Renal Artery Stent Fatigue Test

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Senior Project for Endologix

Final Senior Project Report

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Cal Poly Renal Stent Team

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Statement of Disclaimer

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PART I – Introduction to Project

1. Introduction

In today's world of medical innovation, regulations and requirements set by organizations such as the Food and Drug Administration (FDA), the International Organization for Standardization (ISO), and ASTM International (American Society for Testing and Materials) can inhibit rapid innovation by demanding rigorous testing of new designs. For arterial stents, the standard is that each design must be tested to simulate 10 years of life in an environment congruent to an *in vivo* environment.[1] Endologix in Irvine, California develops and manufactures minimally invasive treatments for aortic diseases, with a focus on stent grafts for the treatment of abdominal aortic aneurysms (AAA). Stents which are deployed in the renal arteries undergo continuous displacement due to respiratory, cardiac, and skeletal motion. This motion is unique and methods for simulating stents near the heart would be misapplied to renal artery stent fatigue testing. Our team was comprised of Mechanical and Biomedical Engineers from Cal Poly – San Luis Obispo, and the goal for our senior project team was to design a functioning fatigue test method for renal artery stents that would simulate the environment and displacement of the stents in the body. This document is a final project report that defines the design requirements, explains how we determined appropriate modeling of renal artery movement, describes our design process, and outlines the timeline for our entire project. The project concluded with a proof of concept fatigue test of Endologix renal artery stents at the highest frequency our team was able to achieve.

2. Background

To gain an overall understanding of the project and renal artery stents, we separated our research into four separate areas per the suggestion of our sponsor. Information on the disease that renal stents treat, the current treatments used, the anatomy and physiology of renal arteries, and industry standards relating to medical device testing is given below. Based on continued research since our proposal, our team has included sections on "Boundary Conditions of the Renal Arteries" and "The Proper Testing Environment", which help to narrow the scope of our project.

2.1 The Disease: Abdominal Aortic Aneurysms

The renal artery stents that our design will be testing are used in conjunction with treatments for abdominal aortic aneurysms (AAA) if the AAA becomes large enough to include the renal arteries. AAA occurs when an area of the aorta becomes very large, often dilating out from the main artery as seen in Figure 1[2]. The aorta is the main blood vessel which transports blood to the legs, pelvis, and abdomen. These abdominal aortic aneurysms are classified by location. They can occur below the kidneys (infrarenal), at the kidneys (pararenal), or above the kidneys (suprarenal).[3] Studies show that there are certain factors which can contribute to the development of abdominal aortic aneurysms, including smoking, high blood pressure, gender, genetic factors, and age. The most common

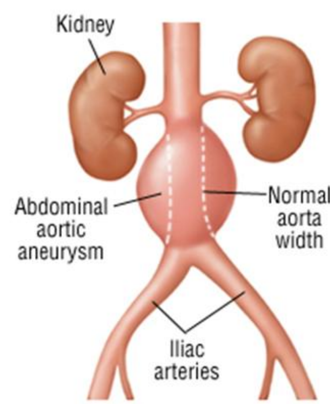

Figure 1: Aorta Anatomy

patient with an abdominal aortic aneurysm is a male over the age of 60 who also has one or more of the risk factors; however, abdominal aortic aneurysms have been found in patients of all ages, genders, and with varying risk factors.[4]

While a serious medical condition, patients with abdominal aortic aneurysms often have relatively little symptoms. Patients often exhibit pain in the abdomen or back, clammy skin, dizziness, nausea, or rapid heart rate.[5] As a result, diagnosing an abdominal aortic aneurysm can be difficult. In looking for an aneurysm, doctors may find a pulsating sensation in the abdomen caused by the irregular blood flow due to the aneurysm. In addition, they may notice a mass or rigidity in the abdomen. If none of these symptoms are apparent, an aneurysm may be found through an ultrasound of the abdomen with a CT scan to confirm the size of the aneurysm. The degree of pain experienced typically varies with the size of the aneurysm.[4]

The main concern with abdominal aortic aneurysms is the risk of rupture. A ruptured abdominal aortic aneurysm will cause heavy bleeding into the abdomen, will require immediate treatment, and can lead to death within minutes. In the case of a ruptured aneurysm, the mortality rate approaches 90 percent when occurring outside of a hospital.[6] As a result, aneurysms are often screened for during most physical examinations as a precaution. Approximately 15,000 deaths occur each year in the United States due to abdominal aortic aneurysms. The risk of a rupture occurring is also proportional to the diameter of the aneurysm. If the aneurysm is small (less than 4.0 cm in diameter), then the risk of rupture is less than 0.5 percent. However, if the aneurysm is large (greater than 8.0 cm in diameter), the risk is up to around 50 percent.[6] The size of the aneurysm has varying rates of expansion among patients. For most patients, an aneurysm will grow slowly over many years. However, in some instances, rapid expansion of aneurysms can occur (defined as 0.5 cm growth in 6 months), and the risk of rupture is significantly increased.[7]

2.2 The Treatment: Current Endovascular Aneurysm Repair

The treatment of endovascular aneurysms is largely based on the risk associated with each possible treatment method. Patients with a relatively small aneurysm (less than 4.0 cm) are less at risk and are typically advised to monitor the aneurysm over time, to see if the condition progresses. Patients with larger aneurysms may be advised to undergo repair procedures.[6]

The first step a doctor will take in advising a patient with an abdominal aortic aneurysm is to tell the patient to cease any behavior associated with increasing the risk for further aneurysm damage. This advice is typically to cease smoking and to monitor and control blood pressure to a reasonable level. In addition, doctors will often prescribe beta blockers to slow the growth rate of the abdominal aortic aneurysms.[7] If the aneurysm is considered to be non-critical, the patient will be monitored regularly in order to track the growth rate of the aneurysm. If the condition progresses surgical repair may be required.

The two primary surgical treatment methods for abdominal aortic aneurysms are through "open surgery" and through the use of an endovascular stent graft. Surgical repair is not advised for patients with abdominal aortic aneurysms that are smaller than 5.5 cm in diameter, are not rapidly expanding, or that do not cause symptoms. As with all surgical procedures, surgical repair of endovascular aneurysms carries certain risk factors. Surgical risk typically increases with the age of the patient, secondary conditions such as heart and lung diseases, and with patients that smoke. Coronary artery disease is also common in patients diagnosed with abdominal aortic aneurysms, and must be assessed prior to surgery. Complications that can arise as a result of surgical repair are irregular cardiac events and strokes, as well as many other conditions.

In open surgery, the patient is put under anesthesia and the dilated region of the abdominal aorta is removed and replaced with a synthetic prosthesis. This procedure allows blood to flow normally through the aorta without aneurysm pressure build-up. This surgery typically takes 4-6 hours and requires four or more weeks of recovery time. While this surgery is able to successfully remove abdominal aortic aneurysms, the risks associated with open surgery often disqualify patients suffering from the condition. Since treatment is required, and the invasiveness of open surgery disqualifies many patients, the minimally invasive endovascular stent graft procedure is commonly used.[7]

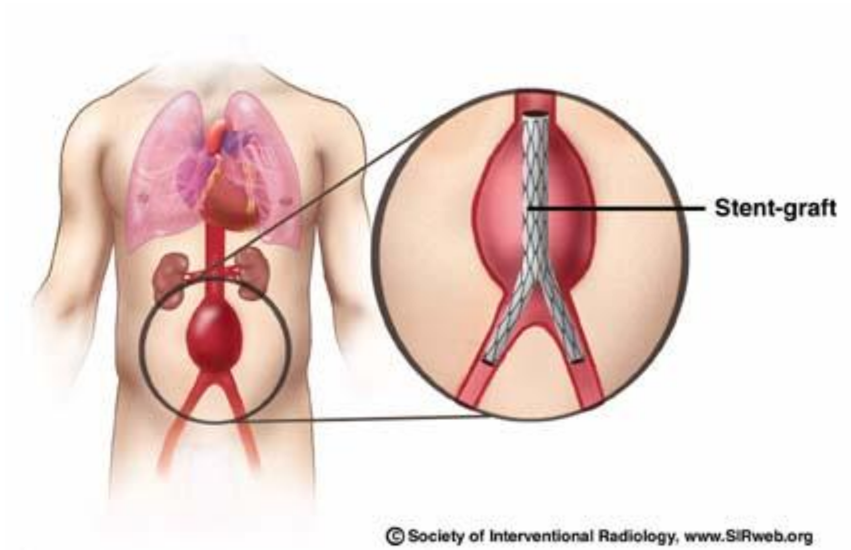

Figure 2: Aortic Stent Deployment

For endovascular stent grafts, specialized catheters are used to place a stent in the area of the aneurysm. Once the device is in the correct position, the stent graft is deployed and expanded with a balloon, pushing it against the aortic wall as seen in Figure 2[8]. While the stent is not sewn into place like in open surgery, the expansion of the stent keeps it in place. In addition, this method does not remove the abdominal aortic aneurysm, but instead directs the flow of blood through the stent graft. As a result, blood will flow through the artery correctly, and pressure to the aneurysm will be reduced.[9]

2.3 The Environment: Anatomy, Physiology, and Motion

The fatigue test method and proof of concept fixture we will be designing will be used for renal artery stents, which are deployed into the renal arteries through holes in the aortic stent for when the aneurysm has expanded to include the renal arteries. The renal arteries branch off the abdominal aorta to deliver blood to the kidneys, transporting approximately ¼ of the heart's blood flow, or ~1.2 liters a minute.[8] The blood is processed in the kidneys and sent back through the renal veins to the inferior vena cava and the right side of the heart. Figure 3 clearly shows the abdominal aorta and

Figure 3: Abdominal aorta and renal arteries (red) and inferior vena cava and renal veins (blue)[9]

renal arteries in red and the inferior vena cava and renal veins shown in blue. Renal arteries increase or decrease blood flow to adapt to mental stress and anxiety from the sympathetic nervous system, and receptors in the muscle wall of the arteries expand and contract to compensate for high or low blood pressure.[10]

While the exact size of renal arteries differs depending on factors in the body and what measurement method is used, a study by Aytac, Yigit, and colleagues in 2003 found mean renal artery diameters to be 5.04 ± 0.74 mm when taken with ultrasound and 5.68 ± 1.19 mm when taken with angiography. Interestingly, the same study found that main renal artery dimensions were smaller when accessory arteries were present, which occurs in 15% and 20% of cases for the right and left kidneys, respectively. In general, however, one renal artery branches off the abdominal aorta, then splits into anterior and posterior division, shown below.[7]

A study published in the *Journal of ASTM International* looked at the movement of the kidneys during respiration and the effects these movements may have on the renal arteries. They observed that the proximal (aortic) and distal (kidney) regions of the renal arteries showed significant deflection, while the middle of the arteries tended to be relatively immobile. They also observed that the left renal artery (LRA) experienced greater motion that the right renal artery (RRA), citing that a total of twelve LRA and six RRA stents have fractured due to metal fatigue. They suggest that the middle region of the LRA may be entangled with the renal veins, creating a fulcrum point that leads to greater bending in the LRA than in the right. They also note that the RRA is supported by the "massive" inferior vena cava, which is positioned to the right side of the abdominal aorta, and may account for the relative lesser motion of the RRA.[11]

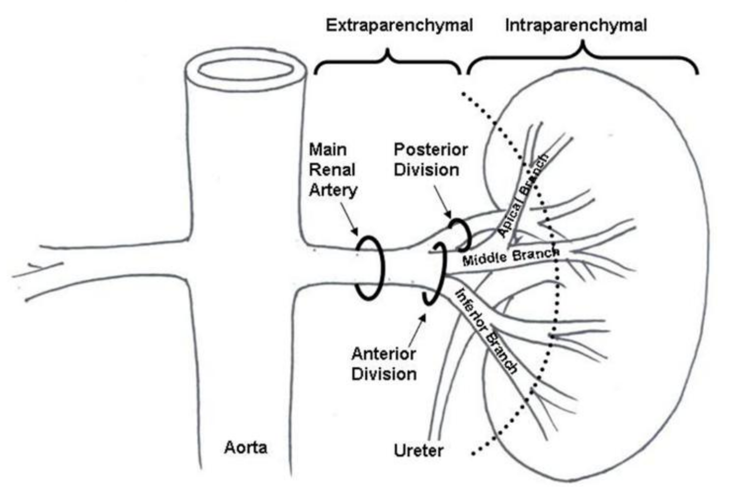

Figure 4: Anatomy of the kidney[8]

In an article published in *American Journal of Roentgenology,* 127 native renal arteries (72 left, 55 right) with more than 50% ostial atherosclerotic renal artery stenosis were measured in 108 male and female patients between the ages of 57 and 97.[12] Accessory renal arteries and those with stents already in place were excluded from the analysis. The results showed that the average lengths of the main renal arteries did not differ significantly for men and woman. The LRA were an average of 3.9 ± 1.3 cm long; the RRA a cm longer at 4.9 ± 1.6 cm.[12]

2.4 Boundary Conditions of the Renal Arteries

In order to properly mimic the renal arteries in testing, we need to know the end conditions of the renal arteries and the significant forces they experience within the body. To determine this, we looked at stent bending and fatigue resistance, effects stents have on renal artery movement, and maximum displacement of unstented renal arteries.

A study found in the *Journal of Medical Devices* quantitatively assessed the bending seen in renal arteries from respiration. An 18mm long cobalt-chromium stent was used in the study, the standard implant size for renal stenting, and respiration was modeled through manual manipulation of the kidneys. This study also removed rigid-body motion (translation and rotation) from the measurements, stating that "rigid-body motion does not contribute to the stent deformation and was therefore removed from analysis." After taking measurements with fluoroscopic images, they found that the change (amplitude) in bending angle between inspiration and expiration was ~1.7 degrees, a minor bending condition for an 18mm long stent, with a max bending angle of 6.5 degrees recorded.[13] They determined that the stent studied demonstrated excellent fatigue resistance under respiration-induced bending and conclude that the 18mm long renal stent studied is not at risk for bending fatigue failure during respiratory motion. They do note that the fluoroscopic images taken show the stented portion of the renal arteries as relatively straight (minor bending), while the renal branch angle was greater in the non-stented portion of the renal arteries. If longer renal stents were to be used clinically, more pronounced bending may occur since the stented portion of the renal artery would become long enough to be forced to conform to the curvature that the renal artery forms during respiration.[13]

In order to quantify the fatigue resistance of longer renal stents, the same team that conducted the study above did a follow-up study of fatigue resistance for both single and overlapped stents.[14] They again used manual displacement of the kidneys up to 40 mm and imaged two separate cadavers in multiple projections of simulated inspiration and expiration positions. They measured bending at both ends of the stent using fluoroscopic images, then performed FEA to assess the bending fatigue resistance of the tested stents. The Goodman Fatigue criteria showed excellent fatigue resistance for both single and overlapped stents, though the fatigue resistance was lower for overlapped stents.[14] The bending angles found were 2.2/3.9 (proximal/distal) degrees for the ends of single stents, resulting in a total bending angle of 1.7 degrees, while the bending angles for the overlapped stents were 3.3/10.3 degrees, which gives a total bending angle of 7.0 degrees. The increase bending angle for the overlapped stents is attributed mainly to the longer overall length and therefore larger curvature.[14] These findings are an important reference for our system, since it shows the variation that stent geometry has on bending and fatigue resistance.

As mentioned above, stents placed in the renal arteries will dampen the movement of the stented portion of the artery, so the stent will not bend as much as the unstented artery. A study done by the Departments of Vascular Surgery and Radiology of the University Medical Center in The Netherlands recorded the difference in renal artery movement before and after stent implantation in 29 specimens using CT scans.[15] They modeled respiration with 20-second breath holds and took measurements of artery movement at distances of 1.2 cm and 2.4 cm from the renal ostia. The study found that the implanted stent inhibited proximal physiological renal motion while the distal renal artery remained unaffected. The original movement at the point of proximal measurement (1.2cm) was 2.0±0.6 mm, while the post-EVAR movement was 1.4±0.7 mm. This represents a 31% decrease in maximal movement at the proximal point of measurement, while the distal point of measurement remained unaffected by stent implantation.[15]

After researching stent durability and stent effects on artery movement, we looked at overall kidney movement and movement of unstented arteries. Since our system must test stents within a mock vessel that is being displaced, we determined that it was more important to model the in vivo conditions of a renal artery than to find values on stent bending. This way, we could apply maximum values of displacement and therefore bending to any stent, regardless of size or material.

One very helpful resource was a Master's Thesis which states that of all the forces imparted onto the renal artery – including any twisting, bending, and axial motion – the most damaging force is derived from the continuously bending and translating distal artery.[16] Normal respiration causes the diaphragm to contract placing a downward force on the kidneys. The proximal end of the artery is relatively fixed, and when taken as a whole, the artery can be modeled as a cantilever beam. Over the course of several respiratory cycles, the displacement force resulting in renal artery translation and, consequently, stent bending, can be visualized as a wave (Figure 5).[16]

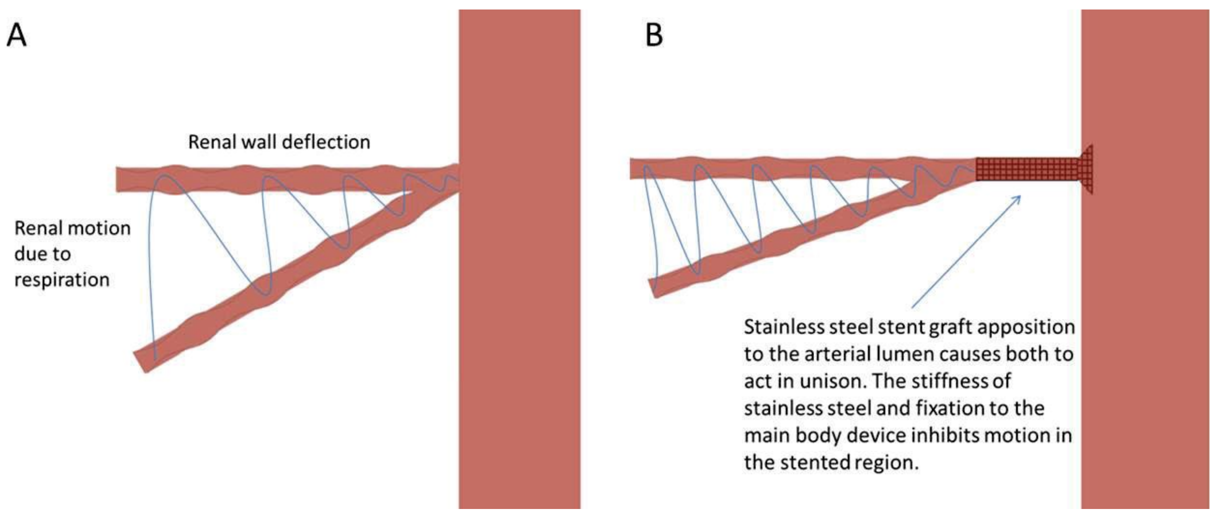

Figure 5: Renal motion due to the respiratory and cardiac cycles. Renal artery translation is affected differently A) de novo and B) post mating stent graft placement

Since the renal artery as a whole can be modeled as a cantilever beam, determining the maximum deflection of the distal end of the artery is an integral part of correctly simulating in vivo conditions a stent will experience. There are three main articles we found that quantify distal displacement, in addition to proximal displacement, and two more that only quantified proximal displacement.

In the first study, five males ages 43-71 were imaged with magnetic resonance angiography (MRA) during 20-second inspiration and expiration breath holds.[17] 3D models were reconstructed using the MRA images and displacements were then measured at the proximal ostia and first bifurcation points of the artery. The results showed that the first renal bifurcation point translated superiorly by 9.7±3.6 mm in the left renal artery (LRA) and 10.8±6.1 mm in the right renal artery (RRA). Superior translation of the ostia was 1.4±2.4 mm in the LRA and 1.5±0.9 mm in the RRA. Changes in branching angle, axial length, and renal ostia locations were not found to be significant.[17] This study showed significant deformation and translation of the arteries, and even though the maximum displacement is greater for the RRA, they found greater deformation of the LRA.

The second study imaged 16 males ages 66-80 also with MRA.[18] Images taken during inspiration and expiration breath-holds were used to reconstruct 3D models with centerline paths, which displacements of the renal ostia and first bifurcation points were then taken from. This study found that the first bifurcation point translated superiorly 14.5±8.8 mm in the LRA and 12.7±6.4 mm in the RRA, while the ostia translated superiorly 2.4±1.9 mm in the LRA and 2.9±1.8 mm in the RRA.[18] It concludes that the LRA and RRA translate superiorly from diaphragm motion and that the RRA deformed less than the LRA during respiration.[18]

A third study imaged 7 males ages 54-71 again with MRA, repeated 2-3 times each.[19] Images were taken during normal inspiration and expiration breath-holds and used to construct centerlines from the renal ostia to the first branch, and motion was tracked at the superior-most point of the kidney. It found that the left kidney translated superiorly 10.0±5.4 mm and the right kidney translated superiorly 13.2±7.0 mm, while the left ostium translated superiorly 1.6±1.3 mm and the right ostium translated superiorly 1.2±1.2 mm.[19]

Two additional studies quantified only ostia translation. The first study imaged five males ages 50-64 during inspiration and expiration breath-holds.[20] Centerlines were constructed through the arteries from the ostia to the first bifurcation point and used to analyze superior displacement of the renal ostia. It found maximum displacement to be 2.9±0.7 mm in the right renal ostium and 2.9±1.3 mm in the left renal ostium.[20] The second study calculated the full motion of the right renal ostium to be 2.3±0.6 mm and 2.1±0.5 mm for the left renal ostium.[21] The first study on distal displacement detailed above concludes that ostia displacements of 1.4±2.4 mm in the LRA and 1.5±0.9 mm in the RRA were not significant. Since the maximum value of ostia displacement found in our research is only 1.4 mm larger than these values, and are from a study with significantly larger bifurcation displacements than the first study, we determined that ostia displacements were negligible for modeling the clinical environment in our test system.

Since the LRA is where most stent fractures occur, our system should be modeled to the LRA specifications. In addition, since the translation values for renal ostia were found to be insignificant, we will use the values for superior translation of the first bifurcation point only. In order to test fatigue for the most conservative configuration, we will use the maximum value for LRA superior translation found in our research. All the studies found use an almost identical method for quantifying displacement; therefore, we will use the value from the test with the largest range of data, i.e. the study that imaged the most males, the second study of distal displacements mentioned above. This study found a maximum superior displacement of 14.5±8.8 mm for the first bifurcation point of the LRA. We will use 24 mm as the displacement of our test system to model the clinical environment of a renal stent.[18] This number was reached by taking the maximum limit of superior displacement, 14.5+8.8=23.3 mm, and rounding up to the nearest millimeter. In this way, we are guaranteed to capture the entire population of possible renal stent patients in our testing and ensure that the stents deployed in their arteries will not fatigue prematurely.

2.5 Standards and Regulations for Stents and Implantable Endovascular Devices

In order to make a practical stent fatigue test fixture, we must look at current stent fatigue testing methods and comply with all industry regulations for stents and implantable endovascular devices. These regulations include, but are not limited to, regulations set by the FDA, ISO, and ASTM. Following these requirements and other stent testing examples will ensure that our fixture complies with all appropriate standards and accurately simulates the environment associated with the renal artery region.

According to FDA standards, a stent should be tested to simulate ten years of average life in the body. Testing in real time for ten years is not practical in a rapidly developing medical device industry, meaning accelerated testing is permitted and encouraged. For accelerated testing of arterial devices, the FDA recommends that the following areas are addressed: sample size, sizes tested, test duration, loading and boundary conditions, overlapping stents, and deployment site. In the case of renal artery stents used to minimize the risk of abdominal aortic aneurysms bursting, sample size refers to the number of stents tested which should be determined based on fatigue analysis. In considering sizes tested, a larger variety of stent sizes that are capable of being tested is beneficial, so that designs may be flexible. The test duration is specified to be ten years, as mentioned earlier. Loading and boundary conditions should model the conditions that the stent will experience in the body, as discussed in the previous section. The last two areas, overlapping stents and deployment sites, are needed to address the possibility of extended wear based on overlapping stents and placement in the body. Many of these overlapping stents are used in suprarenal stent placement, so that the renal arteries themselves are not blocked.

In addition to the FDA standards, we also explored current stent testing methods. One article from the *Journal of Mechanical Behavior of Biomedical Materials* titled "Fatigue and durability of Nitinol stents" describes fatigue testing of Nitinol stents. In this article, they focused their testing efforts on stent over-sizing and cardiac related motion. The researchers tested four "strut V stent subcomponents" in a custom built fixture to test for axial displacement. The test was done at a frequency of 50 Hz, a temperature of 37 degrees Celsius (maintained by a Type T thermocouple), and checked by a laser micrometer to ensure no out of plane motion. This test was run for 10 million cycles (or until fracture).[22]

Another article entitled "Fatigue Testing of Diamond-Shaped Specimens" also describes fatigue testing of stents. This article describes displacement-controlled fatigue testing stating that data was collected from ±4% mean strain and 0.07% to 3% oscillating strain. The conclusion that is drawn from this study was that oscillating strain has the largest effect on durability of Nitinol stents. This conclusion is an important observation to be considered in every aspect of our design going forward.[23]

2.6 The Proper Testing Environment

In order to properly fatigue test renal artery stents with our system, they must be tested in an in vitro environment for a 10-year life (380 M cycles), per ISO Standard 25539-1, which was published in 2003.[24] This standard from the International Organization for Standardization details the regulations required to evaluate the long-term dimensional and structural integrity of cardiovascular implants. It outlines the requirements for conducting bench tests to evaluate fatigue and durability of implantable endovascular devices and specifies that the number of samples, implant sizes, and frequency of test shall be justified, with the frequency set so that the deformation of an implant under test is no less than the deformation of the implant in its clinical environment. The test must also be conducted using physiological temperatures, 37±2 degrees C.[19]

The first amendment for ISO Standard 25539-1 was published in 2005 and includes specifications for mock arteries the stents are placed into, as well as regulations for monitoring the fatigue testing system. The relevant geometries, diameters, and properties of the mock artery must be appropriate to simulate worst-case forces and diametral displacements expected on the device at the intended site of implantation.[25] Operating pressures must be considered when specifying the mock artery's diameter. Compliance of the native artery should be considered when designing the mock artery, and compliance of the mock artery should be defined and measured per the method outlined in ISO Standard 7198, which will be summarized below.[20]

ISO 25539-1 also specifies that the fatigue test system equipment should have provisions for measuring deflection, maintaining temperature, and counting cycles.[20] Deployment must be comparable to in vivo deployment conditions, with the implant being placed in a region where the test displacement is valid. In addition, no end effects may be imposed by the test system.[20]

ISO 7198 provides requirements for mock arteries and the test methods by which to evaluate them.[26] For a uniform straight mock artery, which is what we require for the renal arteries, the size of the mock artery shall be designated by the nominal relaxed internal diameter, nominal pressurized internal diameter, and minimum useable length. The intended clinical use is designated as renal arterial. Compliance of the mock artery is defined as the ability to expand and contract in the circumferential direction in response to a pulsatile direction. Per ISO 7198, the compliance of the mock artery will be measured by measuring the change in diameter under dynamic cyclic simulated vessel loading. The test conditions should approximate for an *in vivo* clinical environment, and the testing apparatus and procedure to measure the compliance can be found within section 8.10 of this same standard.[21]

3. Objectives

The main objective for this senior project was to design a proof of concept device or fixture that accurately models the clinical environment experienced by renal artery stents in the body. The proposed device should be able to test 4-5 samples at a time, with cycles no less than 25 Hz in a clinically relevant environment. Since we were not able to test our proof of concept for the full 380M cycles required in industry, we aimed to test it to a minimum of 10.8M cycles. This value was decreased from 45M cycles after PDR due to the scope of our project and the safety of testing our system continuously for three weeks. In order to accurately and safely monitor our system we planned to only run testing for 8 hours a day, 5 days a week, for three weeks at a minimum frequency of 25 Hz for displacement oscillation, or 1500 RPM on the motor shaft.

3.1 Requirements

In order to ensure that we would design a test device and method that met the needs and requirements of our sponsor, Endologix, we created a Quality Function Deployment (QFD) chart, also known as the "House of Quality." This tool allowed us to relate our customer's requirements to our engineering specifications, as well as compare our specifications to existing competitors. In this way, we ensured that we included specifications to meet each need of our customers, and we analyzed which of our specifications would be most important to our design by looking at which correlated highest to our customer's requirements and to our other specifications. This QFD chart may be referenced in Appendix A.

The first step of the QFD process was to apply weighted ratings to the requirements of the customer. This allowed us to compare the importance of each in the design phase and gave a benchmark with which to compare the competing products against. We decided to rate each requirement 1-4, a 1 meaning of lowest importance and 4 meaning highest importance. These ratings were given after discussion amongst the team, with emphasis on the relevant research and information from meetings with our sponsor. These ratings are shown in the QFD.

The first customer requirement was that the device should be able to test multiple samples at a time. This requirement was one of the first given to us by our sponsor and was desired in this fatigue testing application, but would not have been detrimental to the proof of concept design if it wasn't achieved, so it was given an importance rating of 3. The next requirement was that the device and test method should be able to test multiple cycles quickly. The competing device, a Bose Electroforce Multiaxial Peripheral Test Instrument, is able to test cycles up to 100 Hz; however, in talks with our sponsor, it was determined that 25 Hz was an acceptable test speed for our device, so we determined that this was of lower importance and rated it a 2.

The next customer need was that it be attachable to the current Bose Electroforce Model 3330 Series II Test Instrument that Endologix currently has for fatigue testing. This was a suggestion given to us by our sponsor, and was not something that was required of our design, so we rated it a 1. If possible for our team, designing a standalone system would have also been accepted by our sponsor. However, building a standalone system went far outside the scope of our senior project class and our technical knowledge, so we ultimately decided to make our design attachable. The last two requirements in our QFD were that our device and test method should both meet the standards of the health industry and accurately test the anatomical environment that a renal stent experiences in the body. These two requirements were both rated a 4, since they are integral to our design. If our proof of concept had missed the mark on either of those, it would have been useless to our sponsor.

Before determining our engineering specifications, we compared our current competition to the needs of our customers, in order to see where our customer needs were not being met in the current market and get an idea of improvements to focus on when brainstorming ideas for our new device.

Our customer requirements were compared to the engineering specifications we determined necessary to make sure that each requirement had a corresponding specification. The first specification quantified was "number of samples per test." Per the request of our sponsor, we specified that our device must be able to test 4-5 samples per test. The next was the number of cycles our device had to be tested for to prove its reliability, as well as the amount of time needed to accomplish this testing. Per the request of our sponsor, we specified this as 45M cycles in 3 weeks.

We included in our engineering specifications that our device will test renal stents for failure modes accurately reflecting the clinical environment that renal artery stents are placed into, which may include any combination of bending, axial, and torsional loading. Through our research, we determined that the failure mode induced by bending is the critical failure mode our test system needs to simulate in order to accurately reflect the clinical environment that renal stents are placed into. All damage from torsion and compression or tension is insignificant when compared to the fatigue damage incurred from the continuous bending of the stents.[16] Based on the literature cited above, any fatigue test designed should have the mock vessel fixed at one end and free at the other end to simulate a cantilever beam. In addition, stents should be placed in the fixed end, which will represent a stent placed in the proximal end of the renal artery.

Per the research above, the mock vessels were displaced 24 mm at the distal end, which simulated the maximum recorded values for artery movement.[18] Since the displacement at the distal end was not shown to change with stent implantation we safely translated those results to our testing method.

The final three engineering specifications we had for our device were weight, temperature of testing medium, and cost of the complete system. We determined that the weight of our device or fixture should be less than 30±5 lbs. This will allow the device to be lifted and portable, since it is a fixture to be placed into the current Bose machine on site. The temperature of the testing medium was set at 37±2°C, the normal temperature of the body. Lastly, the budget of our project was $3000.

The final step in the QFD process was to compare the customer requirements with the engineering specifications, to make sure that each requirement had a corresponding specification and to evaluate which specifications were of most importance. From our QFD, we found that the specifications correlated with the requirements of "meets health industry standards" and "tests anatomical environment" were of highest importance and were greatly focused on in our design ideation.

3.2 Additional Design Considerations

In addition to our formal engineering specifications outlined above, we listed several design considerations that were included in our design but didn't necessarily have a quantifiable specification attached to them. They were no less important and were taken into account for our final design. These design considerations were as follows:

The device/fixture must work in Endologix's test bed. An attachable device was determined to be the best design per our specifications, so it was designed to attach to the current Bose fatigue test instrument. It required contact points that meshed securely with the testing platform of the Bose, and fits within the confines of the Bose testing space.

The test must be supported by a detailed test protocol. Final deliverables for this project included a detailed test method per industry standards that will be replicated by the test engineers using our new device. It was written to be clear and concise.

The device must be easily serviceable. Our device is serviceable by maximum of one technician, with easy access to all electronics, pneumatics, sensors, and other equipment needing calibration. It also uses only standard hardware and parts, both in metric and US units.

The stents must be in contact with the saline solution. The Bose test bath is filled with a saline solution and held at a constant temperature. The stents remain in contact with the solution in order to function properly and behave comparable to the *in vivo* environment.

The deflection must be measureable. The mock artery and stent were situated so that data acquisition of displacement was possible.

In addition to the QFD, our team also created a Formal Engineering Requirements table below (Table 1) that equated each engineering specification with a requirement, tolerance, risk, and compliance. Requirement and tolerance quantified each specification with a minimum or maximum value. Risk refers to the difficulty of meeting each requirement and was rated as either high (H), medium (M), or low (L). Compliance refers to how each requirement was verified, by testing (T), inspection (I), analysis (A), or by similarity to existing designs (S).

Table 1 - Renal Stent Fatigue Testing Device Formal Engineering Requirements

Spec. #	Parameter	Target	Tolerance	Risk	Compliance
1	# of Samples per Test	4-5 specimens	Min	L	I
2	# of Cycles	10.8Mcycles	Min	H	T
3	Volume of Device	305 x 279 x 159 mm	Max	M	I
4	Duration of Testing	3 weeks	Min	H	T

5	Fatigue Loading	Distal end of mock artery displaced 24 mm	Max	H	A
6	Device Weight	30±5 lbs	Limit	M	I
7	Testing Temperature	37±2 degrees C	Limit	L	I, T
8	Cost of Device	$3000	Limit	L	A

Through this we found that our highest-risk targets were the number of cycles to test, duration of testing, and fatigue loading required. Those were the main focus of our project and gave us the most difficulty at the completion of our project. The Bose Electroforce Multiaxial Peripheral Stent Test Instrument successfully accomplishes all of these targets; however, it is a very expensive free-standing device that would have had to be configured to the specifications of renal artery stents. Our goal was to design a fixture that would be used in the current fatigue testing equipment available to Endologix engineers, for a fraction of the overall cost.

PART II – Preliminary Design

4. Design Development

In order to find a solution to our problem, our group held several ideation sessions. As a group, we decided that looking at the project as a whole for brainstorming was not plausible. Instead, we split the problem into four different sections. These sections were holding the stent, bending, torsion, and axial. Holding the stent refers to fixing the mock artery on one end and leaving the other end free allowing for cantilever beam motion. Bending, torsion, and axial all refer to ways to create each respective motion. Torsion and axial motion were initially included because ideation was completed before our research was finalized. We used several brainstorming techniques throughout the process including brainwriting, writing on a whiteboard, writing ideas on post it notes and sticking them on the wall, and even walking backwards while thinking about the project to try and generate the most innovative and effective solution to our problem.

To begin brainstorming in each category, we used a whiteboard and sticky notes. Writing the ideas down on a board allowed us to all share our ideas in a very visual manner. Many ideas were sparked because of other ideas that were previously said. This method allowed us to create a large quantity of solutions very quickly. Many of these ideas led to our top concepts.

Brainwriting was another one of the techniques we used when generating ideas for bending. For this technique, we sat in a circle with each team member given a piece of paper. We then drew or wrote ideas we had for bending methods. After one minute of writing on the paper, we stopped and everyone passed their paper to their right. This process was repeated until the paper was back to the original person. Using this technique allowed us to build upon drawings and ideas from other members of our group each time the paper was passed. This session directly resulted in several of our top concepts for bending, including the "Renalever Beam" described in more detail in the next section, and the "Handshake", which is included in a complete list of our concept ideas in Appendix B.

After each of these brainstorming sessions, we did not immediately reflect on our ideas. Instead, we waited until we were done with all ideation and then looked back at the ideas to bring them together and generate our overall concepts. These top concepts for both bending methods and holding the stents are described in the section below.

4.1 Top Concepts

After multiple brainstorming sessions and the completion of our ideation phase, we moved on to evaluating our possible designs against each other and the customer needs and engineering specifications we had previously outlined. The concepts we found to be the best are described in further detail below.

4.1.1 Overall Design

The Renalever Beam shown in Figure 6 was the simplest of our top concepts. The axial displacement of Endologix's Bose machine would be translated to cantilever bending of a mock artery, which the stent would be deployed into, and would simulate the bending of the renal arteries during respiration. The stent and mock artery are labeled "stents in comp. mat'l" (compliant material) in the front view of Figure 6. For this concept, we would have designed a base that could hold multiple stents in a configuration that would allow them to experience the same deflection of the Bose machine at the same time, as well as a fixture that attached to the displacement shaft of the Bose machine to translate axial motion to each mock artery. Since the Bose machine would be applying force onto the mock artery in one direction, one cycle of the Bose machine would correspond to one cycle of fatigue on the stents.

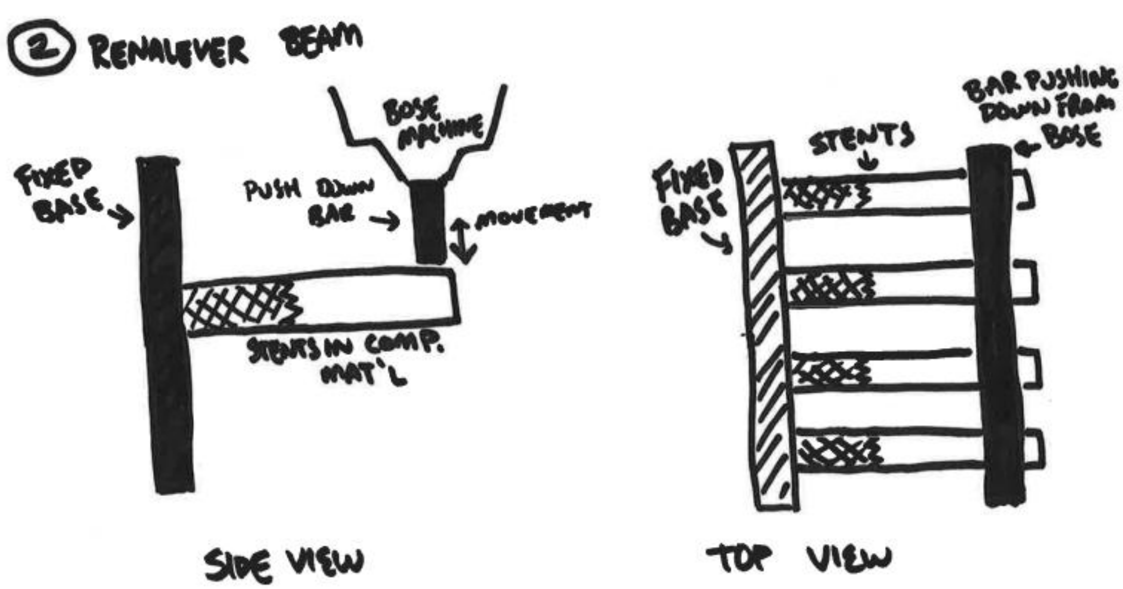

Figure 6: Top Concept, Renalever Beam

The Magnets! idea shown in Figure 7 below was a concept that strayed from one of the core themes of our project, in that it would not have attached to the Bose machine. However, upon looking into the concept more, we found it to be both innovative and a potentially simpler way of fatigue testing the stents. Electromagnets are magnets which have their magnetic field's strength and polarity controlled by a voltage input. By inputting a greater voltage, the strength of the magnetic field would increase, and by reversing the direction of the current, the polarity of the magnet would change. Since current is a flow of electrons, the magnitude and polarity could be rapidly changed to induce movement in whatever magnetic surface the user wanted to propel. This technology is becoming more and more popular in many applications including magnetic levitation trains, hard drives, and MRI machines.

Electromagnets are the primary driving force of many fatigue test machines, including the machine we were designing a fixture for, the Bose ElectroForce 3330 Series II test machine.[27] Our concept would have operated in a similar way, except instead of driving a shaft that would apply the force, we would have had a metallic attachment on the end of the mock vessels which would then oscillate between two electromagnetic rails which would be changing polarity at whichever frequency we put into a driving function generator. In this way, we would have effectively simulated the cantilever motion of the mock vessels at high frequency in a consistent and electronically controlled manner. Ultimately, we found this idea to be successful in its capability to operate at high frequencies with electronically controlled precision, but that the concept of having it standalone and not attach to the existing Bose machine was outside the scope of this project.

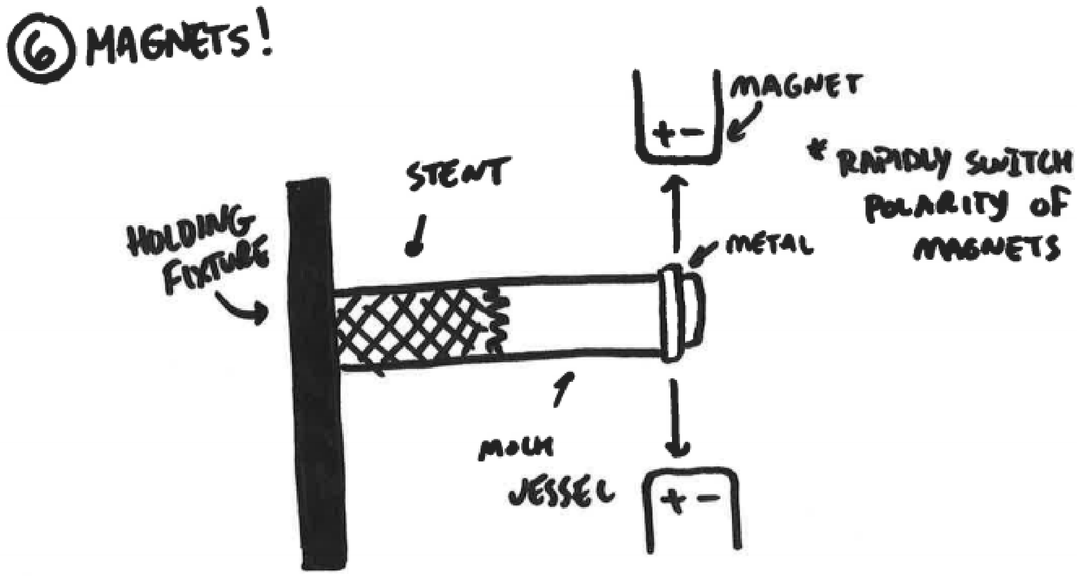

Figure 7: Top Concept, Magnets!

Hole and Sound, seen in Figure 8, was very similar to Renalever Beam but different in one key area: the free end would be in a fixture that directly attached it to the Bose machine. This was significant in that it would effectively double the number of cycles that our testing system could run. Instead of only being bent downward, as in Renalever Beam, the arteries in Hole and Sound would be displaced in both the upward and downward directions. Additionally, the stents were aligned vertically with respect to each other instead of horizontally, but that aspect was not critical to the design. Either way would allow us to easily measure the deflection of each stent.

