, the zero position must be set prior to installation. This can be done by sending the appropriate Pulse-Width Modulation signal to each servo individually and performing a visual inspection for the correct placement.

6.2. Seal

The seal is constructed out of 1/64" thick nitrile and glued together using 3M 847 adhesive sealant. While not tested, products made for patching other nitrile products can likely be used to repair leaks.

6.3. Electronics

The most likely electronics repair will be fuse replacement, the specifications for each fuse is listed below:

Table 1: Fuse Replacement

Location	Replacement Fuse
5V	3AB 10A 250V
12V	3AB 300mA 250V
AC	5x20mm 1A 250V

If upgrading the system power supply keep in mind that the system wiring may need to be replaced to handle greater current, if applicable.

6.4. Calibration

Calibration should be performed whenever a servo adapter has been removed from a servo during repair. If the system had previously been calibrated those calibrations must be removed before beginning.

To calibrate the performance of the X, Y, and Z axis along with Roll, Pitch, and Yaw must be independently quantified.

For example, if the X axis is to be calibrated motion profiles can be generated and executed one at a time from a negative X axis value and slowly progressing to a positive X value. The actual end effector position can then be measured and plotted against the programmed position yielding results like what is shown below.

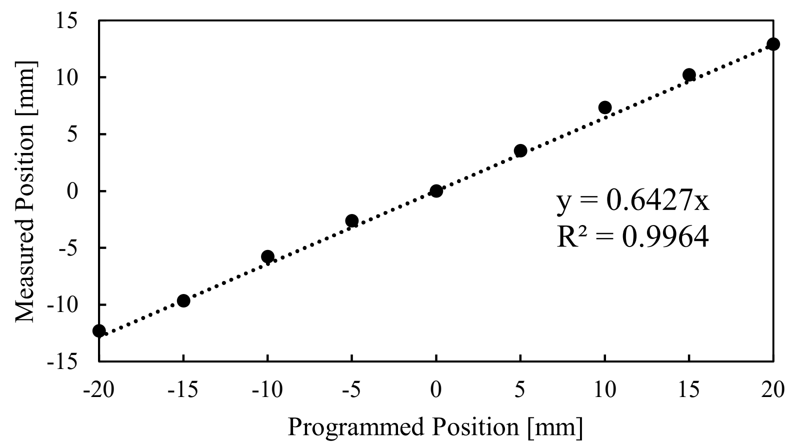


Figure 9. Example calibration curve for X axis.

This information can then be used to modify the PlatformModel.py file as shown below.

```
'convert input orientation into translation and rotation arrays'
x_translation = (1/.6427)*orientation[0] # [mm]
y_translation = (1/.6317)*orientation[1] # [mm]
z_translation = (1/.9512)*orientation[2] # [mm]
x_rotation = (1/.7896)*math.radians(orientation[3]) # [rad]
y_rotation = (1/.7801)*math.radians(orientation[4]) # [rad]
z_rotation = (1/.5844)*math.radians(orientation[5]) # [rad]
```

