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Final Report

Team 1: Stomach Electrical Activity Recording Device

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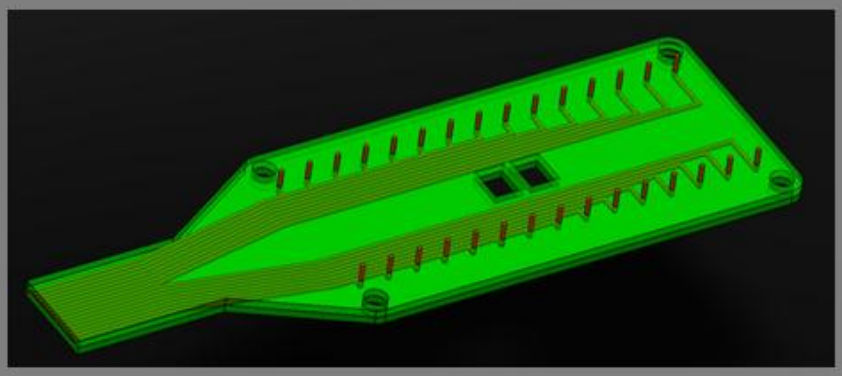

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Section 1: Abstract [6]

An organ consisting of an electrical pacemaker controls stomach contractions and generates continuous rhythmic oscillations known as slow waves, which control frequency and propagation of stimulated stomach contractions. A 3 electrode system, which involves upper endoscopy and is affixed to the stomach's lining, has been developed to measure differences in stomach electrical activity. However, due to this system's limited precision in determining stomach electrical defects, we are designing a more accurate and precise multichannel electrode system.

Section 2: Executive Summary

We are challenged with developing a device and accompanying endoscopic technique for attaching electrodes to the stomach lining non-invasively in order to obtain a more accurate recording of the electrogastric impluses. There is an existing patent for an endoscopic process to attach electrodes to the stomach lining involving a tethering device implanted through the layers of the stomach. We hope to develop an alternative technique that minimizes damage to the stomach tissues.

Based on input from our sponsors, we quantified their requirements into engineering specifications. Our engineering specifications are: having an inert material with tensile modulus between 0 and 5 GPa, maintaining material properties at body temperature, 4-8 clamps or alternative form of attachment, hard-wired or wireless transmission to monitor, and 100% of electrodes maintain contact with the mucosa lining. Also, we determined the following lesser priority specifications: use one tool through the endoscope for removal and installation, ability to record electric signal data for up to 3-4 hours, plate needs to fit 25-35 electrodes, area of the plate less than 8 cm^2, plate width less than 2 cm, less than 2.5 mm between each electrode, and total diameter of the endoscope plus the device must be less than 1.5 cm.

To determine the best design concept, we rated each design based on plate size, plate compressibility, plate surface area for electrodes, ease of affixing to mucosa lining, ability to fit between folds of mucosa lining, and ease of installation and removal. We also rated three wiring scheme concepts based on patient comfort level, ease of incorporation into device, minimizing electrical components to the patient's stomach, and minimizing total volume. Using the best plate concept and the best wiring scheme we developed an alpha design, which was later refined into a final design.

Our final design consists of a 40 x 15.5 x 1mm plate made of cast silicone and tapered approximately 30 degrees on the trailing end. The taper is meant to ease the removal of the device. There are thirty electrodes spaced 2 mm apart, aligned in two rows of fifteen, symmetrically placed on the plate. The electrode arrays are symmetrically placed on the plate to limit interaction between electrodes when the plate is folded. We chose to use .006" magnet wire because it minimizes the total diameter of wires exiting the esophagus. To manufacture the device, we made a primary mold with wire path grooves and a secondary mold to apply a layer over the exposed wires. During the molding process, four dowel pins and two protrusions on the mold created holes on the plate for clamp attachment. The electrodes will relay the stomach's electrical impulses through each lead wire to an external amplifier. The monitoring computer and software receives data from the amplifier output and simultaneously outputs the data on a monitor. After recording is finished, the clamps are removed and the plate is extracted by pulling the lead wires. The whole device is meant to be disposable based on our sponsor's request.

We conducted independent tests of our engineering specifications to determine device functionality. We used a straw of diameter 4.5 mm to test for device compressibility and we used a combination of LabVIEW, a custom built inverting amplifier circuit, and a thermocouple to test for the accuracy of our signal. Our device successfully passed through the straw diameter and we successfully tested for an accurate signal for patient diagnosis. The only specification we were unable to test for was the ability of one tool to be used through the

endoscope. This specification, however, is not necessary for device functionality, but we are confident that this specification would be satisfied because all other specifications were successfully satisfied.

The tapered edges on our plate successfully improved plate compressibility through the endoscope channel. Also, using external amplification minimizes the amount of electrical components through the patient and it reduces the risk of electrical complications. However, we would suggest looking into more automated manufacturing processes that involve the possible use of flexible printed circuit boards, and we would suggest silver-plating the electrodes to improve electrical conductivity and rigidity of the electrodes.

Section 3: Introduction [6]

The slow wave is a continuous rhythmic oscillation that regulates the frequency and propagation of stimulated stomach contractions, which occur from external activities such as eating. Electrogastrography (EGG) is a commonly practiced technique to measure slow waves in patients. EGG uses electrodes placed on the skin overlying the stomach to record electrical oscillations in the stomach.

However, studies have shown that stomach electrical activity cannot be measured simply by measuring a dominant slow wave frequency, indicating that EGG is an ineffective method. Our sponsors, Radoslav Coleski (MD, PhD) and William Hasler (MD, Professor of Gastroenterology), have developed a 3 electrode system, which records slow waves using upper endoscopy and attaching electrodes to the stomach's interior. Unlike EGG, the 3 electrode system is capable of measuring differences in electrical activity. Another benefit of this electrode system is that it can be performed without opening the abdomen through surgery.

However, the 3 electrode system is not precise in determining conduction characteristics, thereby limiting the knowledge of stomach electrical defects in patients with unexplained vomiting and nausea. Therefore, we are designing a multichannel electrode system capable of precisely and accurately measuring these defects by providing high resolution maps of patients' stomach electrical conduction profiles. The goal of this project is to have our electrode system used in research and clinical medicine in the future.

Section 4: Information Sources

Section 4.1: Endoscopic System for Attaching a Device to a Stomach [3]

Mir A. Imran, Oliver L. Colliou, Ted W. Layman, and Sharon L. Lake of Menlo Park, CA (US) issued a patent regarding an endoscopic system for attaching a device to a stomach. The patent outlines a method for diagnosing and treating gastric disorders. They invented a functional device that resides within the patient's stomach and is secured to the stomach wall by an attachment device. The embodiments of this device pertain to the method of attaching a device to the stomach and using the attachment as a guide to introduce electrical stimulation devices, such as electrodes. This invention is in response to previous work conducted involving the gastrointestinal (GI) tract. The previous work involving the GI tract showed that there are several types of electrical potential activity present. The electrical potentials are under the control of an electrical pacemaker located in the mid to upper part of the stomach and generate consistent low frequency waves. Interruptions in these waves are observed to be linked with stomach contractions, and there are many possibilities for the onset of these contractions, such as nausea and vomiting. The functional device invented by the authors of this patent makes four claims regarding the methods and uses of their device.

According to US Patent No. 7,590,452 B2, their "method for treating or diagnosing a patient with a functional device comprises of: visualizing a desired attachment site from within a stomach; advancing a guide from within a stomach so that a distal portion of the guide extends through a wall of the stomach at a desired attachment site along an inner surface of the stomach wall; coupling an electrode to a proximal portion of the guide while the proximal portion and electrode device are accessible from outside the patient; guiding the electrode device with the use of the guide through an esophagus of the patient to the attachment site from within the stomach; advancing an elongate portion of an anchor into the stomach wall and retaining the elongate

portion within the stomach wall by engaging the inner surface of the stomach wall with a first surface of the anchor and engaging an outer surface of the stomach wall with a second surface of the anchor, wherein the elongate portion comprises a stimulating electrode, and wherein the first and second surfaces of the anchor protrude laterally from the elongate portion so as to capture the stomach wall there between and retain the electrode within the stomach wall; and coupling electronic circuitry to the anchor and transmitting signals so as to allow stimulation of the stomach at the attachment site by the functional device.

A method for coupling a functional device to a stomach wall comprises of the following: an anchor having an elongate portion and a coupling portion, and a guide; determining a desired attachment site from within the stomach; attaching the anchor to the stomach wall and retaining the elongate portion within the stomach wall by engaging the inner surface of the stomach wall with a first surface of the anchor and engaging an outer surface of the stomach wall with a second surface of the anchor, wherein the elongate portion comprises a stimulating electrode, and wherein the first and second surfaces of the anchor protrude laterally from the elongate portion so as to capture the stomach wall there between and retain the electrode within the stomach wall; coupling the guide to the coupling portion of the anchor guiding the functional device to the coupling portion of the anchor with the use of the guide; coupling the functional device to the anchor; removing the guide from the coupling portion of the anchor; and diagnosing and/or electrically stimulating the stomach with the functional device using signals generated within the stomach and transmitted from within the stomach."

According to the patent, "The method of claim 2 wherein the guide is removed from the coupling portion after guiding the functional device to the anchor. The method of claim 2 where the step of providing an anchor having a coupling portion comprises providing an elongate portion for receiving the function device, and wherein the step of coupling the functional device to the anchor comprises coupling the functional device to the elongate portion".

The claims made in the patent mentioned above are related to our project because they are congruent with aspects that are fundamental to our objectives. We need to affix electrodes to the stomach lining via upper endoscopy and remove the electrodes via endoscopy. This procedure includes affixing a guide wire to the lining of the stomach; we hope to avoid this process because it causes unnecessary damage to the stomach lining.

Section 4.2: Mapping Slow Waves and Spikes in Chronically Instrumented Conscious Dogs: Implantation Techniques and Recordings [4]

In addition to finding patents with content pertinent to our objectives, we also found work on the recordings of electrical waves in animals. A high spatial resolution has been established for electrical mapping of the stomach. Recent studies performed on tissues in vitro show fundamental differences in propagation between slow waves and action potentials. This work inspired the exploration of custom made electrode arrays that could be implanted in a conscious animal and provide high spatial resolution electrical mapping. These electrode arrays were crafted and implanted on the stomach and small intestine of Beagles during surgery. The wiring from the electrodes was routed through a subcutaneous tunnel and led to the animal exterior. The signal from the electrodes was connected to a 37-pin connector to a 32-channel amplifier. The amplifier was then connected to a Windows-PC via a NI-DAQ-card to record electrode and force transducer signals. Custom software was used for online visualization and the signals were digitized and recorded with a 2-400 Hz bandwidth and a 200-1,000 Hz sample frequency.

This is the first description of electrode arrays with fixed inter-electrode distances being implanted for high spatial resolution measurements: "The advantage of this approach is that accurate maps of slow wave propagation and spike behavior can be constructed off-line, which allows detailed evaluations of local slow wave and spike behavior, and to identify slow wave pacemaker activity". This method, however, does have limitations as the dogs only tolerated the implanted device for a limited period of time.

Overall, this study has shown that there have been innovations in recording and analyzing the electrical events in the gastrointestinal system at higher spatial resolution than previously known. Also, electrode arrays can be custom-made to generate high spatial resolution maps capable of accurately measuring electrical activity. In this study the time frame of recording was shortened because it caused discomfort to the subjects; we hope to avoid this by installing the device via endoscope, which minimizes discomfort and prolongs the recording period.

Section 4.3: High-resolution Mapping of In Vivo Gastrointestinal Slow Wave Activity Using Flexible Printed Circuit Board Electrodes: Methodology and Validation [2]

This study comes from the Bioengineering Institute at the University of Auckland, New Zealand. The report is titled *High-resolution Mapping of in Vivo Gastrointestinal Slow Wave Activity Using Flexible Printed Circuit Board Electrodes: Methodology and Validation* and touches on the utilization of multi-electrode recording arrays for mapping electric slow waves in stomach and bowels. This technique involves placing a spatially dense array of electrodes over the electrically active tissue surface and recording the resultant signals in each electrode site. For high-resolution results of gastrointestinal slow wave mapping, a rigid printed circuit board (PCB) was surgically attached to the exterior of the stomach and bowels of animals. The PCB is inflexible and has contained as many as 240 silver-tipped wire electrodes in dense arrays with an inter-electrode distance of 1-3 mm.

In addition to the time and expense of the circuit board construction, they are too rigid to readily conform to the curvature of the GI organs, which restricts contact between the electrodes and the organ surfaces. More importantly, these platforms are not suitable for integration to human subjects due to the vulnerability to heat or water during the sterilization process. There is also a potential for trapping contaminated matter in the depressions of the board, increasing risk of disease transmission.

The PCB electrode arrays have been implemented in cardiac electrical monitoring systems with some success. These particular models are not useful for recording GI slow wave activity because they are designed with small electrode tip size and high electrode density, which has been customized for substantially higher propagation velocity and amplitude of electrical activity present in the heart.

The authors introduce a new unipolar PCB electrode design suitable for the high-resolution mapping of slow wave activity. The new model uses 68 foot-prints for a standard 68 straight pin PCB plug, a 4 x 8 configuration of 32 electrodes with inter-electrode spacing of 7.62 mm, and a midsection of 28 x 339 mm. The base material is Polymide with inlaid tracks and connectors made from copper. The boards can be manufactured cheaply and quickly with costs of ~$215 for tooling and ~$8 per unit for 100 units.

Porcine experiments were performed in two sedated female weaner cross-bread pigs. The plates were surgically implanted and attached to the exterior of the stomach with a bilateral subcostal laparotomy. Three electrode arrays were aligned side by side and recording was acquired using ActiveTwo System. A reference electrode was placed on the body surface of the lower abdomen to help eliminate noise. Recordings were filtered with a second order Bessel low-pass filter of 4Hz and slow wave activation times were classified using the point of maximal negative derivative of each slow wave event. The slow waves propagated in the normal aboral direction toward the gastric pylorus. Direction of wave flow was determined by the time differences between the spikes of each recording electrode. Average propagation velocity was 12.18 mm/s in the x-direction and 8.19 mm/s in the y-direction. The recording quality was dictated by the average signal to noise ratio of 9.71 dB.

The authors of this study created a flexible PCB electrode array for high-resolution mapping of gastrointestinal slow wave activity. Results from the testing suggest that slow wave propagation was in a broad wave front, predominantly following the longitudinal axis of the stomach. The major disadvantage of the new PCB design is the lower signal to noise ratio compared to the traditional electrode array. In practice, this is not a critical problem because the signals are still strong enough to characterize the desired attributes of slow wave activity. The main issue with the plate PCB electrode configuration is the difficulty in maintaining contact with the

steeply curved areas in the stomach and other areas of interest. In our design we will account for the difficulty in maintaining contact with the stomach wall by constructing the plate from a flexible material.

Section 4.4: Multi-scale Modeling of Human Gastric Electric Activity: Can the Electrogastrogram Detect Functional Electrical Uncoupling?[1]

Similar to the heart, the human stomach generates rhythmic electrical impulses. These impulses control the peristaltic contractions that mix and grind stomach contents. Slow waves are triggered by the interstitial cells of Cajal (ICC) cells in a network that is coupled to the circular and longitudinal smooth muscle layers of the stomach. In a normal scenario, the slow waves originate from the dominant pacemakers located in the corpus region of the stomach. The corpus is the dominant pacemaker region because it generates slow waves at the highest frequency. These slow waves typically occur at a frequency of three cycles per minute.

This electrical activity can be recorded using cutaneous electrodes attached to the exterior of the abdomen. The electrogastrogram (EGG) uses a small number of electrodes to provide an indirect representation of the electrical activity occurring within the abdomen. Typically, three electrodes are used to record a single-channel bipolar EGG, and these electrodes pick up on other electric impulses from other parts of the body (heart, bowels, etc). A band-pass filter is used to eliminate any impulses with a frequency below 1 cycle per minute.