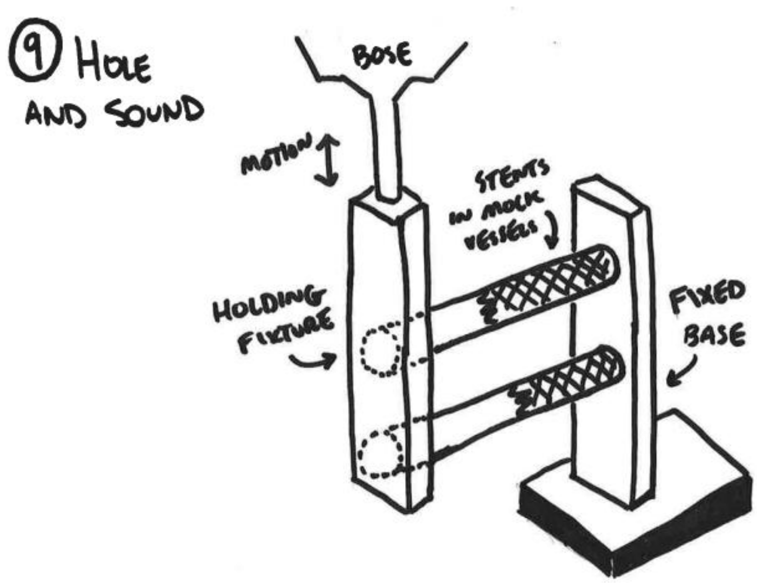

Figure 8: Top Concept, Hole and Sound

Building off of Hole and Sound, our team came up with an iteration that took this same idea, but mirrored it on either side of the holding fixture (Figure 9). This method allowed more stents to be tested at a time, which was something our sponsor requested from us. Apart from that, this "Ideal Design" of Hole and Sound acted in the same fashion as its predecessor.

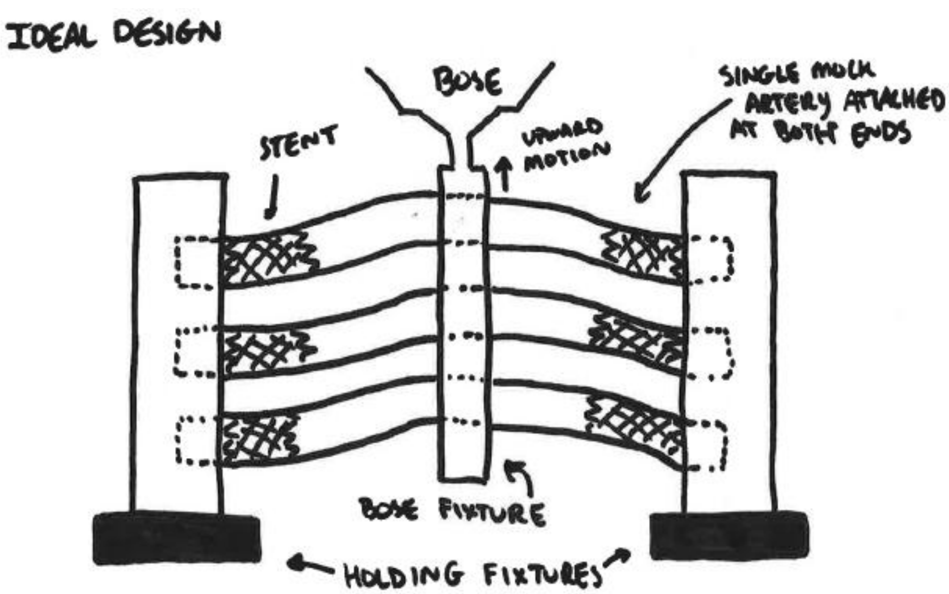

Figure 9: Ideal Design for Hole and Sound

4.1.2 Component Design

The main subcomponent of our design was the holding mechanism we used to fix the mock artery and stent in place. During our ideation, we brainstormed multiple fixing methods to use in our overall design. The top ideas from these brainstorming sessions are detailed below. For a complete list of holding ideas, see Appendix C.

The Clamps idea shown in Figure 10 was the first of our top concepts for the holding mechanism of our design. The clamp would apply pressure to the mock artery to hold it in place, while exerting no extra force on the stent itself. Each mock artery would be clamped individually, so the set-up time required would have been slower than one that fixed them all at once. This design was the simplest and most straightforward idea.

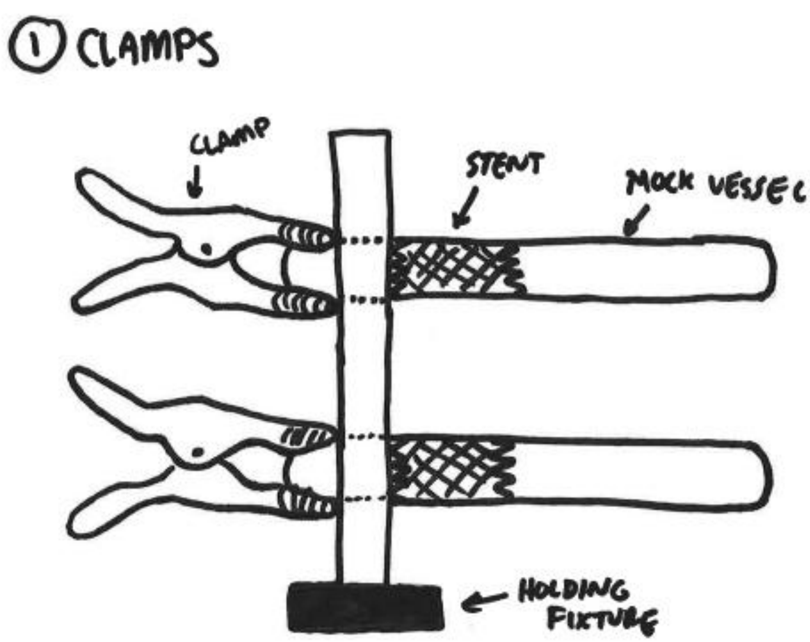

Figure 10: Top Subcomponent Idea, Clamps

The Slotted Pin idea shown in Figure 11 was a more complicated holding mechanism. In this design, the mock artery would need to be fabricated with a hole in it and would then be held in place with a pin. This would again only affect the mock artery individually, and apply no extra force to the stent itself. The biggest drawback to this idea was that the mock artery would need to have a hole punched through it before being placed into the fixture. This would have introduced unnecessary stress concentration in the vessel. This extra step would have also made the set up time much longer than our other ideas. One advantage of this design was that the artery would have been open on the fixed side allowing for the potential of simulating blood flow through the mock artery during the test.

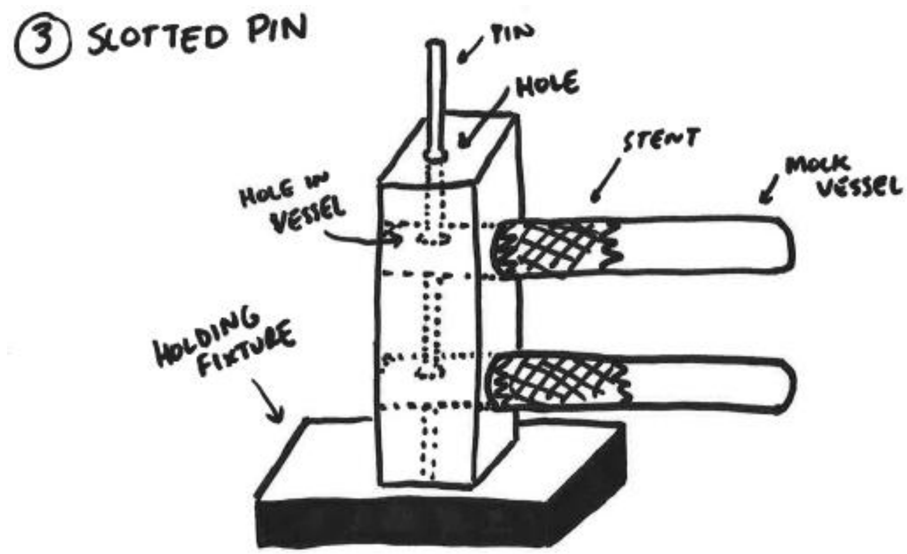

Figure 11: Top Subcomponent Idea, Slotted Pin

The Tie Down idea shown in Figure 12 would utilize a holding mechanism similar to a ring clamp or zip tie. It would require each mock artery to be fixed separately into position as well as a shaft or some other base for the mock artery to be "tied" down to. While the actual holding process would have been a bit more tedious with this design, it would have made up for it because of the capability to hold different artery diameters.

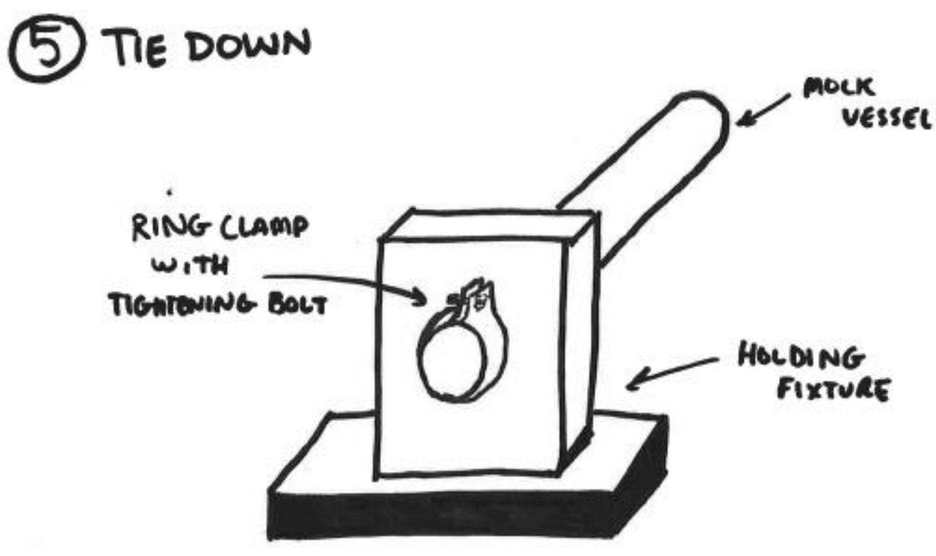

Figure 12: Top Subcomponent Idea, Tie Down

5. Preliminary Design Pugh Matrix

In order to determine an overall top concept for our device, we set up a Pugh Matrix with each of our ideas from the ideation phase of our project. For the Pugh matrix, we modified our list of design requirements into criteria that could be easily rated, instead of the go-no go constraints we have outlined in our objectives section.

5.1 Bending Methods

The criteria we decided to use for our Pugh Matrices were Ease of Loading, Manufacturability, Complexity of Design, Ability to Identify Deflection, Adjustability, and Speed of System. Ease of Loading specifies the difficulty of loading a mock artery and stent into the device. Manufacturability is how difficult it would be to manufacture the device, keeping in mind size, material, number of components, and available hardware. Complexity of Design refers also to the number of components, the manufacturability of those components, and how much analysis the detailed design would require. Ability to Identify Deflection relates to the ease with which we could monitor the stent deflection. If our design was so complex that we did not have access to the mock artery, then we would fail to meet our requirements, since that was an integral part of monitoring our fatigue test. Equally important to our design was Adjustability. One of our customer needs was the ability to test various sized stents, including diameters from 4-12 mm and lengths from 18-36 mm. This required our design to have adjustability in both the holding method for the mock artery and the overall deflection of the mock artery, in order to adjust bending based on the length of the stent being tested. The final criteria was Speed of Device. Our task was to test the renal stents at the fastest frequency possible, so speed was a very important aspect to our final design.

Table 2 - Pugh Matrix of Overall Bending Ideas

	Testing Concepts								
Criteria	The Blossom	Renalever Beam (Datum)	The Octopus	The Handshake	Stressed Out	Magnets!	Bent Plate	Buckle Up	Hole and Sound
Ease of Loading	0	0	-	-	0	0	-	-	-
Maufacturability	-	0	-	-	-	0	-	0	0
Complexity of Design	-	0	-	0	-	-	0	-	0
Ability to Identify Deflection	-	0	-	0	-	0	+	0	0
Adjustability	0	0	0	0	0	0	-	-	0
Speed	0	0	0	+	0	+	0	0	+
Total	-3	0	-4	-1	-3	0	-2	-3	0

The overall top concept that came out of our Pugh Matrix evaluation was the Hole and Sound. This design scored equal to our datum, the Renalever Beam - chosen as our datum because it was deemed the simplest of all our design ideas - in all categories except Ease of Loading and Speed of Device. Both Hole and Sound and Magnets! scored a zero for total score; however, we determined that since the Magnets! idea had a negative score in the Complexity category of the Pugh Matrix, the Hole and Sound was a better concept to move forward with. This idea was rated a negative for Ease of loading and a plus for Speed of Device when compared to the datum. Since the speed of our device was so important to the final success of this senior project, we determined that the extra difficulty of loading the stents would be worth it to obtain the benefit of speed.

The Hole and Sound would achieve this greater speed by having two cycles of fatigue loading per cycle of displacement of the Bose machine. Since the mock artery would be placed through a hole in a linkage that followed the displacement of the Bose machine, each stent would be deflected in the positive and negative axial directions per cycle of the Bose machine. In addition, the Hole and Sound was rated a negative in the Ease of Loading category because the ideal design would utilize one long mock artery through the hole in the displacement shaft to deflect two stents at the same time, fixed to each end of the mock artery (refer back to Figure 9 above). The mock artery would be displaced in the middle, which would bend each stent equally. This multi-loading of the stents in the mock artery would increase the complexity of deploying the stents into the mock arteries, but in return would give us both increased frequency of testing and the ability to test a larger number of samples at a time. These attributes were what distinguished the Hole and Sound as our best design, and the design we moved forward with in our Critical Design Review.

5.2 Subcomponents

We created an additional Pugh Matrix to evaluate our holding mechanism ideas against each other and the criteria we detailed above. Since the Clamps idea was the simplest and most straightforward, and because there was no standard way to fix a mock artery during fatigue testing, we chose this design as our datum.

Table 3 - Pugh Matrix of Subcomponent Ideas for Holding

	Holding Concepts					
Criteria	Clamps (Datum)	Chuck	Slotted Pin	Hooks	Tie-down	Squeeze
Ease of Loading	0	-	0	-	0	+
Maufacturability/ Purchasability	0	-	+	+	+	-
Complexity of Design (Simpler	0	-	+	0	0	-
Effectiveness of	0	+	-	-	-	0
Adjustability	0	+	-	0	+	0
Water Proof	0	-	0	0	+	0
Total	0	-2	0	-1	2	-1

From this Pugh matrix, the Tie Down idea was rated our number one idea. These would be simple to use, simple to attach, and allow for a large amount of adjustability. They would be secured to the outside of the mock artery and would not apply any external or additional forces to the deployed stents.

Upon further inspection and collaboration with our adviser and sponsor, we came to realize that this idea would also not be feasible. We never considered that the arteries are not very rigid and would therefore collapse inward if there wasn't an inner ring to hold against the ring clamp. Our team decided to continue brainstorming the holding component of our design, and we came up with a much more practical approach to the issue. In order to test the samples in water while keeping the fixture dry (for data acquisition purposes) we would need a way to make the ends as watertight as possible. After speaking with Endologix we learned that we would be able to have the mock arteries manufactured with a flange on the ends (Figure 13). This would act as a gasket and would be held down by another block that had a gasket on its end (Figure 14).

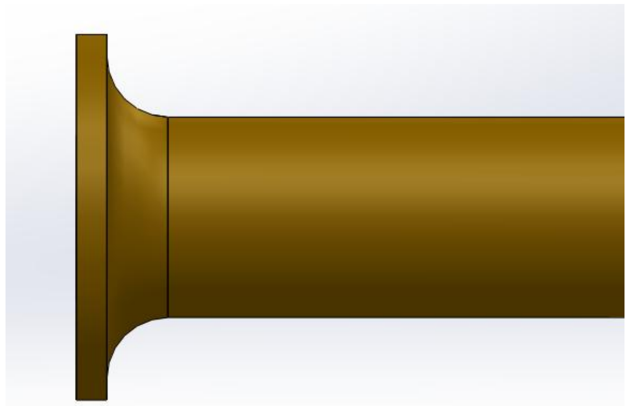

Figure 13: Mock Artery with a flanged end

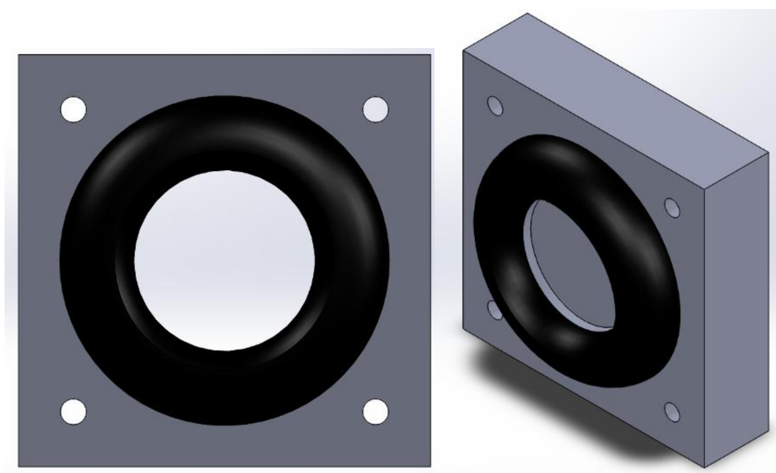

Figure 14: Gasket for sealing tank

6. Technical Content

6.1 Analysis and Modeling

To better visualize our chosen concept, Hole and Sound, we created a Solidworks model as well as a wooden model of our design. The wooden model was built as a mockup to help us visualize the fixture idea and how it would be oriented in 3D space (Figure 15). The mock vessels (straws) would be held on either side with the Bose machine displacing the arteries axially. This setup would allow two stents to be fatigued at a time for each mock vessel.

Figure 15: Wood Model

The CAD model seen in Figure 16 shows our proposed testing mechanism with four mock arteries held by two separate fixtures. The bar in the middle would attach to the axial displacement component of the Bose machine, while the rectangular bar laid across the bottom would attach to three separate fixtures; the axial displacement bar and two holding fixtures for the arteries. On the outsides of the boxes aluminum rectangles with small circular indents would be placed within. These indents would be where the flanged component of the artery would lay into. This would be further covered by another block that had another gasket on the end. This would prevent as much leaking as possible. Because this tank would be placed inside the testing tank in the Bose machine, we decided to call this final design "Tankception" (see the *Testing Considerations* section below).

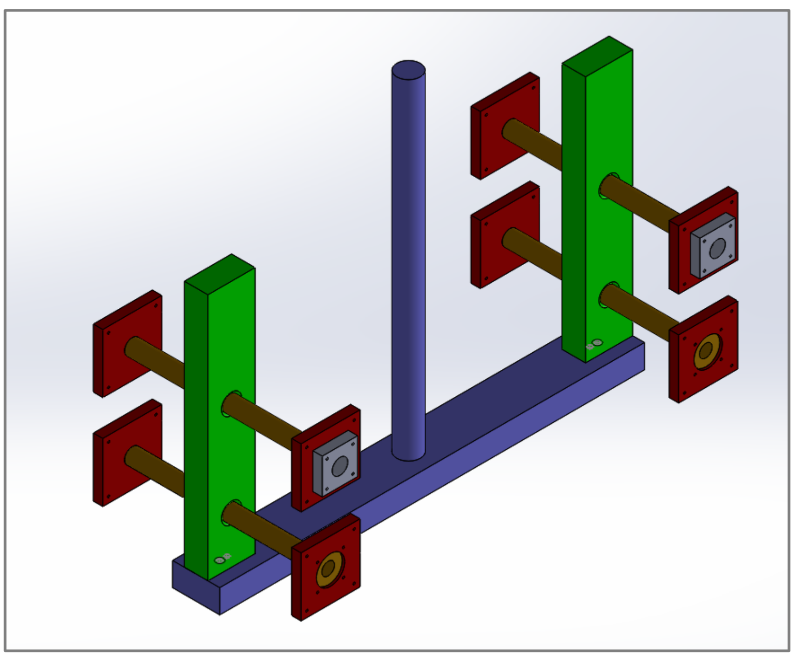

Figure 16: Tankception

Our research suggested that modeling the renal artery as a cantilever beam would be the most accurate method of fatiguing the stents. We believed Tankception to be an equivalent option. We ran preliminary static analysis on the different modeling methods, which can be seen in Appendix D. The results showed that a renal stent in a cantilever beam would bend less than one placed in a double fixed end setup.

Between our prototypes, CAD models, and calculations, we believed that Tankception would accurately model and fatigue a renal stent as if it were in the body. It would keep the fixtures in the middle dry so that we could accurately measure deflections, be held securely on either end but still allow for water to reach the stents, could test up to 8 stents at a time, and could be fitted into the Bose system already in place at Endologix. In addition, our design could be scaled up to test many more stents if Endologix decided to implement our idea (Figure 17).

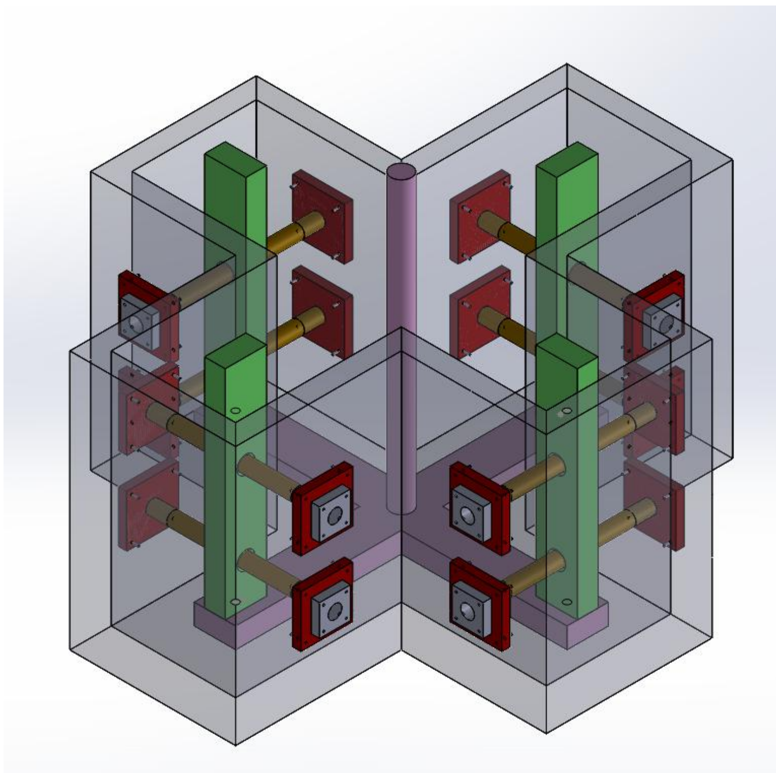

Figure 17: Scalability of our proposed system

6.2 Testing Considerations

In order for our project to be fully successful, we needed to complete at least 10.8M cycles of fatigue testing on our fixture or system. To accomplish this large number of cycles, we planned to test our design for a minimum of three weeks at a frequency of 25 Hz. With such high frequencies and continued testing came many safety concerns we had to address, as well as design considerations for the testing apparatus itself. We determined that electrical power would give us the highest testing frequency possible with the most accuracy and reliability when compared to pneumatic or hydraulic power; therefore, we decided to use an electric motor as the driving force for our testing apparatus. We planned to use a linkage system to translate this rotary motion into axial motion (to simulate the motion of the Bose machine). The final design for that system is given in the following section.

Our device was also required to operate in a saline bath at 37±2 degrees C, so we needed to purchase a saline bath of our own that was equal in size to the Bose machine's saline bath and maintain it at a constant temperature. In order to make sure the apparatus was not tampered with, or that it wouldn't harm anyone should it fail, we planned to use a safety cage made out of t-slot aluminum and Plexiglas. The cage would be locked shut so that individuals using the lab would not have access to it but would be ventilated for air flow to the electric motor and have space for electrical wiring to run through and be accessible in case of any needed emergency shut-off. To monitor the device we planned to have a slow motion camera set up to measure the displacements.

When testing on Cal Poly's campus, we planned to set up two tanks of water on either side of our testing device so that the saline solution could pass through the arteries but keep the fixture dry for deflection measurement purposes (Figure 18).

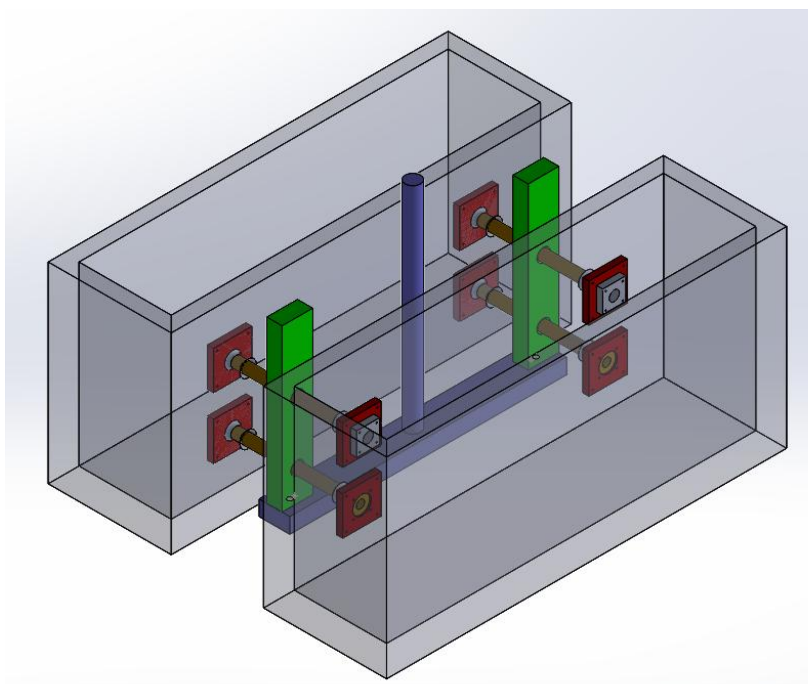

Figure 18: Proposed testing setup for Cal Poly

At the time, we thought Endologix had load cells that could measure the individual deflections and loads on each artery, so the fixture would not need to be dry during testing in order for us to measure deflections. We would have placed our fixture in a tank to help hold the arteries, then placed our tank in the test bath of the Bose machine (Figure 19).

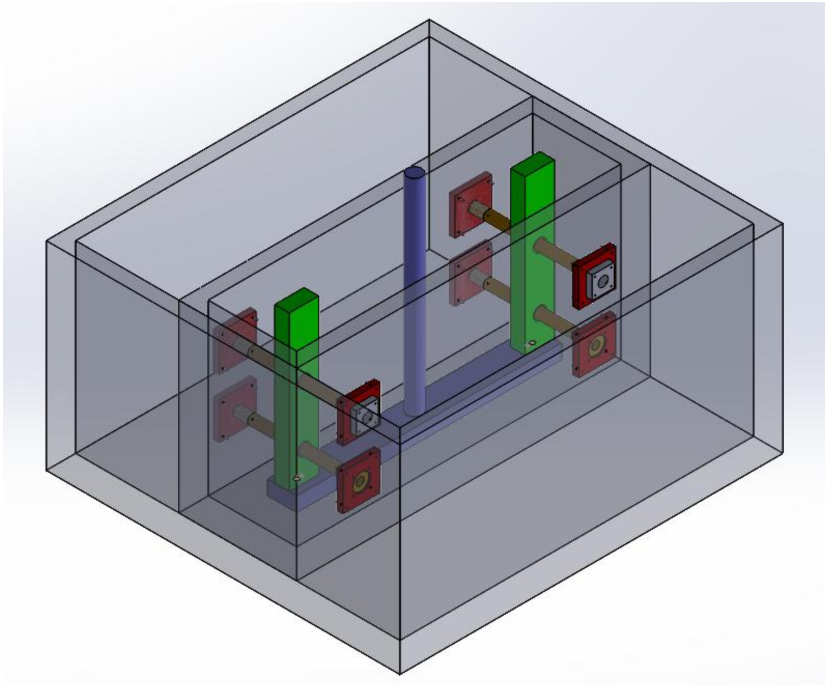

Figure 19: Proposed testing setup for Endologix

PART III – Critical Design

7. Final Design

Shortly after submitting our preliminary design, we were informed that the load cells on the Bose machine did not measure displacement, only force, and that the center shaft of the system was used to measure displacement. This posed a minor setback for our fixture design, since the uprights holding the mock arteries would be screwed into these load cells. However, the load cells being fixed actually turned out to be helpful for simplifying our design. Since they are fixed tapped holes, we were able to use them as additional mounting points for our fixture. This enabled us to attach our fixture straight to the Bose machine, without needing the extra complexity of the tank within a tank design. Our final design is detailed in the following sections. It includes both our deliverables to Endologix and the system required for us to test the fixture on campus. All part drawings and specification sheets can be seen in detail in Appendix E.

7.1 Endologix Deliverables

The components of our design to be used directly with Endologix's Bose machine are the fixture, mock arteries, and custom spider bar. These three components are attachable to their test system and will be used to fatigue test many renal stents in the future (Figure 20).

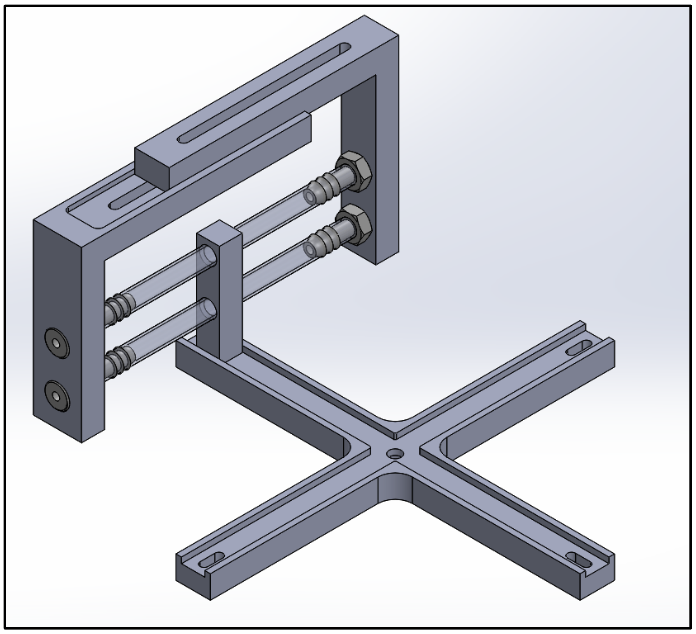

Figure 20: Custom Spider Bar with Upright, Bracket, and Mock Artery

7.1.1 Fixture

The fixture is made of two main components; the bracket and the upright. Each of these has been configured so that they may adjust to different artery lengths and diameters. For our own testing purposes we tested the average human renal artery length, 39mm, and a diameter of 6mm to match the stents Endologix was able to send us.

7.1.1.1 Mock Artery

According to ASTM F2942, Standard Guide for *in vitro* Axial, Bending, and Torsional Durability Testing of Vascular Stents, any mock vessel used for testing should be "durable, capable of withstanding the test conditions, and able to maintain the desired stent deformations." Beyond this there are no specific material properties that the team needed to comply Typically most mock vessels are made from silicon tubing, and initially we had planned to go through a vendor Endologix already uses for their other stent testing, Statasys Direct Manufacturing. Unfortunately the cost of just 8 vessels was quoted at $1418 (mostly to make the mold itself) so we had to look at alternatives. We found tubing on McMaster-Carr (Appendix E, Spec Sheet) that was "made from FDA-compliant resins" and was "cleaned with isopropyl alcohol then bagged and sealed in a clean room." The biggest difference was that the Statasys arteries were rated at a hardness of Shore A40, while the McMaster tubing was Shore A50. This means the arteries made out of McMaster silicone tubing were harder, but not significantly so. This worked to our advantage. Since the tubing was harder we didn't have to worry about ovulation of the artery as much. It retained its shape better.

The artery was held on both ends by hose barbs. This allowed the saline solution to flow through the arteries and contact the stents. To further hold down the arteries, we zip-tied the ends of the arteries to the hose barbs. In addition, the hose barbs we chose have standard 1/4" NPT threading so that they can be switched out if different artery diameters are tested in the future (Figure 21).

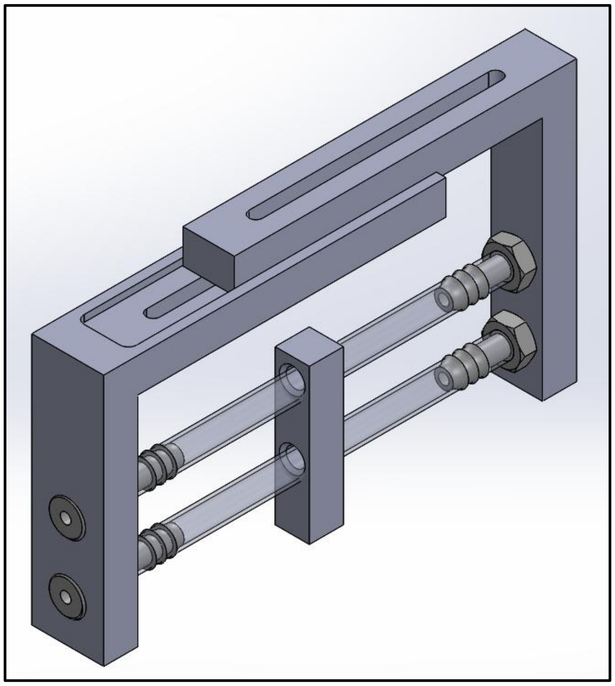

Figure 21: Bracket Assembly with Upright and Mock Arteries

It's important to note that we planned on having two stents for every one artery. Since the displacement occurred in the middle of the artery it bent both stents equally in the same direction. Taking into account the hose barb length on either side, the average artery length, and the upright thickness, we used tubing that was 142.7mm long, with an inner diameter of 1/4" (approx. 6mm) and a thickness of 1/8" (3.175 mm).

In addition, we received a free shipment of artificial renal arteries from Syndaver, a company that specializes in making realistic human anatomy parts based on the most up-to-date literature data. These were given to Endologix for them to test in fatigue. If the arteries are shown to last, Endologix may work with Syndaver to purchase mock vessels in the future.

7.1.1.2 Bracket and Upright

Endologix requested that we make our design adjustable to varying artery lengths and diameters. To make the lengths variable we designed the brackets so that they have one continuous slot along their top (for a #8-32 screw). The amount of adjustability is based on the average artery length found in literature, 3.9±1.3cm. Taking into account the hose barb and the upright thickness, the brackets can be adjusted for an artery length of 24.56mm to 62.62mm (Figures 22 and 23), which almost covers two standard deviations of human artery lengths. This gives Endologix flexibility in any future tests they'd like to run. Ideally we would have covered the entire range of two standard deviations, but the corrosion resistant Aluminum angle stock we purchased was not available in a length long enough to reach two standard deviations.

In order to prevent the brackets from rotating they were designed with a recessed slot in the bottom mating part. An 8-32 screw goes through the slot and screws into the load cell to hold the fixture in place. The uprights hold the middle of the mock arteries and displace them. In the original design they were ½" x ½" and were tapped from the bottom so that they could be screwed into the custom spider bar. Updated designs are given in Section 11.2.

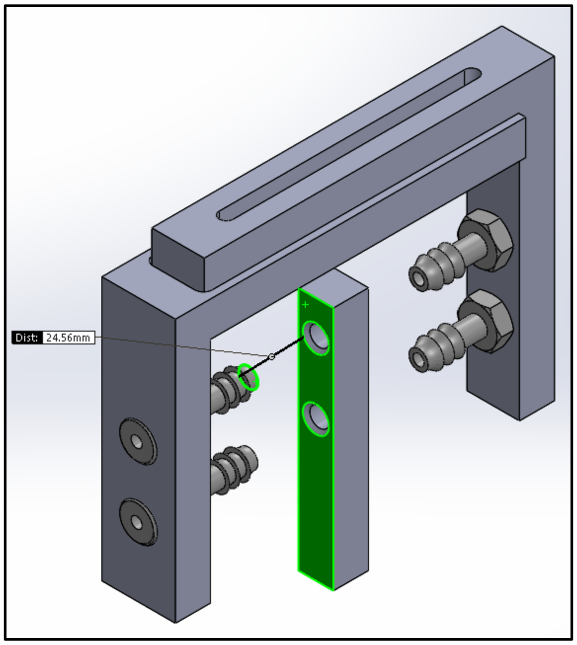

Figure 23: Shortest Length of Bracket

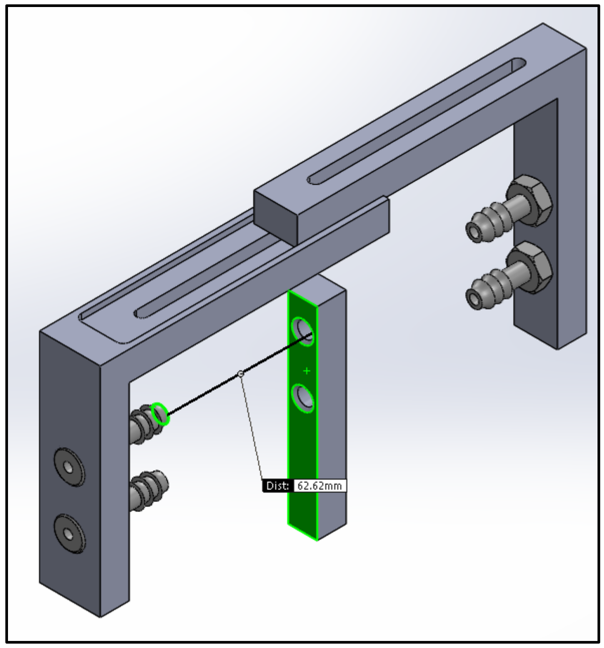

Figure 22: Longest Length of Bracket

7.1.2 Custom Spider Bar

In order to easily attach our upright fixture to the Bose machine at Endologix, we created a new spider bar. This was necessary because the original spider wheel on the Bose machine contains a tapped hole, making it difficult to attach the uprights with a screw from the bottom. After discussing solutions with our sponsor, we decided it would be best to create a custom spider bar. Since the custom spider bar was designed specifically for the bending system, it was simple to incorporate attachment of the uprights into the design. This new spider bar has three main new features. First, the new design only incorporates four spokes instead of 12. Due to space constraints, we were only able to fit four bracket fixtures, so only four spokes were necessary. Removing the other eight spokes from the design saved weight and increased functionality. Second, the new design contains recessed slots to limit rotation of the uprights. This feature replaced the need for a second screw hole or alignment pin and made position adjustment of the upright fixture

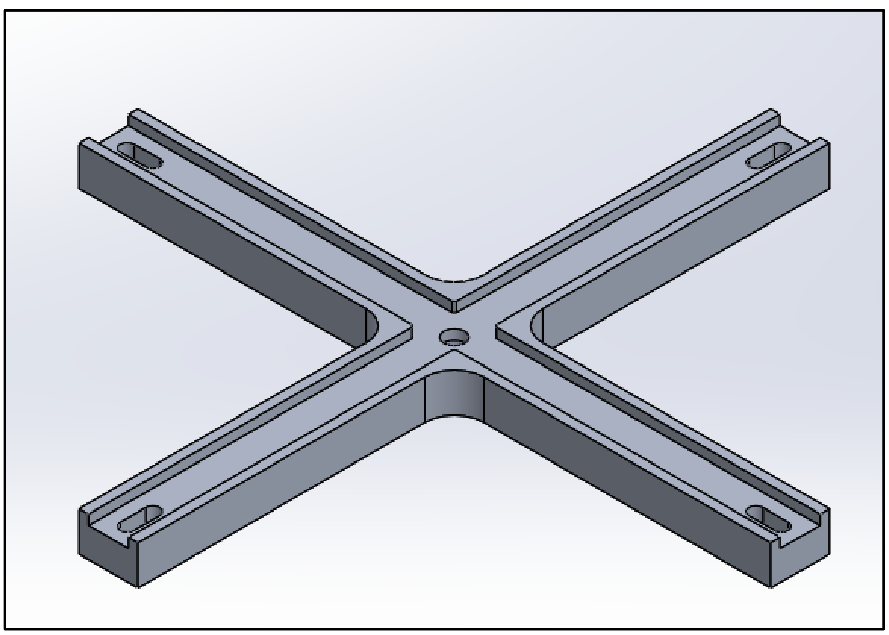

Figure 24: Custom Spider Bar

easier. Third, there is a countersunk slot used with the threaded hole in the uprights to fasten the uprights in place. This slot also allows for adjustability when aligning the upright to the bracket fixture and load cell. These features can all be seen in Figure 24.

The custom spider bar was made out of highly corrosion resistant 5083 aluminum. This aluminum is often used in marine applications, making it ideal for the saline bath environment in the Bose machine. It attaches to the Bose machine with a 1/4”-20 bolt put through the center of the spider bar and threaded into the main shaft of the Bose machine.

7.2 On-Campus Testing

In order to guarantee delivering a quality product to Endologix, we planned to complete 3, 40-hour weeks of on-campus testing of our fixture. To accomplish this we designed our own motor and linkage system to displace our fixture in the same manner as Endologix’s Bose machine. The details of our test system requirements are given in the following sections. It is important to note that while our fixture was designed to be placed into the Bose machine, the entire test setup was used as a standalone system for on-campus testing.

7.2.1 Linkage Design

The Bose machine we are basing our testing system on oscillates linearly ±12.7 mm at up to 100 Hz. For our purposes, we planned to test our system at a minimum of 25 Hz, but we still needed to capture the linear oscillations at a high frequency. Our two first considerations for generating linear motion were a linear actuator or a motor and linkage system. Since we needed such high frequency oscillations, we quickly ruled out linear actuators as an option. After this decision was made, our two main ideas were either a motor with a three-bar linkage system or a cam and displacement shaft mechanism. We decided to design a linkage system, based on a simple three-bar linkage system taught to us in Dynamics lecture, modified with a shaft collar and pin since our needed displacement was so small. We determined that this would be the simplest form of mechanism to use and machine by hand and wouldn’t require an advanced degree or years of experience to avoid cam slop or other cam-shaft design challenges seen in automobile design. A full diagram of our design is given in Figure 25.

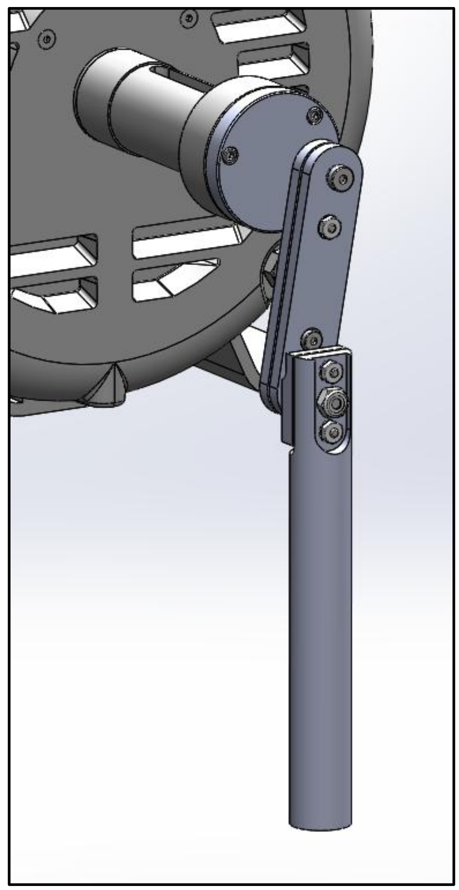

Figure 25: Overall View of Linkage System

The collar face was bolted on to the shaft collar and had a shoulder screw threaded into it, which acted as a pin for the connecting linkage to rotate on. The other end of the linkage was attached to the displacement shaft with another shoulder screw, held on with a locknut. All components were assembled together with PTFE washers in between, due to friction concerns and necessary spacing. An exploded view of the assembly is shown in Figure 26.