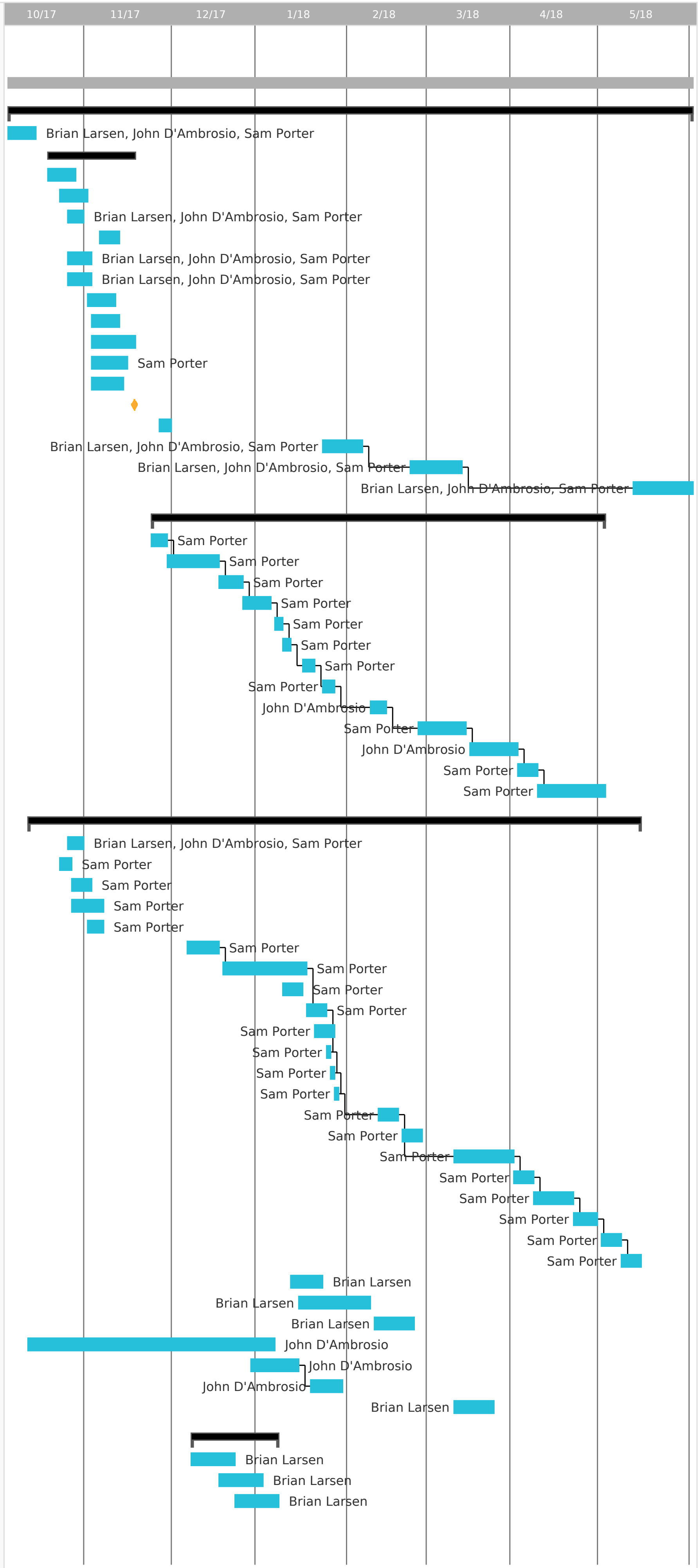
Figure 10. Example of calibration data input into PlatformModel Python file.

If necessary static calibration values can also be added here. If individual servo angles must be calibrated this can be done elsewhere in the python code.