A study examining the accuracy of the EGG cutaneous electrode recording process titled *Multiscale Modeling of Human Gastric Electric Activity: Can the Electrogastrogram Detect Functional Electrical Uncoupling?* The study conducted two sets of simulations testing the hypothesis that the EGG recording and interpretation system is unable to differentiate between normal and abnormal slow wave patterns when an ectopic antral pacemaker is present. Under normal conditions the ICC excitability was at a maximum in the proximal corpus on the greater curvature of the stomach and decreases the most in the longitudinal direction. The conduction velocities within the stomach that were recorded matched those reported in previous independent studies. An inspection of the EGG results show some shape and amplitude variations in the slow waves, but it is unlikely that either of these phenomena would provide enough information to diagnose an abnormality in the slow waves. Both of the parameters above vary with shape and body composition of the subject, resulting in variations in electrode placement. EGG amplitude is also affected by the quality of the electrode contact with the skin.

A typical EGG procedure cannot provide results that clearly diagnose an issue with the slow waves generated. For example, if the primary pacemaker in the proximal corpus was damaged, an antral pacemaker could produce retrograde slow waves that traverse the length of the stomach, which would produce a single dominant frequency and return normal results on the EGG. To determine whether slow waves in the corpus propagate in a normal manner and drive pacemaker activity of the distal stomach, high-resolution recordings of electrical activity with electrode distribution from corpus o distal antrum are required. It is likely that these measurements exceed the capacity of cutaneous recordings of gastro electric activity.

This study suggests that present EGG techniques are not sophisticated or reliable enough to evaluate directional signal propagation. Attaching electrodes to the exterior of the stomach (gastric serosal surface recording) would yield better results, but is not practical because it is an invasive procedure. It is possible that multipoint luminal recording, after placement of electrodes via endoscope, could provide the most suitable means of reliable clinical recording of gastric electrical activity. We hope to improve the accuracy of the signal recordings by attaching electrodes directly to the stomach wall.

Section 4.5: Meeting with Dr. Radoslav Coleski and Dr. William Hasler [7]

We met with Dr. Coleski and Dr. Hasler to gain a better understanding of the project requirements and engineering specifications. Ideally the device will be flexible enough to roll or fold to minimize the profile as it is passed down the esophagus. Also, the plate should be no larger than 2 x 4 cm. The compatibility of the device

is necessary if we plan to deliver it outside the endoscope so that the electrodes and wires do not damage the esophageal lining. Possible means of delivery include: 1) rolling and attaching to the side of the scope to be passed parallel with the scope, 2) rolling and pushing through the largest scope channel, 3) attaching the device in line with the scope to be pushed in front, 4) using a separate tube for the device and wires, and 5) using a capsule that would enclose all abrasive parts. The plate needs to be flexible enough to adapt to the curvature of the stomach but also rigid enough to maintain its shape and press the electrodes into the mucosa.

The plate also needs to be affixed with a clamp-like mechanism that can be manipulated with forceps through the endoscope. The plate will also need to record signals for up to several hours, meaning that the clamps have to be robust and the device will need to operate in body temperature (37°C) and damp and acidic conditions. The signals will be picked up by the electrodes and relayed to the computer via hard-wire connection or wireless transmission. Once recording is complete the device needs to be removed without damaging the esophagus and ideally needs to be disposable.

We observed an upper endoscopy of a patient in the hospital to gain a better understanding of how an endoscope functions. There is a high resolution camera at the end of the scope that allows the operator to clearly see inside the body. The endoscope can maneuver by curving in the x-y plane and pushing or pulling in the z-direction. The tip of the scope has an optical lens, a tool channel, and an additional wider channel that could be used for passing the device into the stomach. We have taken the information from our meeting with the doctors and created a list of engineering specifications, shown in the next section, in order to achieve these goals for the new product.

Section 4.6: Meeting with Dr. Kevin Pipe [8]

We met with Professor Pipe to get a better understanding of electrodes and signal recording processes. The electrodes will transfer the electric potential of the surface they are in contact with. The signal may need to be amplified to overcome the internal resistivity and voltage drop of the wire from the device to the monitoring system. The electrodes need to be connected to both a positive lead and a ground wire in order to effectively relay the signal. Due to the large number of wires needed for the device to operate in the current conditions, serializing the signal is a possible method to limit the number of wires. The analog signal from the electrodes will need to be converted to a digital signal with a chip in order to be serialized. The serialization will make the digital signal relayed from each of the thirty electrodes travel down a single wire to the monitoring system. The contact between the electrodes and the mucosa may need a saline solution in order to conduct properly. Professor Pipe also directed us to Digikey, which is an online chip distributer. We will also need to decide on the type of feedback received from the device, whether it is a two-dimensional display showing wave propagation through the electrode arrays or individual electric potentials recorded over time. Professor Pipe recommended that we schedule a meeting with our sponsors to clear up these questions.

Section 4.7: Meeting with Dr. Radoslav Coleski [9]

We met with Dr. Coleski in order to gain a better understanding of what has already been implemented in the existing three electrode procedure. We also presented some of our conceptual designs for professional feedback. We were shown the existing clamping technique and have decided to implement it into our alpha design. Dr. Coleski favored designs that used a tapered strip. The electrodes will be strong enough to transfer the potentials down the lead wires until they are amplified outside the body. Dr. Coleski mentioned that the electrodes have good conductivity inside the stomach and therefore do not need an additional saline solution. The purpose of a saline solution would have been to account for the acidity of the stomach mucous. The expected feedback is thirty individual measurements; a two dimensional representation is not needed but could be helpful for diagnosis. The monitoring system needs to determine the propagation velocity of the slow waves by measuring the time difference in peaks measured across the electrode array.

Section 4.8: Meeting with Dr. Alexander Ganago [16]

We talked with Professor Alexander Ganago to gain a better understanding of why we could not produce an accurate signal with minimal noise. From this discussion, we found that using a differential amplifier circuit and capacitors could reduce the noise from the power supply and outside atmosphere. The capacitors would be connected to the Vcc- and Vcc+ terminals of the power supply to reduce the power supply noise. Also, we found that we could use a thermocouple to generate the expected signal amplitude of 0.5-1 mV. The thermocouple is placed in freezing water and then in heated water, and this produces a voltage drop that can be calibrated to 0.5-1 mV by changing the temperature of the heated water.

Section 5: Project Requirements and Engineering Specifications

Our goal is to design a device and process capable of implanting a flexible plate of electrodes to the lining of the stomach using a non-invasive endoscopic procedure. Using the electrode-covered plate, we will create a multi-channel system to record the stomach's electrical signals. To determine the engineering specifications for this device, we quantified our sponsor's requests to create fixed engineering targets.

The first functionality requirement is that the device along with the endoscope must travel to the stomach without damaging the esophagus. Since the average human esophagus is about 1.5 cm in diameter, the endoscope with the device must have a diameter less than 1.5 cm to avoid discomfort to the patient. We were given freedom in our method to pass the device to the stomach, but each method has specific corresponding engineering specifications. If the device is going to pass through a channel of the scope, the diameter must not exceed 4.2mm, the channel's diameter. If the device is going to be pushed alongside (parallel to) the scope, the diameter of the device being passed parallel must not exceed 6 mm. All of these methods ensure that the total diameter including the outer diameter of the endoscope (9mm) is less than 1.5 cm. Also, if the device is passed parallel to the endoscope, the outer surface of the device must be smooth to avoid damage to the esophageal tissue.

The plate material must be flexible, yet rigid and able to fold to a profile that will allow an acceptable delivery method. The plate material's flexibility allows easy maneuverability when placed inside the stomach and its rigidity allows the plate to maintain its shape along the curvature of the stomach wall. The tradeoff between these two properties can be expressed by the tensile modulus, which describes the ratio of stress to elastic strain. We determined that a tensile modulus between 0-5 GPa would be satisfactory, as many urethanes and nylons fall into this region and are commonly used in medical practices. The plate will need to be affixed to the stomach lining, which contracts and moves with the onset of electrical stimuli. Also, the lining of the stomach consists of a mucosa layer, making attachment to the wavy slippery surface difficult. To secure the plate to the stomach lining, a group of approximately 4-8 clamps or another form of attachment is required. Doing so will keep the plate fixed and allow the electrodes to maintain contact with the stomach wall during contractions, which is critical for obtaining accurate electric signal feedback.

The attachment components, electrodes, and plate must all be constructed of an inert material that is safe for use inside the human body. The material must perform at the internal body temperature of 37°C and be resistant to potential damage caused by stomach acids and fluids.

The desired area of the plate, which must fit approximately 30 electrodes, is approximately $8cm^2$ and the maximum width 2 cm. By keeping the width less than 2 cm, we will facilitate maneuverability within the stomach. The 30 electrodes will provide the necessary multichannel feedback and improved accuracy and precision. To produce optimal signal recording results, the distance between the electrodes on the plate needs to be maximized. If the 30 electrodes are successfully placed on the plate, the maximum distance between each electrode is approximately 2.5 mm.

The device also needs to either be hard-wired to a power supply or contain its own power source, and the device must provide immediate feedback of the electric signals over a period of several hours. The transmission of these signals also needs to be hard-wired to a monitoring system or have the ability to wirelessly transmit results to a monitoring system to provide the necessary immediate feedback.

Once the signal recording results have been collected, the device must be easily removed from the esophagus. Since the device will be unfolded or unrolled during installation, it must retract into a form similar to delivery. The ability to retract ensures that the device can be removed from the esophagus while keeping abrasive components (such as electrodes) from damaging esophageal tissues. This feature is critical to the design of the device; therefore, the components of the device should be easily accessible and manipulated with the use of tools passed through a channel of the endoscope. It is also essential that the electrodes maintain

Table 1, on the next page (page 14), summarizes our understanding of the sponsor's project requirements and their translation into engineering specifications, as discussed above:

Since the material selection is critical for the device's performance and functionality, we considered any project requirement related to material selection to be a level 1 priority. As expressed by our sponsors, the material selection is going to be of paramount importance. Since this device will need to provide immediate feedback for use by operating persons, we considered immediate feedback to be a level 1 priority as well. In order to produce precise and accurate results, the electrode plate needs to affix to the stomach lining, creating proper contact between all recording electrodes and the stomach lining; thus, we assigned this engineering specification a level 1 priority. It is essential for the device to be powered so that it can operate, which warrants a level 1 priority.

While it is important for the patient to feel no discomfort from the procedure, the device can still maintain full functionality if this requirement is not fulfilled; therefore, we assigned this requirement a level 2 priority. Similarly, although it is important for the plate to fit 30 electrodes, this number can be adjusted as needed based on feasibility; thus, we assigned this a level 2 priority. Although it is necessary for the device to record results for several hours, this is a requirement that is subject to change as needed, so a level 2 priority was assigned. Since ease of removal and installation of the plate is not a requirement that will affect its functionality, but rather will affect ease of usage, a level 2 priority was assigned. Additionally, though it is important to minimize the plate and maximize electrode spacing, these requirements will not affect the overall functionality of our device; thus, we assigned a level 2 priority.

In addition to the project requirements and engineering specifications above, we also plan to consider ease of manufacturing for our device. However, this is not a requirement for the device to function properly, but rather a desire expressed by our sponsors.

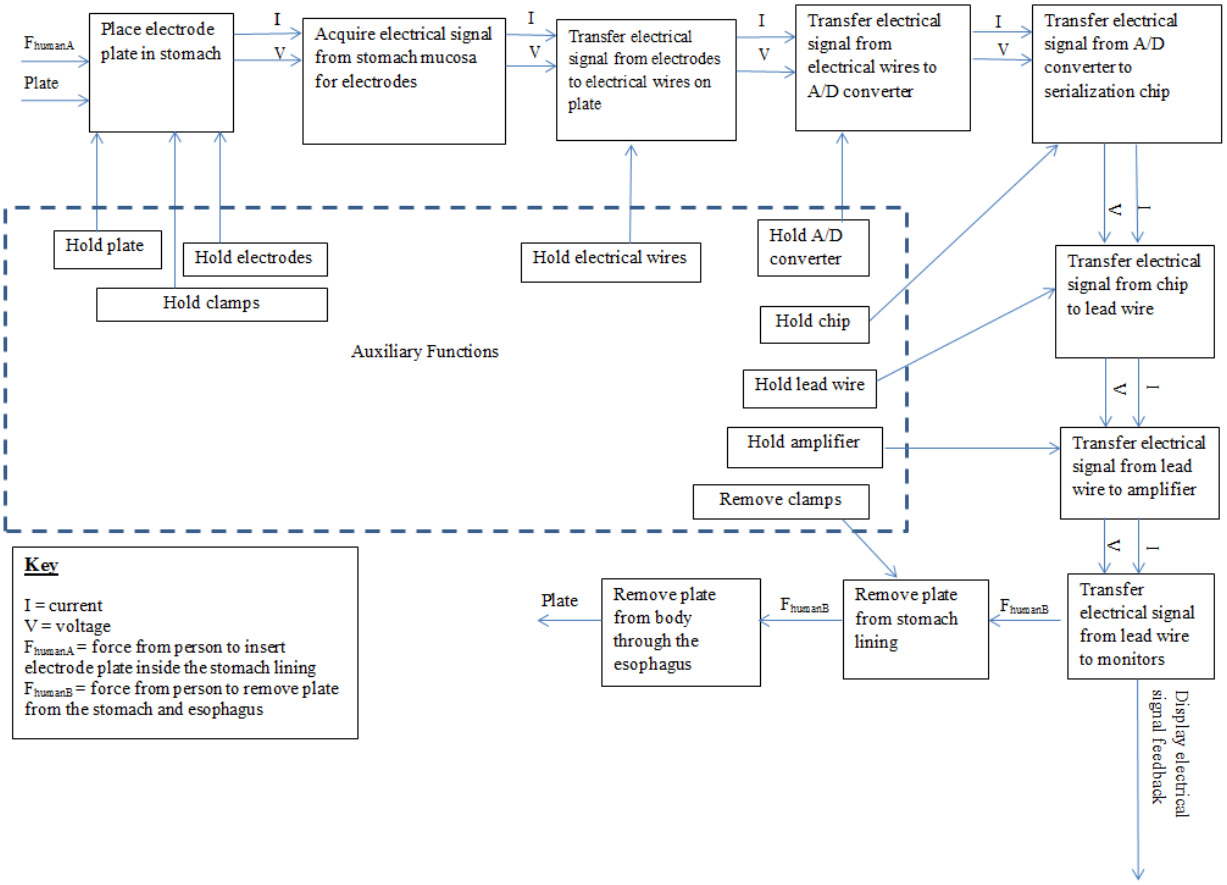
Section 6: Concept Generation

We created a functional decomposition to further break down how our device needs to function for customer use. By doing so we gained more insight into how our preliminary concepts should be generated. First, the electrode plate is placed in the stomach manually and attached by several clamps. The electrodes acquire an electrical signal generated in the stomach mucosa, and this signal is then transferred to the electrical wires on the plate. Next, the electrical signal is transferred to an analog to digital (A/D) converter, which converts the analog signals from the electrodes into digital signals. This signal is transferred to a serialization chip, which organizes the digital signals by cycling through each signal several thousand times per second. The signal is then transferred to a lead wire, which sends the signal to monitors, which then display the electrical signal feedback for the doctors to see. The plate is then manually removed from the stomach to the esophagus and then outside of the subject's body. Figure 1, page 15 shows our functional decomposition.

Table 1: Sponsor driven project requirements accompanied by their corresponding translated engineering specifications and assigned priority level. A priority level 1 indicates a mandatory requirement/specification while a level 2 priority indicates that the requirement is mandatory but subject to change if necessary.