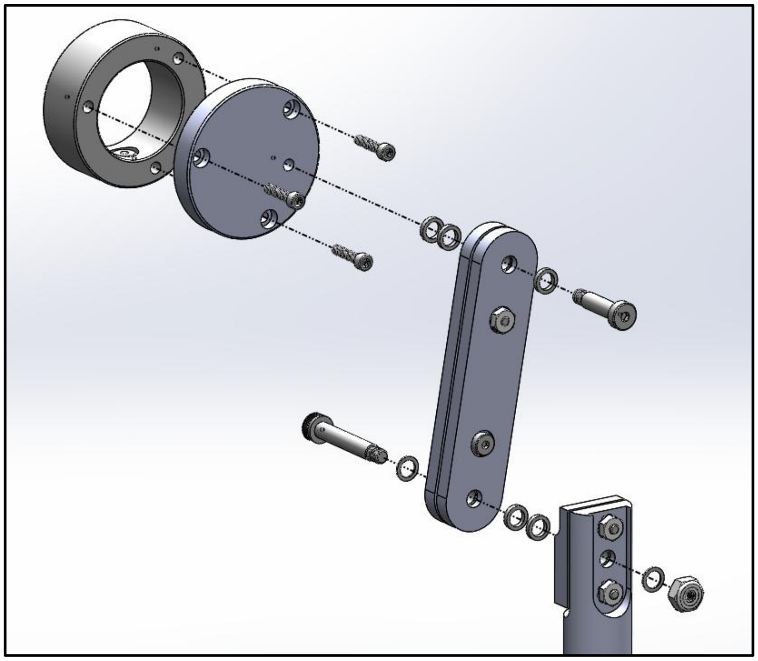

Figure 27: Exploded View of Linkage System

Lastly, the connecting link and displacement shaft were both made up of two plates bolted together with countersunk holes in them to capture the side surfaces of three bearings, which allowed the whole system to rotate and transfer the rotational movement of the electric motor into the vertical displacement of the shaft that we needed to move our fixture. Exploded views of these details are given in Figures 27 and 28.

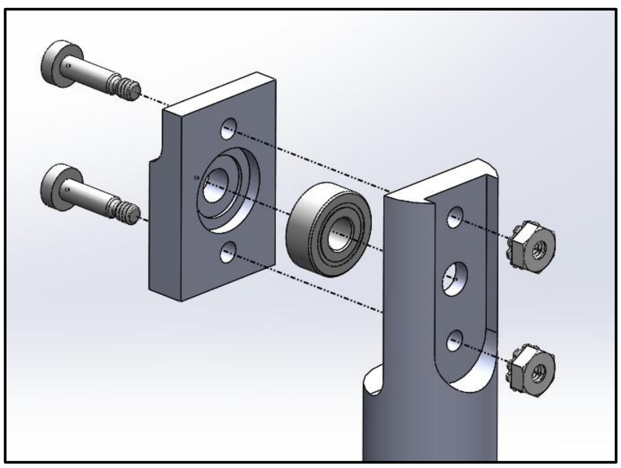

Figure 26: Exploded View of Displacement Shaft

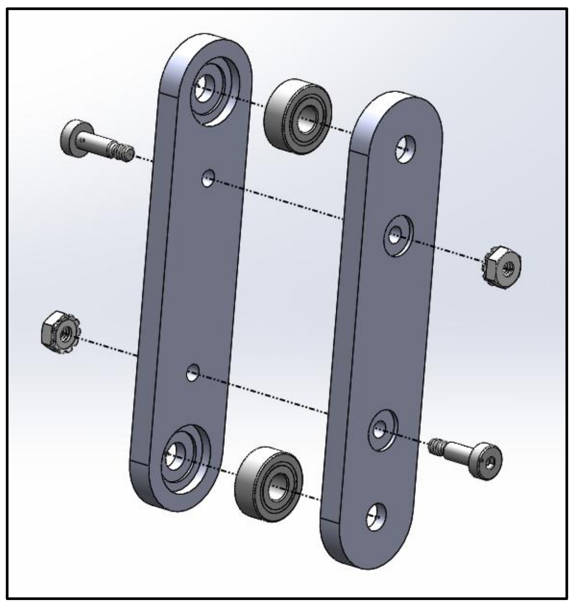

Figure 28: Exploded View of Connecting Linkage

7.2.2 Motor Selection

After designing the overall linkage setup, we performed a kinematics analysis on each of the linkages, complete with equations of motion, free-body diagrams, and mass-acceleration diagrams.

After getting our system of equations for each of these components, we wrote a Matlab code to give us the torque and horsepower required for every angle of the motor shaft's revolution at 1800 RPM (33 Hz). This analysis can be viewed in Appendix F. Our analysis gave us a required maximum torque of 15 lb-ft and 5 hp. Since we weren't using our motor in any sort of specific industrial application, we narrowed our search down to open enclosure motors with base mounting plates. The Cal Poly Electrical Supervisor, Ben Johnson, helped us with these specifications and directed us to Central Coast Bearing, the local vendor for Baldor Motors.

Since our horsepower requirement was so high, we used a 3-PH, 208 V motor with a Variable Frequency Drive (VFD) motor controller. This controller gave us the capability to change the speed of the motor by varying the frequency and voltage supplied to the motor. The VFD we chose was from a local supplier of Allen Bradley VFDs in Santa Maria, per the suggestions of Ben Johnson and Jim Gerhardt. A higher end VFD from Allen Bradley was necessary in our setup since we connected it between the power supply and the electric motor. We did not want any loose wiring or open circuit panels, and the Allen Bradley PowerFlow 4M gave us just that. The model we used was rated for 3 PH, 208/240V power and allowed us to control the speed of the motor with a simple keypad, potentiometer, and digital display.

7.2.3 Tank/Heater Selection

In order to meet our standards, we had to keep the arteries in contact with saline solution at body temperature. We did this by using a tank to contain the saline and submerge the stents and a heater with controller to set and maintain the needed temperature.

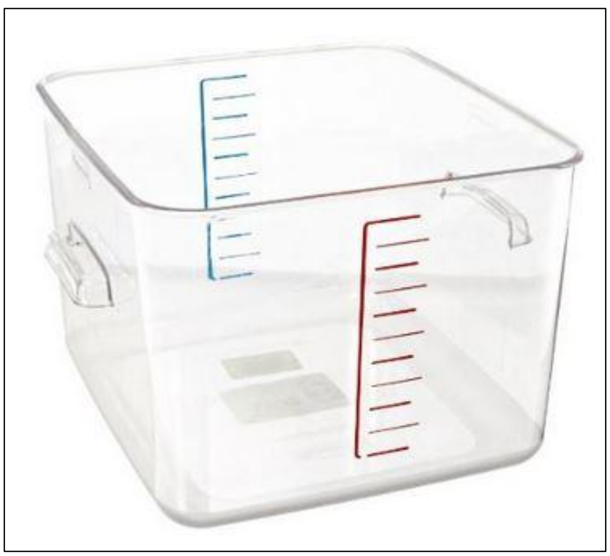

Figure 29: Rubbermaid Space-Saving Container "Tank" that will be used in our test setup on-campus

Because we needed to hold the saline solution around the samples on-campus, we had to choose a tank to fit our needs. This tank had to fit the dimensions of the testing fixture with reasonable clearance. The tank also needed to be made out of plastic so that it would not shatter if impacted by a broken linkage or part. After considering many fish aquarium options, we were unable to find one that suited our needs without being oversized and overpriced. Instead, we decided to use a food storage contain, specifically the Rubbermaid Commercial FG631200CLR Space-Saving Container, 12-Quart Capacity in Figure 29. This was held fixed in our on-campus test setup by industrial strength Velcro.

After selecting a tank, we had to find a heating element that suited our needs. This heater had to be able to heat the saline solution to a temperature between 35 and 39 degrees Celsius. The best option we found for heating a small amount of water was to use an aquarium heater; however, most aquarium heaters do not heat the water to the temperature we needed. After searching on the internet, we were able to find one heater and controller unit able to heat to 99.9 degrees Fahrenheit (or 37.8 degrees Celsius). We ran this heater at the low end of our temperature range, 95 degrees Fahrenheit (or 35 degrees Celsius), in order to put less strain on the heating element. The heater and controller unit we selected was the JBJ True Temp Digital Controller w/ Heater - 150 Watt shown in Figure 30.

Figure 30: JBJ True Temp Digital Controller w/ Heater - 150 Watt that will be used in our test setup on-campus

7.2.4 Safety Enclosure

Since we planned to test a system on campus that required moving parts, we had safety shielding surrounding our set-up to protect from possible projectiles and to keep the more curious students on campus from injuring themselves. In addition, our enclosure was placed in the ME Fluids lab closet where people other than ourselves were permitted, so we needed to ensure a way to keep them safe and keep our test running properly. In order to do this, we designed a safety cage to place over our fixture. The frame of the safety shielding was made out of aluminum extruded T-slots. All but one of the sides of this frame was covered with expanded steel panels. The last side was covered by acrylic in order to allow a

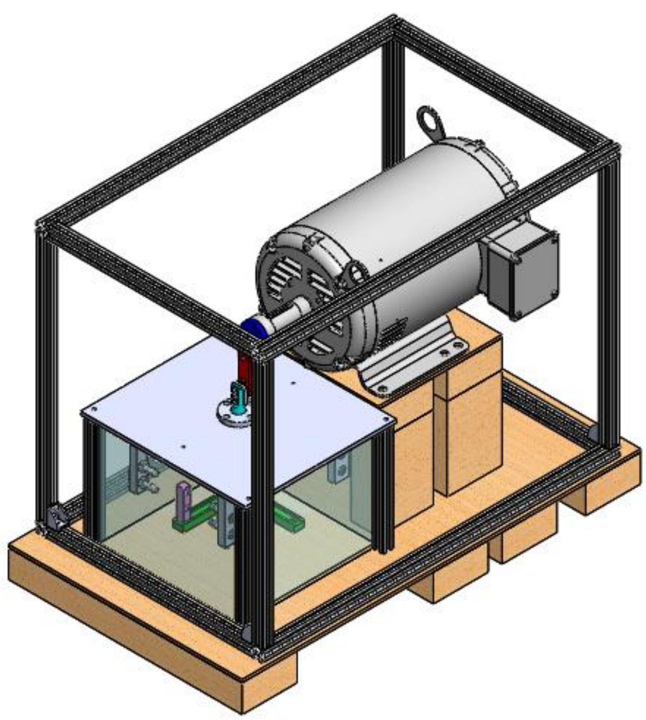

Figure 31: Safety Cage Assembly

clear view to the motor linkage needed for data acquisition. This can be seen in Figure 31.

7.2.5 Top Plate and Linear Bearing System

The top plate was made of 0.25" thick aluminum and had through holes drilled at all four corners so that it could be supported by the t-slot uprights. As mentioned above, there were also two 1" through holes for the face mounts to bolt through. The cover also had four through holes in the middle to allow the linear bearing to sit in place and to help align the system. The final holes were representative of the load cell locations and were the only tapped holes on the plate. These tapped holes allowed the bracket to be held in place from underneath and were what kept the brackets at their desired lengths.

7.2.6 Testing and Design Verification Plan

In order to ensure that we met the objectives outlined in Section 3, we developed a testing plan and two complementary design verification documents: a Design Failure Mode and Effect Analysis (DFMEA) and a Design Verification Plan (DVP) (Appendices G and H). Through the testing plan and these two documents, as well as the data acquisition methods in the following section, we were able to test the effectiveness of our fixture and on-campus testing setup. In addition, we also had a safety checklist (Appendix I) to ensure we considered all possible hazards.

As for the testing itself, since our motor and VFD had such high power requirements, we were required to test in a designated mechanical engineering laboratory on-campus which was approved for and capable of high power testing. In the lab, we setup our system and ensured that all safety regulations were met before beginning the test, per our safety checklist and DFMEA.

7.2.7 Data Acquisition

In order to verify that our motor-linkage and tank design functioned similar to the Bose machine at Endologix, we considered the data that needed to be gathered as our system was being tested on-campus. Besides the temperature of the saline solution, which would be measured by the thermometer built into the heater, we decided that two measurements were critical to verifying our design: displacement and cycle count.

7.2.7.1 Displacement Verification

Displacement data was critical to our design verification because the purpose of the entire project was to replicate the *in vivo* conditions of the renal artery stents which included the displacement of the arteries due to respiration. Thus, to verify that our motor-linkage system was replicating the displacement of *in vivo* conditions, we monitored the displacement of the driving shaft.

We originally planned on monitoring the exact displacement of the driving shaft over the entire course of the project. However, we found that since the motor ran at a continuous rate and the linkage components weren't changing, the numerical displacement was not critical and the only necessary data was the consistency of the machine. Therefore, in our data acquisition plan we focused only on confirming that the displacement of the system was consistent over the course of our testing. By confirming the consistency of our fixture with the axial displacement of the motor system, we could confirm that our fixture will operate as planned in the Bose machine.

Since consistency was the primary concern, we decided to use a Cal Poly provided high-speed camera to visually check the displacement of the linkage pin against a ruler placed beside it. Since the system would remain unchanged, we planned to use the camera only once a day during the testing period. The camera was managed by Professor John Chen who gave the team a one hour training session at the start of our testing period on how to properly use the camera and allowed us to check out the camera whenever we need it. For our testing purposes, the camera operated easily up to 300 FPS at a high resolution and captured frames of the pin at its maximum and minimum positions, showing the full range of displacement. With a well-lit ruler in a millimeter scale, the accuracy of our displacement measurement was to the nearest millimeter. The results of this high-speed camera data are given in Section 12.3.

7.2.7.2 Cycle Count

Cycle count data was critical to our design so that we knew how much fatigue we were simulating and whether we were meeting our 3 week test period cycle goal. In addition, if any component of our system had failed during testing, we would have been able to get a general idea of how many cycles the system had simulated before failure. In this regard, we looked for the simplest and most inexpensive means of counting cycles of our system.

The main concern with measuring cycle count was the sheer speed of oscillation in our design. At 25 Hz, many simple cycle counting systems were either unable to keep up or too expensive. Primarily, mechanical systems could not keep up with the high oscillation frequency. Therefore, we decided to use a Hall Effect sensor system with a LCD incremental cycle count display as it was the simplest and least expensive choice. This system was made up of three components: a magnet, a Hall Effect sensor, and a LCD counter. This sensor is designed for positional and velocity control systems and could easily keep up with our system up to 30 Hz.

A Hall Effect sensor works by generating an electrical signal every time the south side of a magnet passes it. This can be utilized by attaching a magnet to a rotating shaft and positioning the Hall Effect sensor right next to the rotating shaft. As the magnet passes the sensor on each cycle, a pulse is generated. The pulse then passes to the counter which adds one to the display every time the rising side of a pulse is measured. In this way, as a system is running the LCD display continuously updates the amount of cycles it has measured so far, providing an accurate cycle count. The Hall Effect sensor and cycle counter we chose for this purpose can be seen below.

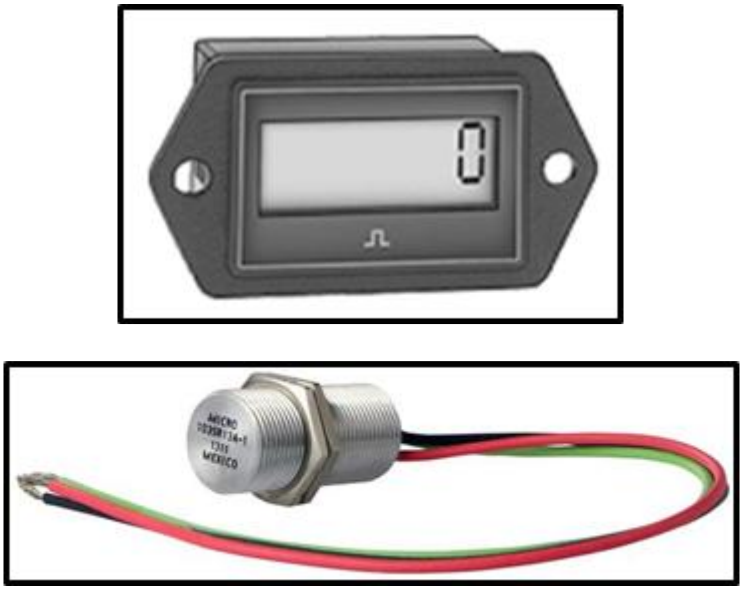

Figure 32: Images of the Hall Effect sensor and incremental counter that were used

This specific sensor was chosen because it was inexpensive, ruggedized, and easily mountable. Since the sensor was rugged, we did not need to be concerned with electrostatic discharge (ESD) that would be a concern for exposed integrated circuits. Also, since the sensor was mounted so closely to the rotating shaft, it was beneficial to have a sensor that could withstand an accidental impact. The sensor was purchased from Mouser electronics.

The specific counter was chosen because of its simplicity, frequency capabilities, and high digit count. First, the counter has a backlit LCD display that shows the current count. This count is useful to visually observe how many cycles have passed rather than having to program a microcontroller. Second, the counter is rated up to 50 Hz, so the 25-33 Hz of testing was well within the counter's operating range. Last, the counter fit the scope of our project because it has 8 digit resolution, meaning it is able count up to 99 million before resetting to 0. That allowed us to try and reach our 10.8 million cycle goal without having to keep track of the number of times the counter reset. Overall, the magnet, sensor, and counter system are an effective and simple means of keeping track of the cycle count.

8. Manufacturing Plan

Our manufacturing process plan for this system was broken down into three main steps: waterjet cutting, CNC, and hand milling. We planned to use CNC to machine the spider bar, per the request of our sponsor, since it required higher tolerances. The overall shape of the other parts would be cut out with waterjet abrasion. All parts would then be hand machined by us in the Cal Poly shops, either from raw material, waterjet cut material, or stock parts that we would modify.

8.1 Waterjet and CNC

All of our components were relatively small, so to save on raw material and manufacturing costs, we planned to order a 12"x12" plate of aluminum and have most of our parts cut out of that single plate. That was the smallest stock size available to us, and it would allow us to get all of the needed components from one plate, with a duplicate of each part in case of machining errors. The layout for this process is given in Figure 33. We planned to outsource the initial machining process to Water Jet Central, a company in Paso Robles that cuts out parts through water jet abrasion. All their orders are completed with the customer present to witness the jetting process, so we would be able to take the parts the same day we brought in the aluminum stock.

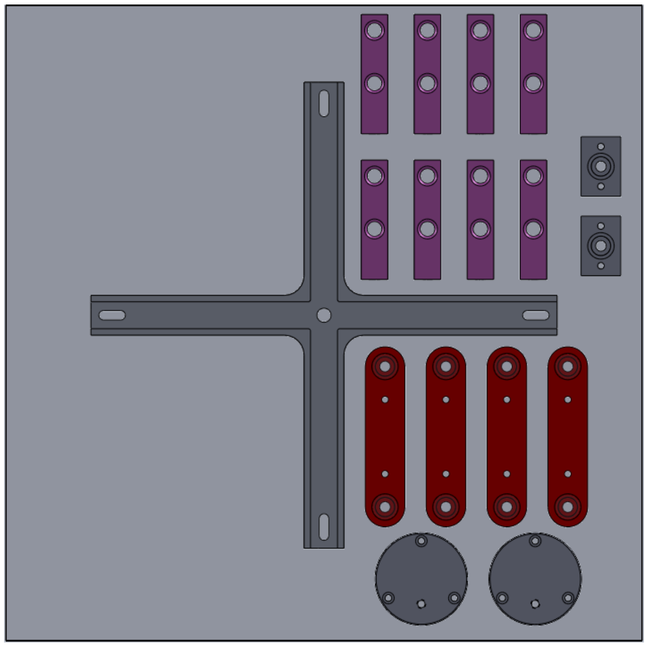

Figure 33: Layout of CNC Waterjet Abrasion Cutting

8.2 Raw Material and Part Modification

The rest of our parts would be machined by hand in the Cal Poly shops. That would include hand milling all of the components that were cut with water jet abrasion, such as the uprights and connecting linkages, as well as modifying some stock components from suppliers like McMaster and Misumi, like the L-bracket stock used in our fixture and the shaft collar used in our linkage system.

8.3 Assembly

Our complete test setup contained many parts and even more hardware and needed a systematic assembly plan to ensure everything fit together nicely. The overall breakdown of steps is shown in Figure 34.

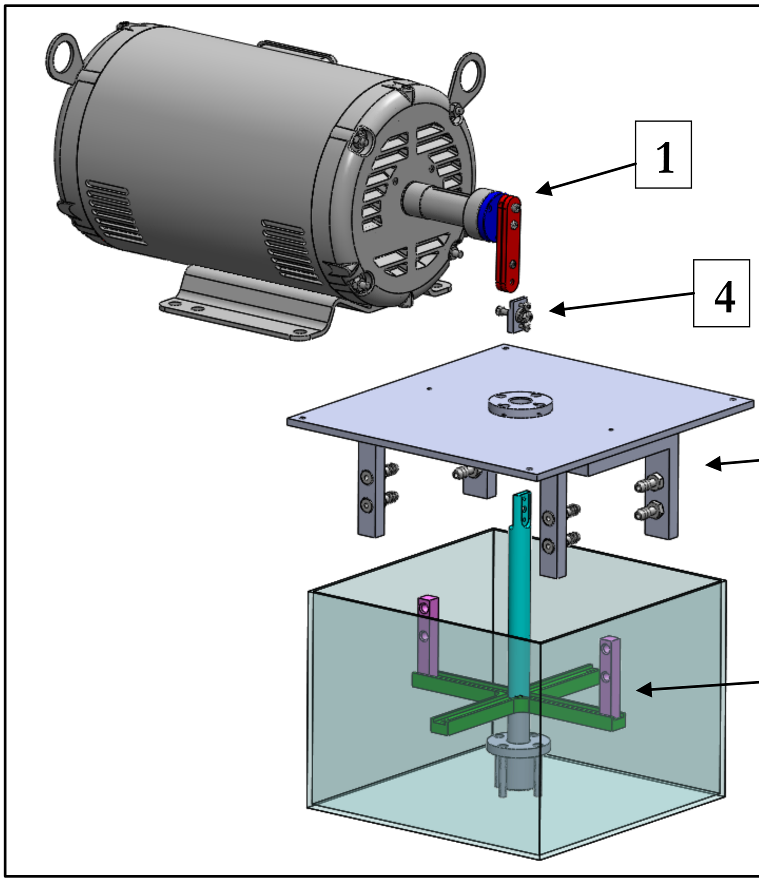

Figure 34: Overall Assembly of Test System

Steps 1 and 2 in the Assembly could happen simultaneously, as they would be independent of each other. The motor shaft collar, collar face, and connecting linkage would have to be assembled together first, while the displacement shaft, custom spider bar, uprights, and spider bar retaining shaft would be installed into the linear bushing secured to the bottom of the tank. After the displacement shaft was installed, the top of the tank and attached brackets could be lowered over the displacement shaft and secured to the aluminum extrusion supports, then the displacement shaft could be secured to the connecting linkage.

PART IV – Product Realization

9. Cost Analysis

To keep track of the cost of our design, we kept a bill of materials (BOM) with the part name, cost, supplier, quantity, estimated shipping cost, and link to purchase the part. The BOM allowed us to keep track of our budgeting, and to provide a list for Endologix to purchase parts at the conclusion of our critical design review. The BOM can be seen in Appendix J, and our most expensive component is discussed below.

9.2 Significant Purchases

The main contributor to our high cost was the VFD, which was required in order to regulate the rotational velocity of the motor. The VFD chosen in particular for our system was of higher quality, since it was a standalone system with its cover and no exposed wires, which attributed to the higher cost of the unit. We were able to keep the cost from rising further by getting the simplest model, as well as buying it from a local vendor. We chose the VFD with the simplest display, since we only need it for speed control. Additional high value purchases included the waterjet cutting and raw materials.

10. Management and Teamwork

Using feedback from both our classroom peers and our advisor, in addition to the feedback from Endologix, we moved forward with the purchasing and manufacturing phase of our senior design project. This stage included purchasing all of the components outlined in our bill of materials and manufacturing the components of our design per the manufacturing plan.

In order to keep to our proposed schedule for the remainder of the project, we maintained a detailed Gantt chart which outlined the specific timing for each category of our project as well as the subcomponents. In Appendix K we have our Gantt chart with the Purchasing & Manufacturing section expanded.

As the Gantt chart shows, we allotted one week for revising our design and report as a result of the feedback we received from Endologix. After our design was finalized, we turned over our bill of materials to be purchased as well as the sources of each component to Endologix to purchase and have shipped to the Mustang 60 shop on Cal Poly's campus.

As our raw materials arrived, we followed the manufacturing timeline shown. Our goal was to have the entire system constructed and subassemblies put together by the start of our finals week, as the machine shops were closed during finals week. Overall, this Gantt chart was updated bi-weekly to reflect our progress through the purchasing and manufacturing components of our project so that we could remain on track for the remainder of the project. For more detailed information about overall project milestones and dates see Appendix L.

9.1 Budget Breakdown

For our project we were allotted $3000. The breakdown is as follows in Table 4.

Table 4 - Final Budget Categorized

Component	Cost
Fixture	$307.39
Data Acquisition	$93.37
Motor and Linkage System	$627.80
Testing Setup	$518.31

McMaster Shipping/Tax	$45.58
Waterjet Central	$220.00
Grand total	**$1,812.45**

Shortly after submitting the critical design report, the team discovered that the campus Electrical Supervisor, Ben Johnson, had a motor that met our requirements that he was able to donate. This saved about $700 from the budget. After manufacturing, several small purchases were made primarily on fasteners for modifications that safety advisors suggested to us. Overall, we were $1100 under budget and consider this a successful aspect of the project.

11. Manufacturing

All custom parts on this project were manufactured by the team. We utilized waterjet abrasion cutting off-campus at Waterjet Central in Paso Robles and then used the Cal Poly machine shops to do the rest of the manufacturing. All threaded holes, straight holes, slots, cuts, and other features were made by the student team to the best of our ability. Some minor changes were made to the original design and are discussed below in section 11.2.

11.1 Processes Used

To begin the manufacturing process, we had the general shapes for the custom spider bar, linkage components, and uprights cut by waterjet abrasion out of a stock 12" x 12" x 0.5" 5083 Aluminum plate we purchased. This process was done at Waterjet Central in Paso Robles. The waterjet machine used can be seen in Figure 35.

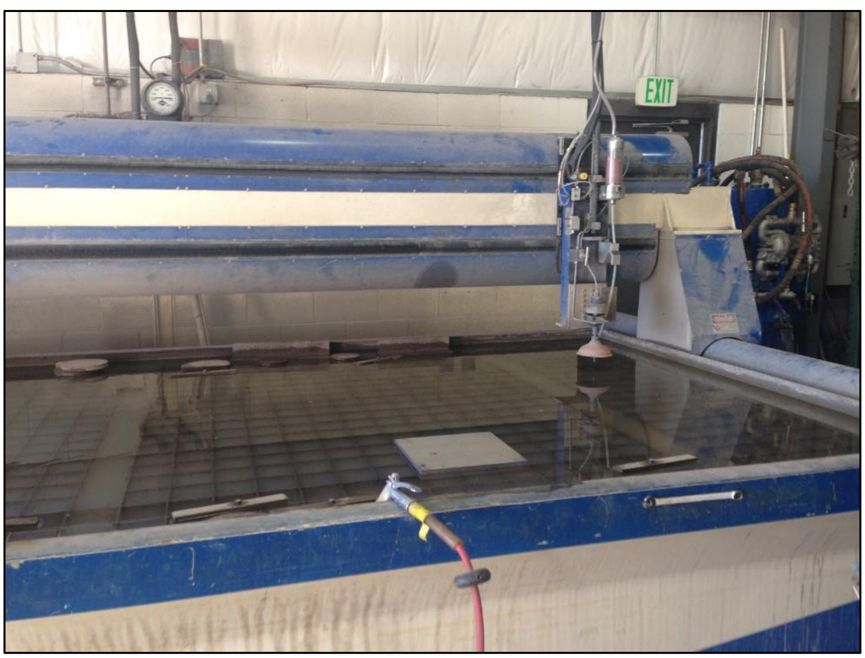

Figure 35: Water Jet Central Abrasion Cutting Machine

Because the size of the parts cut from the plate were relatively small when compared to the overall cutting bed, each part had to have a small tag keeping it attached to the plate and preventing it from falling into the water bath after being cut. Duplicates of every component were cut in case of mistakes during machining; however, the first time we sent the plate for waterjet cutting the dimensions for the uprights were incorrect. The team had to get the uprights cut out one more time to get the correct dimensions, due to our own errors and internal miscommunications The resulting plate with the cut shapes can be seen in Figure 36.

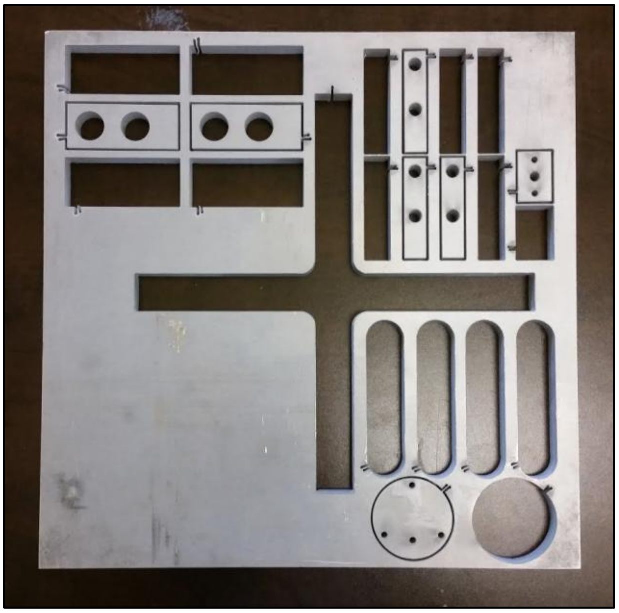

Figure 36: Aluminum Plate after Waterjet Cutting

After all the cutting was done, the plate was removed from the cutting bed and we were able to easily remove each part by gently moving them back and forth until the tag broke. In order to get rid of this excess material on each part, we used a disk grinder in the Cal Poly shops.

To finish the slots and counterbores on the custom spider bar, we had planned on having it CNC machined by Cal Poly. After discussing our design with the head CNC technician, it was decided that the necessary features could easily be done by hand and did not require such precise machining. The slots and counterbores were then created using a mill in the Cal Poly shops by the team. All of these features were manufactured within the correct tolerances. The finished spider bar can be seen in Figure 37.

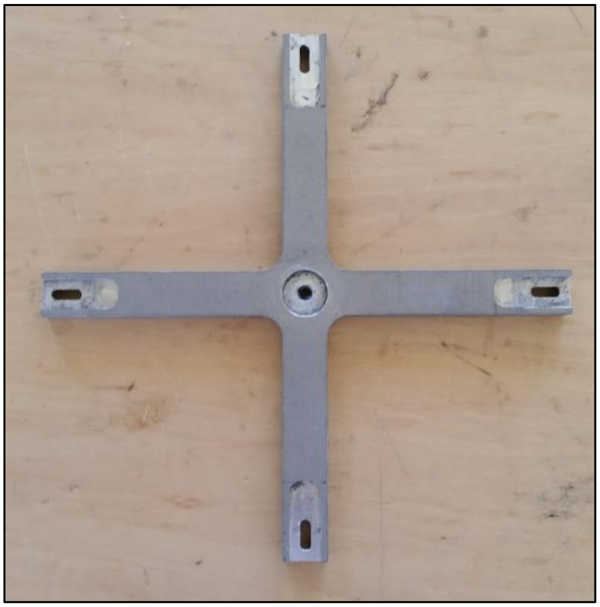

Figure 37: Top View (Left) and Bottom View (Right) of Completed Spider Bar

Figure 38: Upright

The next components that were manufactured were the two uprights. We started with the general shape already cut from the waterjet plate. Next, we used a mill to drill two holes on the side of the upright for the set screws. After those holes were drilled, the upright was flipped upside down, and using a mill, we drilled a single hole into the center. All drilled holes were then hand tapped using a #8-32 tap. To accommodate a variety of artery diameters, we made the holes a standard 16 mm. Nylon bushings slide into the holes and can be purchased in various inner diameter sizes. These are held in place by set screws located on the side of the upright. The completed uprights can be seen in Figure 38.

The brackets were the first component that was not from the waterjet plate. Instead, we used stock 90 Degree Angle, 1/2" Thick, 5" x 5" Legs, 6061 Aluminum. This material came in a 12 inch long piece, so the first step of manufacturing this component was to cut off the stock piece to the specified drawing lengths using the horizontal bandsaw. Because this machine tends to wander and not cut straight, the lengths were oversized and the finalized width cut to size by facing down each side on a mill. Next, two holes were drilled on each piece for the hole barbs. These holes were then tapped by hand using a 1/4" NPT tap. After this, a slot was milled in the center of each piece to serve as the clearance hole for the #8-32 screw eventually securing the bracket. The piece that would serve as the bottom on each bracket pair was then flipped over and a counterbored slot was milled to allow for a screwhead to be flush with the bottom of the bracket. Lastly, another, much larger slot was created using the mill in the same piece to allow for the narrow side to slide. The completed brackets can be seen in Figure 39.

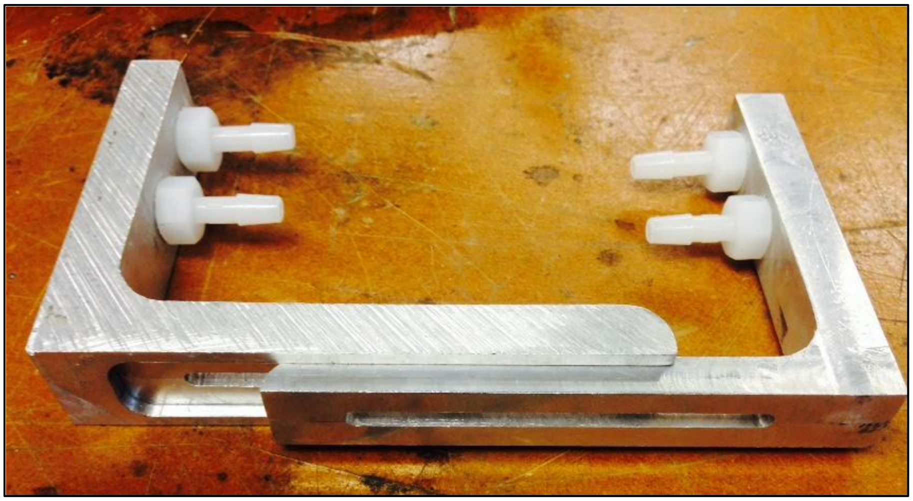

Figure 39: Fixture Brackets

Next, we began to manufacture the linkage components. First, we started with the shaft collar attachment. The circular shape of this piece was created from the waterjet plate. Next, the thickness of this piece was reduced by facing it on a mill. After this was complete, counter bores were added to the waterjet holes and the center most hole was hand tapped with a #8-32 tap. This completed part can be seen in Figure 40.

Figure 40: Shaft Collar Face

After this was complete, we modified a stock shaft collar from McMaster Carr. To do this, we placed the shaft collar attachment on top of the stock shaft collar and used a center punch to mark holes on the stock collar to match with the alignment of the holes on the attachment. Next, using a drill press, we drilled three holes in the collar. Then, we tapped these holes by hand using a #8-32 tap. The modified part can be seen in Figure 41.

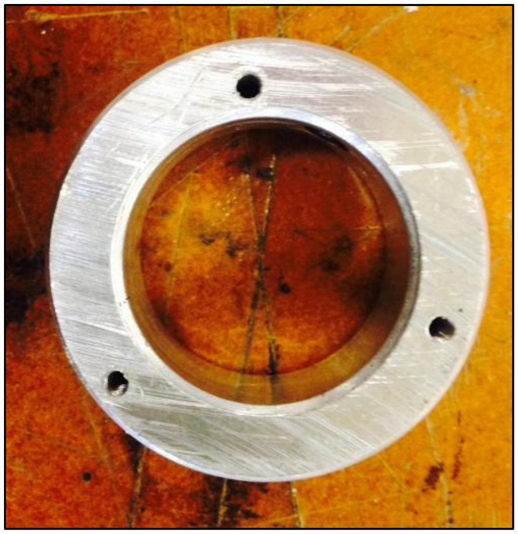

Figure 41: Modified Shaft Collar

Next, the two linkage bars were modified. Starting with the initial shape from the waterjet plate, the two bars were faced down on a mill to reduce the thickness. After, two counterbores for the bearings were added using a mill. Then still using the mill, counterbores were added to other side on the existing waterjet holes for the screw heads. The completed linkage bars can be seen in Figure 42.

Figure 42: Linkage Bars

In order to attach the linkage to the main shaft, modifications had to be made to the stock aluminum ¾ inch diameter shaft. To do this, we used an end mill to mill a section on the end of the shaft flat. Then we created a counterbore for the bearing. Next, we drilled a hole for the pin to slide through and added a counterbore for the head of the pin. To effectively hold the bearing in place, we created another piece to sandwich it. The general shape for this piece was waterjet. To finish the part, we added a counterbore for the bearing. These parts can be seen in Figure 43.

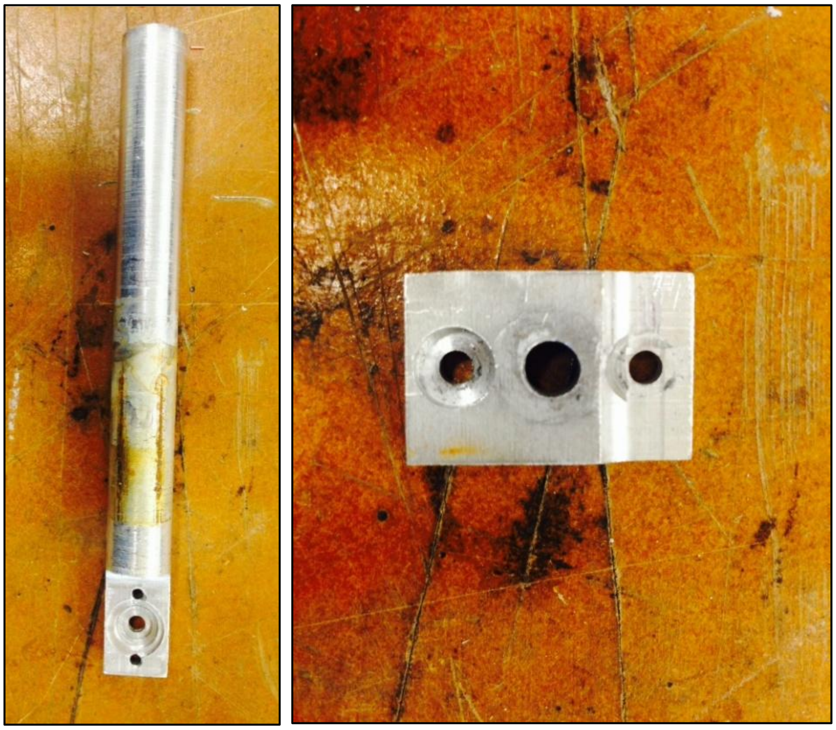

Figure 43: Linkage Shaft and Bearing Retaining Plate

To mount everything in the final assembly, a top plate had to be made to simulate the Bose Electroforce 3330 tank top, hold the linear bearing, and mount the motor. All holes were marked with a center punch and then drilled to the correct size using a drill press in the Cal Poly shops. Then the holes to mount the brackets and linear bearing were tapped by hand using a #8-32 tap and #10-32 tap respectively. The finalized plate can be seen in Figure 44.

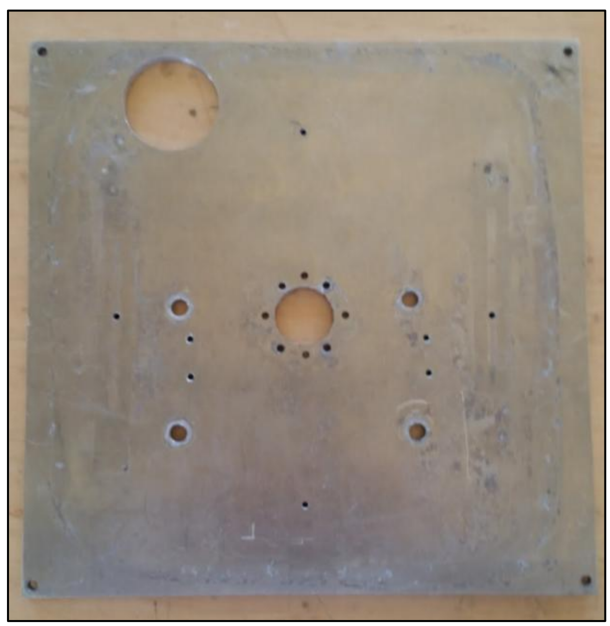

Figure 44: Top Plate

In order to properly attach the motor to our system, two face mounts were created from the same angled aluminum material as the brackets. Each have a ½ inch through slot milled out on one face so that we avoided issues with aligning the bolts pre-existing tapped holes on the motor face. Next, two ⅜ inch holes were drilled on the other face on both of the brackets. These match the spacing on the top plate and served to anchor our motor to the base. These brackets are pictured in Figure 45.

Figure 45: Motor Face Bracket Mounts

Due to safety concerns with our system, we created a safety cage to cover it. This safety cage was constructed of aluminum extruded t-slots ordered pre-cut from Misumi. We also bought expanded steel and acrylic to serve as the walls of the cage. Next, we cut the expanded steel to fit within the slots of the t-slot using shears. Finally, we used the vertical band saw in the Cal Poly shops to cut the acrylic to the correct size. The completed safety cage can be seen in Figure 46.

Figure 46: Completed Safety Cage

To mount all our testing materials together, we purchased stock pieces of plywood, 2” x 4”, and 2” x 2” wood from Home Depot. Using the table saw in the Cal Poly shops, we cut the shape for the motor base and main system base. Next we used the table saw to cut the 2” x 4” pieces to the correct lengths to support the motor. After this, we cut the 2” x 2” pieces to the correct lengths to add to the side of the motor body as support. Finally, using a hand drill, we fastened all parts together using wood screws. This final assembly is pictured in Figure 47.

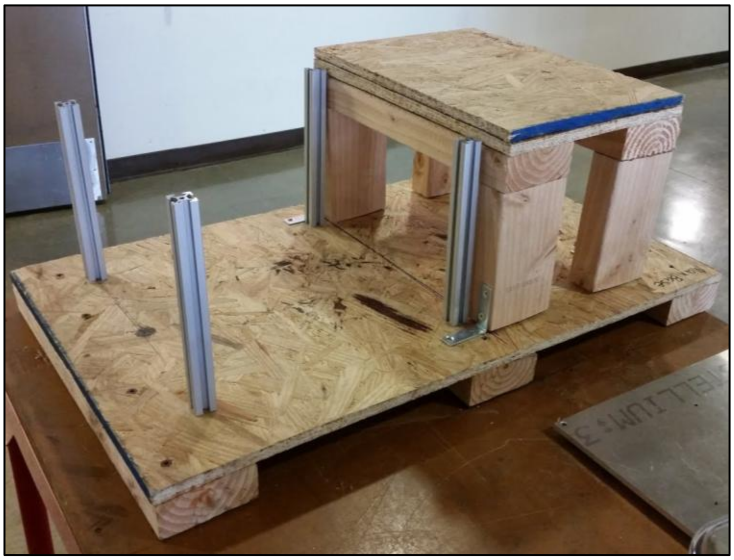

Figure 47: Wood Base with T-slot Supports

11.2 Differences in Actual Prototype

As mentioned earlier, the team simplified the design of the custom spider bar in order to make it easier to machine by hand in the Cal Poly shops. The slots going completely through the spokes of the spider bar were shortened to be 1.25 inches from the edge. A picture of the modified design is shown in Figure 48.

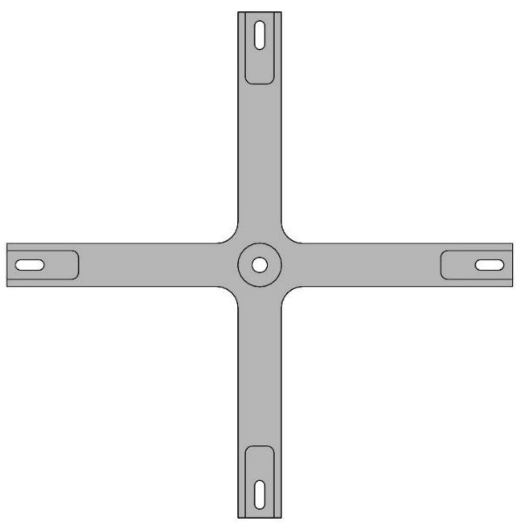

Figure 48: Modified Design of Spider Bar

We modified the original design of the bracket to have a counterbore slot on the underside of the top face to allow for bolt head clearance when screwing the fixture into the Bose machine load cells. A picture of this modification is shown in Figure 49.