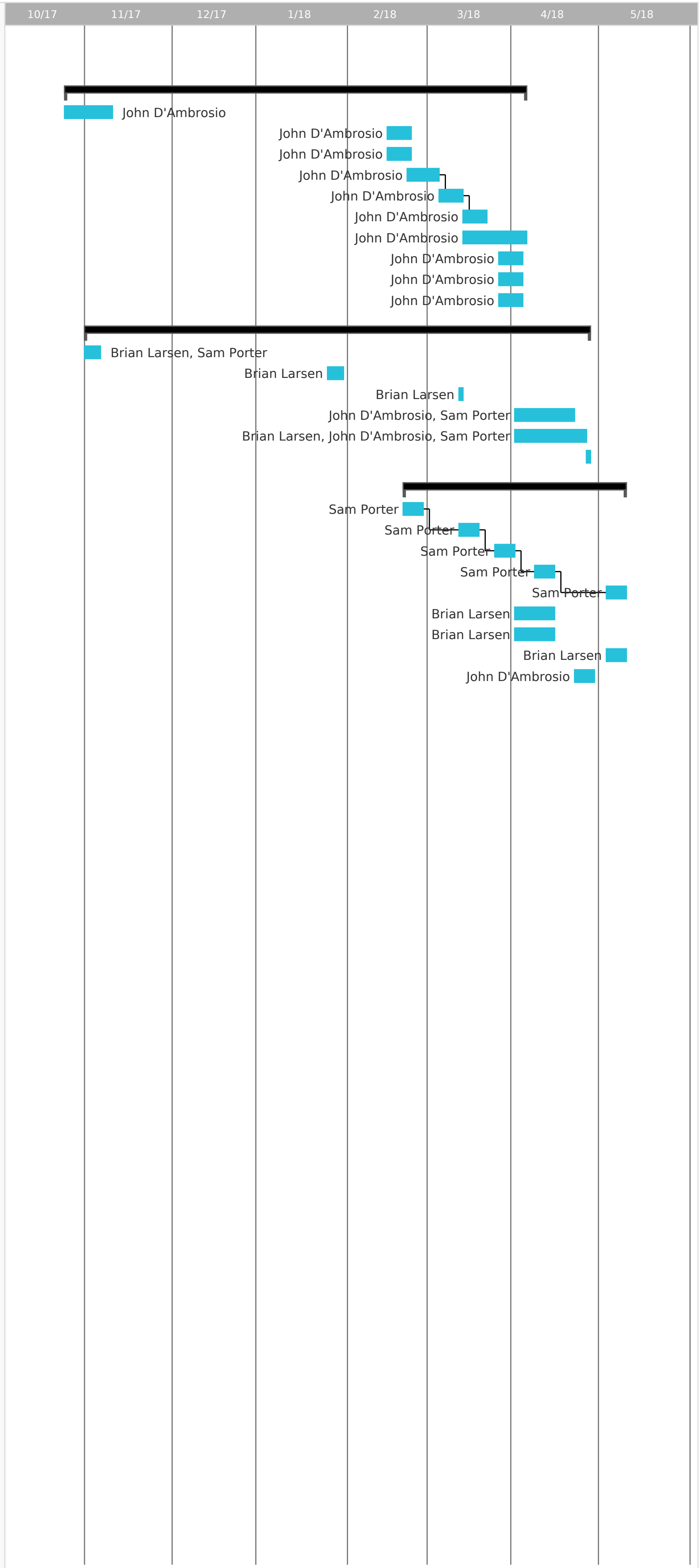
APPENDIX K

GANTT CHART

Task	Hours	% Complete
1-6 Dynamic Ventricle Mode...	**0h**	**100%**
Documentation	**0h**	**100%**
Scope of Work	0	100%
Preliminary Design Review	**0h**	**100%**
Initial Document Setup	0	100%
Sketch Top 5-10 Concepts	0	100%
Pugh Matrices	0	100%
Update SOW Section	0	100%
Weighted Decision Matrix	0	100%
Concept Prototype Plan	0	100%
Describe Process Used to get to Le...	0	100%
Write a Complete Description of Se...	0	100%
Finalize Document	0	100%
Describe Plan for Construction and...	0	100%
PDR Presentation	0	100%
PDR Due	0	100%
FMEA	0	100%
Comprehensive Design Review Doc...	0	100%
Manufacturing and Test Review Doc...	0	100%
Final Design Review Documentation	0	100%
Motion Research and Matlab Model...	**0h**	**100%**
Initial RV Segmentation with ITK-Snap	0	100%
Develop Method for Determining Mot...	0	100%
Model Tissue Adapter in Matlab	0	100%
Integrate Stewart Platform Model into...	0	100%
Identify Critical Bugs in Matlab	0	100%
Implement Changes Based on Bugs	0	100%
Select Actuators	0	100%
Update Swivvle Calculations For Ang...	0	100%
Create Plan for Preparing Software fo...	0	100%
convert matlab functions to python	0	100%
Add GUI	0	100%
Document Motion Analysis Procedure	0	100%
Determine Motion for All Provided Sc...	0	100%
Motion System	**0h**	**100%**
Decision Matrix	0	100%
Concept Model	0	100%
Concept Prototype Plan	0	100%
Preliminary Design Review CAD	0	100%
Concept Protoype	0	100%
Develop Concepts For Tissue Adapter...	0	100%
Design Structural Prototype Based on...	0	100%
Determine Actuator Requirements Us...	0	100%
Determine method of waterproofing	0	100%
Manufacture Stewart Platform Protot...	0	100%
Update End Effector For 3D Printing	0	100%
Update Servo Adapter For 3D Printing	0	100%
Recheck platform geometry	0	100%
Build Second Prototype	0	100%
Find method of using design safe	0	100%
Design Prototype 3 with Manufacturi...	0	100%
Build Prototype 3	0	100%
Revise for Final	0	100%
Build Final Hardware	0	100%
Resolve Prototype 4 Problems and c...	0	100%
Implement Changes as needed	0	100%
Develop Concepts for Flex Seal	0	100%
Further Design/CAD Top Flex Seal Co...	0	100%
Prototype Top Flex Seal Concept(s)	0	100%
Actuation Research	0	100%
Pick MCU	0	100%
Choose Power Electronics	0	100%
Design Tissue Adapters to Test	0	100%
Approach	**0h**	**100%**
Research Existing Models	0	100%
Create CAD Model	0	100%
3D Print Prototype	0	100%



Task		
Software Development	**0h**	**100%**
Task Diagrams	0	100%
Servo Driver Class	0	100%
Timer Driver Class	0	100%
Design GUI for Serial Testing	0	100%
Serial Communication Testing	0	100%
Complete GUI to MCU Demo	0	100%
Desgin PCB	0	100%
Safety Interrupt	0	100%
Upgrade GUI	0	100%
Clean User Task	0	100%
Additional Manufacturing	**0h**	**100%**
Build Concept Prototype	0	100%
Build Structural Prototype	0	100%
Manufacturing and Test Review	0	100%
Electrical Fabrication	0	100%
System Integration	0	100%
Hardware Demo	0	100%
Test	**0h**	**100%**
Demonstrate Feasibility of Using Acc...	0	100%
Produce Test Method to use with Acc...	0	100%
Test Prototype 2 Performance	0	100%
Test Prototype 3 Performance	0	100%
Test Final Product Performance	0	100%
Test End Effectors on Heart	0	100%
Test Flex Seal	0	100%
Test Flex Seal With Final System	0	100%
Test Software Functionality	0	100%



APPENDIX L

MOTION ANALYSIS DOCUMENTATION

Right Ventricle Segmentation & Motion Tracking Method Overview

March 5, 2018

By: Sam Porter

Contents

1. Document Overview

This document provides a high-level overview of the methodology used for determining motion of the right ventricle from 4D CT scans.