Sponsor Driven Project Requirements	Engineering Specifications	Priority (1-2)
Device must be powered	Use battery, capacitor, or wired power supply	1
Immediate electric signal feedback	Device needs to be hardwired or wirelessly transmitted to monitor	1
Plate must maintain shape along stomach wall and maneuver easily	Tensile Modulus 0 GPa ≤ and ≤ 5 GPa	1
Materials safe for use in human being	Choose inert material	1
Device must perform at internal body temperature	Material must maintain properties at 37°C	1
Plate must affix to stomach lining	4-8 clamps or alternative attachment device	1
Electrodes must maintain contact with stomach lining	100% of electrodes on plate must maintain contact with mucosa lining of the stomach	1
Plate must be easily removed and installed	Use one tool through endoscope for removal and installation	2
Device must last for several hours of recording	Must record for up to 3-4 hours	2
Plate must fit ~30 electrodes	Plate should fit 25-35 electrodes	2
Patient should not feel discomfort from endoscope	Diameter of endoscope w/ device: <1.5cm	2
Minimize plate size while maximizing electrode spacing	Area of plate ≤ 8±2 cm^2 with plate width < 2cm and 2.5± 0.5 mm between each electrode	2

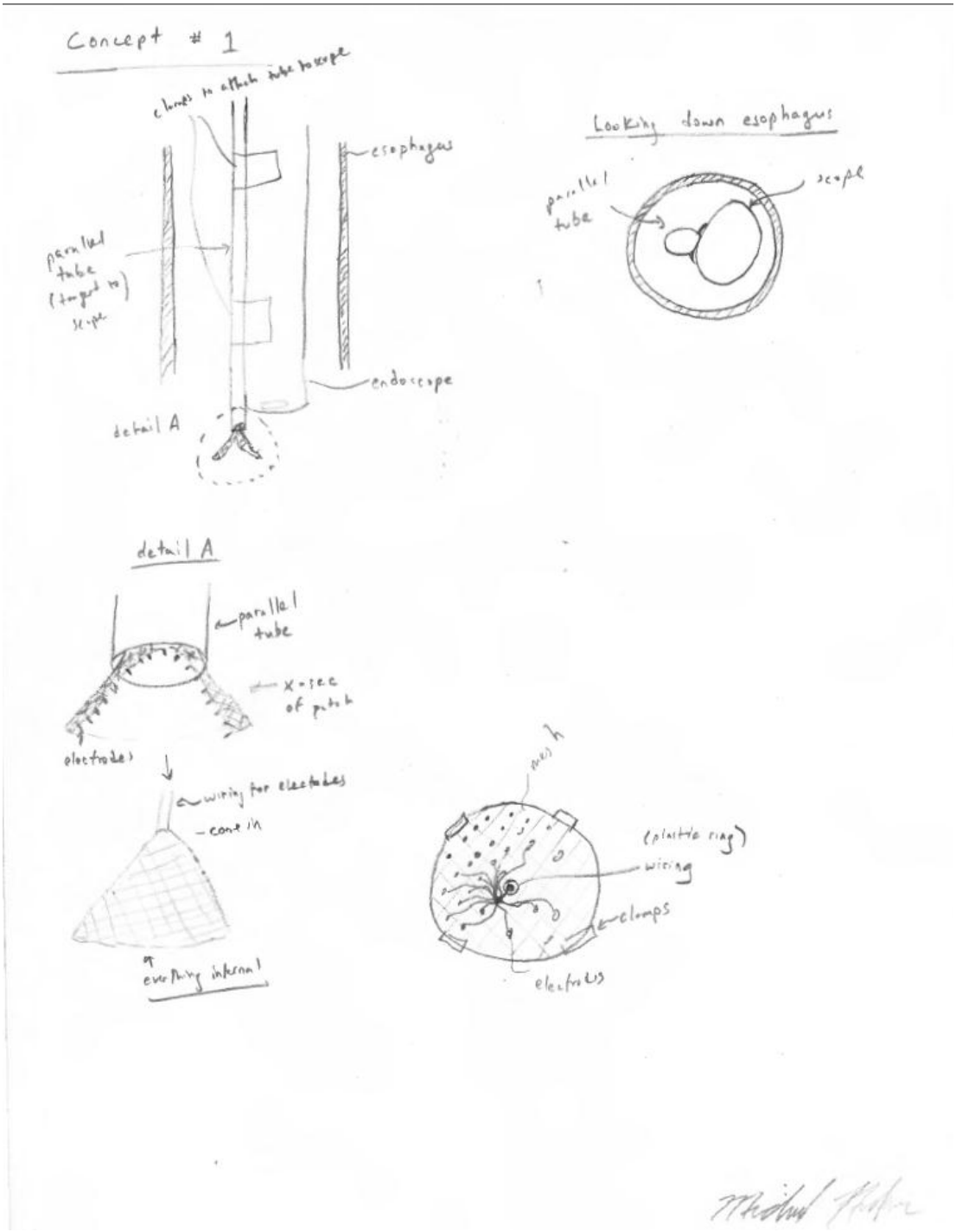
Figure 1: The functional decomposition below divides the device functionality into sub-systems which collectively illustrate the steps required for the device to work properly.



We then generated a series of preliminary concepts with the potential to satisfy the subsystems outlined by the functional decomposition. We narrowed this list of concepts to five by eliminating the concepts that we considered infeasible for prototyping. The eliminated concepts along with their corresponding details can be found in appendix A.

The first concept uses mesh material to enclose all of the electrical wiring. In the open position, the plate takes on a circular shape with the electrodes branching out circumferentially from a rigid, plastic ring located in the middle of the plate. There are four clamps to attach the plate to the stomach lining, and the plate is enclosed in a tube parallel to the endoscope during delivery down the esophagus. The electrodes on the plate are isolated within the plate when enclosed in the parallel tube. The plate then opens up after leaving the tube, exposing the electrodes to the stomach mucosa. For removal, the clamps are retracted one at a time. The patch is then pulled back into the delivery tube by the lead wires. Figure 2, page 16 shows this concept.

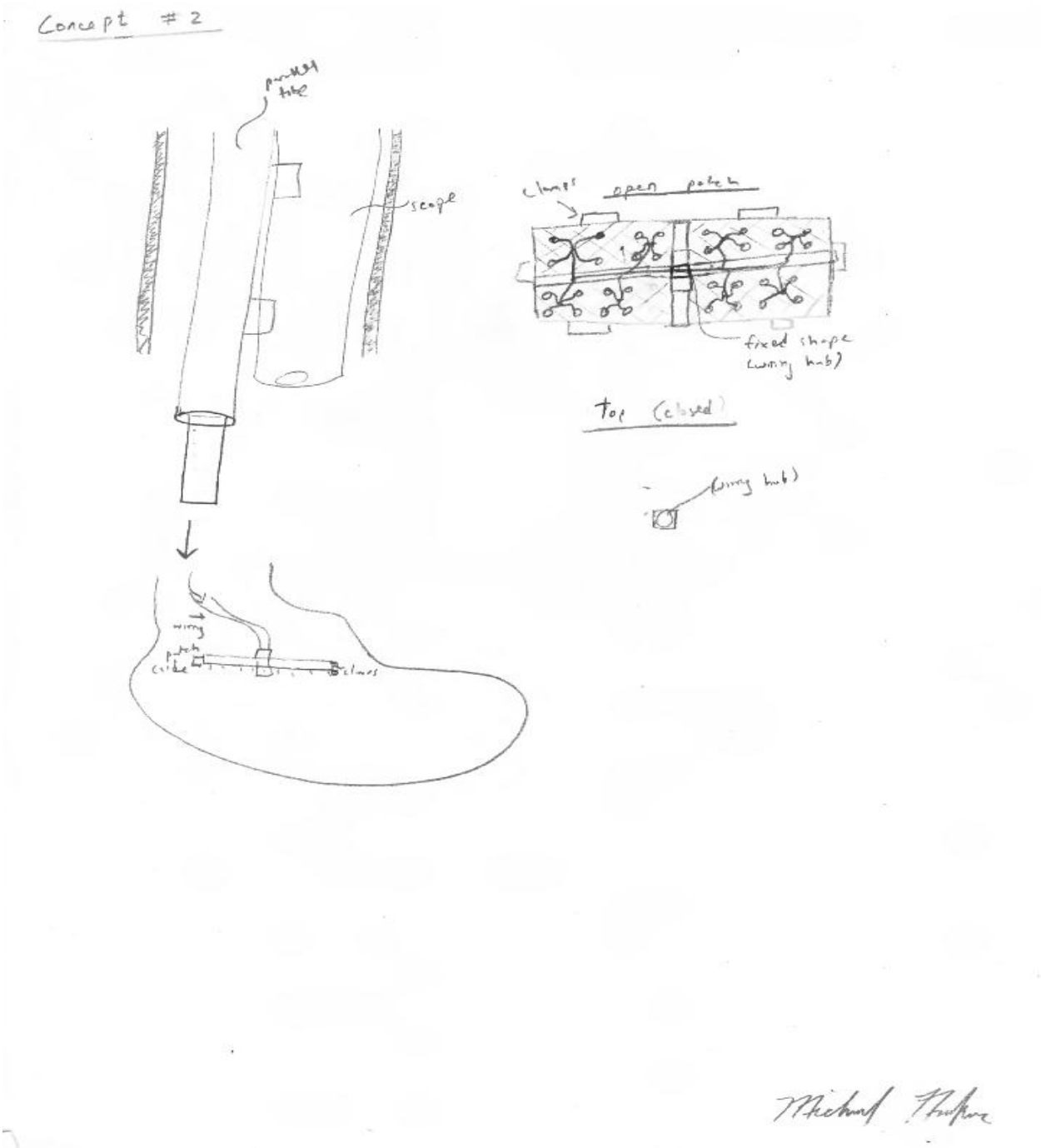
Figure 2: Concept 1



The second concept consists of a rectangular plate with eight branches of electrodes and its electrical wiring originates from a wiring hub in the center of the plate. The plate folds into a smaller rectangular shape to be passed down the esophagus through a tube parallel to the endoscope. There are six clamps to attach the plate to the stomach lining. The clamps are applied using the Boston Scientific catheter clamp mechanism. When the

plate leaves the tube, it opens up into its full rectangular shape where all of the electrodes are exposed to the stomach mucosa. The rigid poles are locked into place to prevent the plate from flexing significantly. For removal, the clamps are removed one at a time, the poles are unlocked, and the plate is collapsed to its original shape, and retracted back into the delivery tube. Figure 3, below, illustrates the second concept.

Figure 3: Concept 2



The third concept is a rectangular plate with a tapered rear end and several holes for clamping to the stomach wall. This plate folds in half and rolls to minimize the profile when being passed into the esophagus via upper endoscopy. When the plate reaches the stomach mucosa lining, it opens up into its full rectangular shape by extending the support poles manually. In this position all of the electrodes are exposed, capable of recording electrical signals. There are three groupings of electrodes consisting of ten electrodes each. The electrical wiring is simplified by organizing the electrodes into six groups of four and three groups of two. The groups tie into a main line traveling down the center of the plate. The thirty analog signals from the electrodes are fed to an analog to digital converter located on the plate. Once the signals are converted, they are fed to the serialization chip located toward the rear end of the plate. The serialization chip then samples the thirty signals in rapid succession and sends all the data down a single lead wire. For removal, the clamps are removed one at a time and the plate is retracted back into the endoscope channel by pulling the embedded wires and allowing the tapered end to enter the tube first. Figure 4, page 19, shows this concept.

The forth concept consists of two rigid curved plates that stack on top of each other in the collapsed position. The electrodes are located on the inner plate and covered by the outer plate so that they will not damage esophageal tissues. The wiring and chips are contained within the inner plate and its sides to protect them from the hostile environment of the stomach. There is a u-shaped clip attached to the back end of the device which attaches to the front of the endoscope. This allows the device to be passed forward of the scope through the esophagus. Once inside the stomach, the outer plate rotates around and locks in place opposite of the inner plate, resulting in a football-shaped device. This exposes the electrodes to the mucosa lining. There are four clamping mechanisms that clip onto the mucosa on either side of the device and ratchet down to tightly secure the device and push the electrodes against the mucosa. For removal, the clamps are removed two at a time, the outer plate rotates to its original position and the u-shaped clip attaches to the end of the endoscope from retraction. An illustration of this concept can be found in Figure 5, page 20.

The fifth concept is a patch made of a flexible material cut into an elongated oval. The patch is placed inside a capsule which has a hook at the front for attaching to the endoscope. The scope pulls the capsule parallel to it while traveling through the esophagus. Once the capsule reaches the stomach, it is unlatched, allowing the patch to be removed from the separating capsule. There are four clamps attached to the plate that are applied to the stomach lining with the forceps fed through the scope channel. For removal, the clamps detach from the lining using forceps and the plate is pulled back into the capsule by pulling on the lead wires. The capsule closes itself upon removal due to the drag experienced during travel through the esophagus in the opposite direction. Figure 6, page 21, shows this concept.