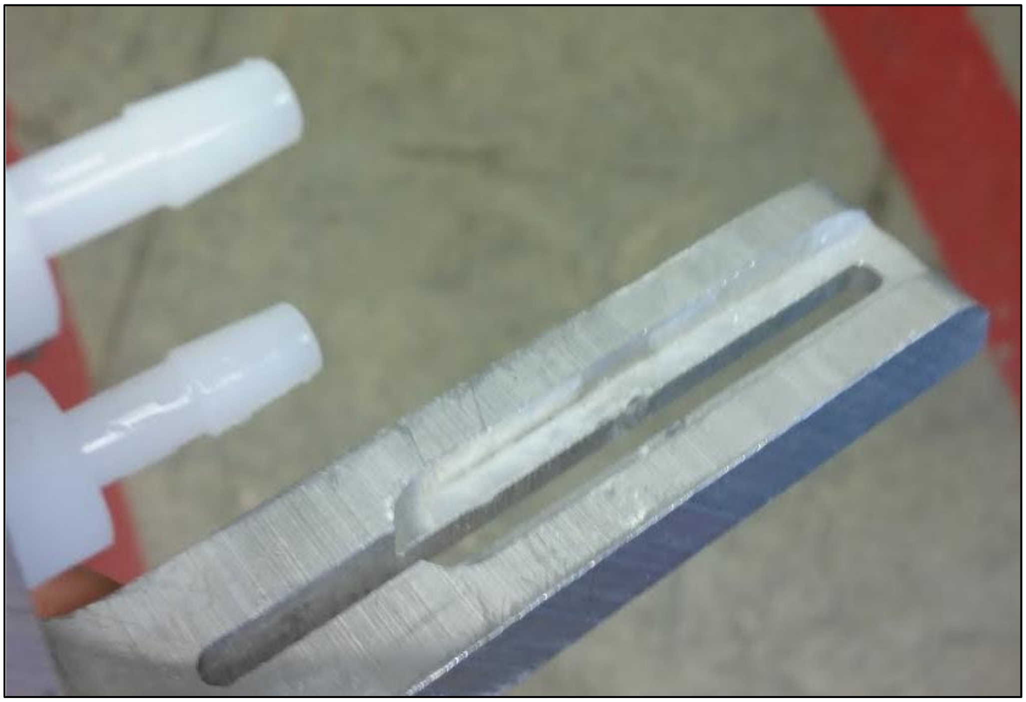

Figure 49: Counterbore Slot on Bottom Face of Bracket

The most significant modification we made to any parts after CDR was to the uprights. After initially cutting out the incorrect size, the team modified the design to be larger and included extra diameter space for a bushing to be able to slide into the holes in the uprights. The change in diameter size was to accommodate more standardized bushing sizes. The bushings are held secure in the hole by a set screw. Bushings can be purchased with various sized inner diameters, which allows for adjustability of stent diameter sizes to be tested. These bushings used along with the hose barbs, available in different outer diameters, allow complete adjustability in diameter of mock arteries and stents.

During assembly of our system, we made several small modifications to our components in order to get the correct fits for our subassemblies. However, all of these small modifications were made to the parts of our system used solely for testing on campus and therefore do not affect the fixture that will be used in Endologix's Bose machine. All modifications affecting the fixture placed inside the Bose machine have been described in the paragraphs above.

11.3 Recommendations for Future Manufacturing

The fixture to be delivered to Endologix was designed and manufactured as a proof of concept, and as such is not meant to be mass produced. It is a custom fixture for specific use in Endologix's Bose machine for their purposes. If Endologix does choose to modify our fixture in the future, we recommend that they change the bracket design to be two attachable pieces, instead of one L-shaped part. L-shaped stock is not a common material for machine shops and also makes certain manufacturing processes more difficult. Because the extra "leg" has to be sticking up when making modifications to the inside face, both the counterbore slot and tapped threads were difficult to manufacture. The counterbore slot could only be cut in halfway along the part before the end mill head interferes with the vertical leg of the part. When tapping the holes for the hose barbs, the vertical leg interfered with the handle of the tap, and it had to be slid out and back in for each half turn. Making this component two separate rectangular parts attached at the corner would alleviate both of these manufacturing hassles.

12. Testing

One of the main objectives of our project was to test our fixture for three weeks continuously. Unfortunately, we were unable to achieve this goal. After running a "bump" test with each of the safety advisors present, we successfully ran a continuous 5 minute test at the desired velocity of 25 Hz. We were also able to successfully mate all our manufactured components together for a smooth testing operation.

12.1 Component Tests

Over the course of our manufacturing we performed a series of component tests on each of our parts to make sure they were manufactured with the correct tolerances and fit nicely with mating parts or hardware. A comprehensive list of all manufacturing steps for each part and the component tests associated with each part feature is given in Appendix M. All the components successfully operated as they were designed to do.

12.2 Fatigue Testing

Due to safety concerns from the facilities manager and shop supervisor of the Mechanical Engineering department, several modifications were made to our system before being allowed to test the fixture. These modifications included adding large brackets to hold our motor in place and waterproofing our system by adding a rubber seal around the tank, gasket material around the tank heater and plastic sheeting over the electrical equipment. After these changes were made, we were required to prove the functionality and safety of our system with a "bump" test, where we turned on the system at its lowest speed with all of the relevant advisors present. After successfully completing the bump test and proving the functionality and safety of the system, we were allowed to run a 5 minute test at full speed in accordance with our testing protocol in Appendix N. Running a 5 minute test did not bring us close to the 10.8M cycles as originally outlined in the project objectives, but it did allow us to observe the behavior of the fixture and test setup while running at full speed.

12.3 Results

While the final test was only 5 minutes in duration, many observations can be made of the system behavior. Primarily, the motor-linkage and shaft system was successful in replicating the Bose machine's functionality of a high frequency linear displacement. The system was able to remain stable and have no critical failures at the full speed of 25 Hz. In addition, high speed video footage of the linkage system confirmed a consistent 24 mm displacement as anticipated, as seen in Figure 50. In this regard, we consider the motor linkage system to be a success.

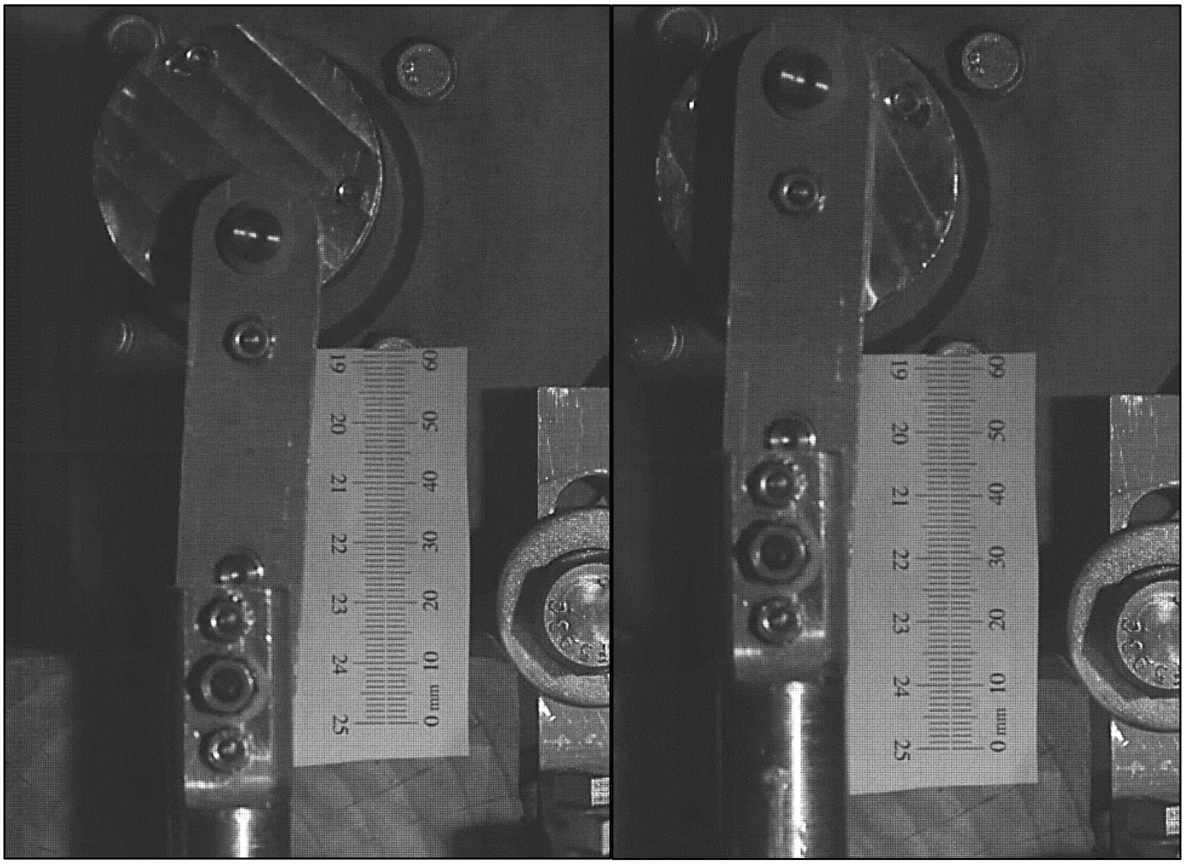

Figure 50: High-speed Camera Footage of Linkage Displacement

High speed video footage of the stents revealed several characteristics of the stents that we were only guessing at previously. First of all, there was an original concern that the high velocity of the displacement might vibrate the stents and cause migration along the mock artery. However, the stents did not appear to migrate at all for the duration of the test. While this does not confirm the behavior of the stents over the course of a longer duration test, or stents of different composition, we are still confident in the assumption of no significant stent migration. Secondly, no noticeable ovalization occurred in the mock arteries during the high velocity test. The concern was that the tensile force of the hose barbs might cause the otherwise circular mock artery to bend into an oval shape, which would be inconsistent with how renal arteries behave. However, as the video footage revealed, any ovalization that may have occurred is negligible and, if anything, would be close to what we expect renal arteries would exhibit when the kidneys oscillate. Lastly, the displacement of the stents themselves matched the 24mm that was expected. However, the bending of the mock arteries did not behave as anticipated and the stents did not experience the complete curvature that was desired. While the displacement was correct, the correlation between the displacement and curvature was observed to be an incorrect assumption, primarily due to the stiffness of the mock arteries. This observed motion can be seen in a screenshot of the high speed footage below in Figure 51.

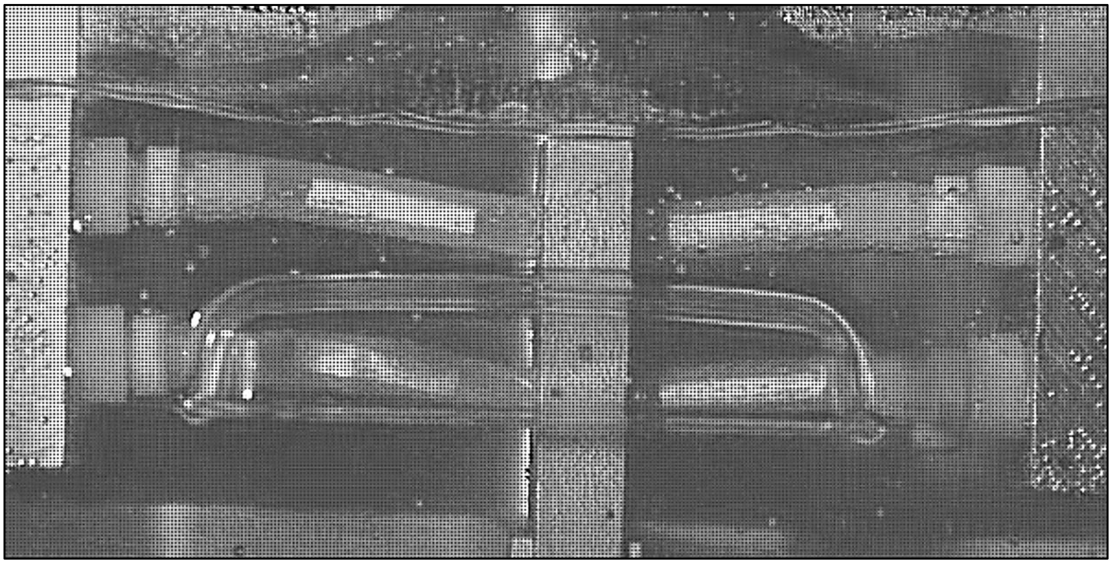

Figure 51: High-speed Camera Footage of Stents in Motion during Testing

As for the test setup, we quickly discovered that the water tight seals used between the tank and the top plate were not perfect. At low velocities, there were no issues and the system ran smoothly and was easily observable. When the motor was ramped up above about 20 Hz, the water became cloudy as it was splashing all around the open space of the tank. At about 23 Hz, the seals leaked and water began leaking onto the wood base and obscuring vision slightly through the Plexiglas window of the safety cage. While this did not affect the testing of the fixture itself, it was disappointing to see water find its way through the seals. As per our safety preparations, the electrical components of the project were kept secure and there were no additional safety concerns. In retrospect, a larger tank with a lower volume of water would allow the system to operate more smoothly.

Another objective of our project was to count the number of cycles the fixture underwent for the three week test duration, but there were electrical issues with the Hall Effect sensor. The counter did not count up at each cycle as expected and after consulting with Ben Johnson and a mechatronics professor, we came to the conclusion that the Hall Effect sensor was faulty. Since we knew we would not be testing for more than the 5 minutes, the original purpose of the cycle count system was somewhat lost, so the team decided that purchasing a new sensor would not be worth the time or cost.

Beyond these observations, the system behaved as expected. The motor was securely mounted and did not seem to move during the duration of the testing. All external hardware remained in place and the safety cage was not required to catch any loose projectiles. Overall, the testing process went smoothly without any critical failures or complications and proved that the fixture held up at the correct frequency and displacement.

13. Future Considerations

As mentioned above, the bending of the mock arteries did not behave as anticipated and the stents did not experience the complete curvature that was desired. After looking at the high speed camera footage, we observed that the stents moved with the arteries and, as a result, were not bending but merely changing orientation. The team believes that two possible solutions to this issue are to use mock arteries with a lower stiffness, or to deploy the stents closer to the hose barbs where the mock arteries are curving more drastically. We used tubing material off of McMaster-Carr which is stiffer than the mock arteries Endologix typically uses from Stratasys Direct Manufacturing. Endologix also has samples of Syndaver mock arteries that they may test, which are closer to real artery properties. Deploying the stents in the region with more curvature and using more compliant mock arteries would create curvature in the stents more accurate to *in vivo* conditions.

For the safety cage, we would suggest making each of the sides out of acrylic. The expanded steel ended up being tough to cut to specification and was more trouble to work with than any benefit it provided. The acrylic was much easier to manufacture and provided us with more assurance as to our safety in addition to giving a better view of the system.

14. Conclusion

In order to test the innovative designs for today's medical devices, several years of fatigue life must be simulated in a short period of time. For arterial stents designed by Endologix, the standard is that each design must be tested to simulate 10 years of life in an *in vivo* environment. Stents which are deployed in the renal artery region undergo continuous displacement due primarily kidney motion from respiration. Since this motion is unique to the renal artery region, a unique test method is required. As a result, the goal for our team was to design a proof of concept fatigue test method for renal artery stents which would simulate the environment and displacement of the stents for a 10 year life, over the course of three months. As this was a student project, this design was purely a proof of concept. After the project concluded, all requested materials were handed over to Endologix.

In the end, although the team was not able to test the fixture for three weeks continuously as originally planned, we believe that the project was a success. The five-minute test at full speed showed promising results as there were no critical failures in the fixture. The high speed video of the shaft displacement showed the success of the motor linkage design in displacing the desired 24 mm and replicating the Bose machine's functionality. Although the high speed video of stents showed that they did not bend as much as expected, it showed consistent displacement at high velocity and no stent migration in the mock artery.

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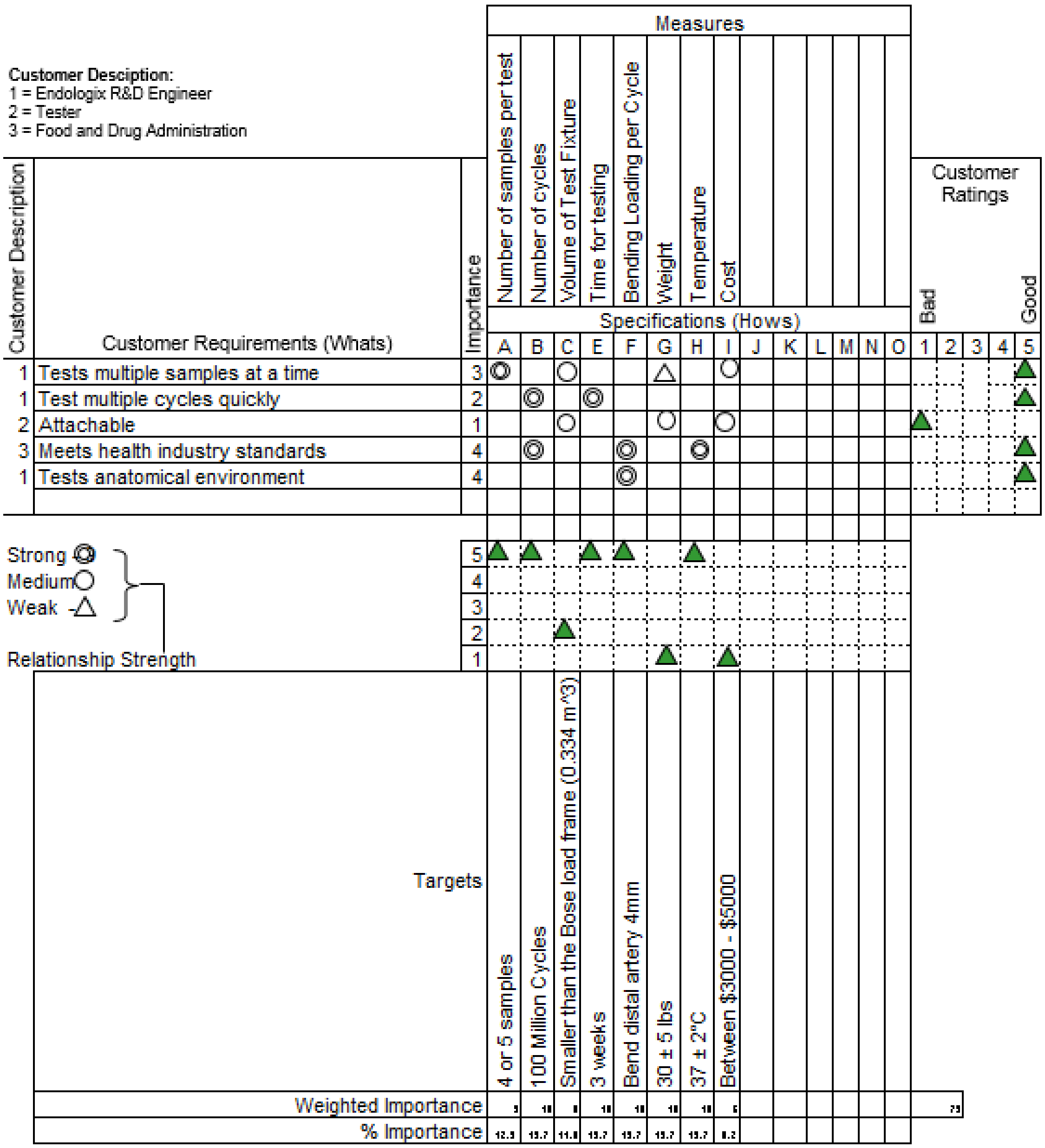
Appendices