The top-level process overview is shown below, followed by more detailed discussion of the segmentation and analysis process.

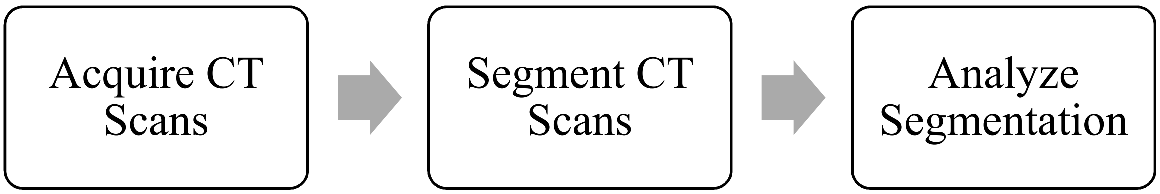


Figure 1. Top-level process overview for determining motion of the right ventricle from 4D CT scans. Segmentation takes place in ITK-SNAP, analysis occurs in a custom MATLAB script.

2. Segmenting CT Scans

Segmentation of the CT scans is the process of identifying and extracting a 3D model of the feature(s) of interest within the scan. This process is completed using ITK-SNAP [1], which is both easy to use and licensed for free use. A top-level overview of the segmentation process is shown in figure 2 and discussed below.

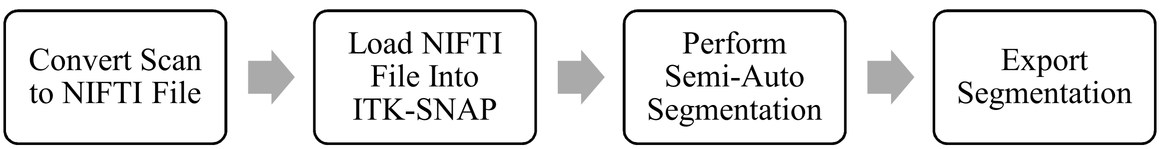


Figure 2. Overview of segmentation process that takes place in ITK-SNAP

2.1. Convert Scan to NIFTI File

Often the native format of a CT scan from the scanner is a DICOM file, which consists of thousands of individual images that constitute the overall scan. In this format it is both difficult to keep track of and to use these files with ITK-SNAP. To resolve this issue, the DICOM files for each scan are converted into a single NIFTI file using a free MATLAB library [2].

2.2. Perform Semi-Auto Segmentation

While ITK-SNAP offers several methods of segmenting CT scans, the approach below focusses on a semi-automated method. While the semi-automated segmentation must be carefully setup, and the results closely scrutinized, the speed and repeatability are far superior to manual segmentation.

The automated segmentation process in ITK-SNAP is outlined in below, along with more detailed discussion.

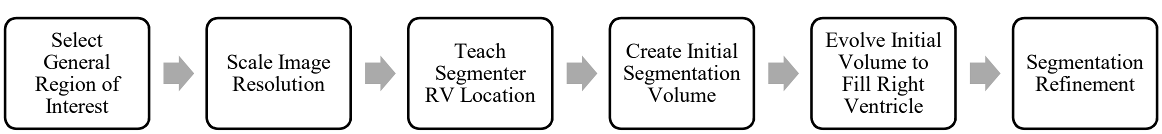


Figure 3. Workflow for performing a semi-automatic segmentation in ITK-SNAP. This process must be conducted for each frame of a scan.

2.2.1. Select General Region of Interest

Selecting a general region of interest is the first step in performing a semi-automatic segmentation. The purpose of this step is to set the bounds in space where the right ventricle (or feature of interest) exists.

Bounding the region of interest makes it easier for the segmenter to determine what is and isn't the right ventricle, and if the segmenter spills over into another feature of the heart, there is less to manually remove during refinement.

In figure 4, an example of bounding the right ventricle prior to segmentation is shown.