Figure 4: Concept 5

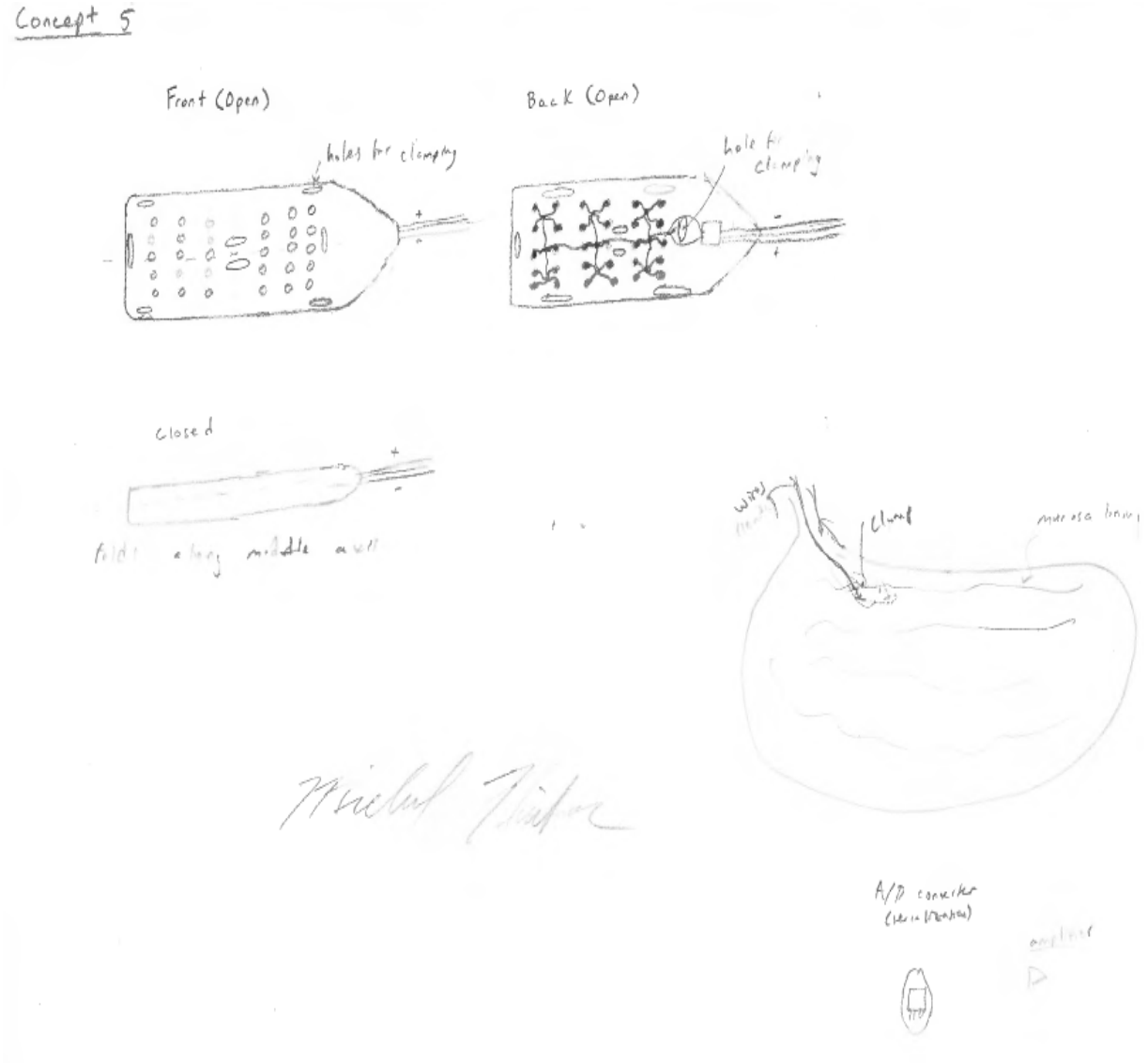


Figure 5: Concept 6

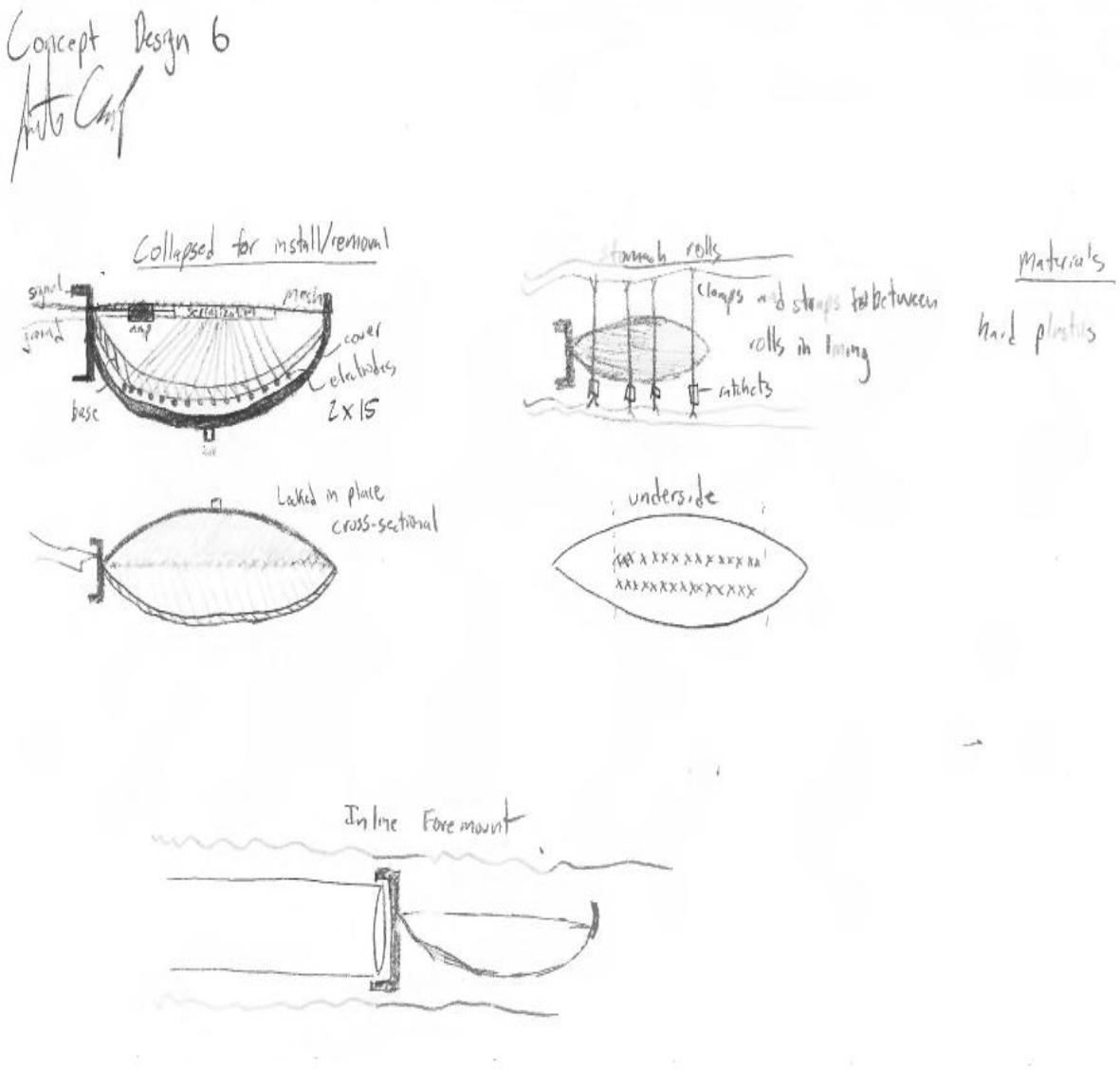
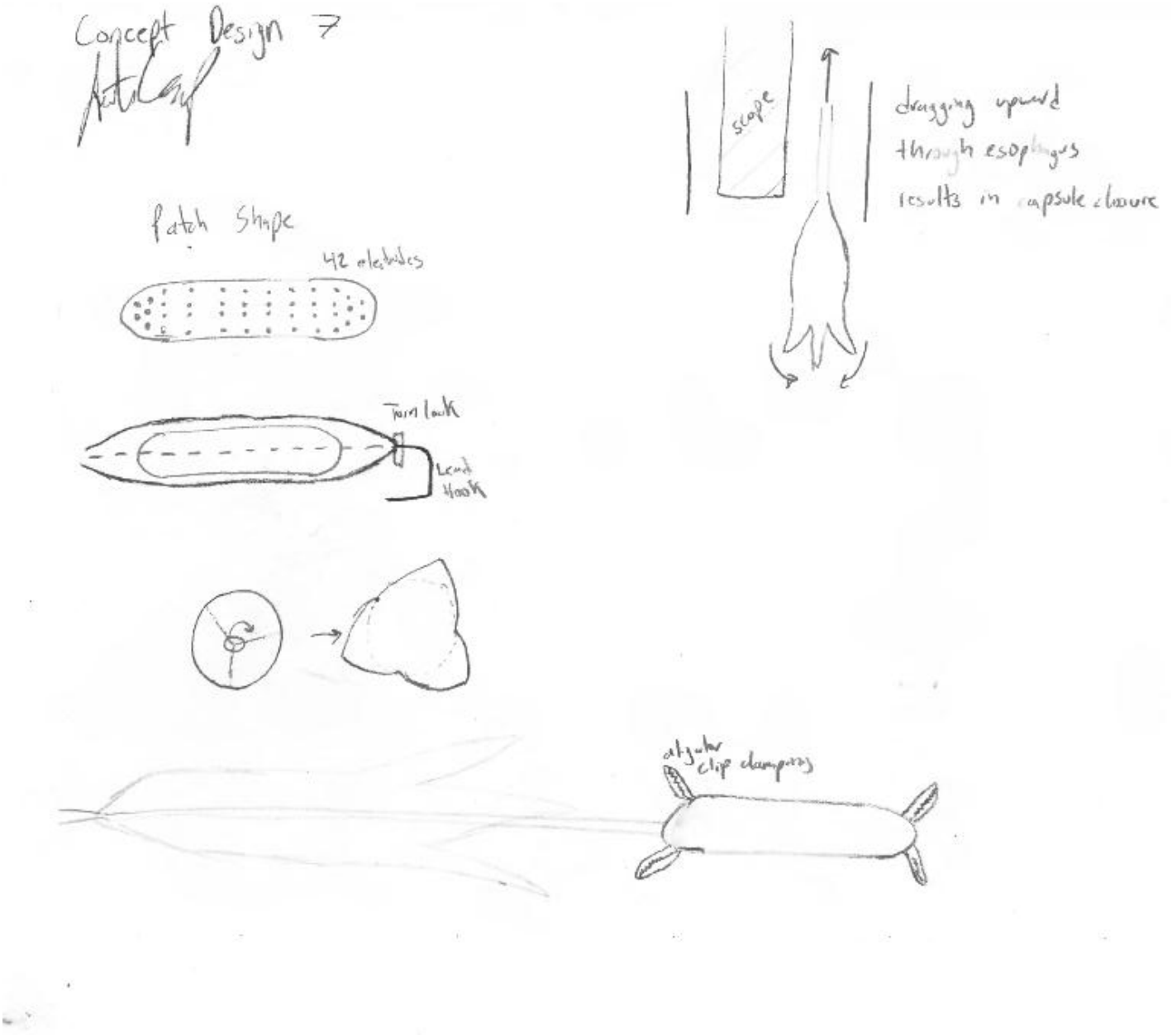


Figure 6: Concept 7



Section 7: Concept Selection Process

Section 7.1: Plate Design Criteria

To select a single concept from our best five concepts, we established a selection matrix to quantify the effectiveness of each design. The criteria for our selection matrix were generated based on the engineering specifications that were translated from our sponsor-driven project requirements. We first determined that all specifications related to material selection would not be considered since all designs would have to account for appropriate material selection, therefore unable to distinguish concepts.

We defined the following criteria to rank our five design concepts: 1) plate size, 2) plate compressibility, 3) plate surface area for electrodes, 4) ease of affixing to mucosa lining, 5) ability to fit between the folds of

mucosa lining, 6) electrode contact with mucosa lining, 7) ease of installation, and 8) ease of removal. We chose to make plate size a criterion because our sponsors clearly communicated a desired plate size of 8±2 cm^2. So, we ranked each concept based on how close we expected each concept to satisfy this plate size. Since our device needs to be passed via upper endoscopy, we ranked the design concepts based on how small we expect each design to be in its compressed position. Our sponsors are hoping that the device will hold 30 ± 5 electrodes. So, we determined that the designed plate needs a sufficient surface area to accommodate the sponsor's request. We scored the area available for electrodes based on the amount of available plate space for electrodes.

Because the device needs to be affixed to the stomach lining, we used this criterion to rank the sophistication and effectiveness of each design's affixation device. To obtain accurate electric signal feedback, the device needs to fit between the folds of the mucosa lining. According to our sponsors, there is approximately 2 cm between each fold. So, we analyzed the shape of each electrode plate to determine its ability to fit in between these folds. In addition to fitting between the mucosa lining folds, 100% of the electrodes need to maintain contact with the mucosa lining. The score for this criterion was also based on electrode plate shape. We determined that installation and removal of the device during upper endoscopy needs to be as simple as possible. Each concept was scored based on the number of "steps" required for installation and removal of the device. The number of "steps" was determined based on the number of actions and processes required for removal and installation. An example of a process is using forceps to open and close the device.

Section 7.1.1: Determining Plate Criterion Weight

Upon determining our plate selection criteria, we were faced with the decision to use a traditional Pugh chart, which weights each criteria based on the importance. It was decided that the traditional "weight system" would not be the best method to decide our best design concept. This decision was based on various reasons. Since our plate selection criteria were derived from our engineering specifications, we had already given priority levels to these specifications. The priority level is not an indicator of importance. The priority level for our specifications is an indication of whether or not a specification is necessary for the functionality of the device. Although priority level 2 specifications are not necessary for the device to function, they are still important and necessary to satisfy our sponsors. Since we aim to please our sponsor, we determined that all of our criteria developed to judge our design concepts were equally important. To further explain this, if our plate size and compressibility, level 2 priorities, are not designed as well as the method to affix the plate to the mucosa lining, then the device will suffer in its effectiveness. The design of the plate for our device is not very intricate; therefore we determined that we did not want to make compromises on which should be "weighted" more than others.

Section 7.2: Scoring and Analysis of Plate Design Concepts

We used a 1 to 5 scoring scale for our selection matrices. A design concept that did not satisfy the criterion received a 1. A 2 indicates the design met the criterion but not at a satisfactory level. A design concept with an average satisfactory level of a criterion received a 3. A 4 indicates the concept satisfied the criterion to an acceptable standard, and a 5 indicates the design concept satisfied the criterion to an excellent standard. Table 2, page 23, shows how our plate design concepts scored.

Table 2: The table below shows the scoring for the five selected design concepts against the determined criteria. The scores received for each criterion were totaled to evaluate which design concept was superior.

	Concept 1	Concept 2	Concept 5	Concept 6	Concept7
Plate Size	5	5	5	5	5
Plate compressibility	3	4	5	1	1
Plate Surface Area for Electrodes	5	4	5	5	5
Ease of Affixing to Mucosa Lining	5	5	5	1	5
Fits Between Folds of Mucosa Lining	2	5	5	5	5
Electrode Contact with Mucosa Lining	2	3	5	2	4
Ease of Installation	4	2	5	3	2
Ease of Removal	5	3	5	3	4
Total	**31**	**31**	**40**	**25**	**31**

The plate size of each our design concepts scored a maximum score of 5. All of the design concepts met the specified engineering specification on the plate size since none of the areas were greater than 8±2 cm^2. For plate compressibility, design concept 5 scored 5 in the selection matrix. This design concept received a score of 5 in this criterion because we determined that it had the best method of compression, which was rolling and folding, and that its plate would be most compact when compressed. Design concept 2 received a score of 4 for this criterion because it would compress to be compact, but the method of compression requires more installation steps, which impedes the functionality. Since it is more difficult to compress this concept, we decided that it could not receive the full score of 5. Concept 1 received a score of 3 for plate compressibility because of the method of compression. We determined that the "bunching" of the material would be fairly crude and could create some further complications in actual practice. Although we determined the method to be crude, we did recognize that the plate was capable of compressing to an acceptable degree. Concepts 6 and 7 received a score of 1 for plate compressibility because neither of the plates compressed to be smaller than their original size.

For available electrode space, design concepts 1, 5, 6, and 7 all received a score of 5 because all of the surface area of the plate is available for electrode placement. Design concept 2 received a score of 4 because it contains rigid rods, which impede the placement of electrodes. Design concepts 1, 2, 5, and 7 all received a score of 5 for the ease of affixing to the mucosa lining because all of these design concepts used the sponsor recommended method of clamping to the stomach, using the sponsor-provided clamps. Design concept 6 received a score of 1 because it uses a ratchet-like device to pull the folds of the mucosa lining. We determined that this would not be effective because the folds of the mucosa lining are not rigid enough to sustain this force while maintaining its shape.

Concepts 2, 5, 6, and 7 have a width of less than or equal to 2cm, meaning that the plates in each of these concepts fit in between the folds of the mucosa lining. So, these concepts received a 5 for ability to fit between the mucosa lining folds. Design concept 1 received a score of 2 for this category because we determined that if the circular plate does not have a diameter less than 2cm, therefore unable to fit in between the folds of the mucosa lining. To score the criteria for electrode contact with the mucosa lining we anticipated how well the electrodes would maintain contact with the mucosa based on the plate shape design and the clamping effectiveness (which would tightly affix the plate to the mucosa lining). Design concept 5 received a score of 5 for this criterion because of the shape of the plate. Since the plate is designed to have a width of less than 2cm, it would fit between the folds of the mucosa lining. Also, since the clamping is designed to have clamps on all edges of the plate as well as the middle of the plate, we determined that the electrodes would maintain contact throughout all of the contractions and motions of the stomach. Because design concept 7 has no space for clamping in the middle of the plate, it is possible some electrodes could lose contact due to the convexity of the stomach. So, concept 7 received a score of 4.

Design concept 2 received a score of 3 due to plate rigidity. In our research, we found in the article titled *High-resolution Mapping of in Vivo Gastrointestinal Slow Wave Activity Using Flexible Printed Circuit Board Electrodes: Methodology and Validation*, discussed in the information sources, that rigidity in the circuit board will create difficulties with the electrodes maintaining contact. Since the board is significantly rigid, the plate will have trouble conforming to the new shape of the stomach lining, thus losing contact with the mucosa lining. Design concepts 1 and 6 both received a score of 2 for this criterion. Design concept 1's plate shape cannot effectively fit between the fold of the mucosa lining, therefore the electrodes will not maintain contact with the desired regions of the mucosa. Design concept 6 received a score of 2 due to plate rigidity. Although the plate is curved with the intention of matching the curvature of the stomach lining, our sponsors have communicated that it is very difficult to match the curvature of the stomach correctly. Further, the curvature of the stomach lining changes due to the contractions being captured, meaning electrode contact will be lost in different regions throughout the contraction.