Appendix A

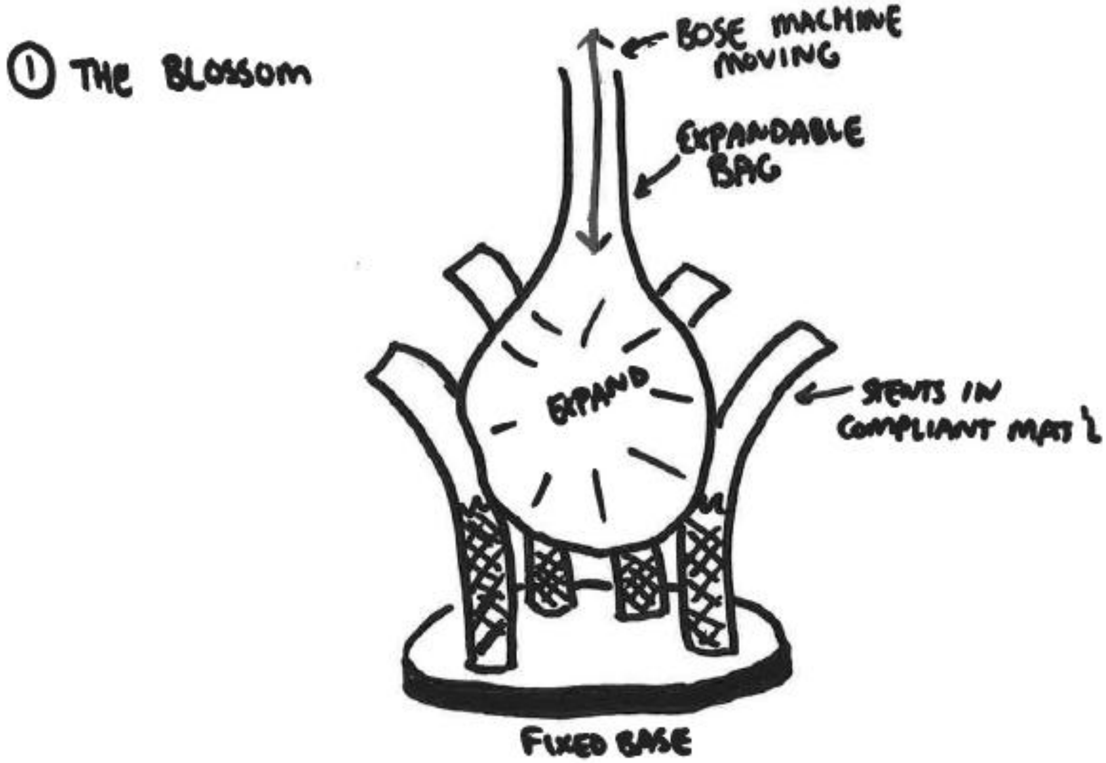
QFD – Quality Function Deployment

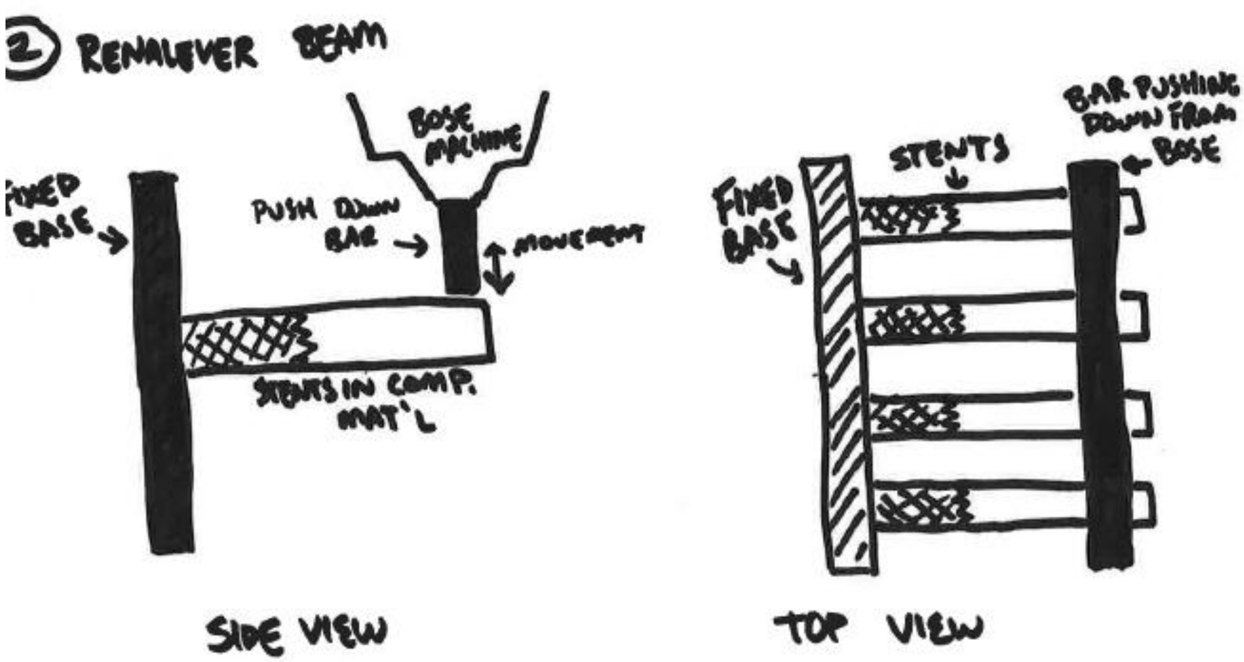


ElectroForce 9400 Mutiaxial Peripheral Stent Test Instrument

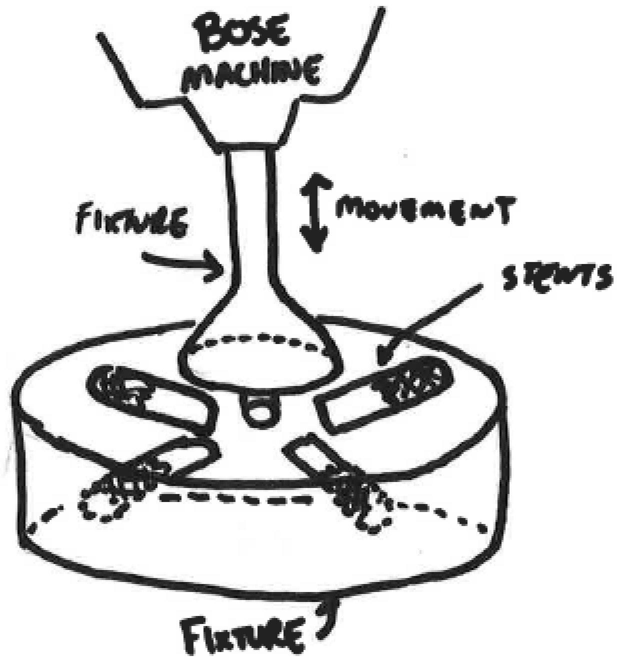
Appendix B

Concept Ideas

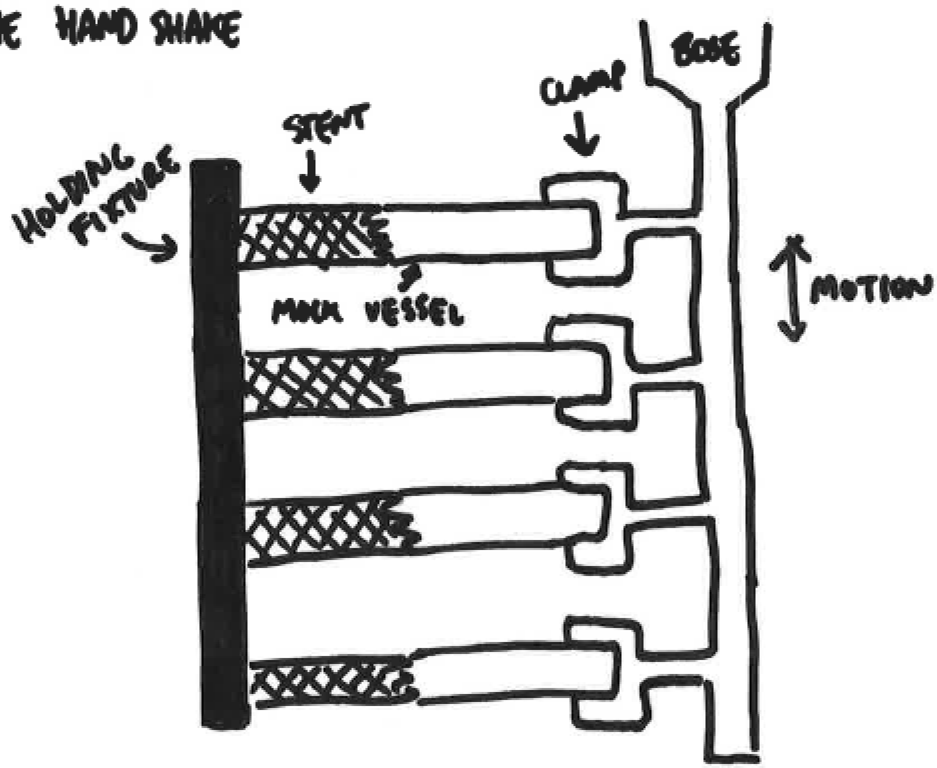


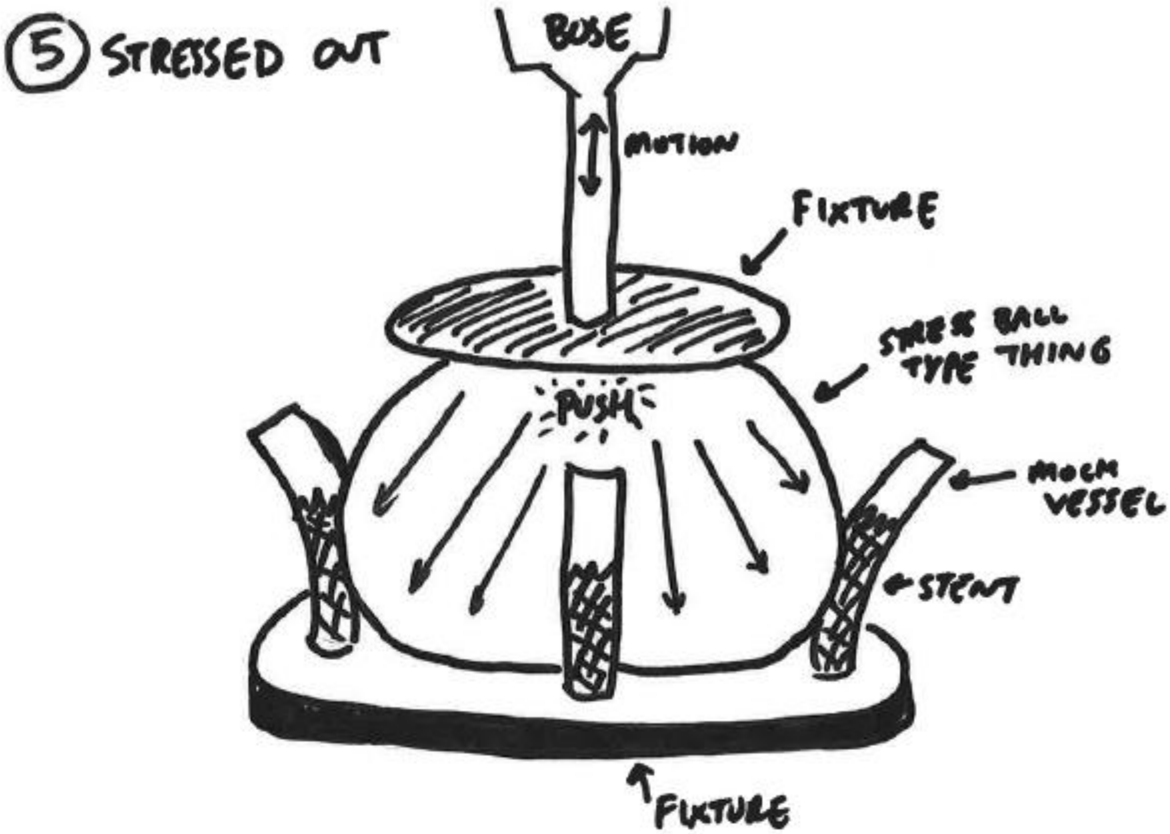


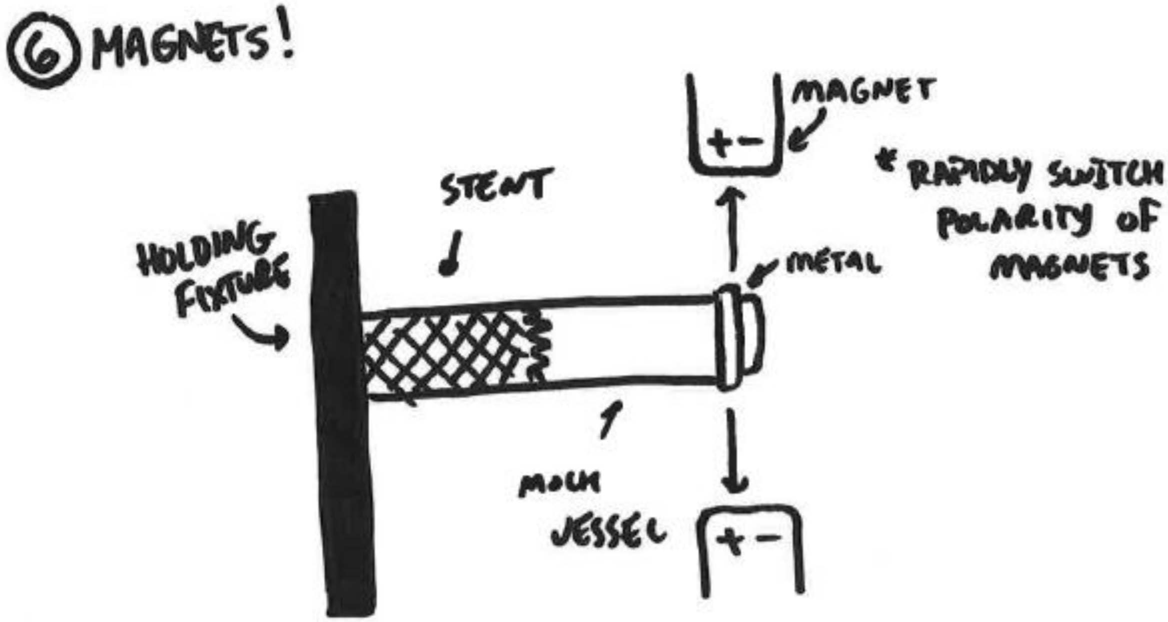
③ THE OCTOPUS



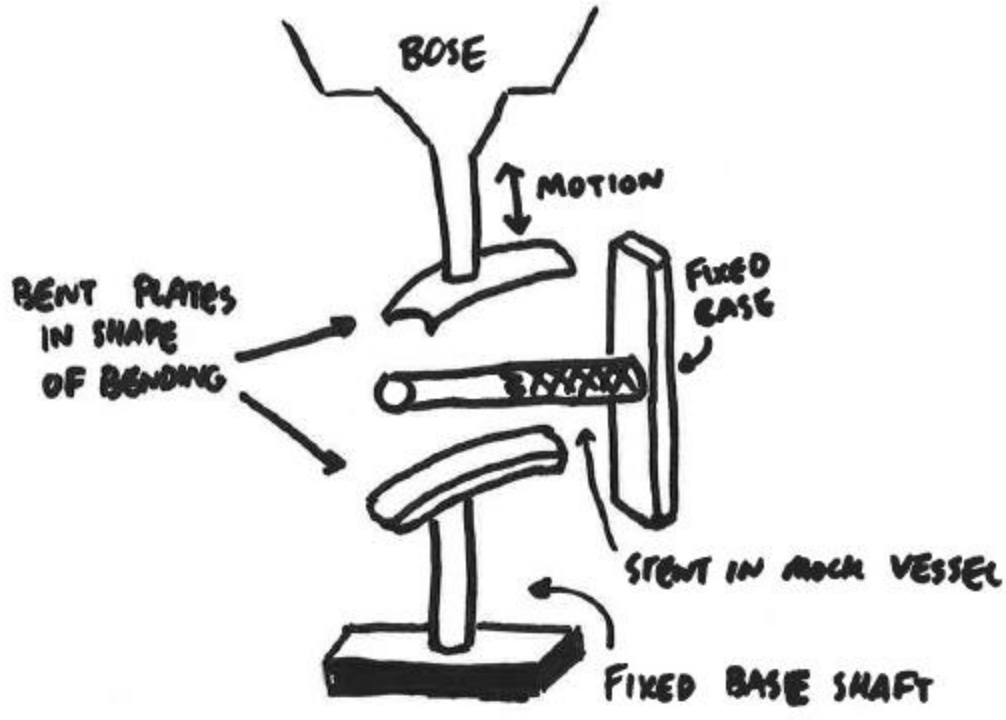
④ THE HAND SHAKE



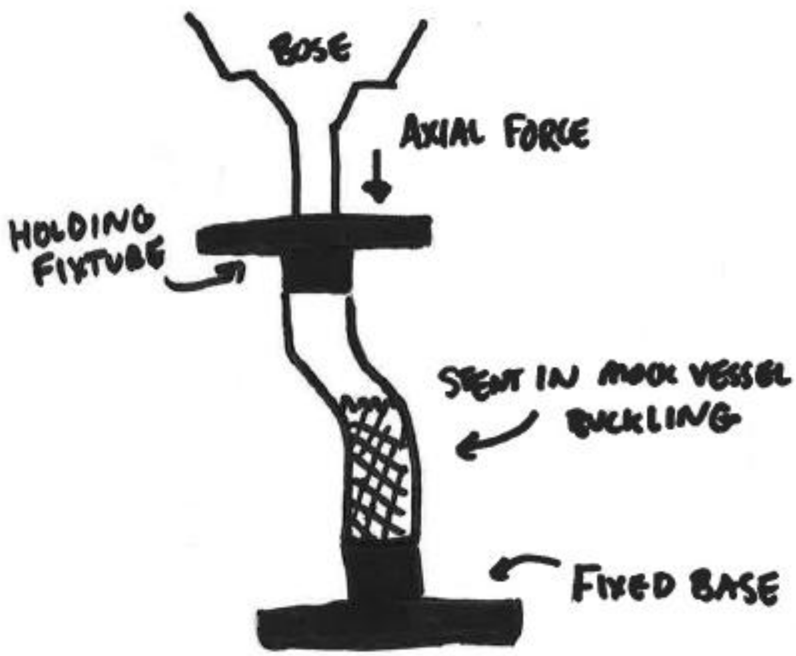

5 STRESSED OUT
BOSE
MOTION
FIXTURE
STRESS BALL TYPE THING
PUSH
MOCK VESSEL
STENT
FIXTURE


6 MAGNETS!
MAGNET
+ -
* RAPIDLY SWITCH POLARITY OF MAGNETS
STENT
METAL
HOLDING FIXTURE
MOCK VESSEL
+ -

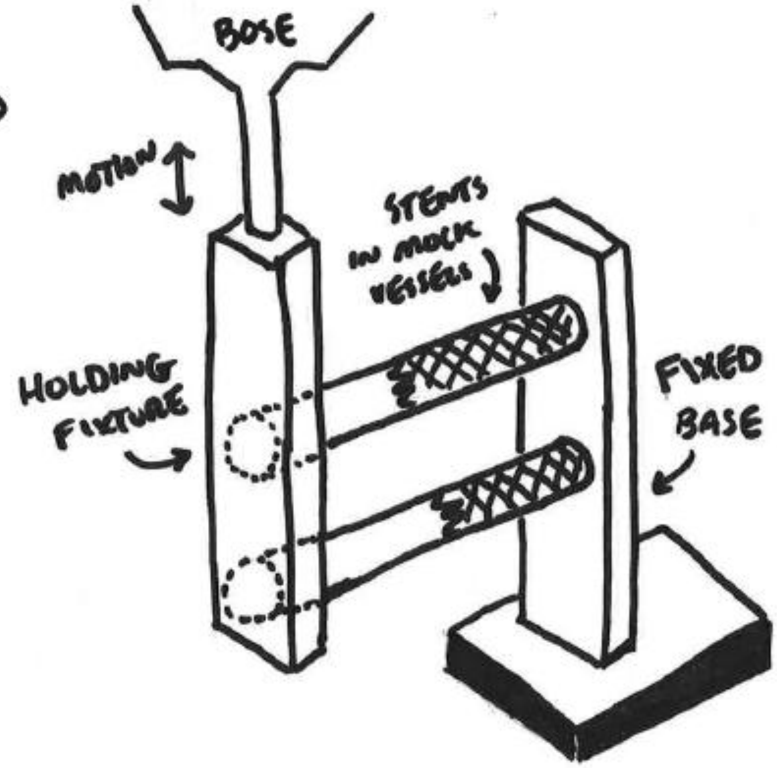
⑦ BENT PLATE



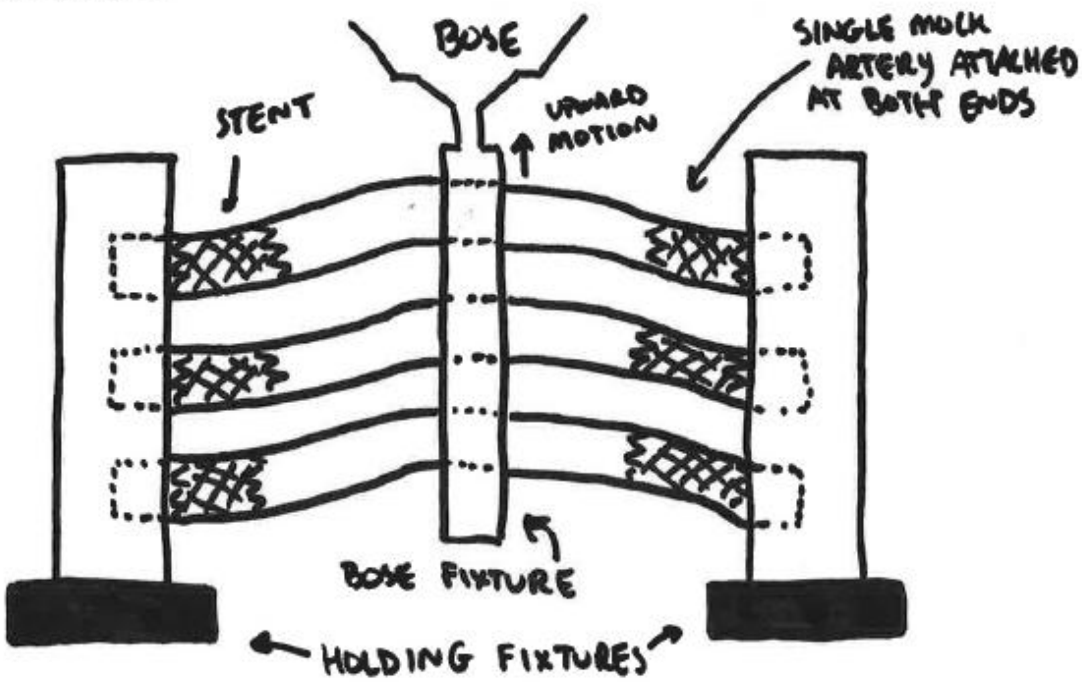
⑧ BUCKLE UP



9 HOLE AND SOUND

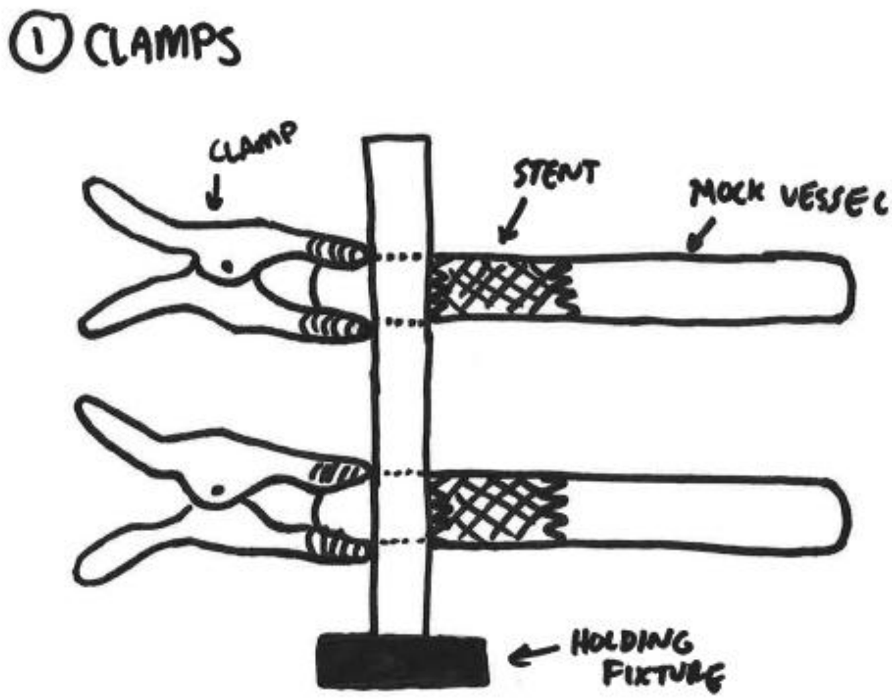


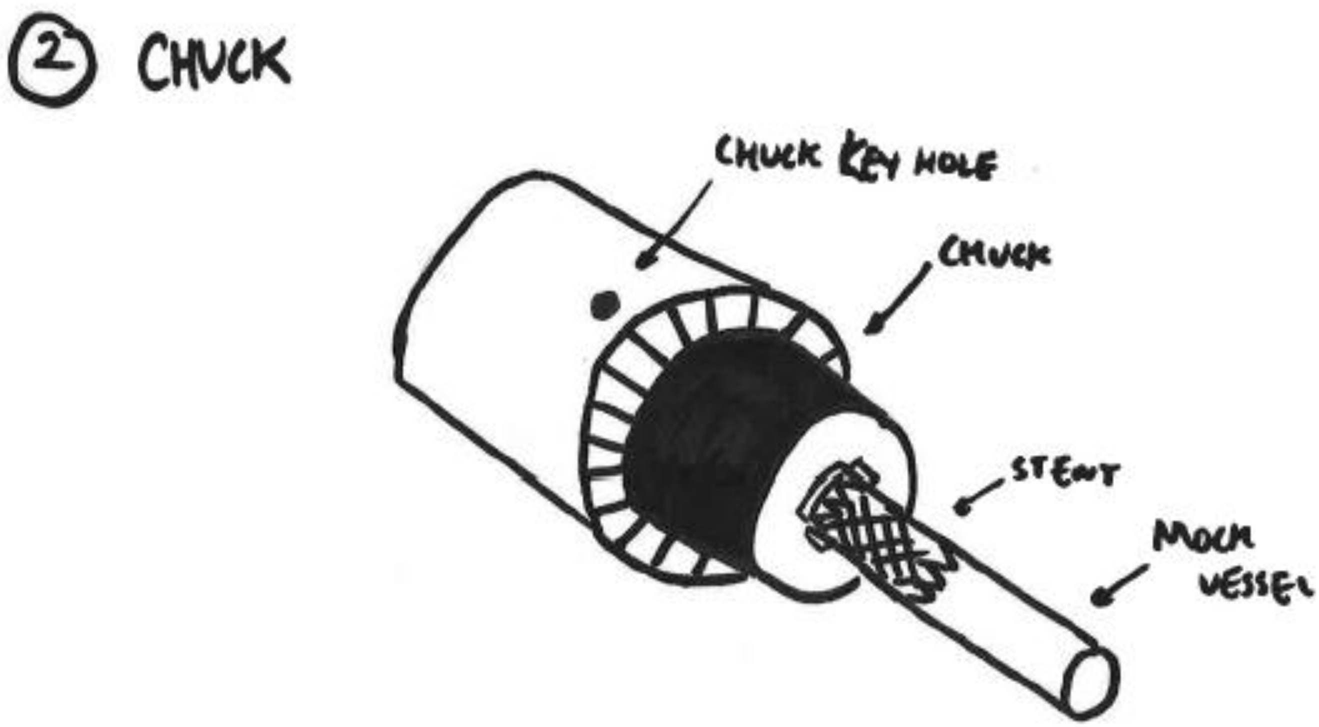
IDEAL DESIGN



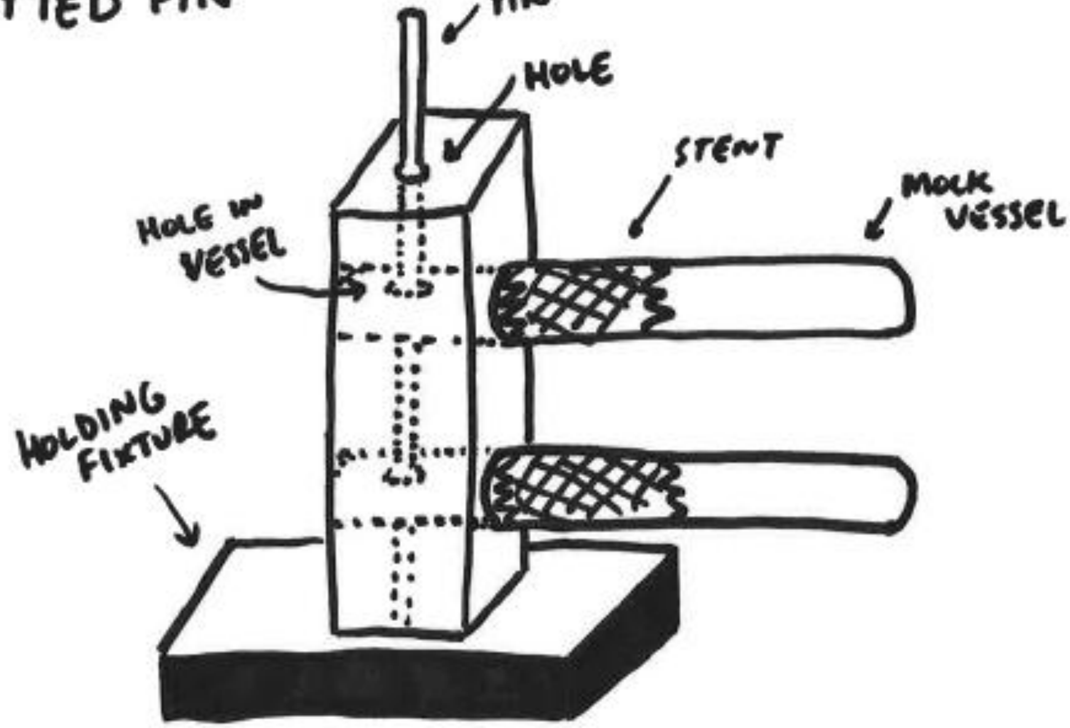
Appendix C

Component Designs

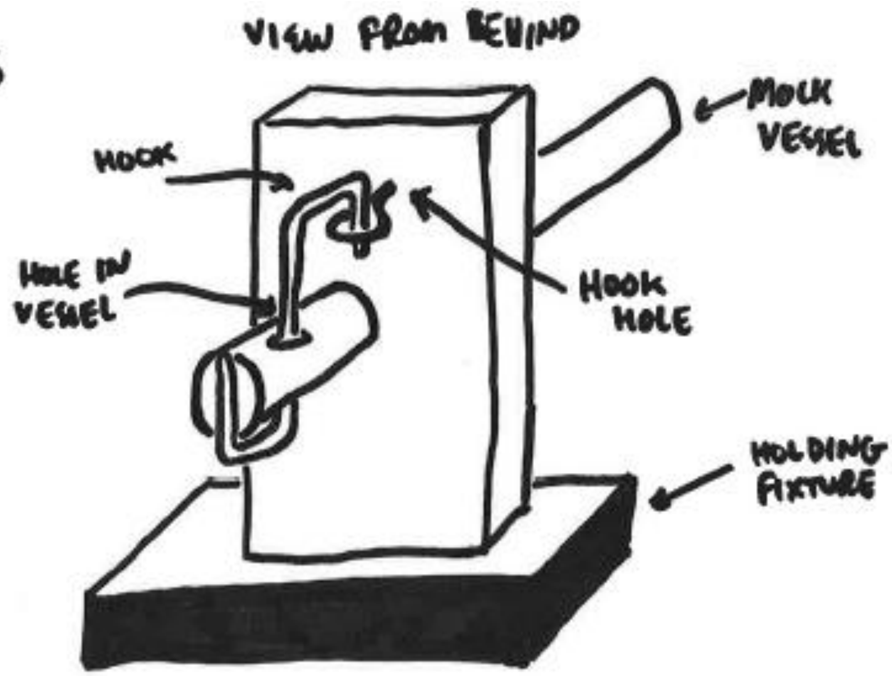




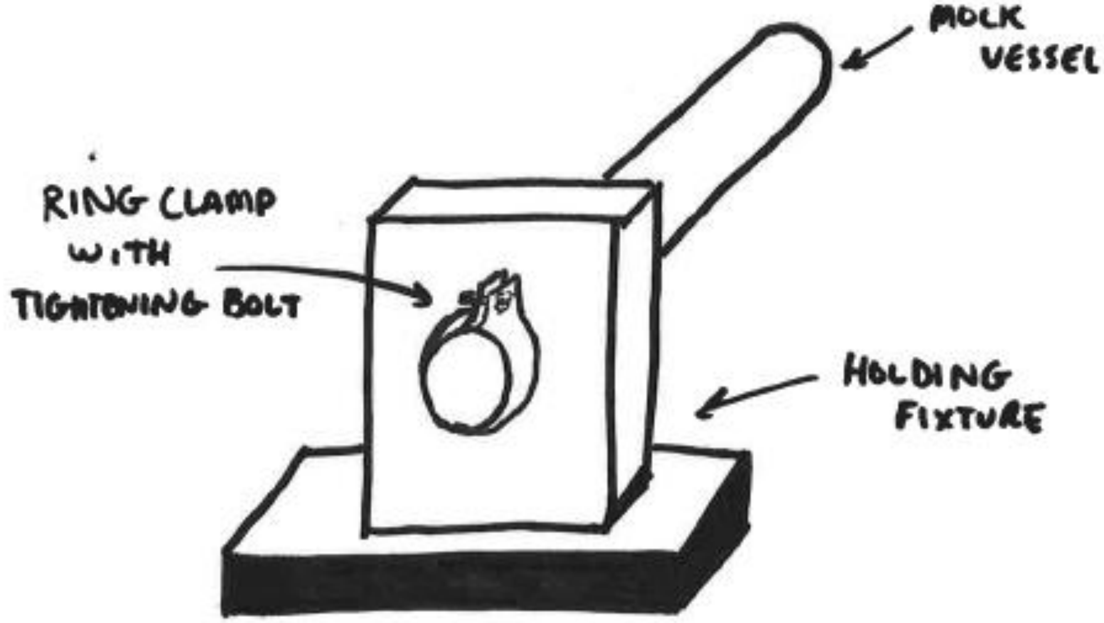
3 SLOTTED PIN



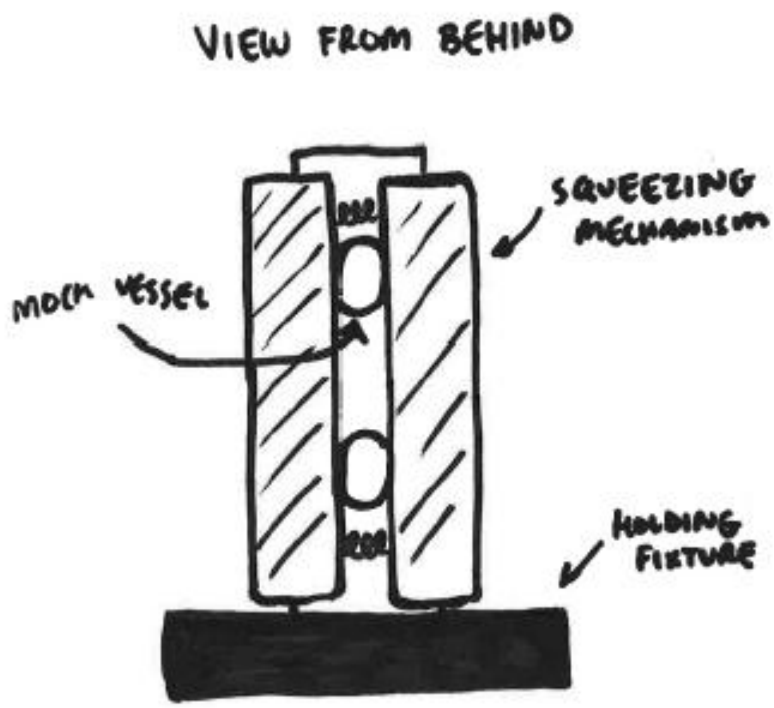
4 HOOKS



⑤ TIE DOWN



⑥ SQUEEZE

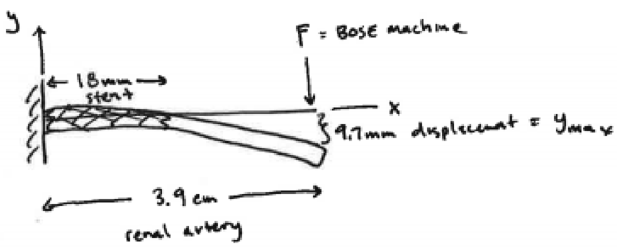


Appendix D

Preliminary Analysis Calculations

There are more stent fractures in the LRA than RRA, therefore we'll model our testing off of the LRA. LRA lengths average 3.9 ± 1.3cm. Average displacement of the distal renal artery equal 9.7 ± 3.6 mm. 18mm stents are the standard implant size for renal stenting. We will use average length for both artery & displacement values in our preliminary calculations.

CANTILEVER BEAM - END LOAD



$$y_{max} = \frac{-F\ell^3}{3EI}$$

$$9.7mm = \frac{-F(3.9cm)^3}{3EI}$$

$$F = -490.6EI$$

$$y = \frac{Fx^2}{6EI}(x - 3\ell)$$

$$y = \frac{-490.6EI\,x^2}{6EI}(x - 3\ell)$$

$$y = -81.76(18mm)^2(18mm - 3(3.9cm))$$

$$y = 0.00262m = 2.62mm$$
= Displacement at end of stent

Approximate Bending Angle

$$\tan\theta = \frac{2.62}{18}$$

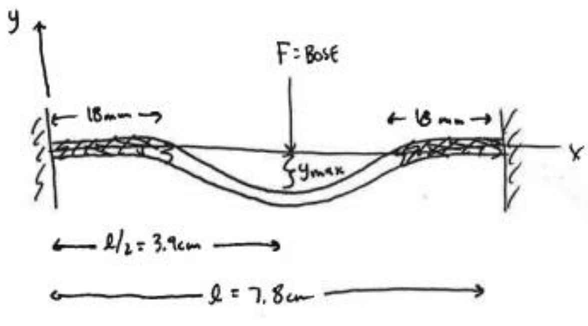
$$\theta = 8.28°$$

θ = 8.28° is much higher than the average bending angle of the LRA, 3.9° & 2.2° for respiration & expiration respectively. Even the max bending angle recorded was only 6.5°.

However, the mock artery will not bend linearly so this approximation is an overestimate. The bending angle in the actual test will be less than this value due to the elastic modulus of the material & stent.

We need to compare the bending angles in Cantilever Beam and Fixed Supports to see how our chosen concept relates to cantilever bending.

FIXED SUPPORTS - CENTER LOAD



DEFLECTION OF STENTS:

$$y_{max} = \frac{-Fl^3}{192EI}$$

$$9.7mm = \frac{-F(7.8\,cm)^3}{192EI}$$

$$-3924.5 = F$$

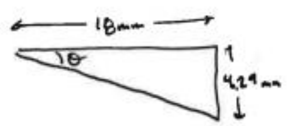
$$y = \frac{Fx^2}{48EI}(4x - 3l)$$

$$y = \frac{-3924.5EI\,(18mm)^2}{48EI}\left(4(18mm) - 3(7.8cm)\right)$$

$y = 0.00429m = 4.29mm$

= Displacement at end of each stent

Approximate bending angle:



$\theta = 13.4°$

This bending is way too much, even when taking into consideration that it'll bend less with a stent in the artery. We need to scale down the displacement to match cantilever motion. We should take the displacent, y, from the cantilever calculation and use it above to back calculate out an appropriate displacement to run this model at.

Using $y = 2.62mm$ from cantilever calculation:

$$y = \frac{Fx^2}{48EI}(4x - 3l)$$

$$\frac{48(2.62mm)EI}{(18mm)^2(4(18mm) - 3(7.8cm))} = F$$

$$F = -2395.976EI$$

↓

$$y_{max} = \frac{-Fl^3}{192EI}$$

$$y_{max} = \frac{2395.976EI(7.8cm)^3}{192EI}$$

$y_{max} = 0.00592m = 5.92mm$
= BOSE machine displacement

5.92mm displacement on the "Fixed Supports" model is the equivalent of 9.7mm displacement on the "Cantilever Beam" model.

We'll develop a MATLAB and/or Excel file to run this calculation for testing varying stent & artery lengths.

Appendix E

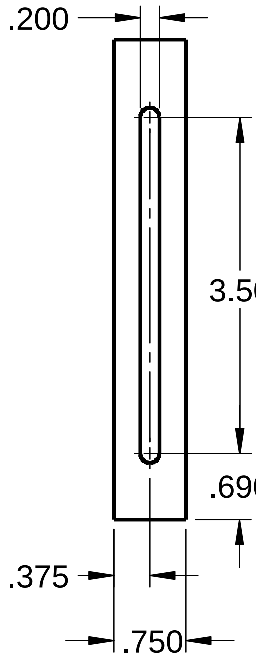
Drawings and Specification Sheets

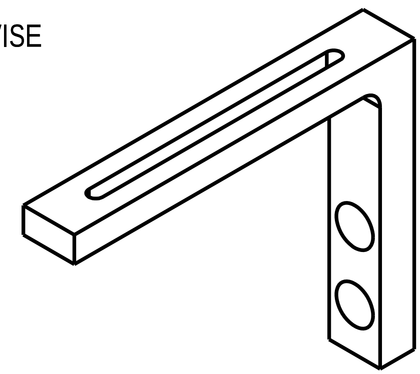
Parts List			
Assembly	**Subassembly**	**Part #**	**Part Description**
CPR	Fixture	01	Top Bracket
		02	Bottom Bracket
		03	Upright
		04	Spider
		05	Hose Fittings
CPR	Linkage	01	Shaft Collar
		02	Collar Face
		03	Link AB
		04	Displacement Shaft
		05	Retaining Plate
		06	Displacement Shaft Spider Clamp

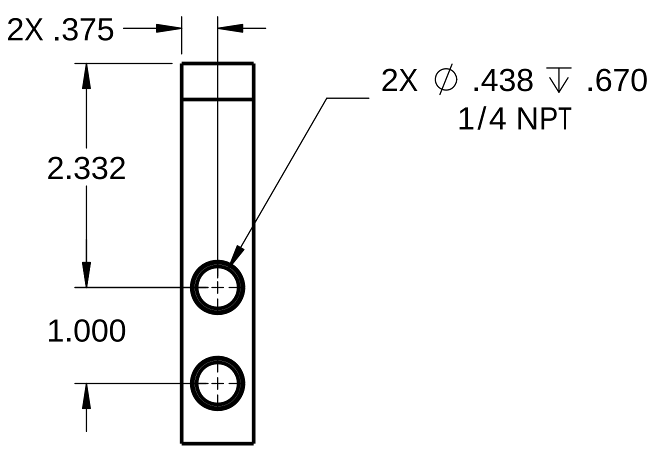
REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
A	TOP BRACKET	1/31/2015	
B	ADDED RADIUS TO REFLECT ACTUAL MATERIAL	6/04/15	JLH

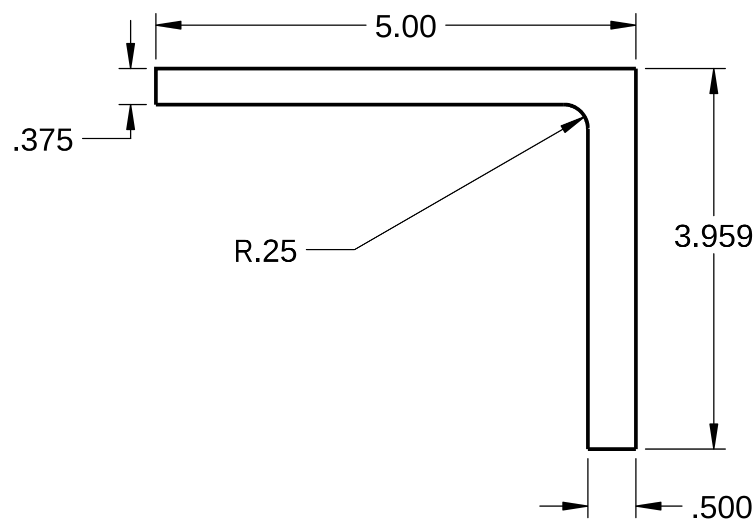
MATERIAL: 6061 ALUMINUM

ALL TOLERANCES UNLESS OTHERWISE SPECIFIED:
.XX= ±.05
.XXX= ±.005



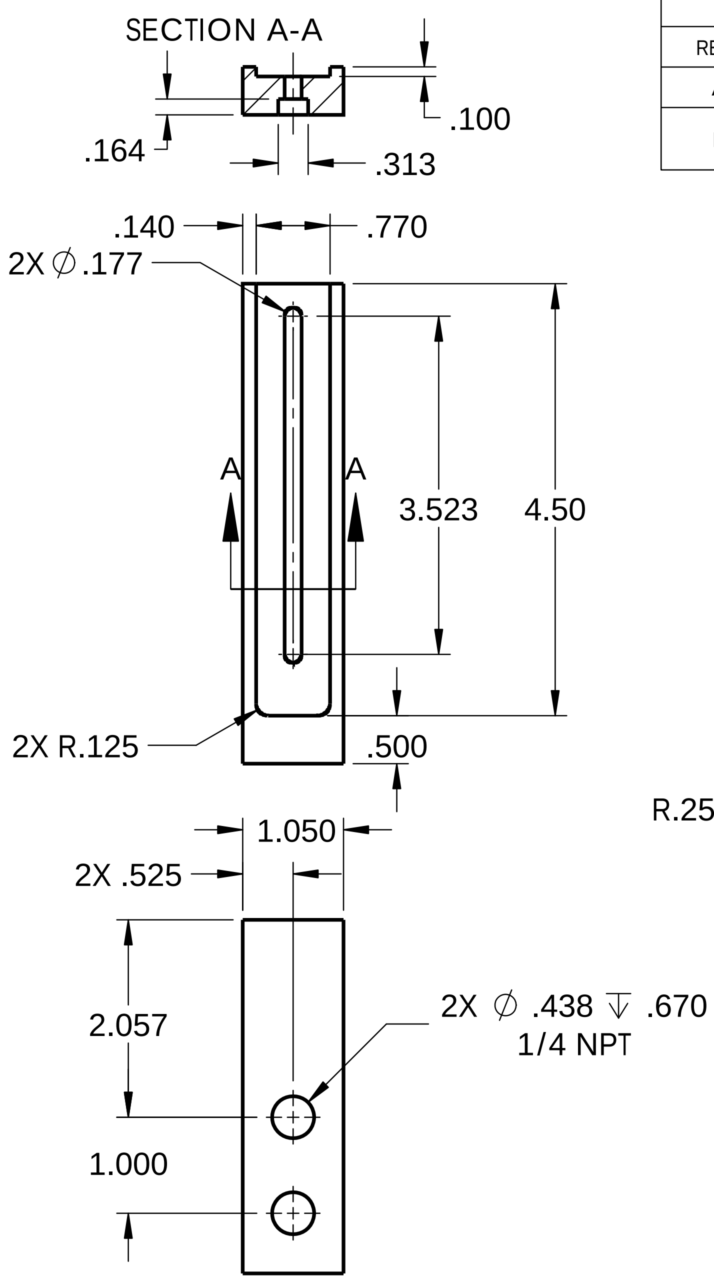


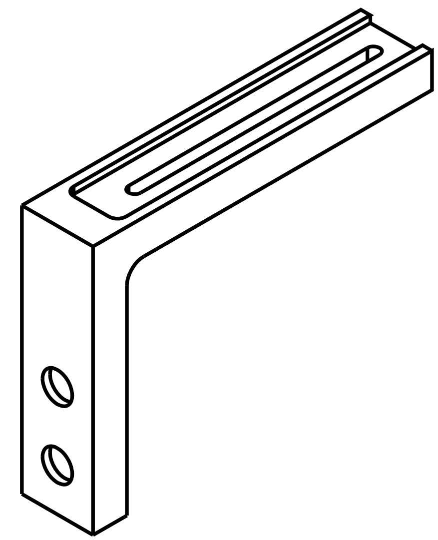


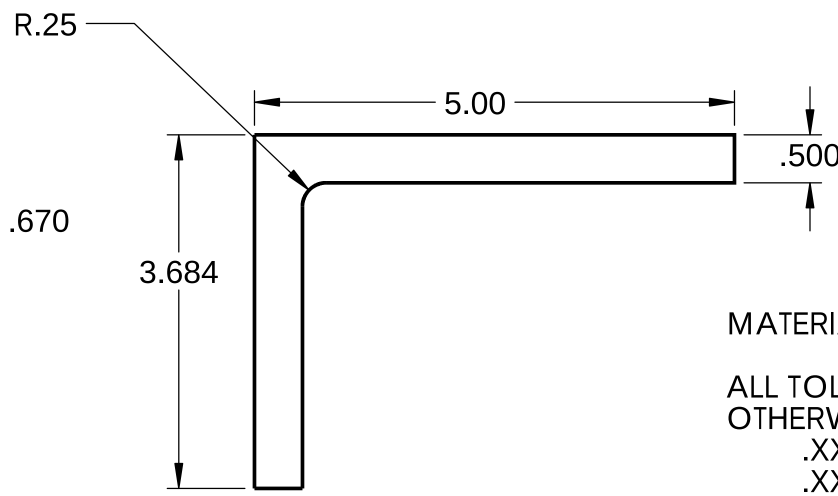


CP Renal Stent Senior Project	Assembly: Fixture	Part Name: Top Bracket		Drwn. By: Munir Eltal
	Part. #: CPR-Fixture-01	Date: 01/31/15	Scale: 1:2	Chkd. By: JEN HAWTHORNE

REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
A	BOTTOM BRACKET	1/31/2015	
B	ADDED RADIUS TO REFLECT ACTUAL MATERIAL AND ADDED COUNTERBORE FOR SMALL SLOT	6/04/15	JLH





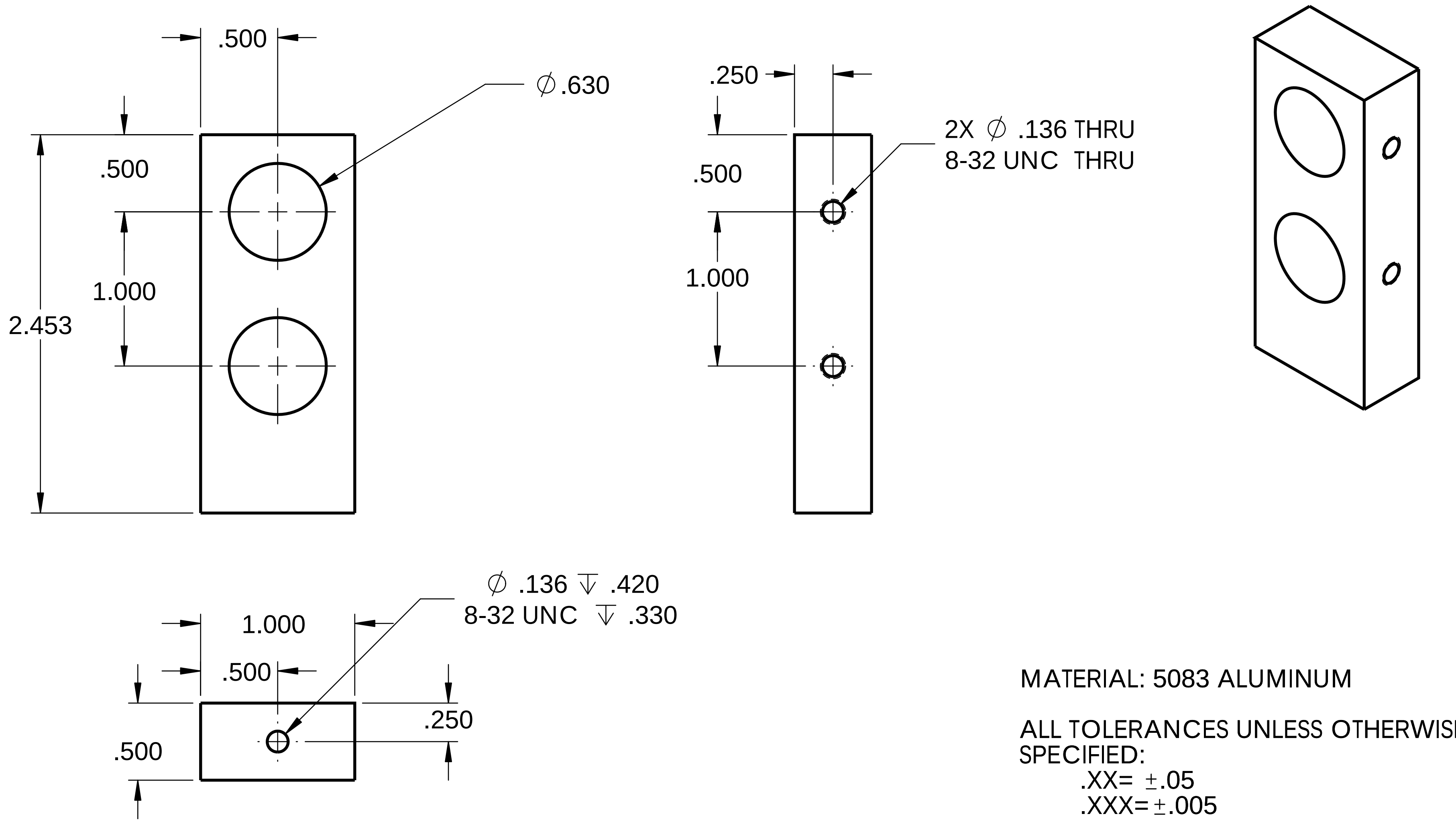


MATERIAL: 6061 ALUMINUM

ALL TOLERANCES UNLESS OTHERWISE SPECIFIED:
.XX= ±.05
.XXX= ±.005

CP Renal Stent Senior Project	Assembly: Fixture	Part Name: Bottom Bracket		Drwn. By: Munir Eltal
	Part. #: CPR-Fixture-02	Date: 01/31/15	Scale: 1:2	Chkd. By: JEN HAWTHORNE

REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
A	INITIAL PROTOTYPE RELEASE	1/31/15	B. C.
B	DIMESNIONS CHANGED AND SET SCREW HOLES ADDED	3/01/15	JLH



MATERIAL: 5083 ALUMINUM

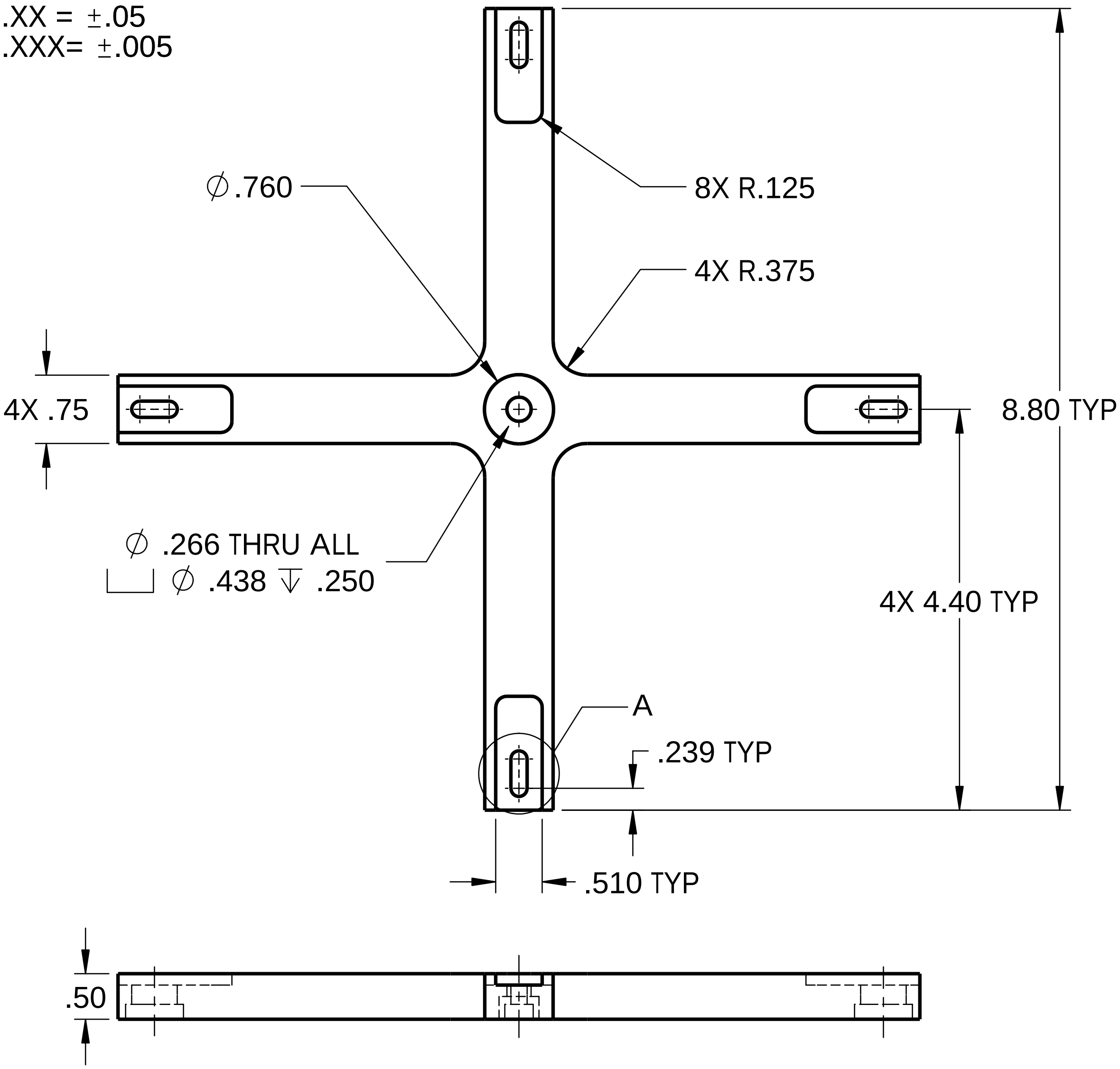
ALL TOLERANCES UNLESS OTHERWISE SPECIFIED:
.XX= ±.05
.XXX=±.005

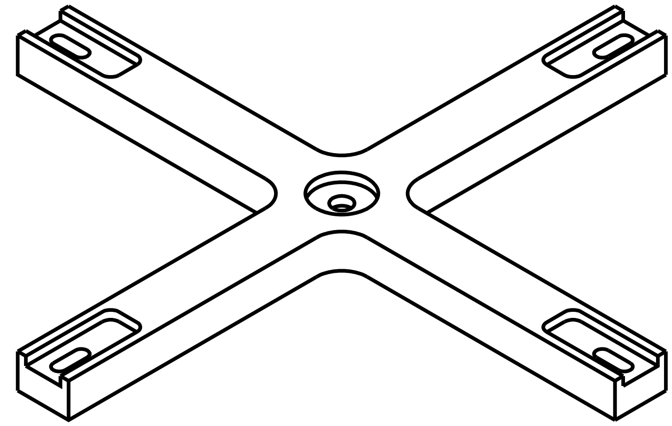
CP Renal Stent Senior Project	Assembly: FIXTURE	Part Name: UPRIGHTS		Drwn. By: BRADEN COOPER
	Part. #: CPR-FIXTURE-03	Date: 1/31/15	Scale: 1:2	Chkd. By: JEN HAWTHORNE

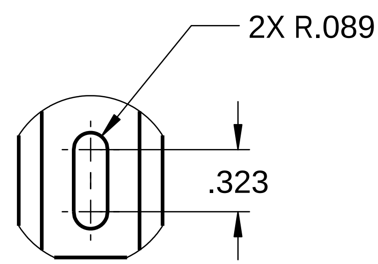
MATERIAL: 5083 ALUMINUM

ALL TOLERANCES UNLESS
OTHERWISE SPECIFIED:
.XX = ±.05
.XXX= ±.005

REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
A	INITIAL PROTOTYPE RELEASE	1/31/15	B. C.
B	SLOTS FOR UPRIGHTS SHORTENED	5/07/15	J.H.





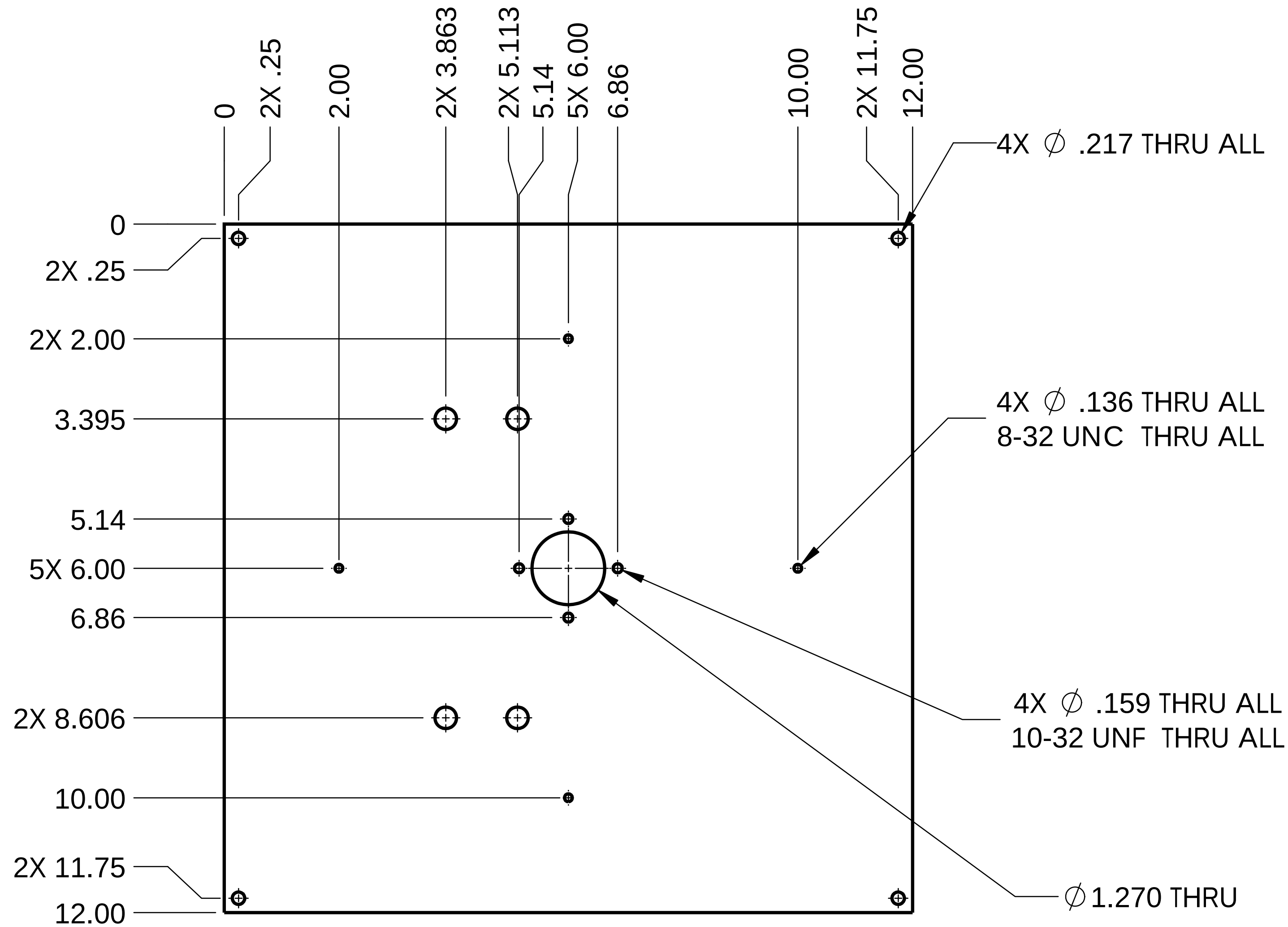


DETAIL A
SCALE 1 : 1

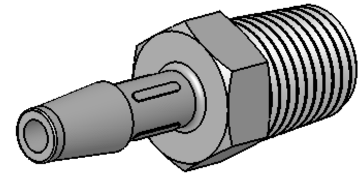
CP Renal Stent Senior Project	Assembly: FIXTURE	Part Name: CUSTOM SPIDER BAR		Drwn. By: BRADEN COOPER
	Part. #: CPR-FIXTURE-04	Date: 1/31/15	Scale: 1:2	Chkd. By: JEN HAWTHORNE

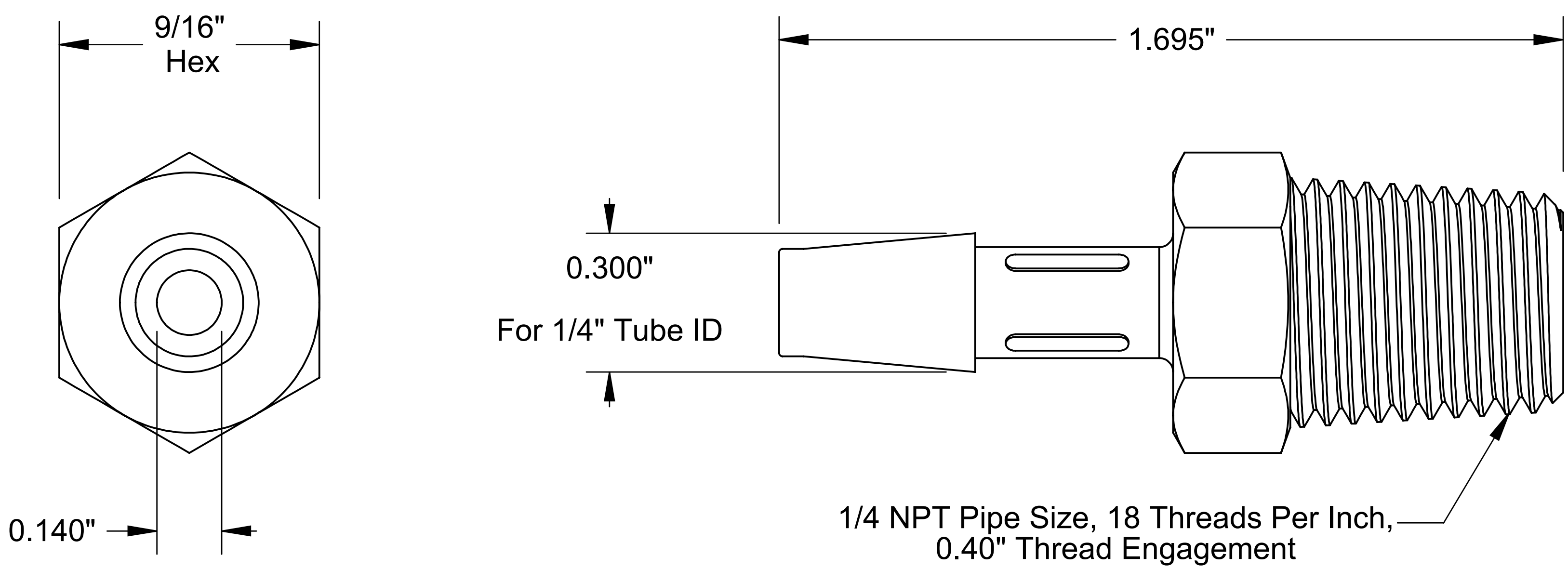
MATERIAL: 5086 ALUMINUM
ALL TOLERANCES UNLESS OTHERWISE SPECIFED:
.XX= .05
.XXX= .005

REVISIONS			
REV.	DESCRIPTION	DATE	APPROVED
A	Top Plate	4/07/2015	
B	ADDED HOLES FOR MOTOR BRACKETS	5/01/15	JLH



CP Renal Stent Senior Project	Assembly: Fixture	Part Name: TOP PLATE	Drwn. By: JEN HAWTHORNE
	Part. #: CPR-FIXTURE-05	Date: 4/07/15 — Scale: 1:2	Chkd. By:



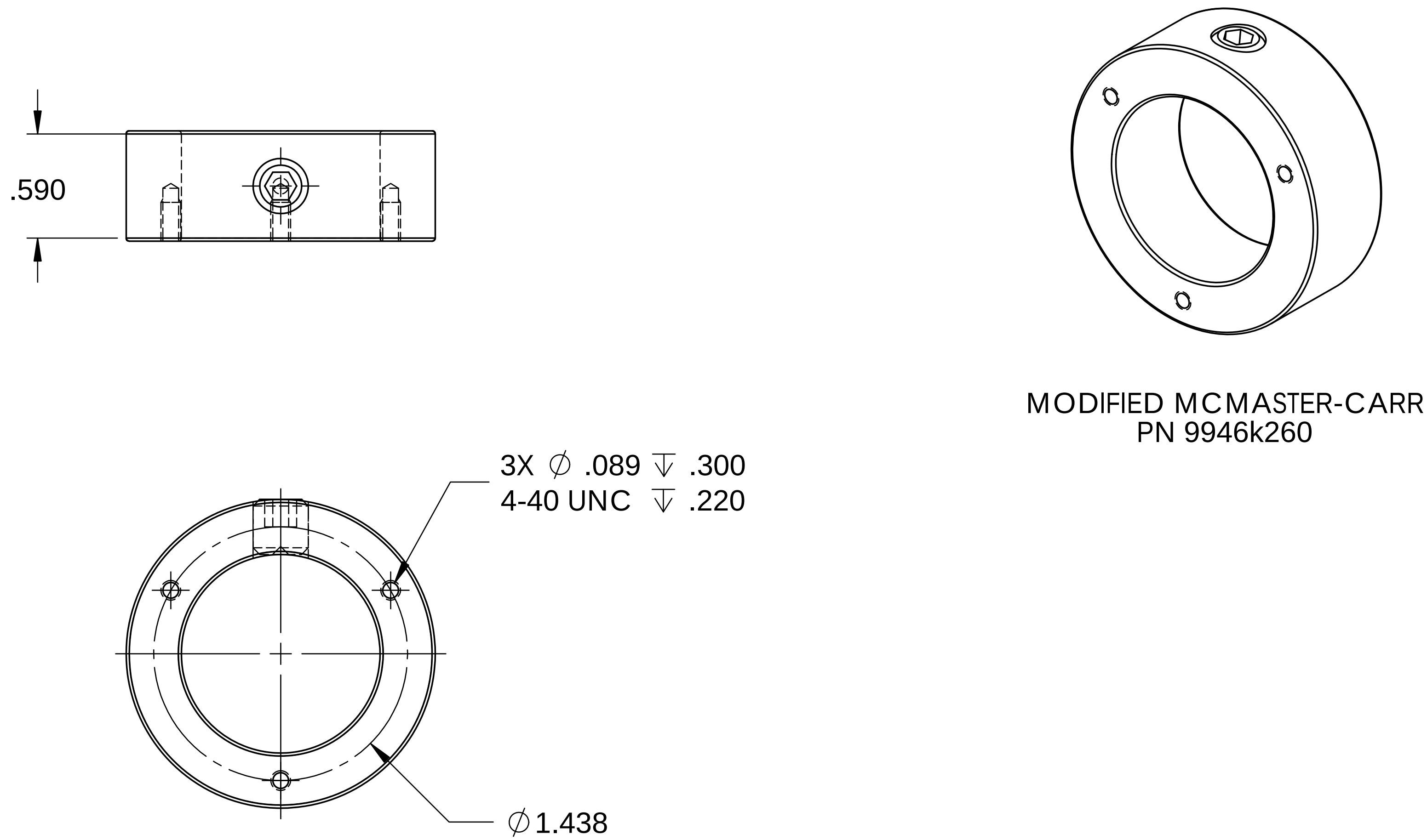


McMASTER-CARR® CAD

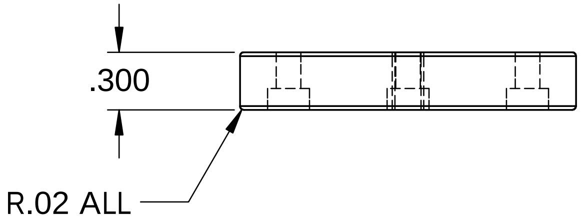
PART NUMBER **2808K27**

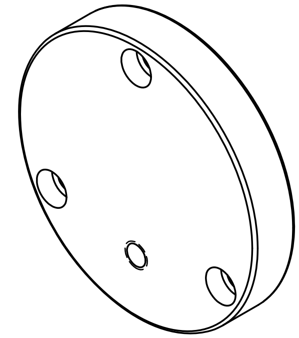
http://www.mcmaster.com

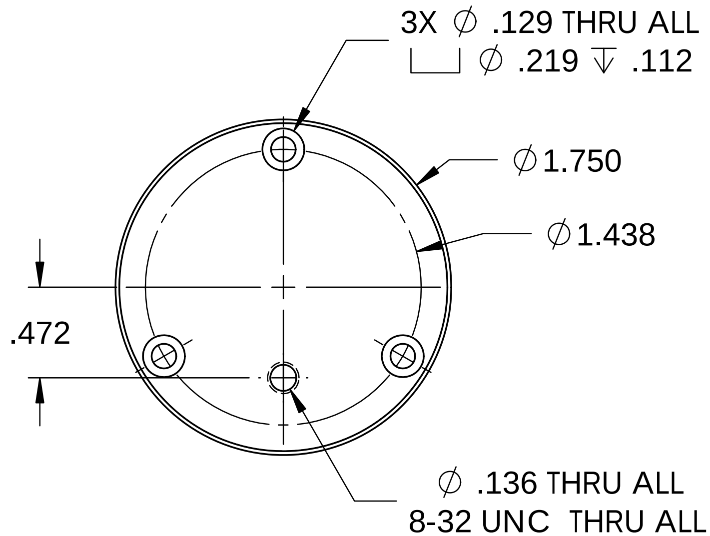
Super-Flow Polyethylene
Barbed Straight Adapter



CP Renal Stent Senior Project	Assembly: LINKAGE	Part Name: MOTOR SHAFT COLLAR		Drwn. By: ASHLEY SCHAEFER
	Part. #: CPR-LINKAGE-01	Date: 2/1/15	Scale: 1:1	Chkd. By: JEN HAWTHORNE



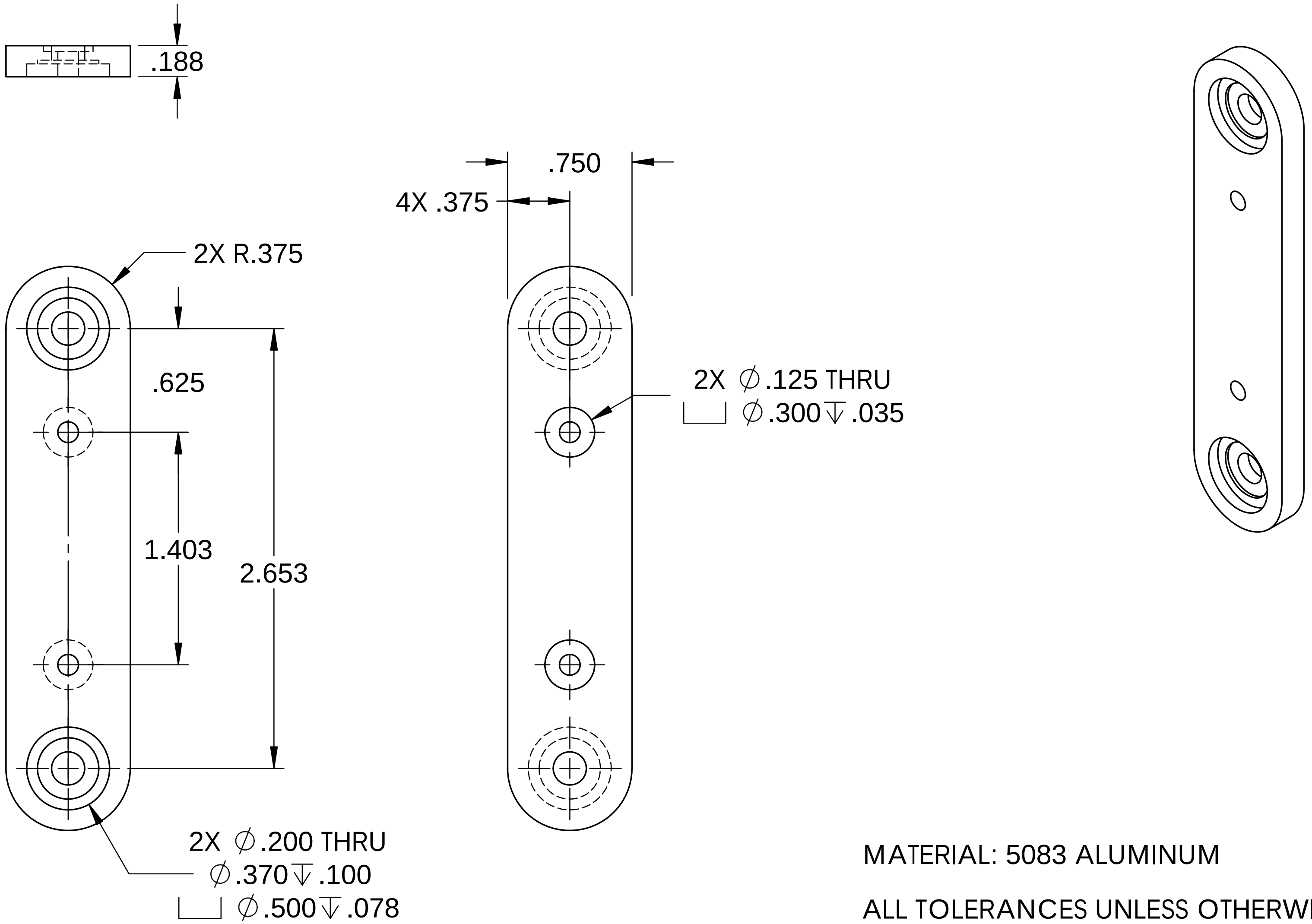




MATERIAL: 5083 ALUMINUM

ALL TOLERANCES UNLESS OTHERWISE SPECIFIED:
.XX= ±.05
.XXX=±.005

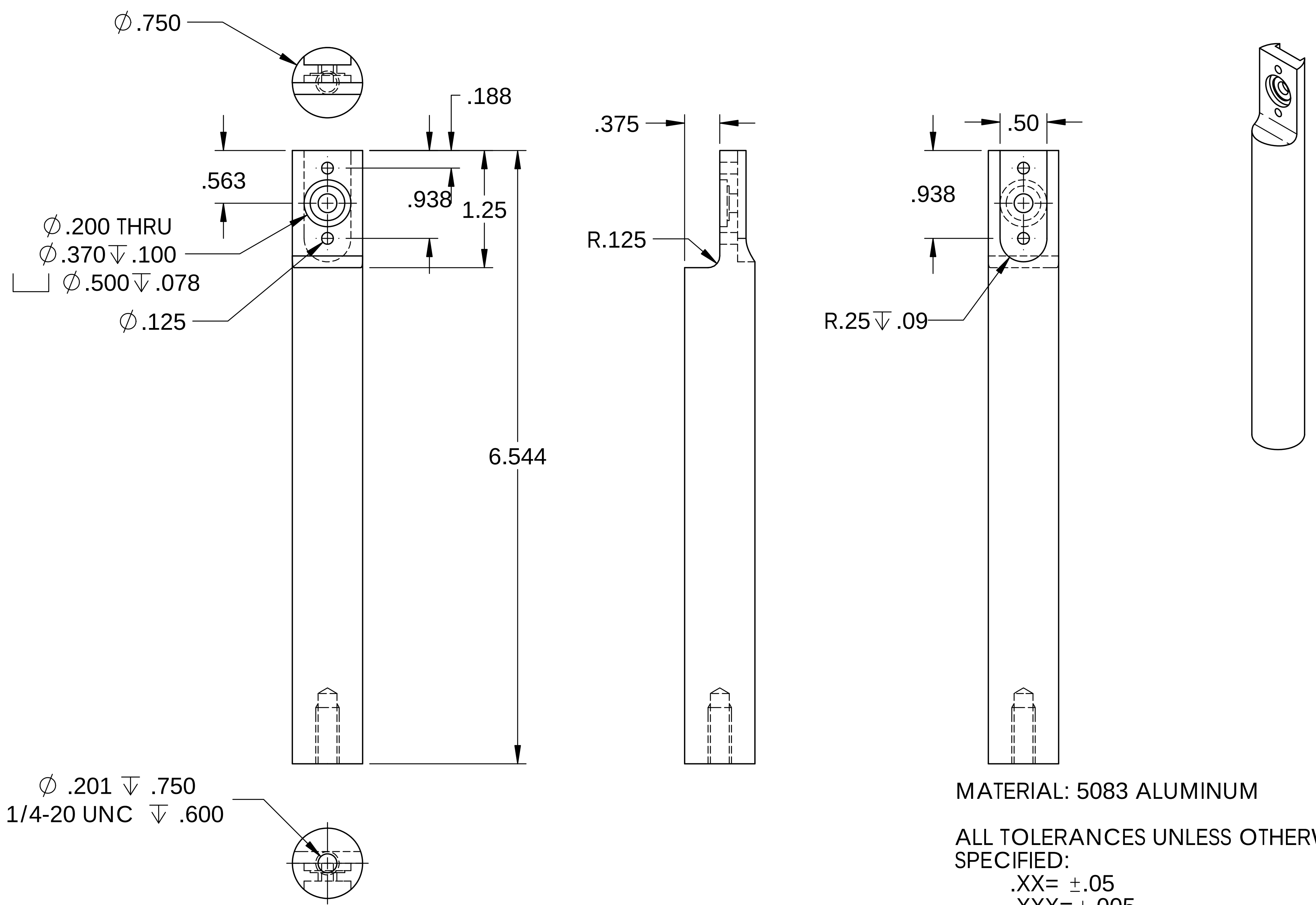
CP Renal Stent Senior Project	Assembly: LINKAGE	Part Name: MOTOR SHAFT FACE	Drwn. By: ASHLEY SCHAEFER
	Part. #: CPR-LINKAGE-02	Date: 2/1/15 Scale: 1:1	Chkd. By: JEN HAWTHORNE



MATERIAL: 5083 ALUMINUM

ALL TOLERANCES UNLESS OTHERWISE SPECIFIED:
.XX= ±.05
.XXX= ±.005

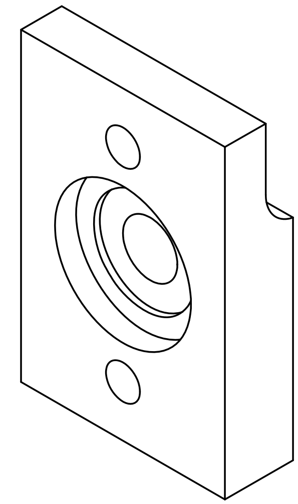
CP Renal Stent Senior Project	Assembly: LINKAGE	Part Name: LINK AB		Drwn. By: ASHLEY SCHAEFER
	Part. #: CPR-LINKAGE-03	Date: 2/1/15	Scale: 1:1	Chkd. By: JEN HAWTHORNE

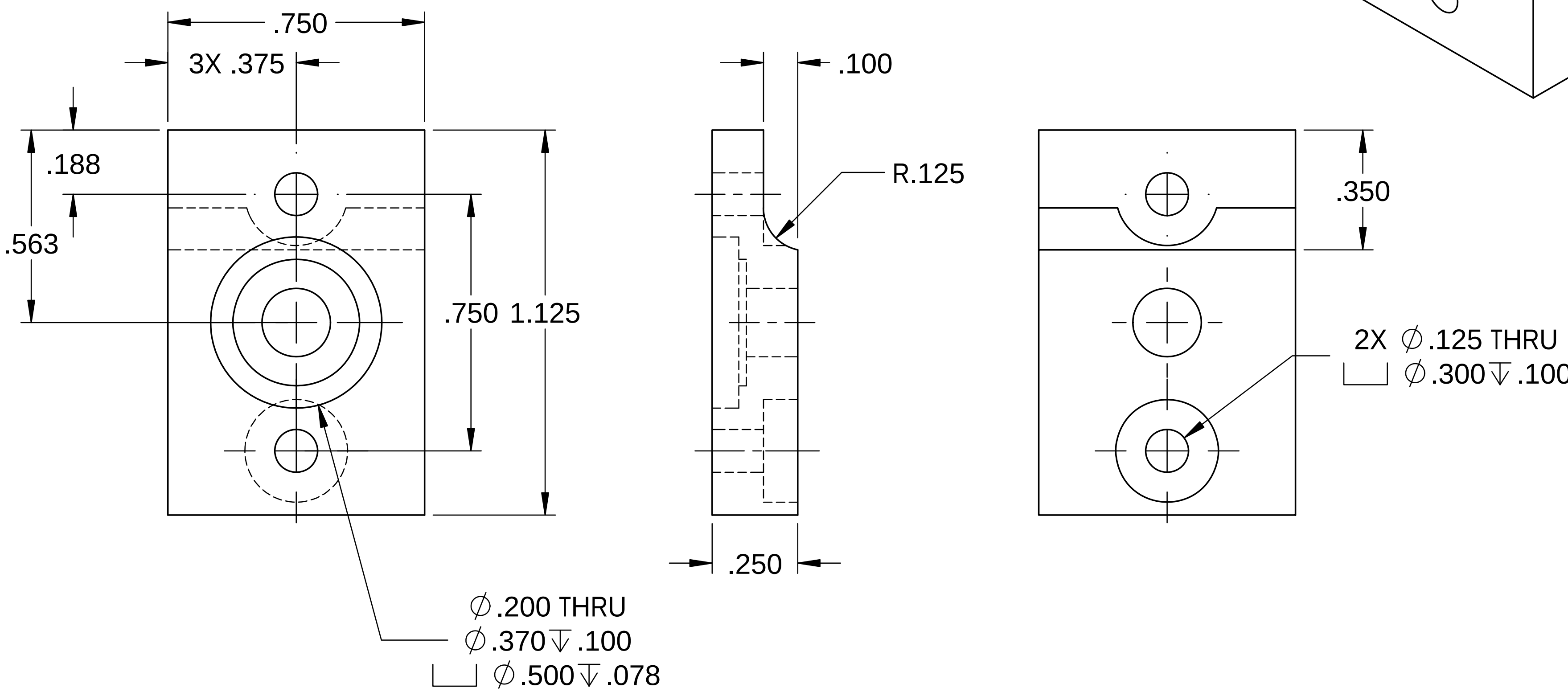


CP Renal Stent Senior Project	Assembly: LINKAGE	Part Name: DISPLACEMENT SHAFT			Drwn. By: ASHLEY SCHAEFER
	Part. #: CPR-LINKAGE-04	Date: 2/1/15		Scale: 2:3	Chkd. By: JEN HAWTHORNE

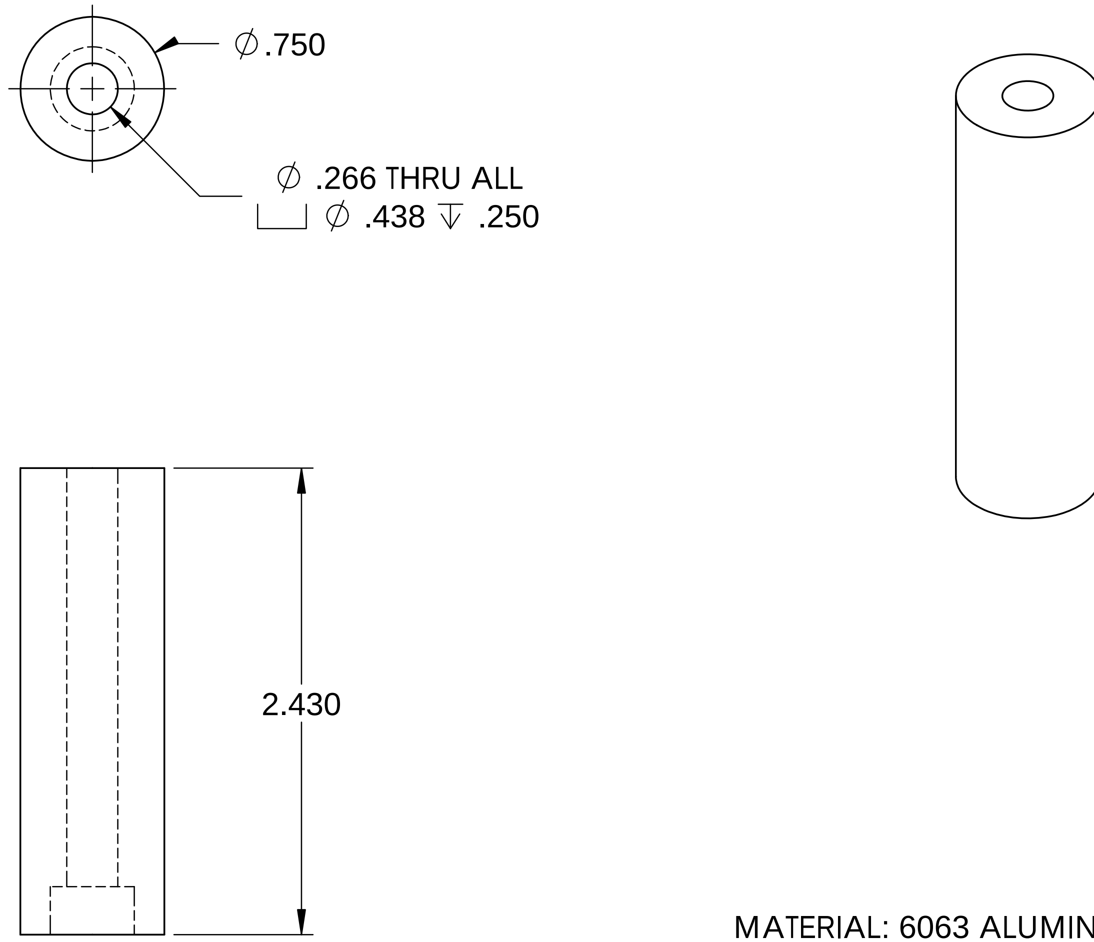
MATERIAL: 5083 ALUMINUM

ALL TOLERANCES UNLESS OTHERWISE
SPECIFIED:
.XX= ±.05
.XXX=±.005





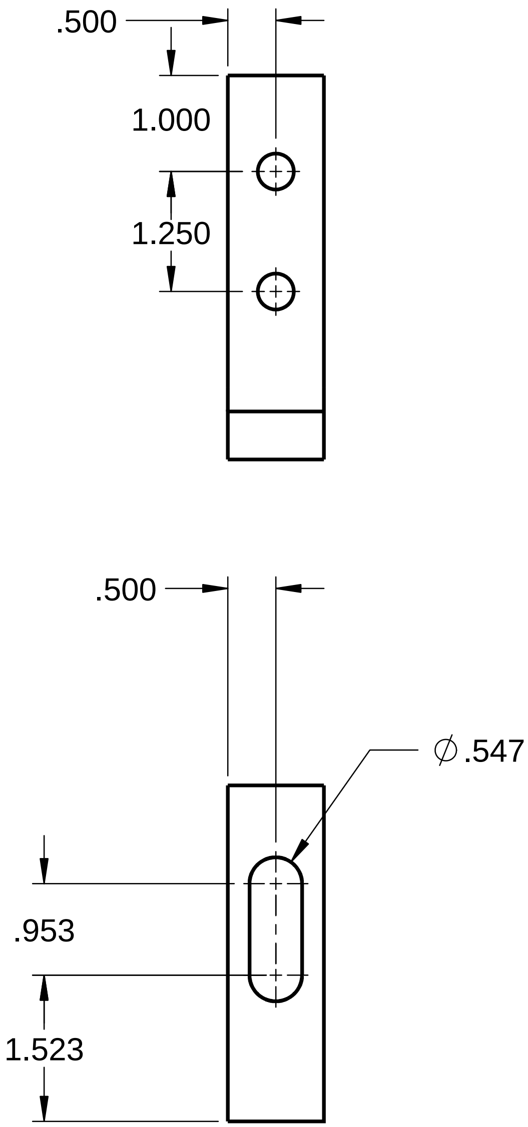
CP Renal Stent Senior Project	Assembly: LINKAGE	Part Name: RETAINING PLATE		Drwn. By: ASHLEY SCHAEFER
	Part. #: CPR-LINKAGE-05	Date: 2/1/15	Scale: 2:1	Chkd. By: JEN HAWTHORNE

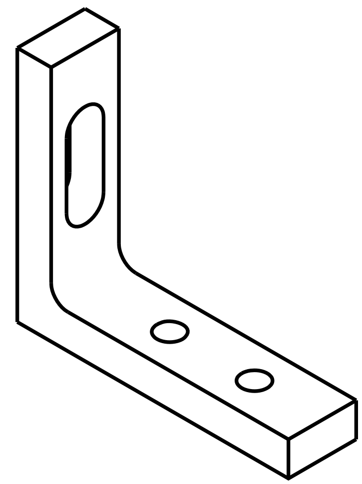


MATERIAL: 6063 ALUMINUM

ALL TOLERANCES UNLESS OTHERWISE SPECIFIED:
.XX= ±.05
.XXX= ±.005

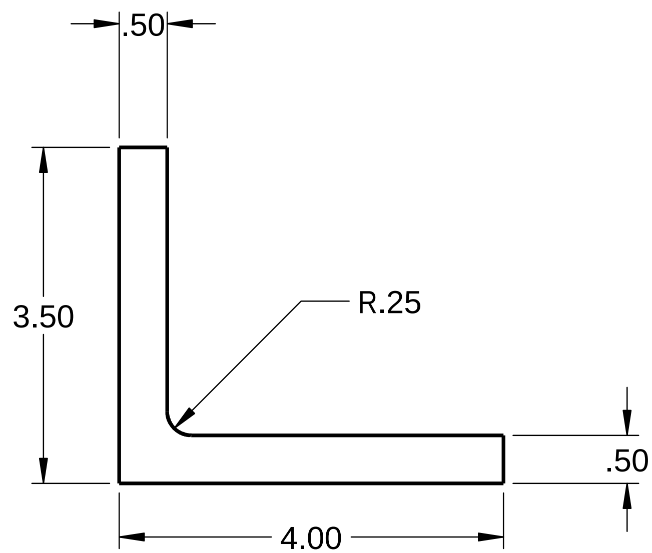
CP Renal Stent Senior Project	Assembly: LINKAGE	Part Name: SPIDER CLAMP		Drwn. By: ASHLEY SCHAEFER
	Part. #: CPR-LINKAGE-06	Date: 2/1/15	Scale: 1:1	Chkd. By: JEN HAWTHORNE





MATERIAL: 6061 ALUMINUM

ALL TOLERANCES UNLESS
OTHERWISE SPECIFIED:
.XX= ±.05
.XXX= ±.005



CP Renal Stent Senior Project	Assembly: MOTOR	Part Name: MOTOR BRACKET		Drwn. By: JEN HAWTHORNE
	Part. #: CPR-MOTOR-01	Date: 4/29/15	Scale: 1:2	Chkd. By:

General Information
- Overview
- Specifications
- Performance Data
- Parts List
- Drawings

More Information
- Where To Buy
- Baldor Sales Offices

Return to List

AC Motors | HVAC |

Specifications: EHFM3218T

SPEC. NUMBER:	36L731S270G1
CATALOG NUMBER:	EHFM3218T
FL AMPS:	14-13.2/6.6
208V AMPS:	14
BEARING-DRIVE-END:	6206
BEARING-OPP-DRIVE-END:	6205
DESIGN CODE:	B
DOE-CODE:	010A
FL EFFICIENCY:	89.5
ENCLOSURE:	OPSB
FRAME:	184T
HERTZ:	60
INSULATION-CLASS:	F
KVA-CODE:	J
SPEED [rpm]:	1750
OUTPUT [hp]:	5
PHASE:	3
POWER-FACTOR:	80
RATING:	40C AMB-CONT
SERIAL-NUMBER:	--
SERVICE FACTOR:	1.15
THERMAL-SELECT:	N
THERMAL-SELECT:	N
THERMAL-SELECT:	Y
VOLTAGE:	208-230/460

* For certified information, contact your local Baldor office.

Product: 22F-B017N103
Description: PowerFlex 4M

Representative Photo Only
(actual product may vary based on configuration selections)

BASE DRIVE INFORMATION	
Input Voltage	240 (208)VAC, 3PH
Output Current	17 Amps
Enclosure Style	IP20 (Open)
Frame Size	Frame Size B
INSTALLED OPTIONS	
Human Interface Module (Type)	LED Display, Fixed Digital Keypad
Internal EMC Filtering	No CE Compliant Filter
Internal Communication Module	No Brake Drive

Honeywell

Hall-effect Position Sensors with Sealed Housing

103SR Series

Datasheet

Hall-effect Position Sensors with Sealed Housing

The 103SR Series Hall-effect position sensor assemblies are sealed in aluminum or stainless-steel threaded housings and meet NEMA 3, 3R, 3S, 4, 4X (stainless-steel housing),12 and 13 requirements. They respond to the magnetic field from permanent magnets or electromagnets. These rugged non-contact sensing products use versatile, reliable Hall-effect sensor ICs that are operated by a magnetic field and are designed to respond to alternating North and South Poles or to South Pole only.

103SR Series Hall-effect position sensors include digital unipolar, latching, and linear magnetic types, available in a number of sensitivities to meet a variety of customers' application requirements. The digital version of 103SR Series Hall-effect position sensors delivers stable output over -40 °C to 100 °C [-40 °F to 212 °F] temperature range with 20 mA current sinking capability, and can accept dc supply voltage from 4.5 Vdc to 24 Vdc. The linear version operates from -40 °C to 125 °C [-40 °F to 257 °F] across a supply voltage range of 4.5 Vdc to 10.5 Vdc.

The standard open-collector sinking output (digital devices) or push-pull output (linear device) of the 103SR Series Hall-effect position sensors can be easily interfaced with common electronic circuitry such as microprocessors, integrated logic, discrete transistors, and SCRs with compatible voltage specifications.

What makes our sensors better?

- Honeywell magnetic sensing experience
- Robust, sealed housing
- Multiple wire types and cable options

Features and Benefits

SOLID STATE RELIABILITY

Unlike electromechanical switches, the 103SR Series Hall-effect position sensors are not affected by contact bounce or wear. They are solid-state devices suitable for applications requiring reliable switching operations and long life.

Choose the best fit option

DIGITAL UNIPOLAR, LATCHING, AND LINEAR MAGNETICS

Honeywell's 103SR Series Hall-effect position sensors offer digital unipolar, latching, and linear magnetic options specifically designed and engineered to meet a number of industrial, transportation, and consumer application requirements.

ELECTRICAL CHARACTERISTICS

The 103SR Series offers current-sinking output (digital) and push-pull output (linear/analog) options to choose from that help address a wide range of applications.

MEETS INDUSTRY STANDARD REQUIREMENTS

The rugged, sealed threaded aluminum housing of the device meets NEMA 3, 3R, 3S, 4, 4X (stainless steel only),12, and 13 requirements allowing them to be used in various environmental conditions.

LEAD WIRE GAUGE AND LENGTH OPTIONS

Lead wires of different gauges, lengths, and insulation allows the customer to choose the best-fit option per their application's requirement.

WIDE SUPPLY VOLTAGE RANGE

The sensor operates over a wide supply voltage range from 4.5 Vdc to 24 Vdc (digital) or 4.5 Vdc to 10.5 Vdc (linear).

OPERATING TEMPERATURE RANGE

The 103SR Series Hall-effect sensors can operate over a broad operating temperature range from -40 °C to 100 °C [-40 °F to 212 °F] (digital) and from -40 °C to 125 °C [-40 °F to 257 °F] (linear).This reduces operating and installation issues and provides greater flexibility of design to engineers.

Protective sealed housing

RUGGED, SEALED, THREADED HOUSING

The sensor ICs in the 103SR Series Hall-effect position sensors are potted and supplied in sealed aluminum or stainless steel housings, protecting them from dust, dirt, and liquid splashing or other harsh environmental operating conditions.

ADJUSTABLE MOUNTING

The 103SR Series Hall-effect position sensors come with threaded metal housings. When installed on a bracket, the relative position of the sensor and magnet can be easily adjusted for optimum performance. This provides the user with greater flexibility in integrating and mounting the 103SR Series Hall-effect position sensors into their system.

103SR Series

Potential Applications

Honeywell Sensing and Control's internal design capabilities and customized options allow use of these Hall-effect position sensors across a number of potential industrial, transportation, and medical applications.

INDUSTRIAL

- Position sensing
- Robotics control
- Linear or angular displacement sensing
- Speed and RPM (revolutions per minute) sensing
- Tachometer, counter pick-up
- Flow-rate sensing
- Motor and fan control

TRANSPORTATION

- Speed and RPM (revolutions per minute) sensing
- Tachometer, counter pick-up
- Motor and fan control
- Seat position

MEDICAL

- Motion detection in motorized medical equipment
- Position sensing in hospital beds

Hall-effect Position Sensors with Sealed Housing

Table 1. Electrical and Magnetic Specifications - Digital Hall-effect Position Sensors (for reference only)

Catalog Listing	Supply Voltage (Vdc)	Supply Current (mA max.) @ 25 °C [77 °F]	Output Type	Output Voltage (V max.)	Output Current (mA max.)	Magnetic Type	Magnetic Characteristics [Gauss]* and Temperature °C [°F]								
							0 °C to 70 °C [32 °F to 158 °F]			-40 °C to 100 °C [-40 °F to 212 °F]			25 °C [77 °F] Typical		
							Max. Operate Point	Min. Release Point	Min. Differential Hysteresis	Max. Operate Point	Min. Release Point	Min. Differential Hysteresis	Typ. Operate Point	Typ. Release Point	Typ. Differential Hysteresis
103SR13A-1	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-2	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-3	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-4	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-6	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-8	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-9	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-10	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-11	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-12	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-13	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-14	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR13A-16	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	475	135	40	495	200	35	350	275	75
103SR14A-1	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	-	-	-	160	5	8	85	58	27
103SR14A-2	4.5 V to 24 V	10	Sink	0.4	20	Unipolar	-	-	-	160	5	8	85	58	27
103SR17A-1	4.5 V to 24 V	10	Sink	0.4	20	Latching	180	-180	80	205	-205	35	100	-100	200
103SR17A-2	4.5 V to 24 V	10	Sink	0.4	20	Latching	180	-180	80	205	-205	35	100	-100	200
103SR18-1	4.5 V to 24 V	10	Sink	0.4	20	Latching	90	-90	40	120	-120	40	50	-50	100

*Unipolar digital Hall-effect position sensor has a positive maximum operate point (South Pole) and a positive minimum release point. One magnetic pole (South) is required to operate and release a unipolar digital Hall-effect position sensor

Latching digital Hall-effect position sensor is guaranteed to switch on with positive (South Pole) Gauss only, and switch off with negative (North Pole) Gauss only

Ring magnets with alternating North and South Poles are usually used with latching digital Hall-effect position sensors

Table 2. Electrical and Magnetic Specifications - Linear Hall-effect Position Sensor (for reference only)

Catalog Listing	Supply Voltage (Vdc)	Supply Current (mA max.) @ 25 °C [77 °F]	Output Type	Output Voltage Span (V)	Output Current (mA max., sink or source, Vs >5 Vdc)	Magnetic Type	Magnetic Characteristics [Gauss]** and Temperature °C [°F]							
							-40 °C to 125 °C [-40 °F to 257 °F]		25 °C [77 °F]**			25 °C [77 °F]**		
							Max. Linearity	Min. Linear Measuring Range [G]	Min. Sens. [mV/G]	Typ. Sens. [mV/G]	Max. Sens. [mV/G]	Min. Null [V]	Typ. Null [V]	Max. Null [V]
103SR19A-1	4.5 V to 10.5 V	10	Push -Pull	0.4 V to Vs -0.4 V (min.); 0.2 V to Vs -0.2 V (typ.)	1	Linear	-1.5 %	±600	3.031	3.125	3.219	2.425	2.500	2.575

**Refer to 103SR19A-1 engineering drawing for sensitivity and null drift vs temperature specifications

Table 3. Absolute Maximum Ratings*

Parameters	4.5 Vdc to 24 Vdc
Supply Voltage (Vs)**	-1.0 Vdc to 25 Vdc
Voltage Externally Applied to Output	25 Vdc max. (OFF only) -0.5 Vdc min. (ON or OFF)
Output Current	20 mA max.
Temperature Operate and Storage	-40 °C to 100 °C [-40 °F to 212 °F]

*Absolute maximum ratings are the extreme limits that the device will withstand without damage to the device. Electrical and magnetic characteristics are not guaranteed as the maximum limits (above recommended operating conditions) are approached, nor will the device necessarily operate at absolute maximum rating

**Vs is the unregulated supply voltage

DIMENSIONAL DRAWINGS

Unipolar Digital Hall-effect Position Sensors

Figure 1. 103SR13A-1

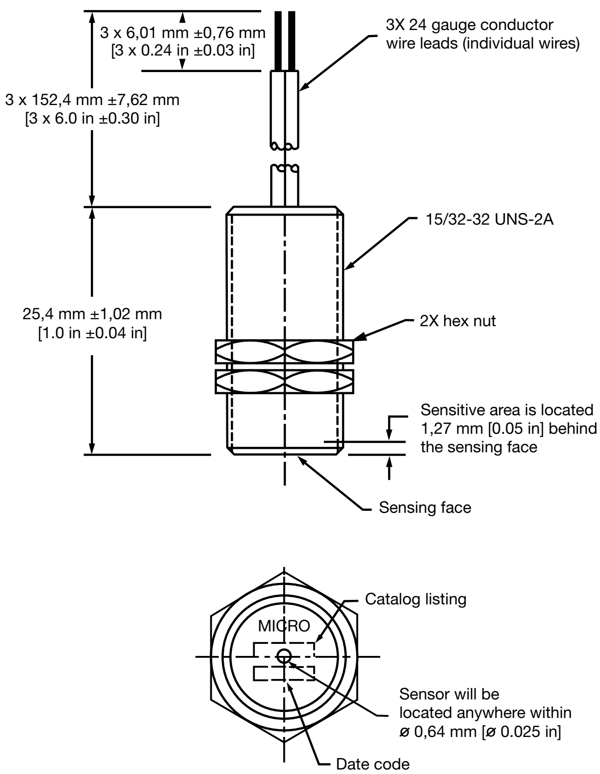
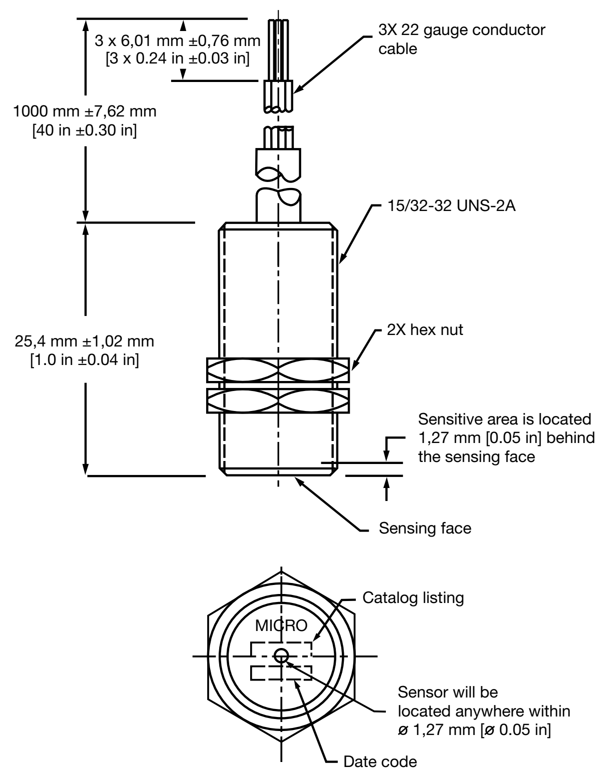


Figure 2. 103SR13A-2



Hall-effect Position Sensors with Sealed Housing

Unipolar Digital Hall-effect Position Sensors

Figure 3. 103SR13A-3

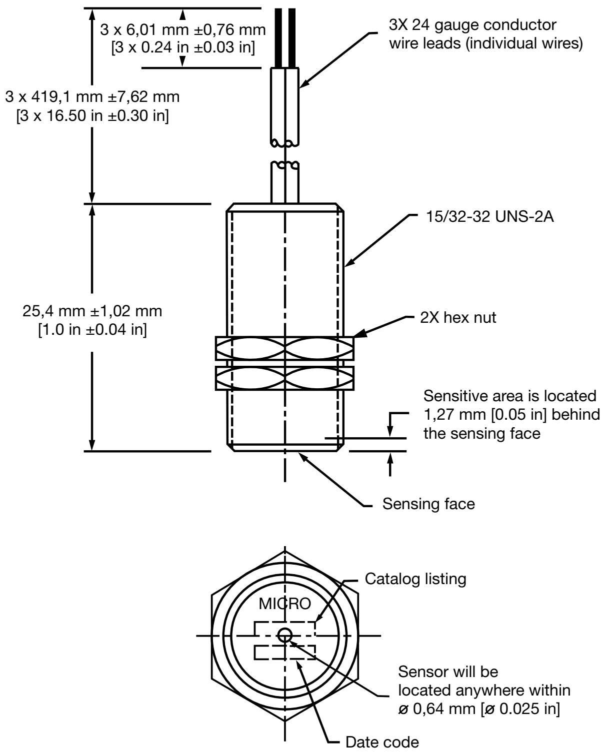


Figure 4. 103SR13A-4

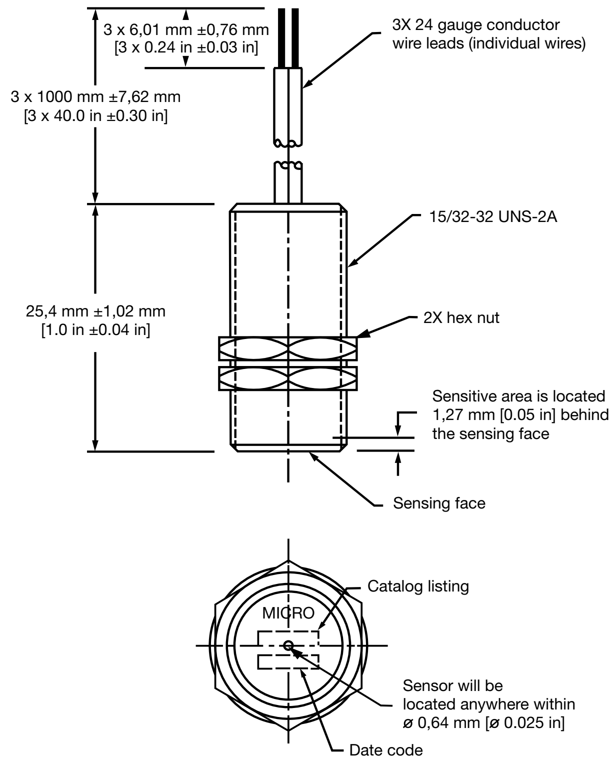


Figure 5. 103SR13A-6

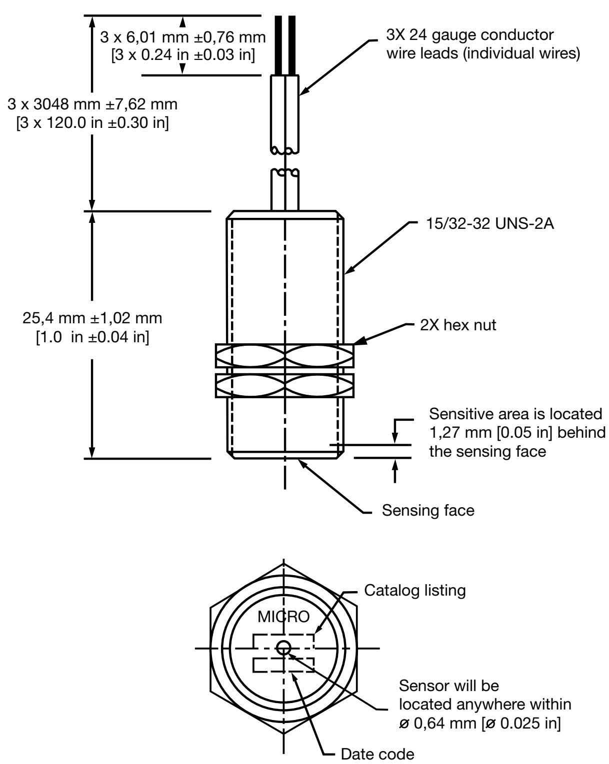
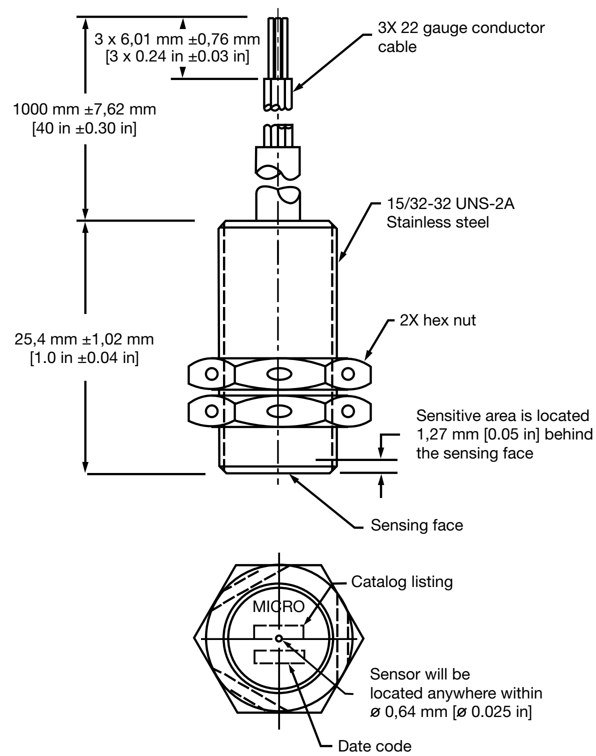