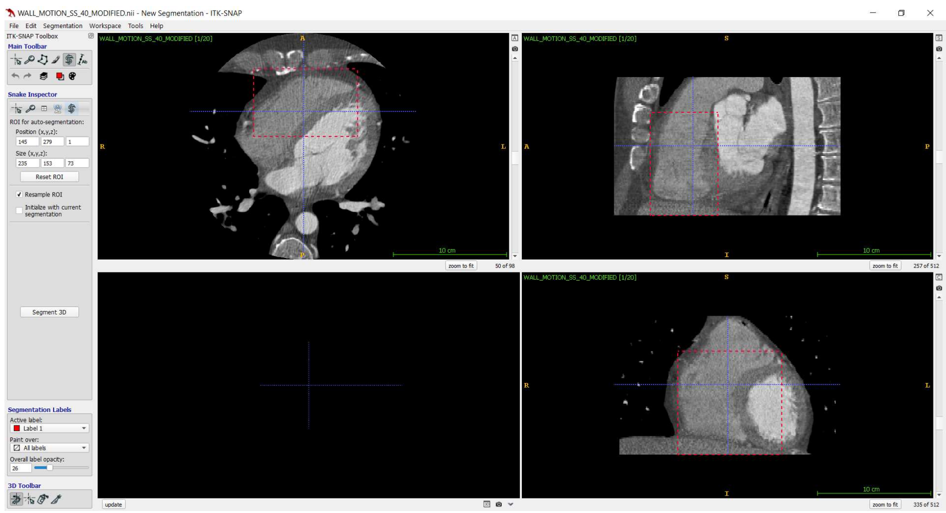


Figure 4. Bounding of the right ventricle portion of interest before proceeding with the semi-automatic segmentation. The dashed red box represents the region that will be considered for segmentation in the following steps.

2.2.2. Scale Image Resolution

When researching the process of determining motion from CT scans, it was found that resolutions greater than 1-2mm provides no benefit. Because this increased resolution present in some scans caused ITK-SNAP to misidentify regions more frequently, resolution is decreased before proceeding with segmentation. Initial and adjusted resolution is shown below.

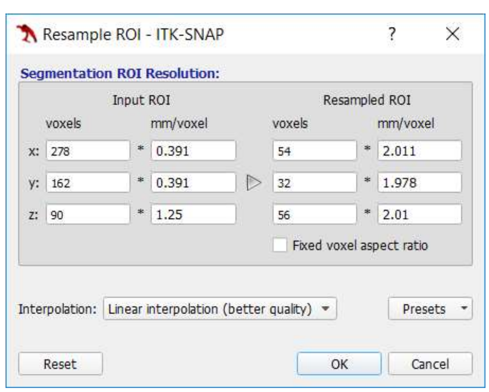


Figure 5. Resolution of the CT scan can be reduced to meet the analysis requirements.

2.2.3. Teach Segmenter RV Location

At this point, the general region of interest within the CT scan has been identified. It is now necessary to specify the exact region of interest. This can be done using several automated methods built into ITK-SNAP. The method shown here requires the user classify different regions by coloring on top of them. As seen in figure 5, this does not need to be done precisely, although outlining the entire right ventricle can reduce the amount of refinement needed later. The white section is what has been identified as the right ventricle in this example.

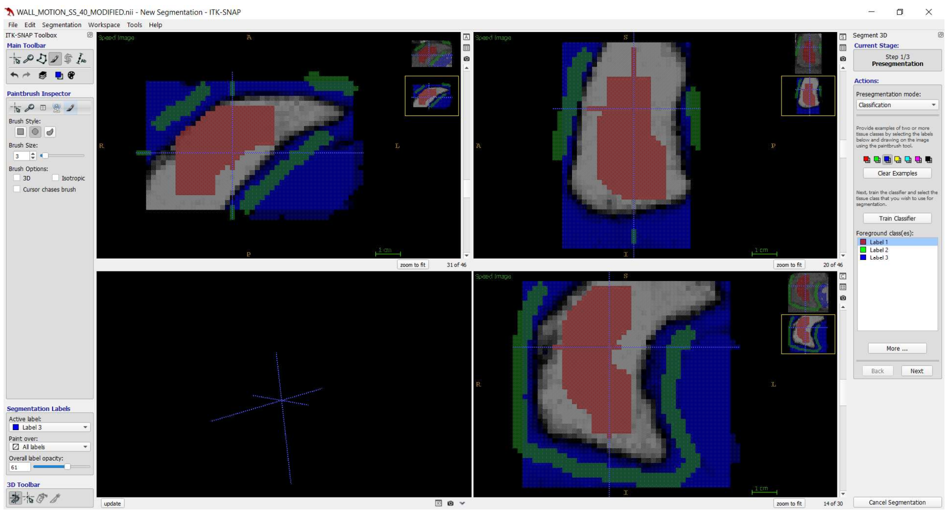


Figure 6. Identifying the right ventricle using the *Classification* method built into ITK-SNAP. This method works by identifying different regions with different colors, which ITK-SNAP then interprets throughout the 3D space.