Design concept 5 received a 5 in both ease of removal and ease of installation because of the simplicity involved with both stages. To install the device, it is simply folded and when it reaches the stomach, it will open by itself. To remove the device, the person simply needs to unclamp the device and pull on the wire, and the tapered end will force the plate to close itself during removal. Design concept 1 received a 4 for ease of installation and a 5 for ease of removal. This design received a 4 for ease of installation because of the crude method of compressibility. Since the plate is "crumpled up," this could cause complications with the passing of the device to the stomach. However, concept 1 can be removed using the same process as concept 5. Thus, concept 1 received a score of 5 for ease of removal. Design concept 6 scored a 3 in both the ease of installation and ease of removal criteria because the method of passing the device to the stomach and removing it are effective, but we deducted the score for this design concept due to the additional steps necessary once the device is in the stomach. These additional steps are caused by the moving parts that need to be manipulated on the device. Concept 2 received a score of 2 for the ease of installation because it has four separate rigid bars that need to be opened and locked once the device reaches the stomach. This concept received a score of three for the ease of removal because it needs to be unlocked before it can be collapsed and removed from the patient.

Additionally, design concept 7 received a score of 2 for the ease of installation because once the device is passed to the stomach, the capsule that it travels in must be unlocked, opened, and the plate must then be taken out of the open capsule. This concept received a score of 4 for the ease of removal because it simply needs to be pulled out using the wires attached to the device, which enters another capsule. Concept 7 did not receive a 5 for ease of removal because of the additional capsule that the plate needs to enter to ensure safe removal. Upon tallying the scores from the selection matrix, it is determined that design concept 5 is the best design concept.

The simplicity of the concept 5 allowed it to score a 5 in all categories. The indicator that this design concept is superior to other design concepts is that this design is fully capable of satisfying all of our engineering specifications. Since our engineering specifications are driven from our sponsor's requirements, moving forward with this design concept will adequately satisfy our sponsor's needs.

Section 7.3: Wiring Scheme Selection Criteria

Since we have three options for a wiring scheme, we created another selection matrix to determine the best option. The first wiring scheme consists of a wire coming from each electrode, totaling thirty electrodes. The thirty wires from the stomach exit through the patient's esophagus and then connect to a monitoring device. The second option utilizes an A/D converter, serialization chip, and an amplifier all travelling to the patient's stomach, meaning that only two wires (positive and negative lead) come out of the patient's mouth. The serialization chip allows the thirty signals to be sent one at a time through the wire to the monitoring device. The third wiring scheme option is allowing the A/D converter and the serialization chip to travel with the device to the patient's stomach. The amplifier is outside of the patient's body, meaning only two wires come from the patient's esophagus, thereby minimizing the electrical circuitry on the device.

Based on our engineering specifications, we determined the following criteria for the wiring scheme selection matrix: 1) patient comfort level, 2) ease of incorporation to device, 3) minimizing electrical components in the patient's stomach, and 4) overall volume. Since the diameter of the device and the endoscope should be less than 1.5cm, we ranked each wiring scheme based on how well this specification would be satisfied. Also, since we do not want a complex wiring system travelling to the patient's stomach, we ranked each wiring scheme based on its ease of incorporation to the device. Our sponsors also indicated they want the device to be "as simple possible," which is another reason that the wiring scheme needs to be easy to incorporate into the device. The patient's safety is also a major factor; so, we determined that minimizing the amount of electrical components travelling to the stomach would mitigate the number of possible complications. The overall volume of the design concept includes the device's wiring, which is another reason electrical components need to be minimized.

Section 7.3.1: Determining Wiring Scheme Criterion Weight

Upon determining our wiring scheme selection criteria, we were again faced with the decision to use a traditional Pugh chart, which weights each criteria based on the importance. We decided to stay consistent with our scoring from the plate design, and stay away from the traditional "weight system" associated with Pugh charts. Ultimately, we determined that all of our criteria were equally important to reaching a solution that would satisfy our sponsor's needs.

Section 7.4: Analysis of Wiring Schemes

Table 3 shows the scoring of all three wiring schemes:

Table 3: Below is the scoring for the three feasible wiring schemes against the determined criteria. The scores received for each criterion were totaled to evaluate which wiring scheme was superior.

	Wiring Scheme 1	Wiring Scheme 2	Wiring Scheme 3
Patient Comfort Level	1	5	5
Ease of Incorporation to Device	5	2	3
Minimal Electrical Components Traveling to Patient's Stomach	5	1	3
Overall Volume	2	4	4
Total	**13**	**12**	**15**

The patient comfort level criterion was directly related to our sponsor-driven engineering specifications and was therefore considered an important criterion for choosing the wiring scheme. Wiring scheme 1 scored a 1 in this criterion because this wiring scheme has thirty wires exiting through the patient's esophagus. Thirty wires exiting from the patients esophagus could theoretically satisfy our engineering specification of having a diameter <1.5 cm, but we did not consider this to be practical option. Also, the endoscope increases the total diameter by 9mm, meaning that the thirty wires would need to be less than 6mm, which is a small diameter for thirty wires. Wiring schemes 2 and 3 received a score of 5 for comfort level because if the signal is serialized on the plate, we will only need two lead wires exiting through the patient's esophagus, which is more comfortable for the patient than thirty wires.

Wiring scheme 1 scored 5 in the criterion of easily incorporating to the device because it would not require any circuitry on the plate, therefore making the plate easier to compress. Wiring scheme 2 received a 1 for this category because an amplifier, and analog/digital converter chip, and a serialization chip on the device are required for this wiring scheme, which could cause unforeseen complications in the device. Also, wiring scheme 3 received a score of 3 for this criterion because it has less complication than wiring scheme 2 in that

we would not need to incorporate the amplifier on the plate. This wiring scheme, however, would still present the same difficulties with the A/D converter and serialization as wiring scheme 2.

The criterion of minimal electrical components traveling to the patient's stomach was scored based on the number of required components. Wiring scheme 1 required no additional electrical components to travel to the patient's stomach so it received a score of 5 for this category. Wiring scheme 2 received a score of 1 for the amount of electrical components traveling to the patient's stomach because all of the possible components used will be internalized in this scheme. Wiring scheme 3 received a score of 3 for this category because the amplifier is not included in the components travelling to the stomach. The overall volume of wiring scheme 1 is fairly large because there are thirty wires traveling from the device to the electrical components necessary for the output. Since there are thirty wires traveling that distance, wiring scheme 1 received a score of 2 for this criterion. Wiring scheme 2 and 3 both received a score of 4 for this category because although the plate may contain slightly more volume, the wiring is reduced by 28 wires, which reduces the overall volume of the device. Once the scoring was completed, wiring scheme 3 was determined to be the best wiring scheme based on the total score. This wiring scheme will be very effective because it will allow us to satisfy our engineering specification regarding the patient's comfort level. Also, the circuitry on the plate will be cleaner and more organized for this wiring scheme.

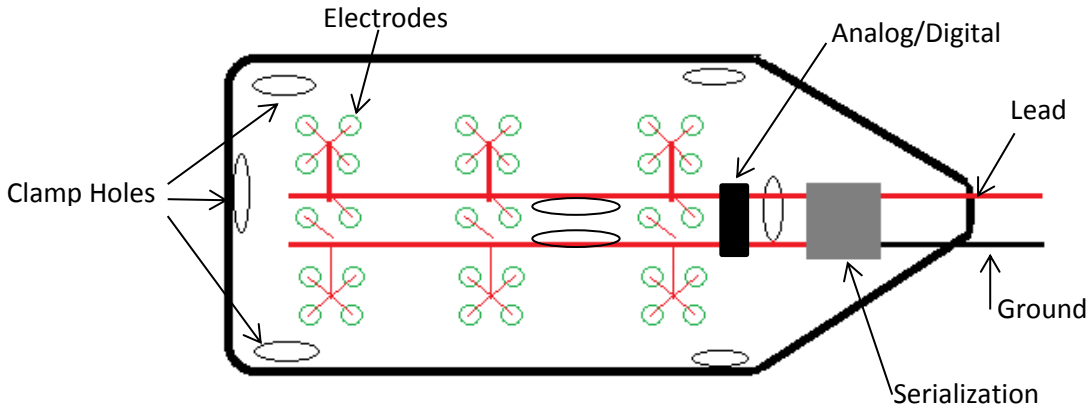
Section 8: The Alpha Design

The conceptual design we have chosen consists of a flat, rectangular plate with rounded corners and a tapered end. The plate itself will likely consist of nylon 12 or a thin urethane material so that it can be rolled to fit inside the 4.2mm diameter channel at the end of the endoscope. There are five rows of six electrodes spaced evenly in aligned rows and columns. The electrodes are arranged into six groups of four and three groups of two in order to better consolidate the wiring. No conductive gel or solution is needed for the electrodes to perform properly since the saliva and mucous inside the stomach are acidic and conduct well. Each electrode will have a lead wire and a ground wire. The presence of the ground wire ensures that no charge builds up inside the wire that could produce inaccurate results.

The wiring will be implanted into the plate itself to protect it from the hostile environment when inside the stomach. The 30 lead wires will be fed into an analog to digital signal converter chip and then to a serialization chip. The signal will be serialized so that it can travel down one wire to the monitoring equipment. Ideally the plate will have two wires that travel to an amplifier outside the body and later to the monitoring equipment. The signal will be recorded separately. Six oval shaped holes are located near the four corners of the main body and the center of the ends. These holes will be used to clamp the plate to the mucosa.

This design will utilize existing clamping techniques. Each clamp is installed individually with a catheter. The clamp is opened inside the stomach with one side threading the holes in the plate and the other grasping stomach tissues. There are seven clamps in all; one clamp is located on each corner, two on the smaller ends, and one in the center of the plate. Once the clamps are installed, they will disconnect from the applicator and remain in place until the doctors are finished with the recording process. The clamps are removed one at a time and the plate is retracted back into the endoscope channel by pulling the exterior wires. The tapered rear end will aid the plate in collapsing back into the endoscope channel. Figure 7, page 27, shows a diagram of the mentioned device.

Figure 7: Two-dimensional representation of the plate for the alpha concept design.



The sub-systems as defined by our function decomposition are: (i) place electrode plate in stomach, (ii) acquire electrical signal from stomach mucosa to electrodes, (iii) transfer electrical signal from electrodes to wiring, (iv) transfer signal from wires to A/D converter, (v) transfer signal from A/D to serialization ship, (vi) transfer signal from serialization chip to lead wire, (vii) transfer signal from lead wire to amplifier, (viii) transfer signal from amplifier to monitors, (ix) remove plate from stomach lining, (x) remove plate from body via esophagus. In step (i), the patch is attached to the stomach lining using the clamping mechanisms described earlier. The patch contains the electrodes, wires, and chips from steps (ii) thru (vii). The patch pushes against the stomach lining and is held in place by the clamps. This force keeps the electrodes in contact with the mucosa, resulting in acquisition of the gastro-electric signals. These electric potentials are relayed from the electrodes through the wiring system to the analog to digital signal converter, to the serialization chip, and down the single lead wire to the amplifier. The signal is amplified and passed on to the monitoring system, which will create a visual representation of the data received. In steps (ix) and (x) the clamps are removed individually through the esophagus. The clamps are secured with sheathing until the catheter removes both at the end of the procedure. The sheathing, however, needs to be removed to open the clamps. Once detached from the lining of the stomach, the plate is retracted back into the endoscope channel. The tapered rear end will result in the plate rerolling into the channel more easily. Once the wires are pulled through the channel and the plate is securely inside the scope, the endoscope is pulled out of the patient.

Section 9: Engineering Analysis

To analyze the design of our device, we will need to draw from our mechanical and electrical engineering backgrounds. Our device has two components: the design of the plate and the design of the wiring scheme. Our engineering analysis will be applied to both of these aspects.

Material selection is a very important aspect of our design. Material selection will be applied to both the plate and the electrodes. We will need to analyze mechanical properties of materials to choose a proper material for our plate. The material chosen will need to be inert, maintain properties of the internal body temperature (37°C), and be resistive to the acidic conditions inside of the stomach. The material will also need to satisfy our engineering specification of having a tensile modulus < 5 GPa. The material selection for electrodes will consist of us analyzing the conductive properties of materials, as well as the capabilities of obtaining the material. To select proper materials, we will use CES Edupack, which will allow us to compare different properties of materials and allow us to choose materials that satisfy our needs. Once the material is selected, we will need to perform a stress analysis to confirm that the chosen material is able to withstand the forces it will be subject to during the endoscopic procedure. The material will be loaded in tension and possible material failure will be due to this tension load.

The electrical components for our design will require circuit analysis and signal processing. The voltage produced by the stomach pulses will need to be routed from the electrodes to a monitoring device. The routing of this signal will involve circuitry because of the design constraints. We will need to convert the analog signals received from the electrodes to digital signals. Once the signals have been converted, we will need to serialize the signals so that we can have a minimal amount of wires running out of the patient's esophagus. We will also need to amplify the signal before it is transferred to a monitoring device. We will need to fully understand signal processing, which will be a new topic to all members of our group. Our selection of the analog to digital converter and the serialization chips will be very important because we need them to be capable of handling the amount and type of signal that is specific for our application. The amplifier will also need to be analyzed, so that it can properly amplify the signal received. Once the signal is amplified, it will need to be output to a monitor. This step will involve programming. We will need to use programming to make sure that the signal can be filtered and that we only output the necessary electrical activity. The propagation velocity will also need to be calculated from our output data. If it is possible to program the output to display the propagation velocity, we will further please our sponsor.

Once the plate and accompanying electronic fixtures are assembled, the device will be tested on a dead canine stomach. This will confirm the effectiveness of the attachment technique, which consists of an industry standard clamp that our sponsors have specified they prefer to use. We then hope to conduct testing in live dogs and possibly pigs to calibrate the electronics which will assist us in displaying the proper signal feedback.

Section 9.1: Parameter Analysis

To finalize our design, we needed to ensure that every aspect of our alpha design was properly justified. In addition to justifying and improving our final design, we needed to make decisions regarding our material, electrode, and wiring selections.

Section 9.1.2: Wire Selection

To make a selection for the wires, we considered the application and the design constraints present. We considered the electrical resistance and the physical size (with insulation) of the wires as design constraints. The electrical resistance of the wires is important because the expected strength of the signal acquired is between 0.5 and 1 mV [6], and we would like to minimize the resistances effect on the signal. The physical size of the wire is more important to our design than the electrical resistance, which led to our decision to use .006" diameter magnet wire. The magnet wire is especially useful for our application because it utilizes a thin enamel coating that resists moisture and resists heat up to a maximum temperature of 200 °C [15].

The magnet wire will be functional for our application because the human body temperature will be about 37 °C, which is well below the maximum temperature specified for the enamel coating. The inner part of the wire is made of solid copper, which has a high conductivity and is also the standard electrical wire. Since copper has a high conductivity, it is effective at transmitting electrical signals. Once we decided to use magnet wire, we determined that removing the enamel on the tips of the wire and coating the wire tips with silver plating would be the best option for the electrodes. With this method, we will eliminate any unnecessary electrical connections that would arise from using electrode "pins" and connecting our wires to these pins. Any possible electrical connections could create problems because we could potentially lose signal transmission with an improper connection, and we do not want to use solder or adhesive since both methods could potentially harm the patient.

By removing the enamel from the tips of the magnet wire and plating them, we would improve the conductivity of our electrodes. Silver has a 5.7% higher conductivity than copper, which is the material used for the wire, and silver will conduct a stronger signal. The signal will be picked up from the silver plated tips and fed to each wire and eventually to the recording/output system. The silver plating would add no more than .0005" to the diameter of the wire tip, which would be about the same as the original wire since the enamel would be removed. If necessary, the plating thickness can be increased to improve the rigidity of the electrode tips. The

length of the electrodes will be 1 mm long, which is subject to change, based on testing, but we determined that a length of 1 mm would be satisfactory for the final design because we are anticipating that the electrodes will be subject to bending due to the small diameter. By making the electrodes 1 mm long, the wire will be stiffer and more resistant to potential bending. Because our electrode distribution has a minimum spacing of 2 mm between each electrode, we determined that if the electrodes bend to be parallel to the plate, then the electrodes will not interfere with each other. However, in this case the plate needs to be clamped tight enough to the stomach so that a signal can still be transmitted from the electrodes. We also aligned the electrodes such that the two rows of electrodes are asymmetric about the plate center. This asymmetry ensures that when the plate is compressed, the electrodes will not interfere with each other.