Figure 6. 103SR13A-8



103SR Series

Unipolar Digital Hall-effect Position Sensors

Figure 7. 103SR13A-9

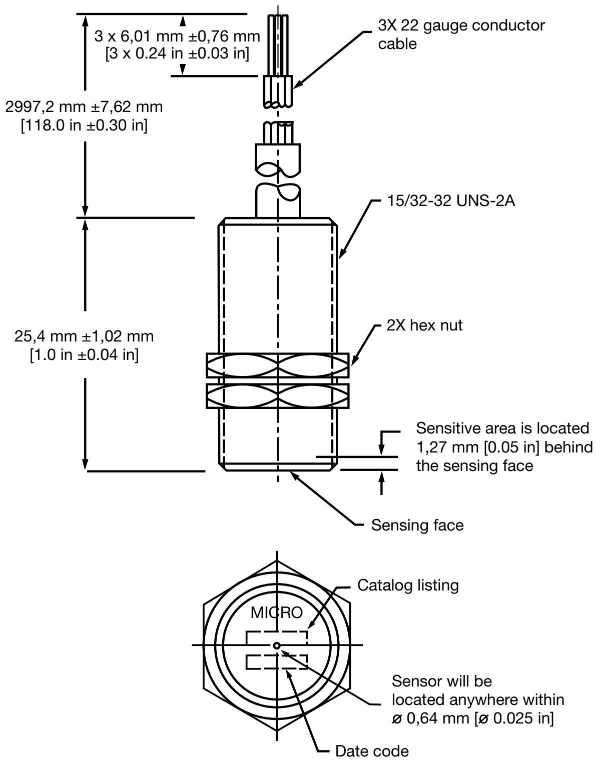


Figure 8. 103SR13A-10

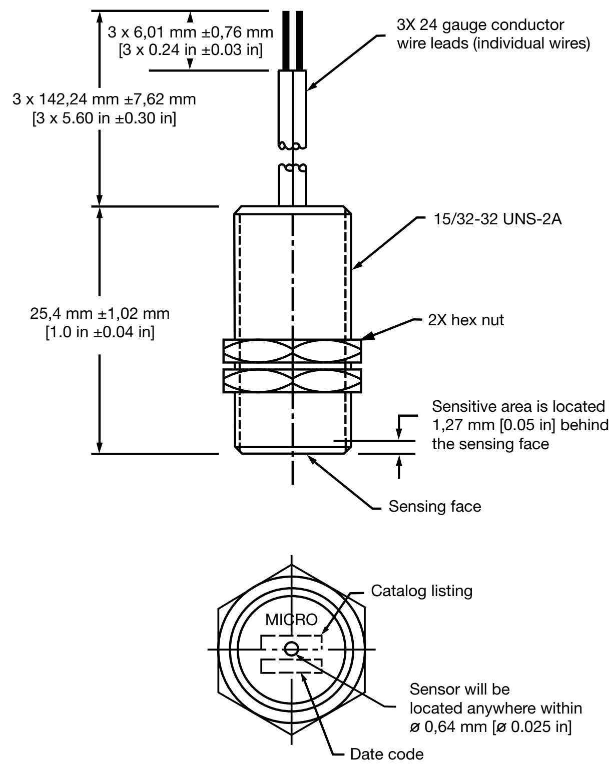


Figure 9. 103SR13A-11

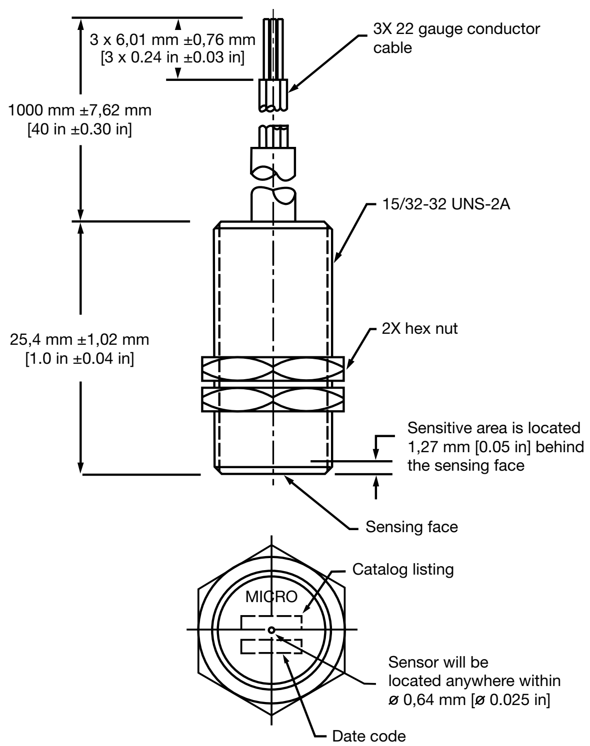
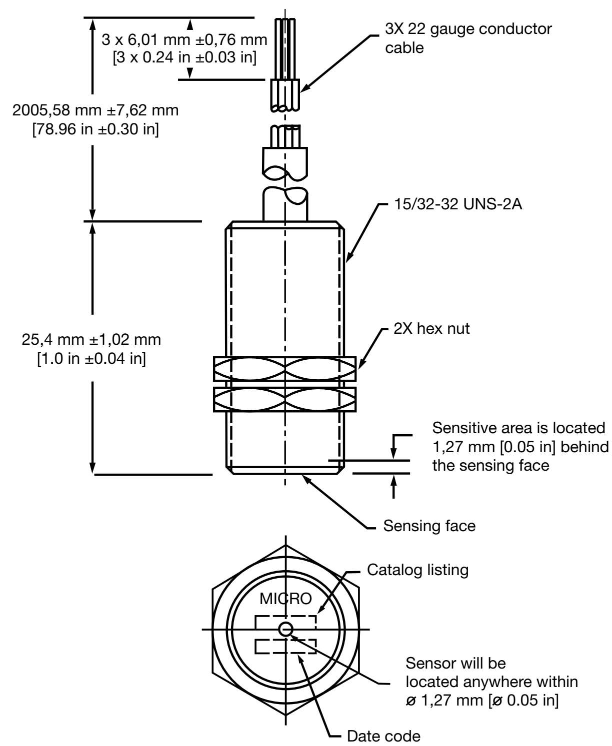


Figure 10. 103SR13A-12



Hall-effect Position Sensors with Sealed Housing

Unipolar Digital Hall-effect Position Sensors

Figure 11. 103SR13A-13

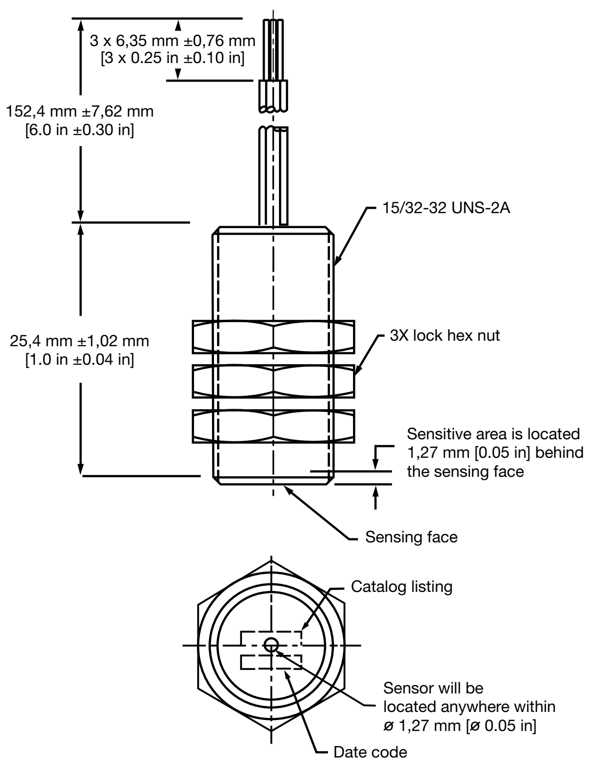


Figure 12. 103SR13A-14

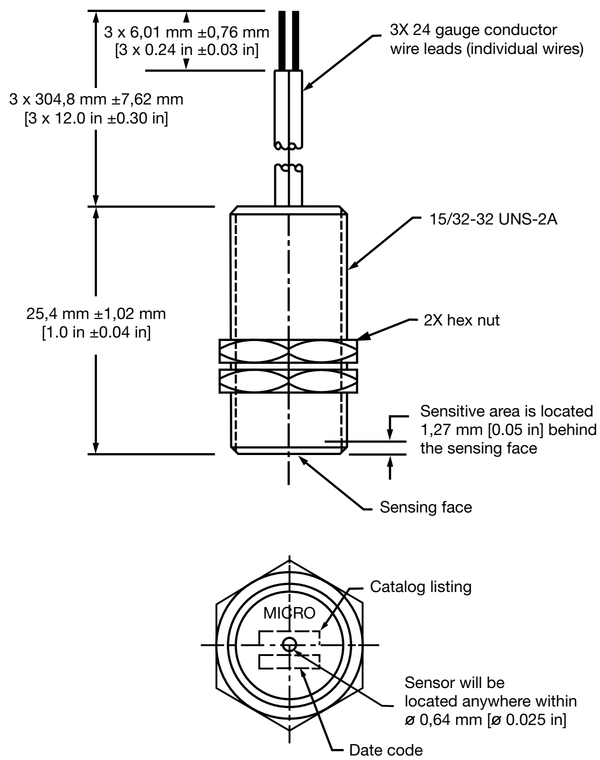


Figure 13. 103SR13A-16

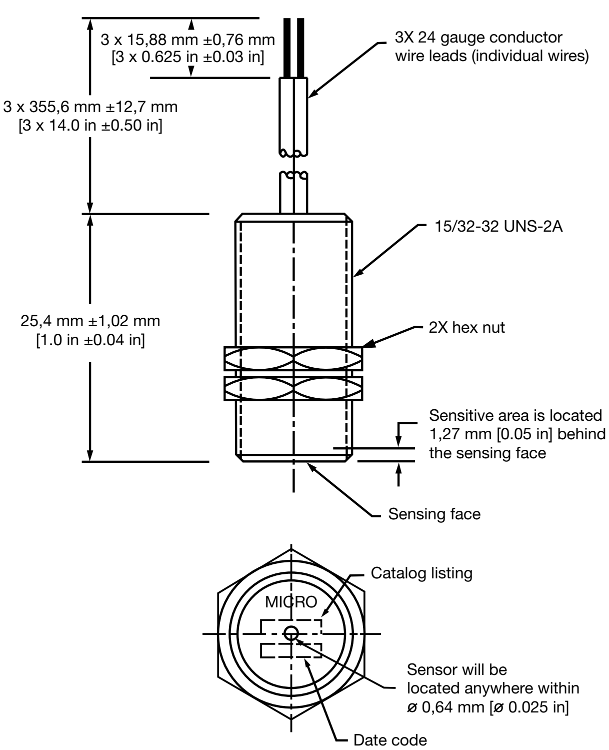
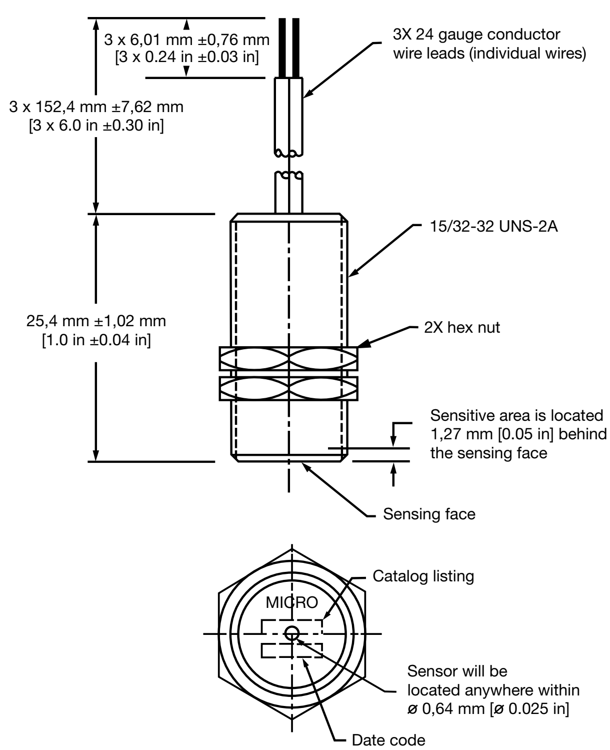


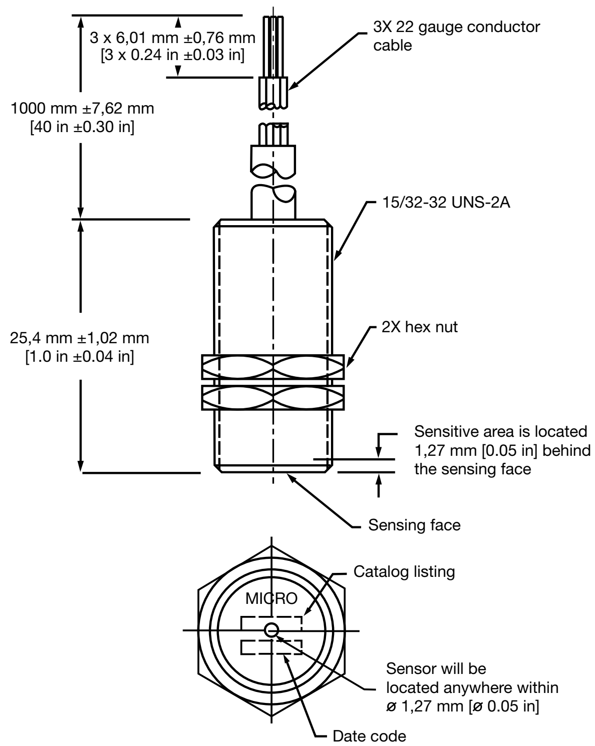
Figure 14. 103SR14A-1



103SR Series

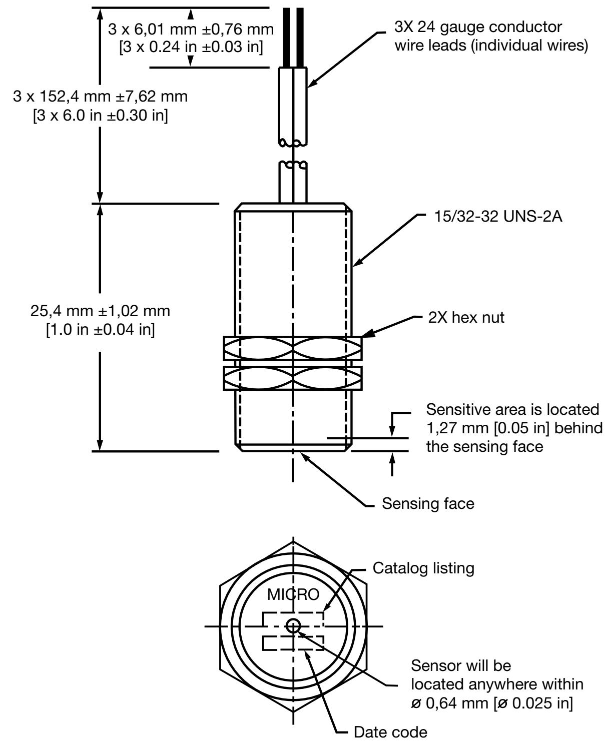
Unipolar Digital Hall-effect Position Sensors

Figure 15. 103SR14A-2



Latching Digital Hall-effect Position Sensors

Figure 16. 103SR17A-1



Latching Digital Hall-effect Position Sensors

Figure 17. 103SR17A-2

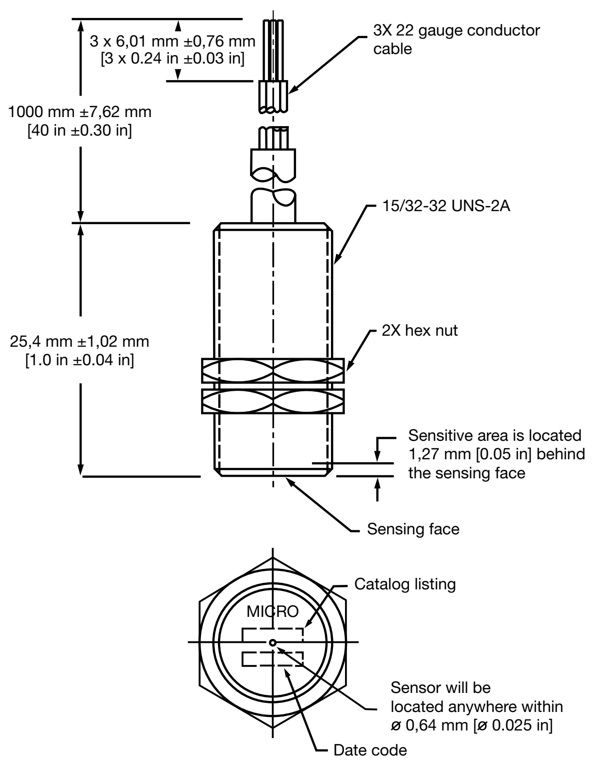
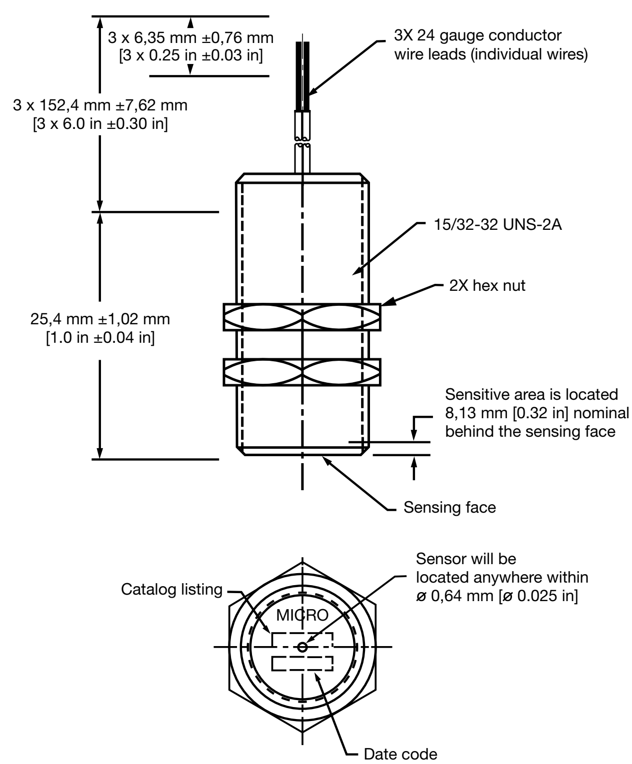


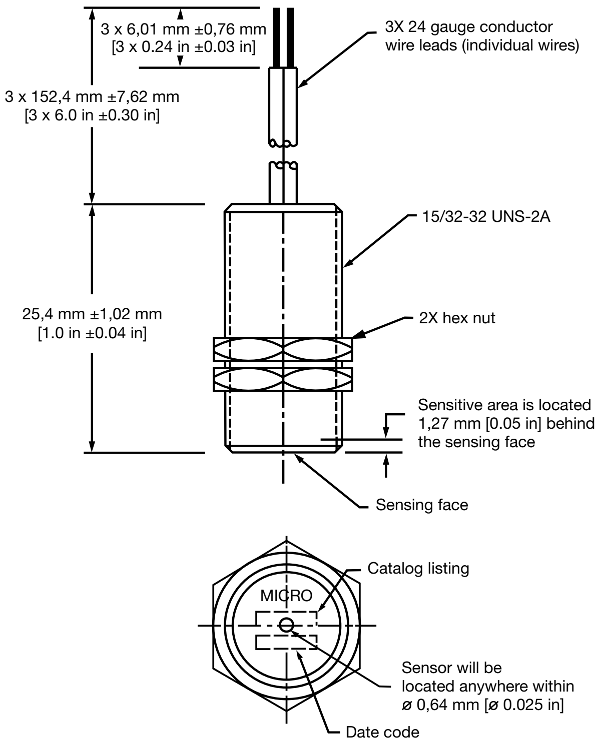
Figure 18. 103SR18-1



Hall-effect Position Sensors with Sealed Housing

Unipolar Ratiometric/Analog Hall-effect Position Sensors

Figure 19. 103SR19A-1

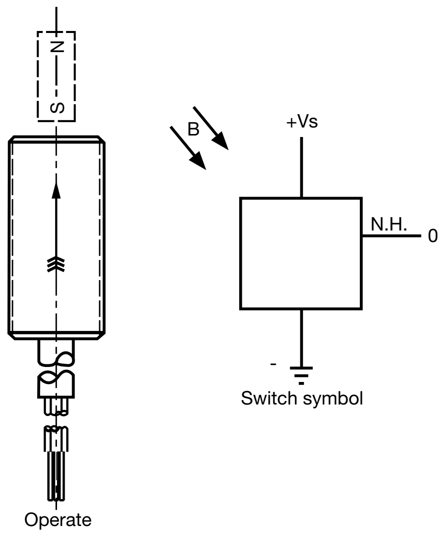


103SR Series

OPERATING MODE

Figure 20. Unipolar Digital Hall-effect Position Sensors

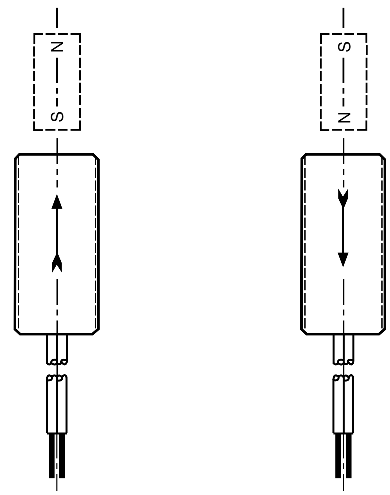
103SR13A-1, 103SR13A-2, 103SR13A-3, 103SR13A-4, 103SR13A-6, 103SR13A-8, 103SR13A-9, 103SR13A-10, 103SR13A-11, 103SR13A-12, 103SR13A-13, 103SR13A-14, 103SR13A-16, 103SR14A-1, 103SR14A-2



Note: Flux entering to the South Pole of the magnet will operate the sensor when magnet is positioned as shown in above drawing. This assumes the convention that the direction of the external flux of a magnet is from the North to the South Pole of the magnet

Figure 21. Unipolar Ratiometric/Analog Hall-effect Position Sensors

103SR19A-1



Output voltage increases from Vnull (2.5 V typ.) as South Pole gets closer to sensor

Output voltage decreases from Vnull (2.5 V typ.) as North Pole gets closer to sensor

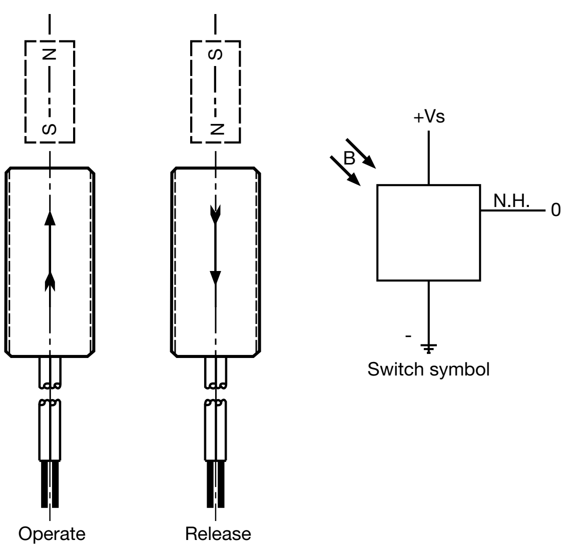
Note: In the above drawing the magnet field direction is defined as follows:

(+) Positive Gauss represents the South Pole of the magnet facing the sensing the area

(-) Negative Gauss represents the North Pole of the magnet facing the sensing the area

Figure 22. Latching Digital Hall-effect Position Sensors

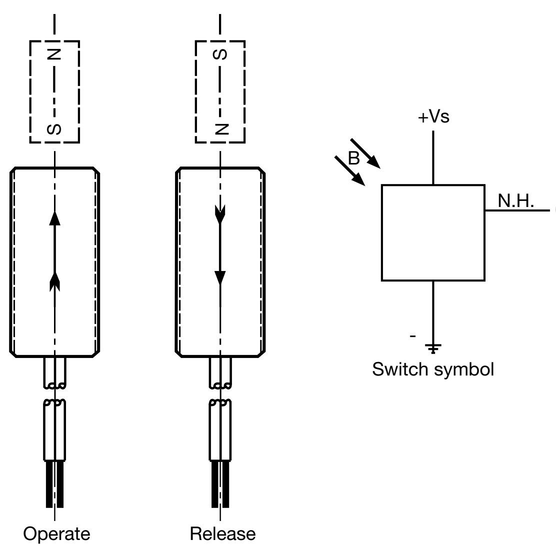
103SR17A-1, 103SR17A-2



Note: Flux entering to the South Pole of the magnet will operate the sensor when magnet is positioned as shown in the above drawing. This assumes the convention that the direction of the external flux of a magnet is from the North to the South Pole of the magnet. Latching devices requires both South and North Poles in order to ensure sensors operate and release respectively

Figure 23. Latching Digital Hall-effect Position Sensors

103SR18-1



Note: Flux entering to the South Pole of the magnet will operate the sensor when magnet is positioned as shown in the above drawing. This assumes the convention that the direction of the external flux of a magnet is from the North to the South Pole of the magnet. Latching devices requires both South and North Poles in order to ensure sensors operate and release respectively

Hall-effect Position Sensors with Sealed Housing

TROUBLESHOOTING

If sensor does not operate, follow these steps:

1. Assure wiring is correct. Load must be connected.
2. Measure supply voltage across red (+) and black (-) leads to verify presence of proper voltage.
3. Connect positive voltmeter lead to green, white, or brown (output) lead, and negative voltmeter lead to black (ground).

Table 4. With magnet removed (or North Pole present), reading should be:

Catalog Listing	Voltage Reading
103SR13A-1	Vs
103SR14A-1	Vs
103SR17A-1*	Vs

Table 5. When magnet (South Pole) moves toward sensor face (beyond operating point), output should change state and read:

Catalog Listing	Voltage Reading
103SR13A-1	0.4 V max.
103SR14A-1	0.4 V max.
103SR17A-1*	0.4 V max.

*North magnetic pole must be present to ensure device is OFF due to bipolar magnetic operation

LEADWIRE COLOR CODE

Table 6. Leadwire Color Code - Stranded

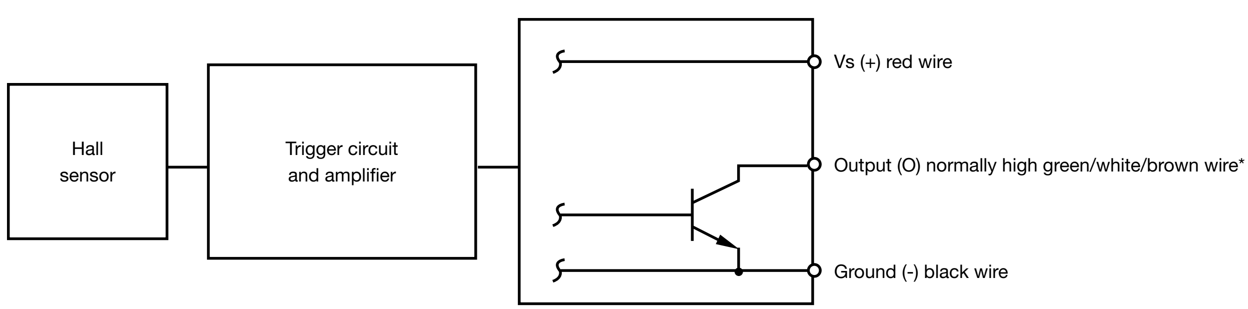
Catalog Listing	Color	Description
103SR13A-1, 103SR13A-2, 103SR13A-3, 103SR13A-4, 103SR13A-6, 103SR13A-10, 103SR13A-13, 103SR13A-14, 103SR13A-16, 103SR14A-1, 103SR17A-1, 103SR18-1, 103SR19A-1	Red	Vs (+)
	Black	Ground (-)
	Green	Output (digital or linear)

Table 7. Leadwire Color Code - Cable

Catalog Listing	Color	Description
103SR13A-8, 103SR13A-12, 103SR14A-2, 103SR17A-2	Red	Vs (+)
	Black	Ground (-)
	White (Type 2)	Output (digital)
103SR13A-9, 103SR13A-11	Red	Vs (+)
	Black	Ground (-)
	Brown (Type 3)	Output (digital)

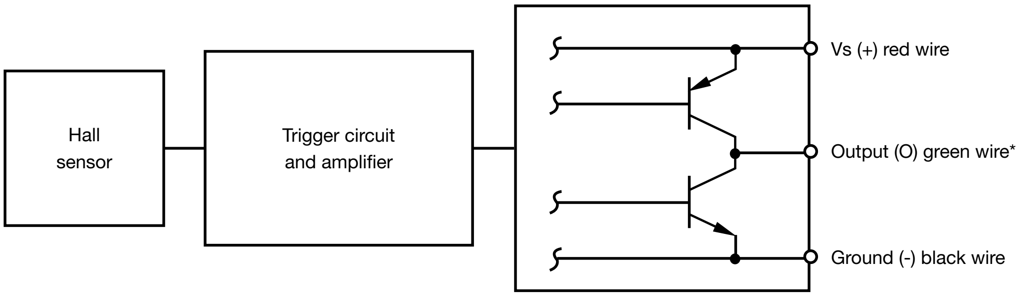
BLOCK DIAGRAM

Figure 24. Digital Hall-effect Position Sensors: Current Sinking Output



*Refer Table 6 and Table 7 for output wire color

Figure 25. Linear Hall-effect Position Sensors: Push-Pull (Sink Source) Output



*Refer Table 6 and Table 7 for output wire color

INTERFACING SENSING AND CONTROL HALL-EFFECT SENSORS

The schematics shown are typical of the outputs with which Honeywell Sensing and Control Hall-effect position sensors can be interfaced. Values shown are representative only.

Current-Sinking outputs

Current flows through load into sensor. Output terminal is open collector. In the un-operated condition (I_L = 0), the output voltage is normally high.

Figure 26. Interface Circuit - ac Load

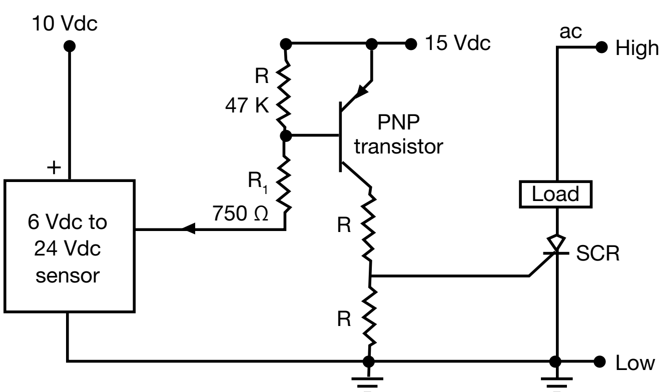


Figure 27. Interface Circuit - dc Load 50 mA

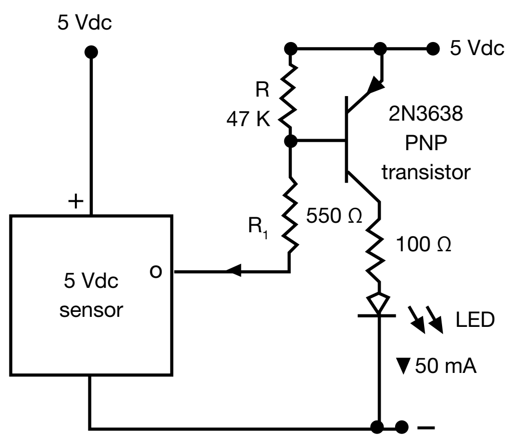


Figure 28. Interface Circuit - dc Load 150 mA

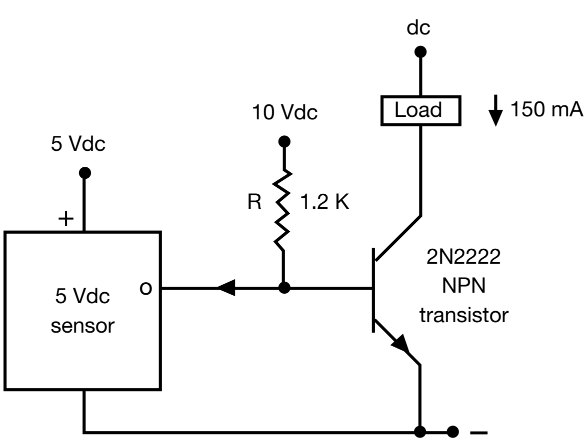
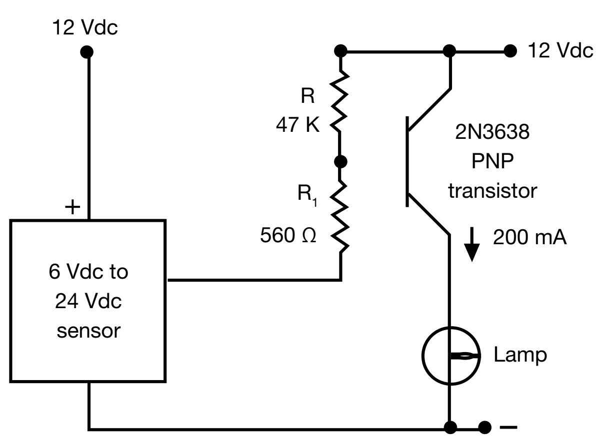
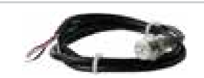
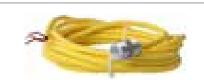
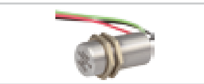
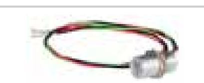
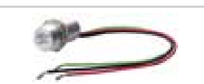
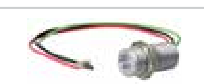
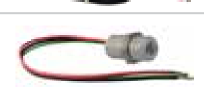
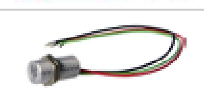


Figure 29. Interface Circuit - dc Load 200 mA



Hall-effect Position Sensors with Sealed Housing

Order Guide (Measurements for reference only)

Image	Catalog Listing	Description	Cable/ Leadwire Type*	Magnetic Characteristics	Cable Length
	103SR13A-1	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	152 mm [6.0 in]
	103SR13A-2	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 2	Unipolar	1000 mm [40.0 in]
	103SR13A-3	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	419 mm [16.5 in]
	103SR13A-4	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	1000 mm [40.0 in]
	103SR13A-6	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	3048 mm [120.0 in]
	103SR13A-8	Sealed, 15/32-32 UNS-2A in cylindrical **stainless steel** housing; two hex nuts	Type 2	Unipolar	1000 mm [40.0 in]
	103SR13A-9	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 3	Unipolar	2997 mm [118.0 in]
	103SR13A-10	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 2	Unipolar	142 mm [5.6 in]
	103SR13A-11	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 3	Unipolar	1000 mm [40.0 in]
	103SR13A-12	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 2	Unipolar	2006 mm [79 in]
	103SR13A-13	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; three hex nuts	Type 1	Unipolar	152 mm [6.0 in]
	103SR13A-14	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	305 mm [12.0 in]
	103SR13A-16	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	356 mm [14.0 in]
	103SR14A-1	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Unipolar	152 mm [6.0 in]
	103SR14A-2	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 2	Unipolar	1000 mm [40.0 in]
	103SR17A-1	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Latching	152 mm [6.0 in]
	103SR17A-2	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 2	Latching	1000 mm [40.0 in]
	103SR18-1	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 4	Latching	152 mm [6.0 in]
	103SR19A-1	Sealed, 15/32-32 UNS-2A cylindrical aluminum threaded housing; two hex nuts	Type 1	Linear	152 mm [6.0 in]

*Cable/Leadwire type

Type 1 - 24 gauge stranded, irradiated polyethylene insulated

Type 2 - 22 gauge PVC insulated conductor with black molded PVC jacket

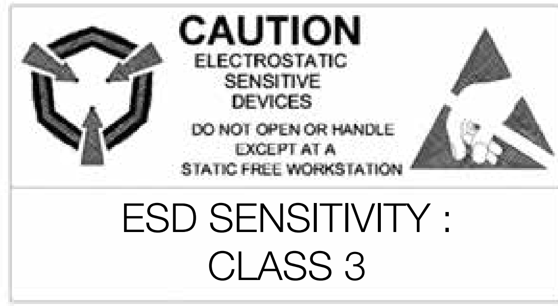
Type 3 - 22 gauge insulated conductors with yellow thermoplastic polyurethane jacket

Type 4 - 24 gauge irradiated polyethylene

ADDITIONAL INFORMATION

The following associated literature is available on the Honeywell website at sensing.honeywell.com:

- Product line guide
- Product range guide
- Product installation instructions
- Application Notes:
  - Sensors and Switches in Front Loaders
  - Sensors and Switches in Mobile Cranes
  - Blood Recovery System
- Technical Notes:
  - Solid-State Sensors Glossary of Terms
  - Interpreting Operating Characteristics for Solid-State Sensors



⚠WARNING

PERSONAL INJURY

DO NOT USE these products as safety or emergency stop devices or in any other application where failure of the product could result in personal injury.

Failure to comply with these instructions could result in death or serious injury.

⚠WARNING

MISUSE OF DOCUMENTATION

- The information presented in this product sheet is for reference only. Do not use this document as a product installation guide.
- Complete installation, operation, and maintenance information is provided in the instructions supplied with each product.

Failure to comply with these instructions could result in death or serious injury.

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Golden Valley, MN 55422
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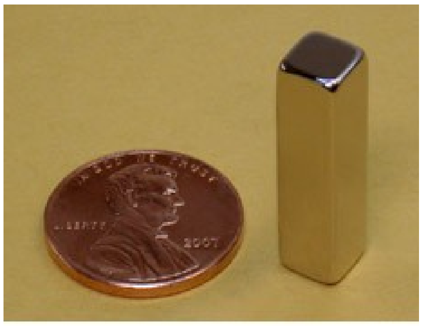
Honeywell

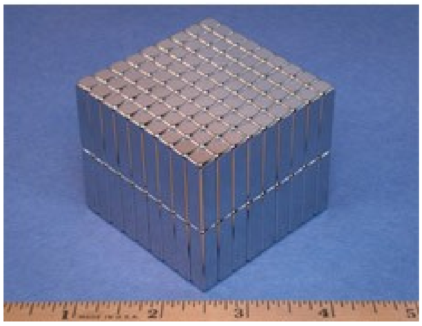
005971-1-EN IL50 GLO
March 2014

B44X0 Specification Sheet

Product Specifications

Type:	BLOCK
Dimensions:	0.25 x 0.25 x 1 thk (in)
Tolerance:	All dimensions ± 0.004 in
Material:	NdFeB, Grade N42
Plating:	NiCuNi
Max Op Temp:	176ºF (80ºC)
Br max:	13,200 Gauss
BH max:	42 MGOe





Performance Specifications

Pull Force, Case 1, Magnet to a Steel Plate:	5.41 lb

Surface Field values are derived from calculation and verification with experimental testing. These values are the field values at the surface of the magnet, centered on the axis of magnetization. Measurement of the B field with a magnetometer may yield varying results, depending on the geometry of your sensor. Pull Force values are based on extensive product testing in our laboratory. Different configurations of magnets and surrounding ferromagnetic materials may substantially alter your results.

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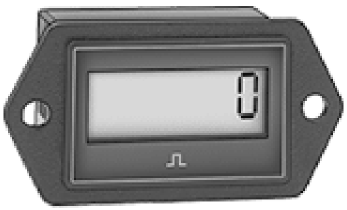
Voltage-Actuated Digital Counter

Panel-Mount, 8 Digit, 2400 Counts/min, 20-300V AC

In stock
$30.43 Each
1874T91



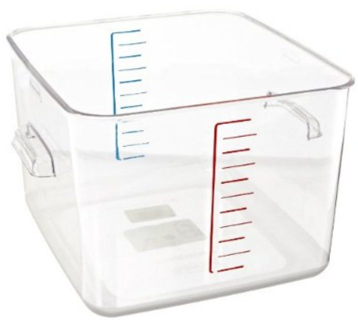
Number of Digits	8
Maximum Counts/Minute	2,400
Overall Size	
Height	1.1"
Width	2.1"
Depth	1.2"
Panel Cutout	
Height	1"
Width	1.5"
Screw Size	No. 5
Housing	Plastic
Input Voltage	20-300V AC
Additional Specifications	With Reset—Digital Display Panel-Mount MSDS
Shipping	Regulated by the U.S. Department of Transportation

Used on machine tools, printing presses, and packaging machinery, these count up as they receive an input from a switch, sensor, or encoder (not included; see proximity switches and light beam sensing switches). Counters have wire leads, unless otherwise stated. Mounting fasteners not included, except for Styles F, G, and M. Temperature range is 14° to 122° F.

With Reset—Counters have a push-button, knob, or key reset.

Digital counters have a battery-powered LCD. Styles M and N have 1/4" spade terminals and are UL and C-UL recognized.

Industrial & Scientific › Janitorial & Sanitation Supplies › Waste Receptacles & Liners › Trash Cans



Roll over image to zoom in

by Rubbermaid Commercial

Rubbermaid Commercial FG631200CLR Space-Saving Container, 12-Quart Capacity

See all 7 in this Product Family

55 customer reviews

List Price: ~~$25.80~~
Price: $16.25 & **FREE Shipping** on orders over $35. Details
You Save: $9.55 (37%)

In Stock.

Ships from and sold by Amazon.com. Gift-wrap available.

Want it tomorrow, Feb. 7? Order within **13 hrs 7 mins** and choose **Saturday Delivery** at checkout. Details

7 new from $16.25

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$27.94 Add to Cart
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Sold by: Wasserstrom Restaurant Supply

$28.00 Add to Cart
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$23.61 Add to Cart
+ $7.81 shipping
Sold by: U.S. Plastic Corp.