2.2.4. Create Initial Segmentation Volume

Before a 3D model of the right ventricle can be generated, ITK-SNAP must be given a starting volume (or volumes). This is done by simply placing a sphere within the bounds of the right ventricle as shown.

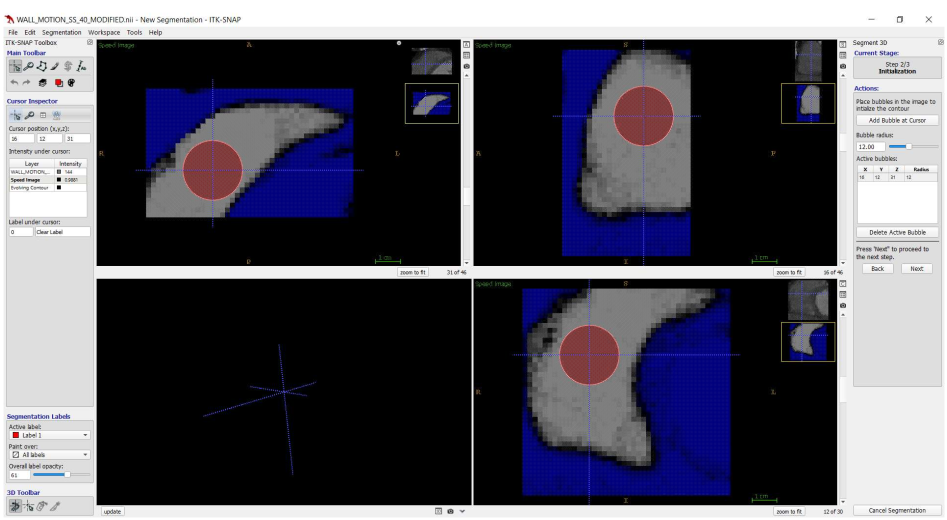


Figure 7. The segmentation must be initialized by providing some starting volume which will be expanded to fill the entire region identified. This can be done by simply placing a single sphere in the center of the desired region.

2.2.5. Evolve Initial Segmentation to Fill Right Ventricle

It is now possible to let ITK-SNAP autogenerate the 3D model of the right ventricle. This happens quickly, and a live preview is available as shown in figure 8. At this point it is still possible to go back and adjust previous settings before finishing the semi-automated segmentation.

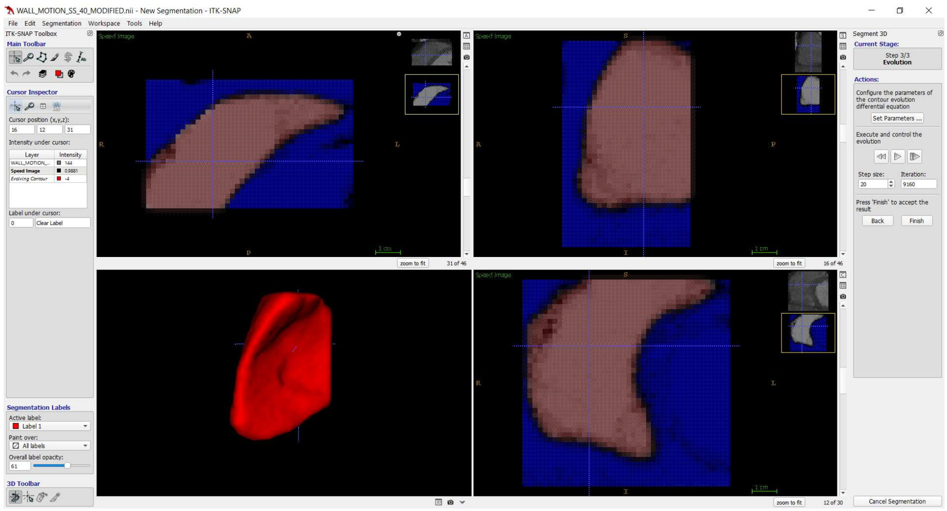


Figure 8. Segmentation results after evolving initial volume produced in step 2.2.4. to fill right ventricle region.

2.2.6. Segmentation Refinement & Exporting

After completing the semi-automatic segmentation, there may be portion of the right ventricle that the segmenter missed, or areas where it identified portion of other structures such as walls. To improve the segmentation before exporting the user can draw or erase the segmented region (identified in red) as shown in figure 9. After completing refinement, the segmentation can be saved as a standalone NIFTI file (which is what the MATLAB analysis software uses) or as various 3D files such as a STL file.