Section 9.1.3: Material Selection

To ensure that the plate will compress to an acceptable standard, we looked for materials that matched our engineering specifications. Our sponsors communicated that our material needs to be inert, have a balance between flexibility and rigidity, and maintain its properties at the internal body temperature. Our sponsors recommended exploring plastics commonly used in medical applications. We found that urethanes and silicones are polymers commonly used in applications similar to ours. Although these materials are commonly used, they are not readily available for purchase in small quantities. Also, sheets of polymer would not be the best option for us because we would need to laminate the material once the wires were routed on the plate so that none of the electrical components would be exposed to the environment inside the stomach. To combat the aforementioned issues, we looked into liquid compound plastics, specifically urethane and silicone compounds.

The urethane and silicone liquid compounds we found fit all three of our material-based engineering specifications. Liquid compounds are commonly specified by durometer hardness scales. The durometer hardness scales for these compounds put the different shore urethanes and silicones into categories based on the hardness or softness of these compounds. Since the categories on the durometer hardness scale compare the hardness to well-known objects such as a rubber band or a tire tread, we cannot be certain of the hardness and its ability to compress. We cannot determine these properties because in our application, the material will be very thin and narrow, and we would like the plate to bend about its stiffer axis (the axis along the length of the plate).

We purchased three compounds of suitable shore hardness, and we plan to make samples comparable to the scale of our actual device. Making these samples will allow us to physically feel the material and understand its flexibility and rigidity tradeoff, therefore giving us a more accurate depiction of what we are looking for. Our sponsor has also expressed desire to physically inspect the specimens before finalizing the material selection.

Section 9.1.4: Plate Design Parameters

As a result of finalizing our electrode and wire selection, our plate design differs slightly from our alpha design in that we decreased the width of the plate. We were able to change the width of the plate because we initially overestimated the size of the wire gauge. We chose to decrease the width of the plate rather than the length because our plate is going to compress along an axis that runs parallel to the length. Our electrode distribution along with decreasing the width will allow us to decrease the profile of the plate when it is compressed and allow the device to fit more easily between the folds of the stomach mucosa.

To ensure that our device is compactable within a satisfactory level, we decided to make two rows of 15 electrodes instead of having electrodes placed in a grid-like pattern. The two rows of 15 electrodes will run along the direction parallel to the length of the plate, allowing the center to remain open for compression. The overall size of our plate will satisfy our engineering specification of having a plate area ≤ 8 cm^2. The taper for our final design is at an angle of approximately 30°. The purpose of the taper is to allow the plate to retract easily into the endoscope channel or parallel tube, which will force the plate to curve itself to fit the curvature of the mentioned removal device. We chose to make the taper approximately 30° because we will have all of our

routed wiring parallel to the length of the plate and exiting on the tapered end. If the taper was at a steeper angle, the wires would protrude further than the wires and would negate the effects of the taper.

In addition to choosing the electrode distribution to improve plate compressibility, we also spaced the electrodes in a systematic manner. We aligned the electrodes in each row in a straight line, translated 2 mm to the side. This is advantageous because the electrodes are easily identified from a reference coordinate, making the propagation velocity calculations easier for the user.

In our final design, each electrode will have its own wire that will run from the electrode, through the patient's esophagus, and to the monitoring device. This concept has changed from the alpha design because we found that we were unable to find electrical components that will be small enough for our application. Also, since we were able to find wires with a very small diameter, the patient comfort criteria from our wiring scheme selection matrix would have received a higher score, which makes the scheme using thirty wires the optimal selection. Using thirty wires exiting from the patient's esophagus will also eliminate any electrical connections that would be more prone to failure. To accommodate the thirty wires on the plate, we added grooves to the plate so that the wires could stay on a fixed path. These paths run parallel to the length of the plate and are consolidated so that the wires will not inhibit plate compressibility. The wires will run in succession along a path that is 2 mm from the placement of the electrodes and will need to be placed into the proper grooves on the plate.

The available space on the plate was used to cut holes for the clamps. The clamps are made by Boston Scientific and are passed to the stomach via a catheter. The clamps are put into position and sheathing is deployed that holds the clamp closed as they attach to the plate and the stomach mucosa. The clamp holes are placed on the four corners of the plate to ensure that the plate stays fixed in the desired orientation. We also added two holes for clamping in the middle of the plate so that it can maintain electrode contact with the stomach mucosa. We minimized the size of the clamp holes to accommodate the clamps and minimized the distance between the clamp holes so that the clamp will tightly affix the plate to the mucosa lining. The size of the clamp holes at the corners was determined by the dimensions of the clamp. Since a clamp hole will accommodate half of a clamp jaw, we made each corner clamp hole slightly larger than the size of half a clamp jaw. The center clamp holes are made to be as large as possible and rectangular because this will be a difficult area to apply a clamp. So, maximizing the area of these center clamp hole sizes will make it easier for the user to place clamps here.

Section 9.2: Stress Analysis

In analyzing our design, we realized that there are a few possibilities for mechanical failure associated with our design. The failure modes will be experienced in the tensile force applied to the device during removal. The first mode of failure for our device is the wiring for the device failing in tension. The second failure mode is the material of the plate failing in tension. Since we have three possible material options, we did the stress analysis on each material. To find the force necessary to cause failure in the wires and material, we determined that we could use the tensile strength of the wires and the material and use their respective cross-sectional areas perpendicular to the tensile force to compute the applied force required for device failure (seen in Eq. 1 below). In Eq. 1, σ is the tensile stress in *psi* (pounds per square inch), F is the force in *lbs*., and A is the cross-sectional area in in^2.

$$\sigma = F/A \qquad \text{(Eq. 1)}$$

To perform the stress analysis on wires, we treated the force as a distributed load on the thirty wires exiting the esophagus. Since the diameter of each wire is the same, we multiplied the cross-sectional area by 30 and multiplied that value by the tensile strength of copper. We obtained a force of 24.6 lbs. needed for the copper wires to fail. A similar technique was used to calculate the force needed to cause failure in the plate. We calculated the cross-sectional area of the plate by multiplying the thickness by the width of the plate.

Since the plate's cross-sectional area remains constant, the only varying parameter is the tensile strength. By multiplying the cross-sectional area by the tensile strength of each material, we obtained the force needed for each material to fail. We determined the failure force for Shore 20A urethane to be 9.79 lbs, Shore 40A urethane to be 16.9 lbs., and Shore 40A silicone to be 9.80 lbs. (calculations seen in Appendix B).

In addition to performing a stress analysis for failure in tension, we conducted an analysis on the possibility of the material failing in tear. It is common with plastics and rubbers (materials similar to the ones we have chosen) to perform an analysis on the tear properties of the material. The tear modulus, which has units of force per unit length, relates the force required for the material to tear and the thickness of the material. To calculate the force needed to tear each material, we multiplied the thickness of the material, which is the same for all three materials, by the tear strength of the material (seen below in Eq. 2). We found the force needed to tear the material was 4.72 lbs. (calculations seen in Appendix B) for all three of the materials since each material had the same tear modulus value. In Eq. 2, T is the tear strength in *pli* (pounds per linear inch), F_t is the force in *lbs*., and t is the specimen thickness in *in*.

$$T=F_t/t \qquad \text{(Eq. 2)}$$

The stress analysis conducted is an approximation and we are uncertain of the accuracy since we cannot take measurements of these possible forces. Since we are using mixed compounds for our materials, it is difficult to find generally accepted material properties. In our case, we were able to find material properties, but we acknowledge that they are not necessarily accurate to an accepted degree of confidence and they are being used to give us a depiction of the magnitude of forces that would cause our device to fail. Also, the resistant forces present during the removal of the device would be friction from the tube and the initial force needed to retract the device into the tube. In our approximations, we are considering that the device is being loaded in tension only. We believe this is an acceptable approximation for our device because the friction forces should be very low based on the coefficient of friction between two plastics (our material and the tube in our case). Also, the tensile forces experienced by our device will have a much larger magnitude than any other possible forces, so we feel that an approximation of the tensile forces will be sufficient.

Section 9.3: Signal Strength Analysis

In addition to analyzing the stresses in our device, we analyzed the signal captured by our electrodes. Since our electrodes are being used to measure the slow wave propagation in the stomach, we needed to justify that there will be no discrepancy between the signals captured by the separate electrodes. In speaking with our sponsors we can expect the signal to range from 0.5-1 mV [6] depending on the magnitude of the wave. Each signal from the electrode will travel from the electrode to the wire device, which will be approximately 2 m in length. Since there is a space of 2 mm between each electrode, the maximum spacing between two electrodes on the plate is 28.99 mm. Because the distance travelled by a signal is 2 m and the distance maximum distance between the electrodes is 28.99 mm, we expect the difference in signal magnitude between the furthest electrodes to differ by approximately 1.4%. This result is valid because the majority of the signal would be altered in the 2 m of wire that the signal needs to travel.

Because the difference in signal magnitude between the furthest electrodes is only 1.4%, we do not expect this difference to affect the electrode signals because the percent difference is negligible. Also, this percent difference in signal amplitude is between the furthest separated electrodes, so electrodes that are closer in distance will have a lower percent difference than 1.4. Therefore, the difference in signal between each electrode should not have a significant effect on our results.

Section 9.4: Final Remarks on Analysis

While the stress analysis is somewhat simplified, it still gives us an idea of the types of forces we can expect to cause failure in our device. In our prototype, we will need to consider other factors that we cannot currently model. An issue that we are anticipating is the effectiveness of the mold setting around the wires. However, we are going to neglect this possibility because we cannot model this situation with any level of accuracy. If the compound does not set around the wires properly, the wires could be ripped out of the plate. To analyze this potential for failure, we will need to conduct tests on the prototype in which we can exert a known force on the wires and determine if the wires or material will fail in tension before the wires are ripped out of the plate. Forcing our prototype to failure may not be possible in our case because of the intricacy of our design and time constraints of manufacturing. To combat this issue, we will load the device to 75% of the failure forces expected for material and wire failures. If we observe any displacement in the wires, then we can further analyze possible failure modes to make sure that our design is not being compromised.

Along with neglecting the aforementioned issue, there is a potential issue with the distance between the corner clamp holes and the edges of the plate. This is a very thin portion that could have a high potential for failure. Although we are acknowledging that this type of failure is a possibility, there is no way for us to accurately model the type of stresses the plate will experience in those locations. We do, however, believe that those locations will not experience any forces that would cause failure stresses because the plate will be fixed to the stomach lining at these locations. Since the plate will be fixed to the stomach lining at these locations, there will be no displacement that would cause the material to fail. Once the clamps are removed from the plate, we are not concerned if the material fails at these locations because the plate is meant to be disposable, as requested by our sponsors. As long as the possible failure of the material at these locations does not occur before clamping, the clamp holes will be completely functional. To further analyze this issue, we will have to observe these locations during testing and inspect the material after use.

Section 9.5: Summary of CES EduPack, SimaPro, and Safety Reporting Results

From our CES EduPack analysis, we found that copper was the best material for the electrodes and that silicone was the best material for the electrode plate. Although EduPack's top choices did not directly correspond to these material choices, we used sponsor's input and prior knowledge to help make a more educated decision on material selection. In short, while CES EduPack is a useful for gaining an understanding of good materials, it is still important to use prior knowledge and other variables to make a final decision in selecting materials for various design components.

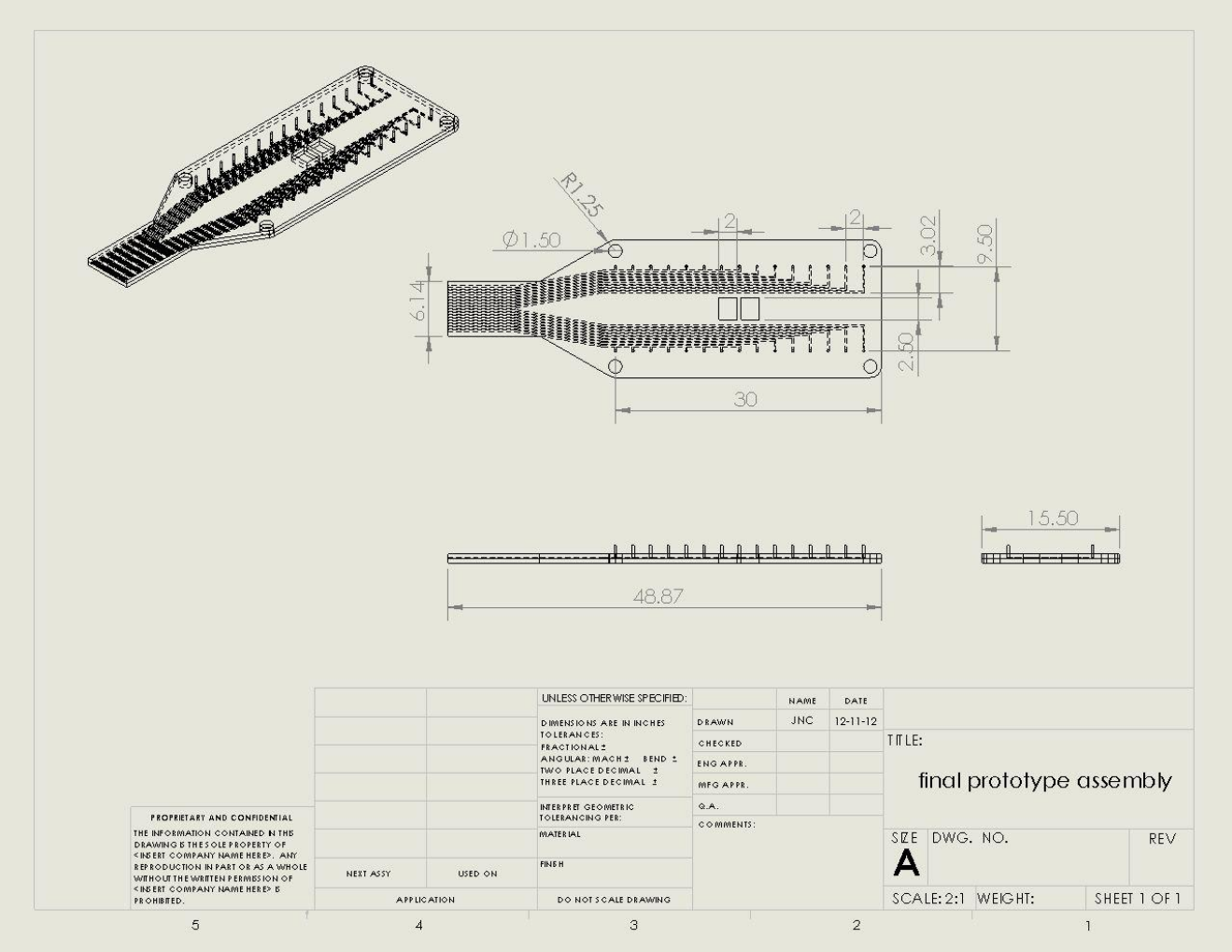
After examining our SimaPro analysis, we determined that copper would have a much bigger environmental impact due to its greater amount of mass compared to silicone. The amount of copper used compared to silicone is a much higher magnitude, so it is inevitable that copper will give off more emissions and will therefore have a greater impact on the environment. However, it is important to note that SimaPro was unable to select silicone due to is limited database, so it is possible that the results in SimaPro may not have been sufficiently accurate.

From our safety report, we realized that because our signal amplitudes are very small, any issues with electrical components should not be an issue. The largest safety hazards in our electrical components relate to the possibility of capacitors blowing up and forgetting to turn off the power supply when fixing our circuit. Both of these issues can be easily avoided. Also, in machining our parts, there were very minimal safety hazards, so there was very little concern in the safety of manufacturing our plate. The biggest concern in machining our plate was to make sure that we had proper eye protection when machining the plate.