7 new from $16.25

Have one to sell? Sell on Amazon

Product Specifications

Capacity	12.0 quarts	Overall Height	7.75 inches
Color Name	Clear	Overall Length	11.3 inches
EAN	00947037073 , 00868760440	Overall Width	10.5 inches
External Testing Certification	NSF, HACCP	Part Number	FG631200CLR
Item Weight	1.59 pounds	Size Name	12-Quart
Material Type	Copolyester	UPC	094703707342 , 086876044027

Specification for this product family (See all 7 products)

Brand Name	Rubbermaid Commercial	UNSPSC Code	48102100
Number of Items	1		

Customers Who Bought This Item Also Bought

Home » Saltwater Aquarium Supplies » Heaters » Titanium » JBJ True Temp Digital Controller w/ Heater

JBJ True Temp Digital Controller w/ Heater

Read 76 reviews | Write A Review

Item #: Please make a selection
Watts Please select...
Quantity: 1

$99.99 to $199.99 + Add to Cart

60 DAY RETURNS | ASK THE EXPERTS

Product Description | Customer Reviews | Accessories & Similar Items

JBJ True Temp Digital Controller w/ Heater Information

Product Manuals & Documentation

JBJ U.S.A

JBJ introduces the TRUE TEMP digital heater controller and titanium heating system. The TRUE TEMP is the most complete heating system to date with the most advanced features that set it apart as the leading heater for professional hobbyists.

Our digital microprocessor boasts amazing +/- 0.5 F accuracy, a calibration setting, indestructible titanium heating element with thermal shut off, smart memory chip, LED heating indicator, safety guard, remote temperature probe, and a large constant LED display of the current temperature.

Maintaining the correct temperature for tropical fish may be the single most important factor for a successful aquarium. Since fish do not have the ability to regulate their own body temperature, it is crucial that we can provide consistent water temperatures with minimal fluctuations.

Majority of fish cannot cope with stress from constant temperature fluctuations, which leads to a compromised immune system. This increases the probability of avoidable diseases, parasites, and bacterial infections.

ADVANCED FEATURES:

100% DIGITAL OPERATION
Don't be fooled, some controllers still incorporate analog dials and knobs without the precision accuracy of TRUE digital controllers. Our advanced microprocessor constantly reads and displays the correct temperature to a tenth of a degree with a large LED display. Easy push buttons make setting your desired temperature simple and easy.

TITANIUM
The perfect submersible element for fresh or saltwater aquaria. Virtually indestructible with the benefits of fast heat transfer without any corrosion. Integrated thermal shut off and out of water safety mechanism.

Model Wattage Length x Diameter Power Cord Tank Size

TT-150
150 WATT
9.5" X 1.5"
6 FEET
30 - 50 G

TT-300
300 WATT
13.1" X 1.5"
6 FEET
60 - 100 G

TT-500
500 WATT
13.1" X 1.5"
6 FEET
100 - 160 G

TT-800
800 WATT
16.7" X 1.5"
6 FEET

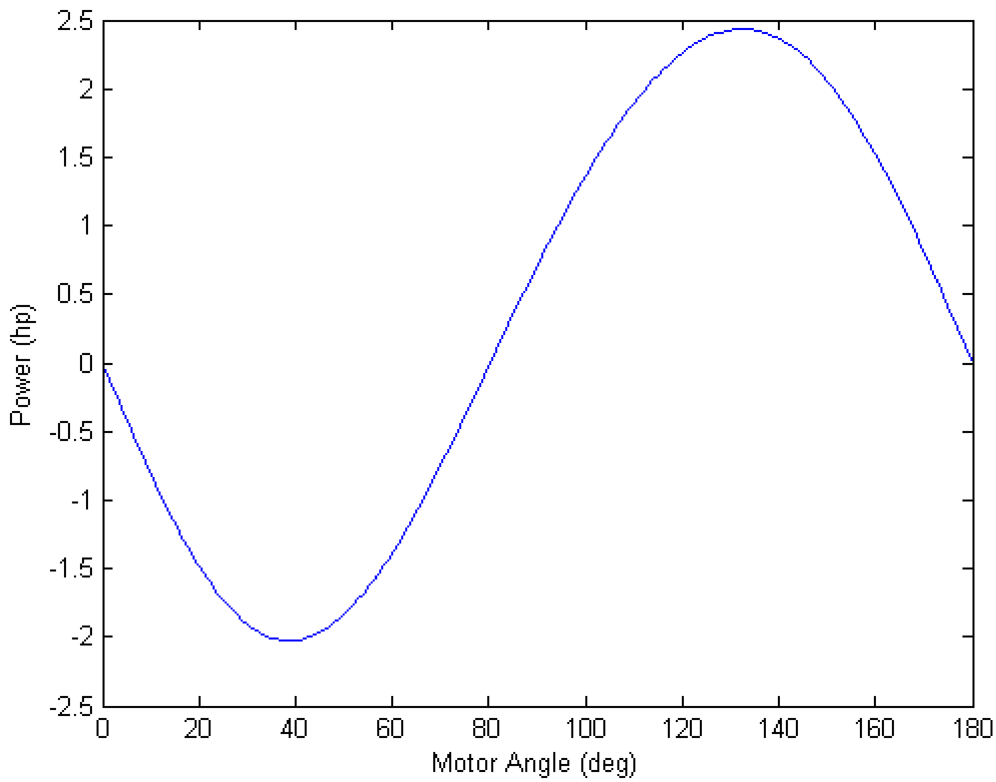
Appendix F

Motor Linkage Analysis

```
l_ab=.472; %inches
l_bc=2.653; %inches


mtr_angle=0:1:180;
vb_ans=zeros(length(mtr_angle), 3);
mtr_angle=mtr_angle*pi()/180; %Convert angles to radians
mtrspd= 1500; %RPM
wab= [0 0 mtrspd*2*pi()/60];

%masses (using Aluminum 5083)
%(http://www.mcmaster.com/#standard-aluminum-sheets/=viyz17)
mbc=.41* 0.096/32.2;
mcd=(5+5.5)*0.096/32.2;

vc_ans=zeros(length(mtr_angle),2);
ab_ans=zeros(length(mtr_angle),3);
ac_ans=zeros(length(mtr_angle),2);
am_ans= zeros(length(mtr_angle), 2);



%vb
for i=1:length(mtr_angle)
    rba= [l_ab*sin(mtr_angle(i)) -l_ab*cos(mtr_angle(i)) 0];
    ab_ans(i,:)= -wab(1,3)^2.*rba; %might be error here...
    vb= cross(wab, rba);
    vb_ans(i,:)=vb;
end

%w_bc and v_c
for i=1:length(mtr_angle)
   shaft_angle=l_ab*sin(mtr_angle(i))/l_bc;
   A=[-l_bc*cos(shaft_angle) 0;
       l_bc*sin(shaft_angle) 1];
   B=[vb_ans(i,1);
       vb_ans(i,2)];
   vc_ans(i,:)=A\B;
end

%a_c and alpha_bc
for i=1:length(mtr_angle)
   shaft_angle=l_ab*sin(mtr_angle(i))/l_bc;
   A=[0 -l_bc*cos(shaft_angle);
       1 l_bc*sin(shaft_angle)];
   B=[ab_ans(i,1)+vc_ans(i,1)^2*l_bc*sin(mtr_angle(i));
       ab_ans(i,2)+vc_ans(i,1)^2*l_bc*cos(mtr_angle(i))];
   ac_ans(i,:)= A\B;
end

%a_m (bc)
```

```
for i=1:length(mtr_angle)
    shaft_angle=l_ab*sin(mtr_angle(i))/l_bc;
    am_ans(i,1)= ab_ans(i,1)+ac_ans(i,2)*l_bc/2*cos(shaft_angle)+vc_ans(i,1)^2*l_bc/2*si
n(shaft_angle);    %i components
    am_ans(i,2)= ab_ans(i,2)-ac_ans(i,2)*l_bc/2*sin(shaft_angle)+vc_ans(i,1)^2*l_bc/2*co
s(shaft_angle);   %j components
end

%Effective Forces BC
f_bc=zeros(length(am_ans),2);
f_bc=mbc*am_ans;

%Effective Forces CD
f_cd=zeros(length(ac_ans),1);
f_cd=mcd*ac_ans(:,1);

%Force Cy
cy=zeros(length(f_cd),1);
for i=1:length(f_cd)
    cy(i)=f_cd(i)+mcd*32.2;
end

%Force By
by=zeros(length(f_bc),1);
for i=1:length(f_bc)
    by(i)=f_bc(i,2)-cy(i);
end

%Force Bx
bx=zeros(length(f_bc),1);
for i=1:length(f_bc)
    bx(i)=f_bc(i,1);
end

%TORQUE!!!!!!
torque=zeros(length(mtr_angle),1);
for i=1:length(mtr_angle)
    torque(i)=by(i)*l_ab*sin(mtr_angle(i))+bx(i)*l_ab*cos(mtr_angle(i));
end

%POWER! (HP)
power=zeros(length(mtr_angle),1);
for i=1:length(mtr_angle)
    power(i)=torque(i)*mtrspd/63025;
end

plot(mtr_angle*180/pi(), power);
xlabel('Motor Angle (deg)');
ylabel('Power (hp)');

max(torque)
max(power)
```

```
ans =

  102.1800


ans =

    2.4319
```



Published with MATLAB® R2014a

Appendix G

Design Failure Mode and Effects Analysis (DFMEA)

Potential
Failure Mode and Effect Analysis
(Design FMEA)

System | **Subsystem** | **Component**

FMEA Number:

Design Responsibility: **CP Renal Stent**

Page 1 of 1

Model Year(s)/Vehicle(s):

Key Date: **12/2/2014**

Prepared By: **Braden Cooper**

Core Team: **Braden Cooper, Munir Eltal, Jen Hawthorne, Ashley Schaefer**

FMEA Date (Orig.) **(Rev.)**

Item / Function	Potential Failure Mode	Potential Effect(s) of Failure	Sev	Potential Cause(s) / Mechanism(s) of Failure	Occur	Crit	Recommended Action(s)	Responsibility & Target Completion Date	Action Results: Actions Taken	Action Results: Sev	Action Results: Occur	Action Results: Crit
The Inner tank should keep water out of main mechanism. Measurable: Is there water in the inner tank?	Leaking into the tank caused by cracking	Water would contact the main mechanism possibly causing corrosion. Drop in measurement accuracy due to water in the inner tank	7	Dropping the tank, excessive impact, DOA, long-term fatigue, insufficient material strength.	3	21	Handle tank with care, add fragile warning labels.	Braden Cooper, throughout testing				
	Leaking into the tank caused by deformed seal	Water would contact the main mechanism possibly causing corrosion. Drop in measurement accuracy due to water in the inner tank	7	Melting, vibrations, fatigue, cracking, deformation, tolerance buildup, imperfect fit, environment (salt water).	4	28	Check seal before use, monitor saline bath temperature, ensure proper installation	Braden Cooper, throughout testing				
The motor should consistently operate at our desired frequency for a three week duration without user intervention Measurable: Natural Frequency, Voltage/Current	Motor can stall	Fire can occur, stents would not be fatigue tested, can damage whatever object stalled it, fixture can be destroyed	9	Object stuck in motor, internal error, voltage spike, insufficient lubrication.	3	27	Add a warning label and monitor the motor continuously. Turn off motor if any signs of stalling occur.	Jen, Throughout testing				
	Motor breaks	Mechanism is no longer fatigue testing renal artery stents	8	Power to the motor is cut, internal short circuit, motor is dropped, waterlogged.	4	32	Be careful with the motor, transport cautiously and inspect before each use and as it runs.	Jen, Throughout testing				
	Linkage breaks	Mechanism is no longer fatigue testing renal artery stents, motor could be rotating loose parts at high frequencies.	9	Fatigue crack in linkage, joint failure, improper mounting, jammed, slipping of fasteners.	5	45	Inspect linkage before use to ensure proper connections and monitor throughout testing.	Ashley, throughout testing				
Our test fixture should oscillate the fake arteries at our desired deflection consistently over a three week duration without user intervention. Measureable: Deflection	Fixture is damaged	Mechanism is no longer fatigue testing renal artery stents	8	Corrosion, stress concentrations, fatigue fractures, improper mounting, dropping, excessive impact.	5	40	Handle the test fixture with care, mark with fragile label, keep away from saline solution, inspect test fixture for fractures or abnormalities.	Ashley, throughout testing				
The fake arteries should hold the stents in place and be bent by the test fixture to the desired displacement and should allow saline solution to contact the stents. Measureable: Deflection, is water contacting the stents	Fake artery is punctured	Water leaks out of fake arteries into dry tank and the stents are no longer in the proper physiological conditions.	7	Sharp objects coming into contact with the fake arteries, test fixture with sharp edges, clamping mechanism pinch points.	3	21	Break all sharp edges in manufacturing processes, do not overclamp the fake arteries.	Munir, throughout testing				
The holding mechanism should hold the fake arteries in place as they undergo oscillations from the test fixture. Measurable: Are the fake arteries held in place?	Fake artery falls out of holding mechanism	Water leaks into dry tank, stents are no longer being fatigue tested, uncontrolled deflection occurs.	7	Insufficiently clamped, vibrations, deformation of holding mechanism, slipping, deformation of artery.	5	35	Inspect that the fake arteries are secured before fatigue testing, continue to inspect throughout.	Munir, throughout testing				
						0						

Appendix H

Design Verification Plan (DVP)

CP Renal DVP&R								
Report Date: 6/5/15			Sponsor: Endologix					
Item No.	Specification or Clause Reference	Test Description	Acceptance Criteria	Test Stage	TIMING		TEST RESULTS	
					Start date	Finish date	Test Result	
1	CP Renal Stent	Saftey Cage	The safety cage sufficiently shields the observer from any potential harm, and prevents misuse of the device to a reasonable degree.	During MFG	2/6/2015	4/27/2015	The safety cage has 4 expanded steel sides and one plexiglass which are impact resistant. The cage will be locked in place to prevent tampering	
2	CP Renal Stent	Circuit Box / Power	When the circuit breaker switch if turned on, **the system should turn on**. This includes power to the limit switch, hall effect sensor, counter, VFD, motor, and any other peripherals. The **motor's power should be dependent on the limit switch being activated** by the correct placement and locking of the safety cage.	On Startup	5/4/2015	5/4/2015	The circuit box operated as intended	
3	CP Renal Stent	High Speed Camera	The high speed camera should be **able to verify displacements** of +/- 1 mm upon review.	On Startup	5/4/2015	5/4/2015	Displacement was confirmed to be 24 mm from high speed camera video at 300 FPS	
4	CP Renal Stent	Cycle Count	The hall effect sensor should be triggered by the magnet attached to the shaft as the motor spins, which should increment the counter by a count of one.	On Startup	5/4/2015	5/4/2015	The hall effect sensor was found to be faulty and cycle count did not work	
5	CP Renal Stent	Stent Migration	The stents, once installed, should **not significantly migrate during the duration of the testing**. The stent location will be checked against a mark placed on the mock artery at the time of installation.	Test Duration	5/4/2015	5/25/2015	There was no noticeable stent migration	
6	CP Renal Stent	Mock Arteries	The mock arteries should remain well seated on the hose barbs with the zip-tie holding them in place. There should be **no fractures, ruptures, or significant ovalization** during the testing duration.	Test Duration	5/4/2015	5/25/2015	Minimal to no ovalization occurred, and the mock arteries stayed securely on the hose barbs for the duration of the test	
7	CP Renal Stent	Tank seal	The tank should hold water and have **no noticeable leaking.**	Test Duration	5/4/2015	5/25/2015	There was leaking when the system was turned above 23 Hz. This would have been a more serious problem had we done further testing	
8	CP Renal Stent	Stent Displacement	The stent should displace to our desired displacement, in millimeters, to a tolerance of +/- 2 mm	Test Duration	5/4/2015	5/25/2015	The free end displaced the desired distance, but we did not see the desired curvature	
9	CP Renal Stent	Motor Frequency	The motor should continuously drive the system at 25 Hz with a a tolerance of +5/-0 Hz.	Test Duration	5/4/2015	5/25/2015	The motor ran as intended	
10	CP Renal Stent	Components	The individual components of our device should remain in their intended places and fulfill their intended purpose without breaking or deforming in any significant way.	Test Duration	5/4/2015	5/25/2015	Each component stayed securely in place	
11	CP Renal Stent	Noise	The overall loudness of the system while running should not exceed an acceptable volume as defined by the professor in charge of the lab in which we are operating.	Test Duration	5/4/2015	5/25/2015	At full speed, the system was quite loud. This would inhibit testing during a scheduled lab class	

Appendix I

Senior Project Critical Design Hazard Identification Checklist

		Team: CP Renal Stent Advisor: Sarah Harding
Y	**N**	**Description of Hazard**
X		Will any part of the design create hazardous revolving, reciprocating, running, shearing, punching, pressing, squeezing, drawing, cutting, rolling, mixing or action, including pinch points and sheer points?
X		Can any part of the design undergo high accelerations/decelerations?
	X	Will the system have any large moving masses or large forces?
	X	Will the system produce a projectile?
	X	Would it be possible for the system to fall under gravity creating injury?
	X	Will a user be exposed to overhanging weights as part of the design?
	X	Will the system have any sharp edges?
	X	Will any part of the electrical systems not be grounded?
X		Will there be any large batteries or electrical voltage in the system above 40 V either AC or DC?
	X	Will there be any stored energy in the system such as batteries, flywheels, hanging weights or pressurized fluids?
	X	Will there be any explosive or flammable liquids, gases, or dust fuel as part of the system?
	X	Will the user of the design be required to exert any abnormal effort or physical posture during the use of the design?
	X	Will there be any materials known to be hazardous to humans involved in either the design or the manufacturing of the design?
	X	Can the system generate high levels of noise?
	X	Will the device/system be exposed to extreme environmental conditions such as fog, humidity, cold, high temperatures, etc.?
X		Is it possible for the system to be used in an unsafe manner?
	X	Will there be any other potential hazards not listed above? If yes, please explain on next page.

Safety Checklist Actions List

Description of Hazard	Corrective Actions to Be Taken	Planned Completion Date	Actual Completion Date
Running electrical motor attached to linkage for project testing	Will create safety cage that will be placed around device and locked to prevent accidents	3/13/15	
Electric motor will be running at high frequencies (≥25 Hz)	Will create safety cage that will be placed around device and locked to prevent accidents	3/13/15	
Our motor will be operating well above the 40 V described above.	Operate the system in the space designated by Jim Gerhardt, with signs posted warning of high voltage.	3/13/15	
It is possible for our system to be used in an unsafe manner if somebody were to try to touch the system while it was running, or change the VFD to run past its limits	We will have a safety cage installed around our device with warnings posted to tell potential tamperers of the dangers associated with tampering with our system.	3/13/15	

Appendix J

Budget/BOM

Subcomponent	Vendor	Item Description	Item Number	Unit Price	Qty	Unit	Shipping Cost	Total Price
Artery	Home Depot	7" cable tie hand twist white	N/A	$5.00	1	Pk		$5.00
Artery	Home Depot	1/4 x 1/4 Brass Adapter Barb x MIP	N/A	$3.32	2	Ea		$6.64
Artery	Home Depot	3/8 OD x 1/4 ID x 10ft Tube	N/A	$17.95	1	Ea		$17.95
Tank	Amazon	Rubbermaid Commercial FG631200CLR Space-Saving Container, 12-Quart Capacity	N/A	$16.25	1	Ea		$16.25
Testing	Marine Depot	JBJ True Temp Digital Controller w/ Heater - 150 Watt	JB1531	$99.99	1	Ea		$99.99
Counter	McMaster Carr	Panel-Mount, 8 Digit, 2400 Counts/min, 20-300V AC	1874T91	$30.43	1	Ea	$45.58	$76.01
Spider /Uprights	McMaster Carr	Aluminum 5083-12"X12"X.5"	4058T51	$82.20	1	Ea		$82.20
Tank	McMaster Carr	Super-Adhesive-Back General Purpose Hook and Loop (1" X 5 ft)	94985K811	$9.25	1	Ea		$9.25
Top of Tank	McMaster Carr	Aluminum 5086-12"X12"X.25"	5865T51	$26.23	1	Ea		$26.23
4-40 Hex Nut	McMaster-Carr	Zinc-Plated Steel Hex Nut with Tooth Washer, 4-40 Thread Size, 1/4" Nut Width, 7/64" Overall Height	90675A005	$2.67	1	Pk		$2.67
4-40 Shoulder Screw	McMaster-Carr	Low Profile 18-8 SS Shoulder Screw, 1/8" Dia X 5/16" Long Shoulder, 4-40 Thread	90337A167	$5.63	2	Ea		$11.26
4-40 Shoulder Screw	McMaster-Carr	Low Profile 18-8 SS Shoulder Screw, 1/8" Diameter x 3/8" Long Shoulder, 4-40 Thread	90337A168	$3.67	2	Ea		$7.34
8-32 Shoulder Screw	McMaster-Carr	Low Profile 18-8 SS Shoulder Screw, 3/16" Diameter X 5/8" Long Shoulder, 8-32 Thread	90337A187	$9.79	1	Ea		$9.79

8-32 Shoulder Screw	McMaster-Carr	Shoulder Screw, 3/16" Diameter x 1" Long Shoulder, 8-32 Thread	91259A168	$2.19	1	Pk		$2.19
Artery	McMaster-Carr	5ft Ultra-Purity White Silicone Tubing - 1/4" ID, 1/2" OD, 1/8" Wall Thickness	2124T7	$33.80	1	Ea		$33.80
Artery	McMaster-Carr	10x Super-Flow Polyethylene Barbed Tube Fitting - Straight for 1/4" Tube ID x 1/4 Male Pipe Size	2808K27	$6.05	1	Ea		$6.05
Bearings	McMaster-Carr	SS Ball Bearing - Double Shielded, 3/16" ID, 1/2" OD, .196" Width	57155K374	$5.38	3	Ea		$16.14
Bracket	McMaster-Carr	Multipurpose 6061 Aluminum - 90 Degree Angle, 1/2" Thick, 5" x 5" Legs	8982K78	$49.15	1	Ea		$49.15
Bracket	McMaster-Carr	50x Coated Alloy Steel Socket Head Cap Screw 8-32 Thread, 1-1/4" Length	91274A076	$12.98	1	Ea		$12.98
Bracket/Upright	McMaster-Carr	100x Neoprene & 18-8 Stainless Steel Bonded Sealing Washer Number 8 Screw Size, 0.180" ID, 0.375" OD	94709A112	$12.66	1	Ea		$12.66
Linkage	McMaster-Carr	2", 10-32, Stainless Steel Standoffs	91125A250	$3.10	4	Ea		$12.40
Locknut	McMaster-Carr	18-8 SS Thin Nylon-Insert Locknut, 8-32 Thread Size, 11/32" Wide, 11/64" High	90101A009	$6.77	1	Ea		$6.77
PTFE Washer	McMaster-Carr	PTFE Flat Washer, Number 8 Screw Size, 0.197" ID, 0.013"-0.017" Thick	95630A239	$2.51	1	Pk		$2.51
PTFE Washer	McMaster-Carr	PTFE Flat Washer, Number 8 Screw Size, 0.197" ID, 0.045"-0.055" Thick	95630A240	$3.22	1	Pk		$3.22
Screws-Shaft Collar	McMaster-Carr	316 SS SHCS, 4-40 Thread, 1/2" Length	92185A110	$8.05	1	Ea		$8.05
Shaft Collar	McMaster-Carr	Aluminum w/ 5/16"-18 set screw	9946K260	$5.24	1	Ea		$5.24
Upright	McMaster-Carr	50x Coated Alloy Steel Socket Head Cap Screw 8-32 Thread, 1/2" Length	91274A056	$10.45	1	Ea		$10.45

Hall Effect Sensor	Mouser	Industrial Hall Effect / Magnetic Sensors 2 hex nuts 152.4 mm	785-103SR13A-1	$25.19	1	Ea		$25.19
Center Shaft	Online Metals	Aluminum 6063-T52, Round Extrusion, .75" OD x 24"	n/a	$6.36	1	Ea		$6.36
	Water Jet Cutting	Water Jet Central - Paso Robles	n/a	$129.00	1	Ea		$129.00
	Water Jet Cutting	Water Jet Central - Paso Robles	n/a	$70.20	1	Ea		$70.20
Plywood	Home Depot	7/32" X 4 " X 8"	N/A	$12.97	1	Ea		$12.97
Wood	Home Depot	2X4X10	N/A	$3.60	10	Ft		$36.00
Shaft Magnet	K&J Magnets	Neodymium magnets 1/4x1/4x1" and 1/4x1/4x1/2"	B44X0, B448	$3.54	1	Ea		$3.54
Linear Bushings	Misumi	Flanged - 0.75" shaft dia, 1.25" OD, 1.625" overall length	U-LHFC0.75	$25.18	2	Ea		$50.36
Outer Box	Home Depot	18 in. x 24 in. x .220 in. Acrylic Sheet	241929	$19.97	1	Ea		$19.97
Safety Cage	Misumi	HFS5-2020 Extrusions - L= 457.0 mm	HFS5-2020-457	$2.60	4	Ea		$10.40
Safety Cage	Misumi	" "- L=690.0 mm	HFS5-2020-690	$3.39	4	Ea		$13.56
Safety Cage	Misumi	" "- L=379.0 mm	HFS5-2020-379	$2.16	4	Ea		$8.64
Tank Top Support	Misumi	" "- L=203.0 mm	HFS5-2020-203	$3.03	4	Ea		$12.12
Safety Cage	Misumi	Brackets - 5 Series, Reversal Brackets with Tab	HBLFSNF5-SET	$1.45	16	Ea		$23.20
Safety Cage	Misumi	Aluminum Hinges with screws and nuts	HHPSN5-SST	$6.15	2	Ea		$12.30
Outerbox	Misumi	Panel Clamps L=3000 mm	HSPF1HB-2000	$13.60	1	Ea		$13.60
Outerbox	Misumi	Panel Clamps L=2000 mm	HSPF1HB-3000	$20.40	1	Ea		$20.40
Arteries	McMaster-Carr	Metric High-Temperature Silicone Rubber Tubing,10ft, 6 mm ID, 9 mm OD	5041K54	$11.90	1	Ea		$11.90
Arteries	Misumi	Resin Collar, MC Nylon, OD 16, ID 10, L 12.5mm	CLJW10-16-12.5	$7.68	4	Ea		$30.72
Outerbox	McMaster-Carr	Black Wire Mesh Panels for Aluminum T-Slotted Framing	47065T287	$13.67	1	Ea		$21.66
VFD	Royal Wholesale Electric Supply	AC Drive: 3 PH, 240 V	2F-B017N104	$466.45	1	Ea		$466.45

AC/DC power supply	Auto Direct	208VAC to 12VDC	PSB12-015-P	$21.50	1	Ea			$21.50
Fuse Holders	Auto Direct	1-pole	EHM1DU	$8.00	1	Ea			$8.00
Fuse Holders	Auto Direct	2-pole	EHM2DU	$16.50	1	Ea			$16.50
Junction Box	Independent Electric Supply			$26.79	1	Ea			$26.79
Misc. Electrical	Home Depot			$20.00	1	Ea			$20.00
Corner Brace	Miners	3-1/2" corner brace		$6.99	1	Ea			$6.99
Fastener	Miners			$0.09	4	Ea			$0.36
Fastener	Miners			$1.19	4	Ea			$4.76
Fastener	Miners			$1.79	2	Ea			$3.58
Fasteners	Miners			$1.17	8	Ea			$9.36
Fasteners	Miners			$0.99	4	Ea			$3.96
Fastener	Miners			$0.27	2	Ea			$0.54
Fasteners	Miners			$16.76	1	Ea			$16.76
Fastener	Miners			$0.14	4	Ea			$0.56
Fastener	Miners			$0.23	2	Ea			$0.46
Fastener	Miners			$0.09	4	Ea			$0.36
Fastener	Miners			$0.26	4	Ea			$1.04
Fastener	Miners			$0.44	4	Ea			$1.76
Fastener	Miners			$0.69	4	Ea			$2.76
Fastener	Miners			$0.09	4	Ea			$0.36
Fastener	Miners			$0.35	4	Ea			$1.40
Fastener	Miners			$0.40	4	Ea			$1.60
Hinge	Miners	2BR Hinge Medium		$6.99	1	Ea			$6.99
Sponge Ruber	Miners	Sponge Rubber 1/4X1/2X10' BLK		$3.59	1	Ea			$3.59
Visqueen	Miners	Visqueen by the foot		$0.69	3	Ft			$2.07
Gasket	Miners	Non-asbestos 12x20 gasket		$4.99	1	Ea			$4.99
Corner Brace	Miners	Corner brace in 3-1/2" Zn		$6.99	1	Ea			$6.99
Threadlocker	Miners	Threadlocker Blue 2.5 mL		$4.59	1	Ea			$4.59
Bag	Miners	bag		$0.10	1	Ea			$0.10
Fastener				$0.85	4	Ea			$3.40
Fastener				$0.35	4	Ea			$1.40
Salt	CVS	salt		$0.99	1	Ea			$0.99
Water	CVS	2.5G		$3.49	1	Ea			$3.49
Water	CVS	1G		$1.77	1	Ea			$1.77
Cardboard	CP Bookstore	cardboard		$2.35	1	Ea			$2.35
Fastener	Miners			$0.49	4	Ea			$1.96
Fastener	Miners			$1.89	5	Ea			$9.45
				Non-McMaster Shipping					**37.39**
				Total					**$1,791.65**

Appendix K

Gantt Chart

✓	**CP Renal Stent Gantt Chart**	**183 days**	**Thu 10/2/14**	**Thu 6/11/15**	**100%**
✓	**1 Start of Project**	**16 days**	**Thu 10/2/14**	**Tue 10/21/14**	**100%**
✓	**2 Preliminary Design Report**	**20 days**	**Wed 10/22/14**	**Tue 11/18/14**	**100%**
✓	**3 Critical Design Report**	**57 days**	**Wed 11/19/14**	**Thu 2/5/15**	**100%**
✓	**4 Purchasing & Manufacturing**	**67 days**	**Fri 2/6/15**	**Sun 5/10/15**	**100%**
✓	4.1 Update CDR and Design	19 days	Mon 2/9/15	Thu 3/5/15	100%
✓	4.2 Safety Cage Design	21 days	Sun 3/15/15	Fri 4/10/15	100%
✓	**4.3 Purchase Parts**	**44 days**	**Fri 2/13/15**	**Wed 4/15/15**	**100%**
✓	4.3.1 Motor	32 days	Fri 2/13/15	Mon 3/30/15	100%
✓	4.3.2 VFD	32 days	Fri 2/13/15	Mon 3/30/15	100%
✓	4.3.3 Arteries	2 days	Fri 2/13/15	Mon 2/16/15	100%
✓	4.3.4 Raw materials	32 days	Fri 2/13/15	Mon 3/30/15	100%
✓	4.3.5 Cycle Counter Things	32 days	Fri 2/13/15	Mon 3/30/15	100%
✓	4.3.6 Safety Cage Components	3 days	Mon 4/13/15	Wed 4/15/15	100%
✓	**4.4 Manufacture Parts**	**41 days**	**Mon 2/23/15**	**Mon 4/20/15**	**100%**
✓	4.4.1 Water Jet Cutting	1 day	Mon 2/23/15	Mon 2/23/15	100%
✓	4.4.2 Water Jet Cutting 2	1 day	Wed 4/8/15	Wed 4/8/15	100%
✓	4.4.3 Spider Bar	27 days	Tue 2/24/15	Wed 4/1/15	100%
✓	4.4.4 Fixture	36 days	Tue 2/24/15	Tue 4/14/15	100%
✓	4.4.5 Motor Linkage System	36 days	Tue 2/24/15	Tue 4/14/15	100%
✓	4.4.6 Safety Enclosure	3 days	Thu 4/16/15	Sat 4/18/15	100%
✓	4.4.7 Total Assembly	2 days	Sat 4/18/15	Mon 4/20/15	100%
✓	4.5 Create Testing Protocol	29 days	Wed 4/1/15	Sun 5/10/15	100%
✓	4.6 Project Update Report	21 days	Thu 2/12/15	Thu 3/12/15	100%
✓	**5 Testing**	**31 days**	**Fri 4/10/15**	**Fri 5/22/15**	**100%**
✓	5.1 Component Testing	30 days	Fri 4/10/15	Thu 5/21/15	100%
✓	5.2 Total Assembly Setup/Prep	23 days	Tue 4/21/15	Thu 5/21/15	100%
✓	5.3 Five-minute full speed test	1 day	Fri 5/22/15	Fri 5/22/15	100%
✓	**5.4 Prepare for Expo**	**32 days**	**Wed 4/15/15**	**Thu 5/28/15**	**100%**
✓	5.4.1 Make Poster	10 days	Thu 5/14/15	Wed 5/27/15	100%
✓	5.4.2 Other things	1 day	Thu 5/14/15	Thu 5/14/15	100%
✓	**6 Ethics Project**	**21 days**	**Fri 2/20/15**	**Fri 3/20/15**	**100%**
✓	**7 Senior Design Expo**	**1 day**	**Fri 5/29/15**	**Fri 5/29/15**	**100%**
✓	**8 Final Project Report**	**10 days**	**Fri 5/29/15**	**Thu 6/11/15**	**100%**

Appendix L

Detailed Calendar

Project Milestone	**Description**	**Due Date**
Preliminary Design Report (PDR)	The main goal of this Preliminary Design Report is to document our chosen concept for our design and support that decision with appropriate evidence	11/18
PDR Presentation	Present PDR to sponsor	11/19
Thanksgiving Break	No work is being done	11/26 – 11/30
Winter Break	Working on Critical Design Report	12/13 – 1/5
Critical Design Report (CDR)	This report should contain all the information a third party needs to build your design without any other help. Appendices should include detailed part drawings and assemblies. Provides sufficient information about purchased parts and materials so someone could purchase them.	2/5
CDR Presentation	Present CDR to sponsor	2/3
Project Update Report	This report is written once our manufacturing is done and will include a hardware review.	3/12
Spring Break	No work is being done	3/21 – 3/29
Initial Testing	Manufacturing is complete and ready to test	4/6 - 4/14
Continuous Testing	Test to 10.8M cycles	4/15 - 5/13
Possible Design Iterations/Additional Testing	Based on initial testing results	5/13-5/22
Senior Design Expo	Present our project to the public	5/29
Final Project Report	In general we will need to update the description of the design and drawings to account for any changes we have made during construction or after testing. We will then need to add chapters for manufacturing, testing, and conclusions	6/5

Appendix M

Manufacturing Verification Plan

Component	Mfg. Detail	Completed?	Percentage	Test	Completed?
Bracket - Top	SHCS slot	✓	100%	Clearance	✓
	Tapped holes	✓		Hose barbs fit	✓
Bracket - Bottom	SHCS slot	✓	100%	Clearance	✓
	Sliding fit slot	✓		Slide and no twist?	✓
	Counter bore slot	✓		Clearance	✓
	Tapped holes	✓		Hose barbs fit	✓
Bracket - Upright	Water jet cutting	✓	100%	-	
	Tapped hole - set screw	✓		Set screw fits	✓
	Tapped hole - SHCS	✓		SHCS fits	✓
Artery	N/A - purchased	✓		Fit on hose barb	✓
				Fit through bushing	✓
				No Ovalization	✓
Spider	Water jet cutting	✓	100%	-	
	Slot - uprights	✓		Clearance	✓
	Slot - SHCS counterbore	✓		Clearance	✓
	Hole - shaft counterbore	✓		Clearance	✓
Linkage - links	Water jet cutting	✓	100%	-	
	Mill - face to thickness	✓		Measure	✓
	Counterbore - screw/nut	✓		Clearance	✓
	Counterbores - bearing	✓		Clearance	✓
Linkage - collar face	Water jet cutting	✓	100%	-	
	Mill - face to thickness	✓		Measure	✓
	Counterbores - SHCS	✓		Clearance	✓
	Tapped hole - "pin"	✓		Shoulder screw fits	✓

Linkage - retainer	Water jet cutting	✓	100%	-	
	Mill - face to thickness	✓		Measure	✓
	Counterbore - screw/nut	✓		Clearance	✓
	Counterbore - bearing	✓		Clearance	✓
	Mill - face for clearance	✓		Measure	✓
Linkage - shaft	Cut to length	✓	100%	Measure	✓
	Mill - face flat side	✓		Measure	✓
	Slot - screw/nut	✓		Clearance	✓
	Counterbore - bearing	✓		Clearance	✓
	Hole- shoulder screw	✓		Clearance	✓
	Hole- tapped	✓		Screw fits	✓
Linkage - shaft collar	Tapped holes - SHCS	✓	100%	Screws fit	✓
Tank Plate Cover	Tapped holes - bracket	✓	100%	Screws fit	✓
	Tapped holes - bearing	✓		Screws fit	✓
	Center hole for bearing	✓		Bearing fits	✓
	Tapped holes - tslot	✓		Screws fit	✓

Appendix N

Testing Protocol

In-Vitro Accelerated Fatigue Testing Protocol

This is a test plan for accelerated, bending fatigue testing of Endologix renal artery stents. The duration of this test simulates 25M cycles of implantation life

Author: CP Renal Stent

Document ID: Pending

Approved By:

______________________________ ______________

DATE

______________________________ ______________

DATE

______________________________ ______________

DATE

1.0 SCOPE

This bench top test is intended to provide empirical evidence for the continued structural integrity of the Endologix renal artery stents when subjected to mechanical bending fatigue replicating *in vivo* conditions. The test is designed to simulate the stent fatigue due to respirational bending of the renal arteries at the *in vivo* deployment site. The test is accelerated to obtain results in a shorter time period than physiological rates would allow. The test is conducted under simulated physiological conditions with saline at 37˚C +/- 2˚

All parts and devices were purchased and/or manufactured by the Cal Poly senior project team.

Testing will be conducted in the Cal Poly San Luis Obispo Fluids Lab, in San Luis Obispo, California under the direction of the Cal Poly senior project team members.

2.0 OBJECTIVE

The testing objective is to meet the 25M cycle requirement for the *in vitro* mechanical fatigue testing set by the stent manufacturer. The test will demonstrate the integrity of the device under bending mechanical fatigue for a minimum of 25M cycles post-implantation. The stents will be reviewed for any broken or cracked strut or graft tear visible at the end of each testing day. Endologix may also examine the stents post-testing and provide further acceptance and/or failure criteria.

3.0 SAMPLE SIZE AND IDENTIFICATION

Samples will be representative of stents prepared for commercial distribution. The table below may be used for identification.

Stent	Size	Lot or ID#
1		
2		
3		
4		
5		
6		
7		
8		

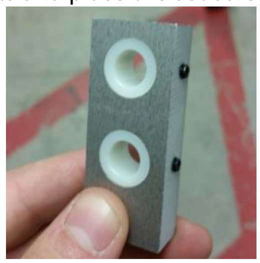
4.0 EQUIPMENT

a) Cal Poly Testing Motor
b) Spider Bar
c) Uprights
d) Artery Inserts
e) Shaft
f) Sliding Brackets
g) Required number of stents – 8
h) Mock Arteries
i) Tank
j) Tank cover
k) Saline solution
l) Associated paper work

1. Test Set Up Checklist
2. Daily Data Sheets

5.0 INSTALLATION

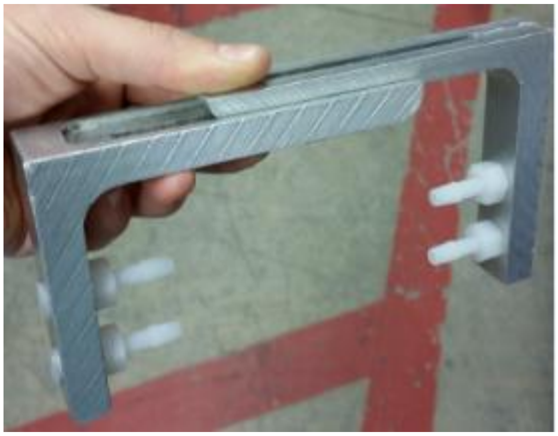
a) Place the artery inserts into the uprights and place the set screws to hold the inserts in place



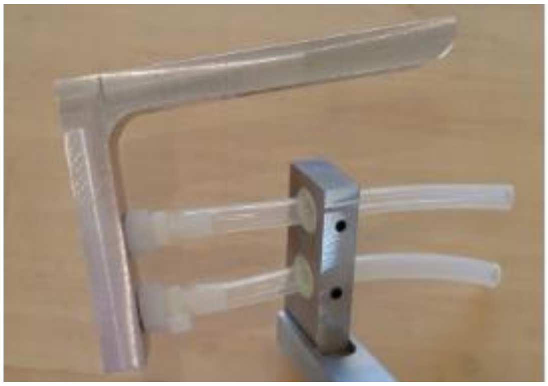
b) Attach the uprights in the spider slots using the 8-32 bolts, making sure the upright is flush with the spider

c) Thread the hose barbs into the brackets

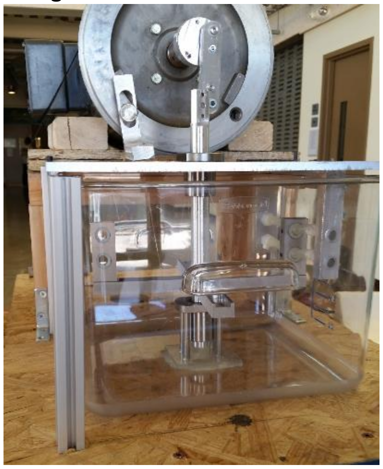
d) Slide the brackets to the desired length and place the 8-32 bolt through them both and thread it into the tank cover



e) Place the synthetic arteries on the hose barbs and zip tie them for added security. Make sure to feed arteries through uprights



f) Thread the shaft into the spider bar center
g) Align the shaft with both linear bearings



h) Attach shaft to the collar assembly on the motor

6.0 TEST DEVICE DEPLOYMENT

a) Visually inspect the synthetic arteries prior to deployment and remove any unsuitable samples
b) Flush the synthetic arteries with saline water and install on the tester
c) Fill the tank with saline solution
d) Cal Poly students will deploy the stents in the arteries

7.0 SAFETY CHECKS

a) Make sure the heater is back in place with the gasket properly enclosing it.
b) Ensure that the weather stripping is properly sandwiched between the tank and tank top
c) Tighten the bolts on the face bracket
d) The motor strap needs to be fully ratcheted down
e) Check that the electrical boxes are all covered
f) Before running it, lock the cage to the base plate

8.0 FATIGUE TEST START UP

a) Ramp up the motor to the required frequency. Start at 10Hz, and move up in increments of 5Hz, checking at each point for irregularities in the system (shaking, artery detachment, stent migration)
b) Once the motor reaches 25Hz, do a final inspection of the system to ensure it is operating normally (no leaks, no excessive vibration, no loosening of linkages)
c) Record the starting temperature and displacement
d) If an abnormal observation occurs, shut down testing and immediately contact the Cal Poly Senior Project team

9.0 MONITORING

a) Set up data acquisition to electronically capture cycle count and high speed camera to check shaft displacement
b) Manually record displacement, cycle count and temperature approximately every two hours
c) Daily monitoring
   a. Record pre-determined parameters on the Daily Data Sheet
   b. Observe for stent migration
   c. Observe for stent failure
   d. If an abnormal observation occurs, shut down testing and immediately contact Cal Poly Senior Project team

10.0 TEST SHUTDOWN: PROTECTIVE LIMITS

a) Press the "off" bottom on the VDF controller to shutdown device
b) When the motor has come to a complete stop, unplug the device from the wall
c) Take the lock from the safety cage and place on the electrical box switch

11.0 TEST COMPLETION

a) Document the date of test cycle completion
b) Inspect the stents while still in the fixture
c) Inform Endologix of the test completion and inspection results
d) Remove the test samples from the fixture
e) Return the test samples, mock arteries, and all components of the testing device to Endologix

12.0 PROJECTED SCHEDULE FOR TESTING

Sample Number_________ Cycles__25 MILLION___ Frequency_______

Cycle Start Date_________________

Predicted Cycle End Date___________________

These times reflect an estimate for the time to complete the various stages of testing. As the test proceeds, more definitive dates may be established to account for set up, artery adjustments, data acquisition, problems, etc.

Revision History:

Version	Change	Date
1.0	Rough Draft Protocol for Cal Poly Team	5/13/15