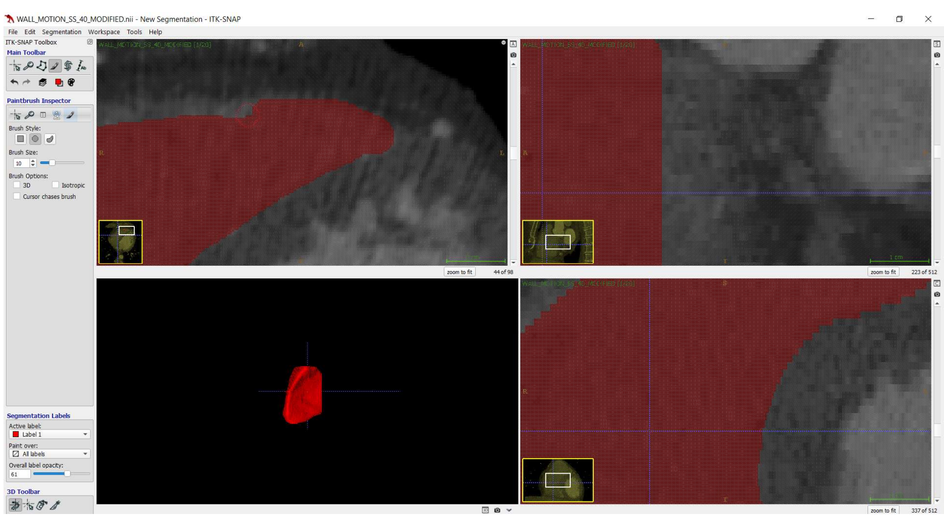


Figure 9. Refinements to the auto-generated right ventricle can be made by drawing onto or erasing the regions identified by ITK-SNAP.

3. Analyzing Segmentation

Once the above segmentation procedure has been completed for all frames in an image set, the exported segmentations can be imported into a custom MATLAB script for analysis to determine motion of target regions. This MATLAB script functions by following the process outlined in figure 10.

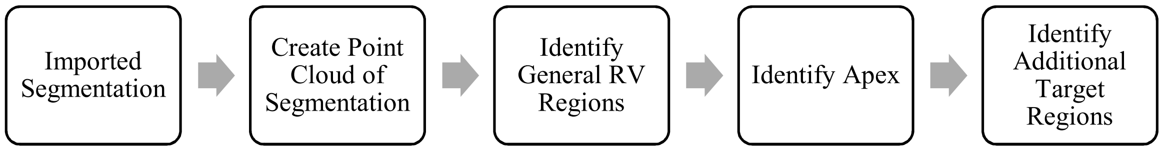


Figure 10. Right ventricle motion analysis workflow in custom MATLAB script.

Segmentations of the right ventricle at various points in time are imported by loading the segmentation NIFTI files saved by ITK-SNAP using a MATLAB Library [2]. These imported files are then converted to point clouds of *x,y,z* coordinates within MATLAB, and scaled by the scaling specified in the image file.

3.1.1. Identify General Right Ventricle Regions

After generating all necessary point clouds, general regions within the right ventricle (free wall, septal wall, front edge) as shown below are identified. Several user variables can be used to adjust how each region is defined.

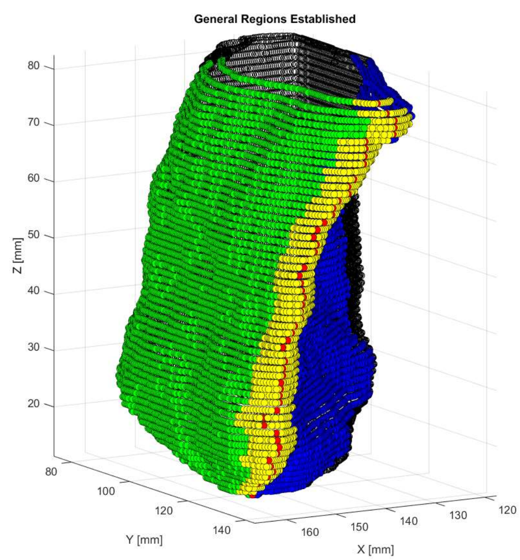


Figure 11. General region identification of right ventricle by MATLAB script. Green: Free Wall, Yellow/Red: Front Edge, Blue: Septal Wall, Black: N/A

3.1.2. Identify Apex & Additional Target Regions

First the apex location of the right ventricle is identified, this is done using the points in the point cloud identified as the front edge in the general region identification step. Next a target location on both the free and septal wall are identified, using the apex as a reference point.

Because there is no way to track a given location within the free or septal walls on their own, the location of the apex through time is used to guide the selected locations on these walls through time. Again, the user can adjust parameters of the selection.

While target locations are identified as a single point initially, noise in the source images and segmentation can cause any given point to shift substantially from one point in time to another. To resolve this, a sphere of a user defined radius is drawn around the anticipated target location point. All points in the point cloud within the target locations general region (i.e. a septal wall target and the septal wall general region) that fall within this sphere are identified and the average location of these points is treated as the location of that target point, for that instance in time. This collection of points is also used to draw a vector normal to them to determine orientation of this target location at the instance in time they are being analyzed.