Section 10: Final Design Description

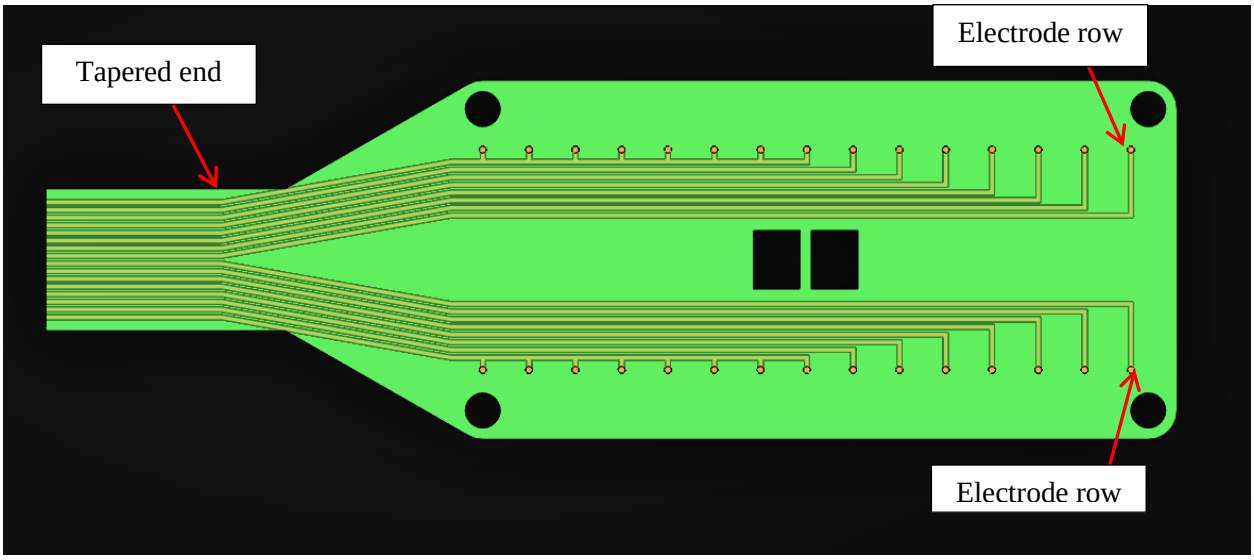
Our final design has thirty .006” diameter magnet wires, which are also used as electrodes. The wires are made of copper and contain an enamel coating capable of resisting heat and moisture. The enamel on the tip of the wire is removed, exposing the copper wire at the tip. The final plate is made of Quick-Sil silicone rubber with a shore hardness rating of 40A. Figure 8 below shows the dimensioned drawing of our final design.

Figure 8: The figure below has two major components: the copper wire, part #7588K27 and silicone compound, part # RC45581DR. The rest of the minor components can be found in the bill of materials in Appendix E.



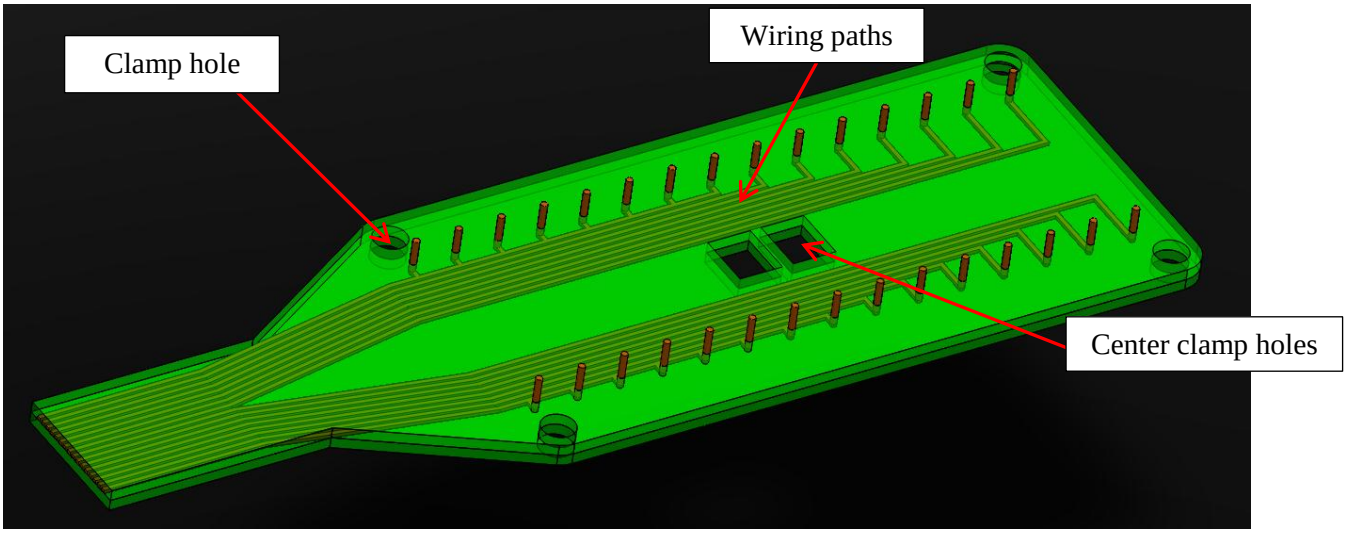
We aligned the electrodes on the plate in two rows of fifteen to maximize plate compressibility (see Figure 9, page 34). These two rows are oriented parallel to the direction of the wires, therefore allowing the center of the plate to remain vacant so there is an axis for compression. The two rows of electrodes are also designed such that they are symmetric about the plate center. This symmetry ensures that when the plate is rolled in the endoscope channel, the electrodes will not interfere with each other. The electrode plate contains a taper on the end that the wires exit from which improves the plate’s ability to retract back into the endoscope channel. The angle of the tapered edges is 29.7°, which allows the wiring to run parallel to the length of the plate and exit from the tapered end without altering the plate thickness uniformity due to wiring overlap (see Figure 10, page 35).

Figure 9: The figure below displays the two rows of 15 electrodes and the 29.7° tapered ends. The symmetry of the two electrode rows can also been seen in this figure.



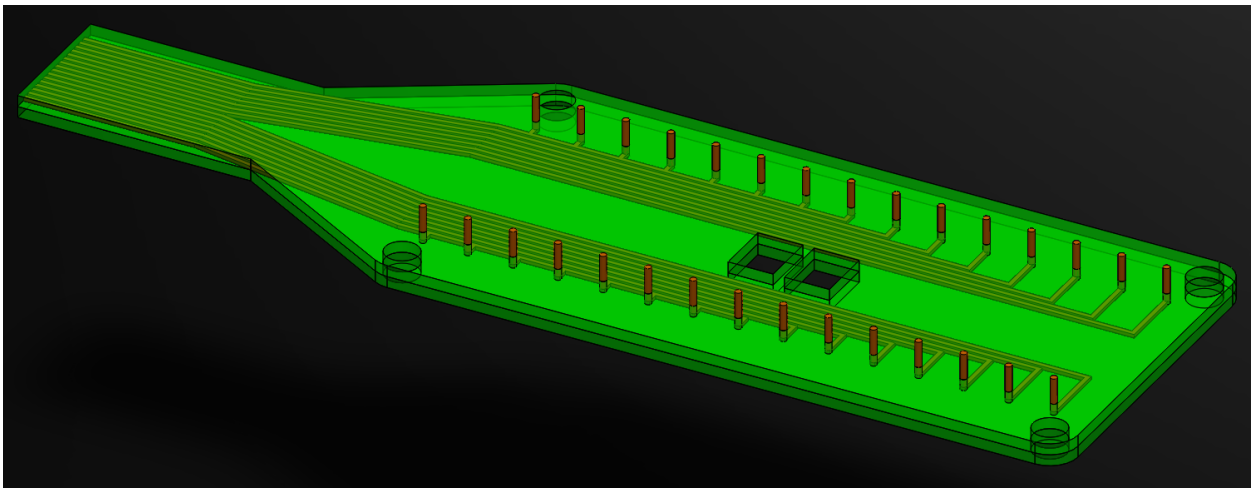
Each electrode, in their respective row, is separated by 2 mm. This separation helps the user determine the propagation velocity of the slow wave stomach pulses because of the known pattern of the electrodes. By using the known distance between the electrodes and the time delay between the acquired signals, the operator can calculate the stomach pulse direction and velocity. Also, each electrode will have a wire running from the electrode to the external amplifier. As discussed in the parameter analysis, using thirty wires will eliminate the risk of electrical components failing inside the stomach, and because the wires are very thin, patient comfort level will not be a major concern. The total diameter of combined wires exiting the patient through the esophagus is 2.43 mm at the widest point. Due to the amount of wires on the electrode plate, the wires need to be consolidated and run parallel to the plate length so that the plate compressibility will not be compromised (see Figure 10, page 34). To ensure that the wires will stay parallel to the plate and away from the axis of compression, the wires will be placed into grooves on the primary mold, which will secure the wires throughout the molding process.

Figure 10: The figure below displays the wires molded into the plate, all aligned into their respective grooves. The holes in the plate illustrate locations where the plate will be clamped to the stomach lining.



Our final design contains four holes on the corners of the plate and two holes in the center of the plate (seen in Figure 10, above). The two center clamp holes are present because we aligned our wires to leave the plate center open for this purpose. The center holes are a result of protrusions in the molds and the corner holes are the result of molding around the dowel pins. These holes are used to accommodate the clamps used by our sponsors that will clamp the plate to the stomach mucosa lining. Half of the clamp jaws will enter the hole on the plate and the other half will attach to the stomach lining. Sheathing is then used to cover the clamp and ensure that the clamp remains closed. The clamps that are used by our sponsors are a product by Boston Scientific, which are regularly used in endoscopic procedures. The corner clamp holes are each 1.5 mm in diameter and the center clamp holes are 2 mm x 2.502 mm. Figures 9, 10, and 11 detail all of the different features of our final design.

Figure 11: The figure below is a CAD model of our final design seen from an isometric view and displays the bottom of the plate where the thirty electrodes, internal wires, and clamp holes can be seen.



During installation, an endoscope will be passed to the patient's stomach. The plate will be compressed about its axis of compression (longitudinal axis) and will be fed into the channel of the endoscope. Forceps will be fed into the same channel of the endoscope, aft of the compressed plate, and will push the plate into the patient's

stomach. The forceps are then used to position the plate in the correct location in the stomach. A catheter device, which contains a clamp, is then passed through a channel of the endoscope and is positioned to one of the clamp holes. Once in position, sheathing is pushed over the clamp which will hold the clamp in place and keep the position of the plate affixed to the mucosa lining. This procedure is repeated five times so that each clamp hole is used and the plate is completely affixed to the stomach lining. When the plate is completely affixed to the stomach, the electrodes will maintain contact with the stomach lining throughout the entire procedure and conform to the curvature of the stomach during and between contractions. Each electrode will detect the slow wave pulses generated by stomach contractions and conduct a signal from the stomach contractions. The signal conducted is then transmitted via the copper wire to an external amplifier. Once amplified, the signal will be output to a monitoring device where the amplitude of voltage and the time between contractions can be observed. After about 3-4 hours, when electrical activity recording is complete, the plate is removed from the stomach lining by the user by removing each clamp from its position. Once the clamps are removed, the plate will be gently pulled back into the endoscopic channel using the electrical wires. The electrode plate folds up into the endoscope's channel, using its tapered end, for device removal.

The external amplifier was a custom built circuit incorporating thirty separate amplifiers. We chose to use Texas Instruments part number RC4558IDR operational amplifiers. We purchased three 6" IC bread boards for mounting the circuits. The external ends of our thirty electrode wires were stripped of the enamel coating from the last 5mm. This stripped end was then clamped and soldered into pins that improved the wires compatibility with the breadboard. The amplifiers are designed for surface mounting so lead wires were soldered to the pins and then anchored in the bread board. Since we are expecting a signal strength of 0.5 to 1 mV (a figure that we obtained from our sponsors earlier study on the three electrode non-invasive recording procedure), we designed the amplification circuit to have a gain of one thousand. We used resistors in pairs of 1.1kOhm and 1.1MOhm resistances and also 2.0 kΩ and 2.0 MΩ resistances. This gain will multiply the signal amplitude by one thousand, resulting in the expected signal amplitude of 0.5 to 1 V. To eliminate noise we made the signals move through a low pass filter transfer function of $\frac{3.1259}{s+3.1259}$. Also for noise reduction, we decoupled the circuit from the positive and negative 15 Volt power supplies by incorporating 22µF capacitors in parallel. A picture of our circuit is shown below in Figures 12, 13, and 14. To monitor and record the amplified signals we used a LabVIEW program to intake the 30 separate signals from the DAQ and display them on a graph of voltage versus time. The block diagram of our LabVIEW program is shown in Figure 15, page 37.

Figure 12: This image shows a single inverting amplifier. The op-amp, lead to the electrode, output to the DAQ, resistors, and capacitors can be seen below. This circuit is replicated for each of the electrodes, resulting in thirty identical circuits.

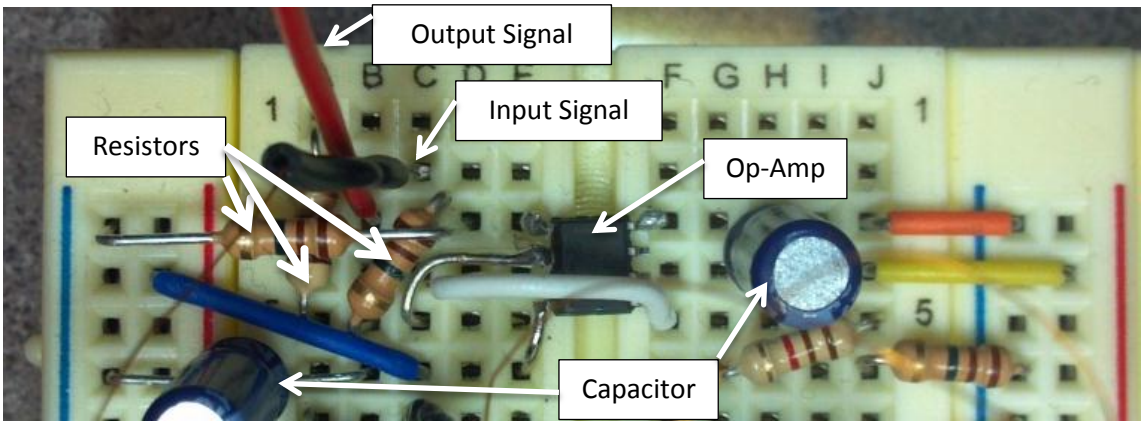


Figure 13: Our total amplification circuit board. The circuit pictured in Figure 12 is repeated thirty times on three bread boards. Each electrode lead is labeled with a number from 1 to 30 corresponding to the location on the plate.

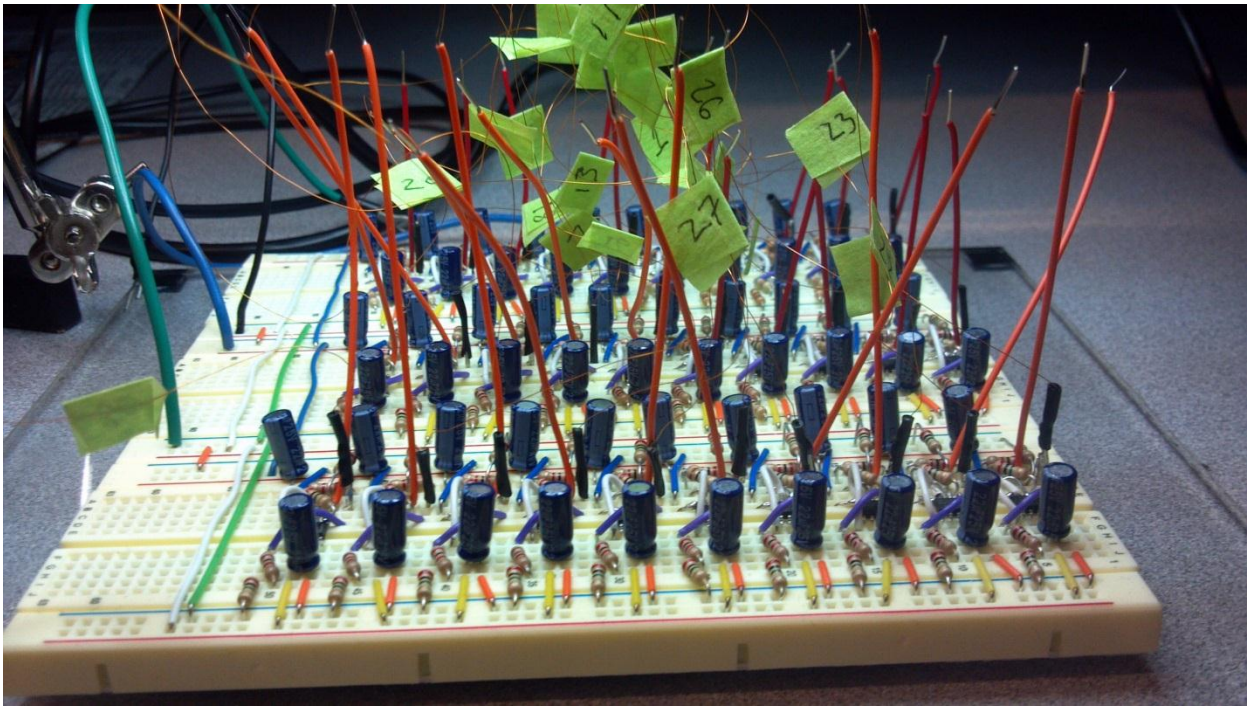


Figure 14: The leads to the power supply. Blue attaches to the V- port on the power supply. Green attaches to V+. Black attaches to COM, the ground.