This method allows for less noise in the resulting motion, along with better visualization of where motion is being determined. One drawback of this approach is that rotation about the axis normal to a given surface cannot be determined. However, without physical points to track along a surface of the right ventricle, it is unlikely that this motion could be determined, even with a different analyses method.

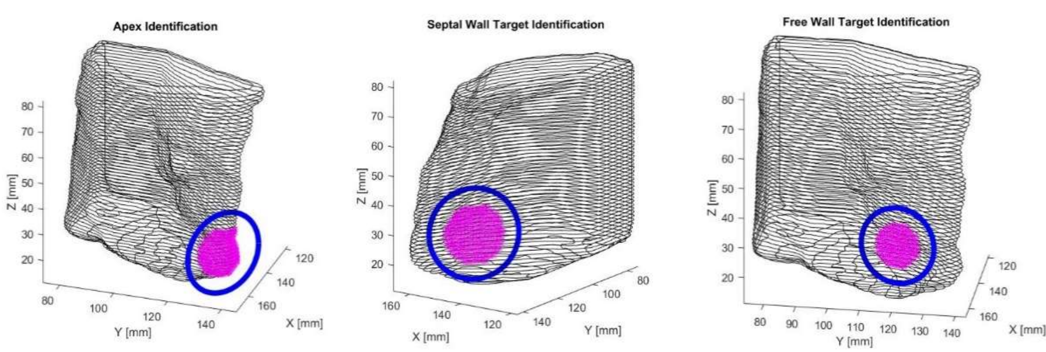


Figure 12. Example of identified target locations at one point in time. The shape constructed of black lines is the segmented right ventricle. The magenta portion represents the points selected within the target region, while the blue circle is on a plane normal to, and through the center of the magenta region.

3.2. Results

Ultimately, the output of this analysis position coordinates and a normal vector for each target location at each point in time. For this data to be useful, it is necessary to transform these quantities into a coordinate system that is meaningful to the application at hand. An example of output data is shown below.

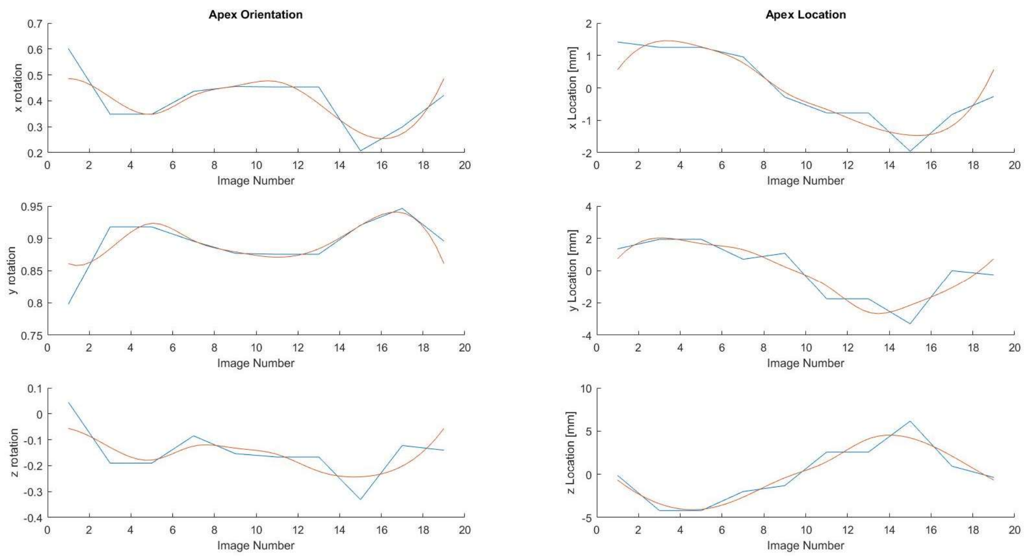


Figure 13. Example of output data from the motion analysis of the Apex for one set of right ventricle segmentations through time. Apex orientation is shown here as the components along each axis of a vector drawn normal to the apex target location. Motion is the translation of the apex target location. Keep in mind the axis have not been oriented in a meaningful way at this point. The blue line represents raw data, while the orange line has been interpolated.

References:

[1] http://www.itksnap.org/pmwiki/pmwiki.php

[2] Li, Xiangrui. "DICOM to NIFTI converter, NIFTI tool and viewer." *MathWorks*, 2018.01.19, 19 Jan. 2018.

[3] Ohnesorge, Bernd. "Clinical Examination Protocols with 4- to 64- Slice CT." Link.springer. N.p., n.d. Web.