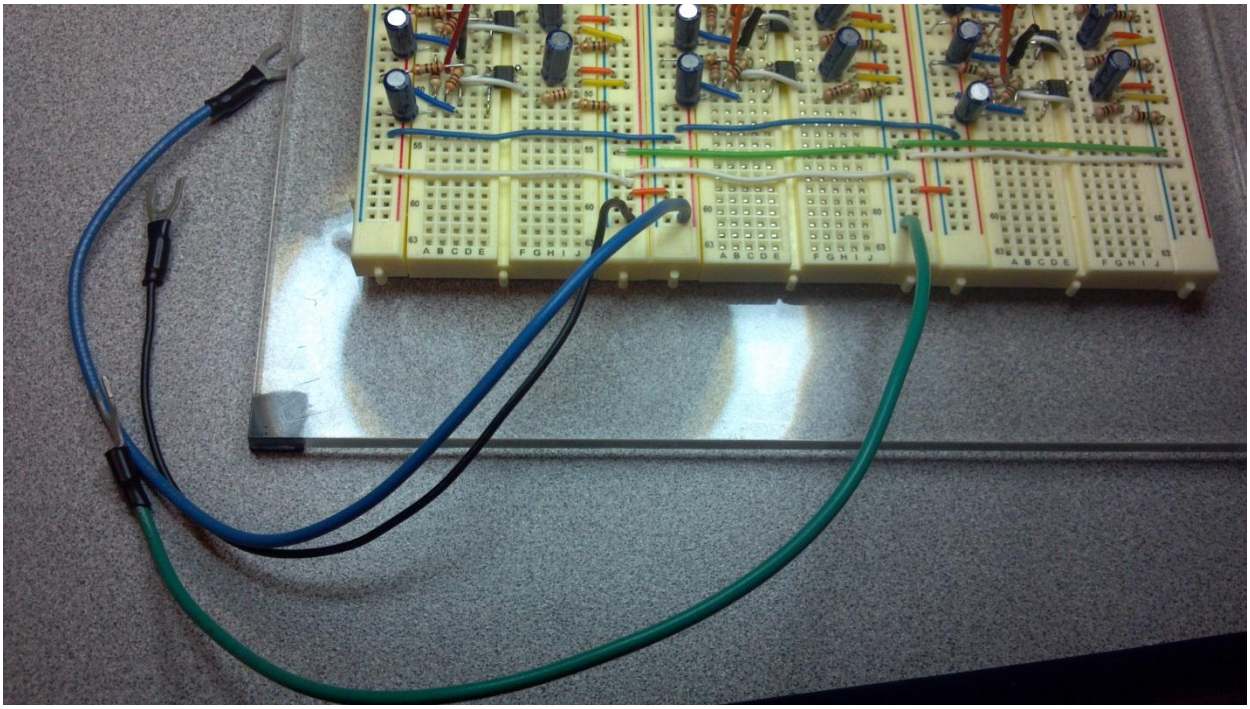
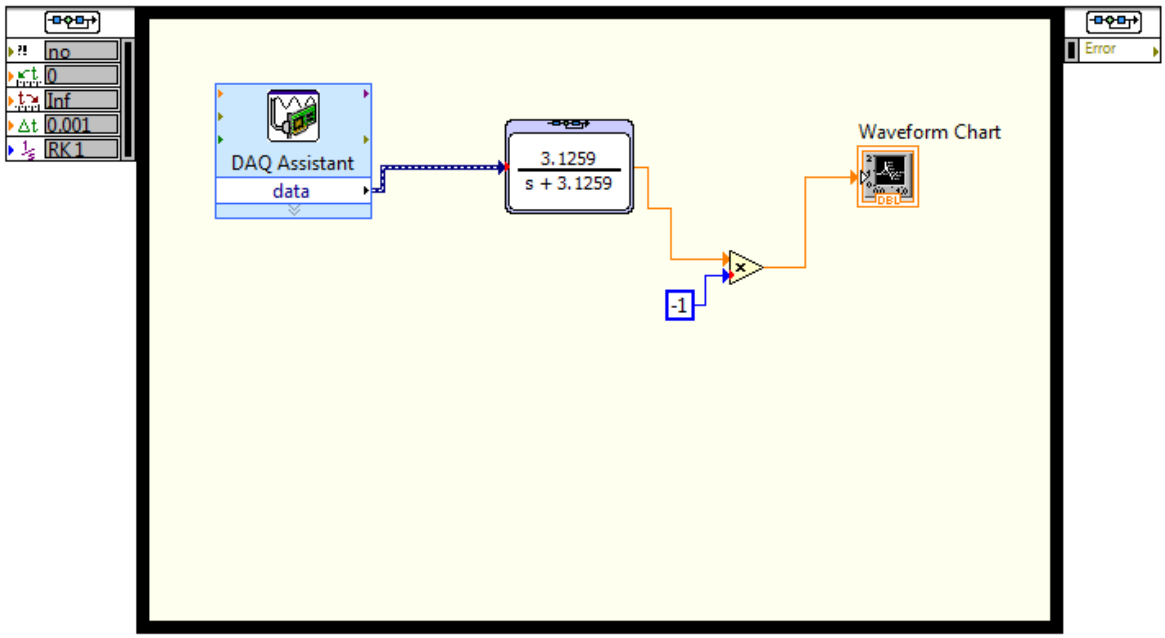


Figure 15: This is a snapshot of our LabVIEW block diagram. The signals are acquired though the DAQ, then move through a low pass filter transfer function, then are multiplied by -1 to offset the inverting characteristic of the amplifier, then displayed on the screen via the waveform chart.



The prototype we have produced is identical to our final design, with the exception of s few minor plate manufacturing imperfections. The prototype is shown in Figures 16 and 17. The prototype operates in the same manner as our final design and validation of the functionality of the prototype validates the final design in all aspects. Figures 18 and 19 show the molds used to make the prototype.

Figure 16: Top view of the prototype electrode plate.

Figure 17: Side view of the prototype electrode plate.

Figure 18: The primary mold used to implant the wires into the plrimary half of the electrode plate. The visible wire grooves hold the wires in place during the molding process. The dowel pins and center protrusions form the clamp holes in the electrode plate.

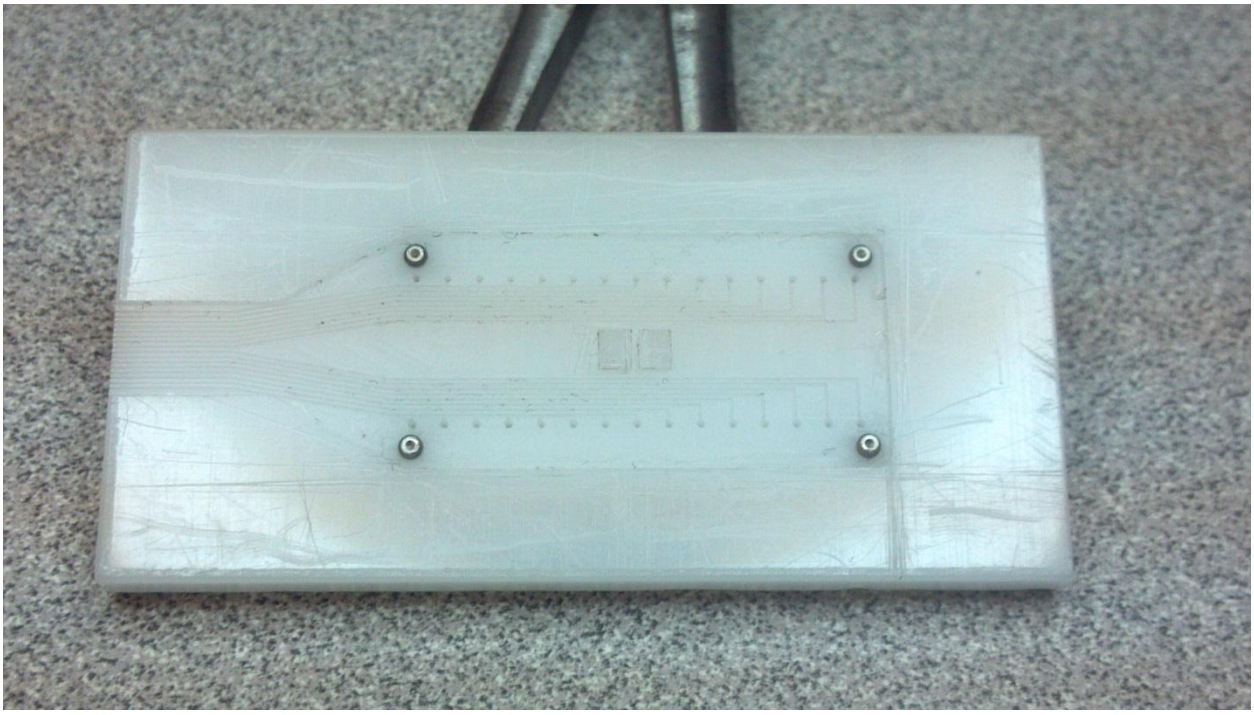
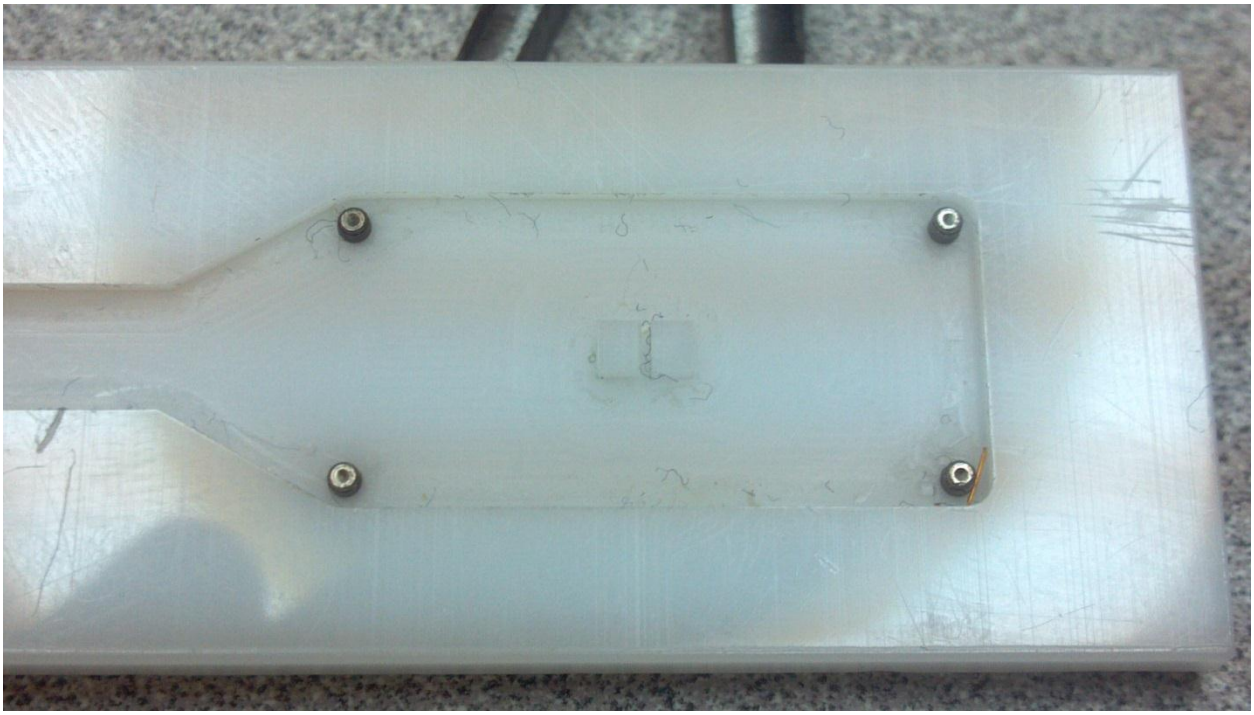


Figure 19: The secondary mold, pictured below, accepts the inverting primary half of the electrode plate with the electrodes extended into the air. A second 0.5 mm layer is then added the secondary side of the electrode plate.



To validate that the final design is on target we simulated the signals expected from the stomach by using a Copper and Nickel-Alloy Thermocouple to generate voltage potentials. The magnitudes of the voltages produced by the thermocouple are approximately 0.5 mV. By moving between heated and room temperature water, we generated oscillations three times per minute to simulate the frequency of the stomach waves. The signal was passed through wires identical to the wires used in our prototype and final design and amplified using a differential amplifier with the same gain values as our prototype amplifiers to show that the prototype and final design will function properly when implanted onto a live stomach.

All of the features in our final design were implemented with our engineering specifications in mind. Picking up a strong signal from the wires is critical for the user to properly analyze the electrical activity in the stomach because if the signal is not accurate, then analysis of the signal will not be accurate for diagnosis. All three of the materials being tested are inert and have a tensile modulus between 0 and 5 GPa, therefore satisfying our engineering specifications. Our final design will be made of one of these materials, but regardless of the chosen material, we know that our engineering specifications and customer requirements will be satisfied.

We accounted for plate compressibility by making sure that the thirty wires run parallel to the length of the plate and that the wires are kept in these positions by using grooves on the plate. We placed clamp holes in locations that provide the best attachment to the stomach lining, namely the four corners of the plate and the center of the plate. Placing clamp holes at the four corners ensures that the device stays attached to the stomach lining, while the center clamp holes ensure that the electrodes maintain contact with the mucosa lining. While creating our final design, we made sure that the area of the plate, distance between each electrode, and the width of the plate all satisfied our engineering specifications, so we are confident that our final design successfully minimizes plate size and maximizes electrode spacing. Since our final design satisfies all our sponsor-driven engineering specifications, we believe that our design will function properly.

Section 11: Prototype Description

Our prototype reflects the majority of the characteristics and parameters discussed in our final design since we have all of the necessary materials and most of the resources to manufacture the device. Therefore, our prototype is a nearly identical representation of our final design. We made the prototype out of silicone compound, and our prototype also has the same tapered edges and dimensions (height, width, and thickness) as our final design. Because our prototype is not a scaled version of our final design, we will have a good idea of whether or not the electrode plate size will be effective during the endoscopic procedure.

Additionally, we used magnet wires for the electrodes on our prototype. Because the final design also uses magnet wires with enamel coating removed as the electrodes, the testing conducted for the wires' ability to transmit an electrical signal gave an accurate depiction of the final design's ability to transmit a signal. Also, using the same magnet wires in our prototype that are used in our final design provided an accurate depiction of how consolidated the wiring will be relative to the electrode plate. Our final design uses grooves to hold the magnet wires in place so they can be molded inside of the plate. We used these same wire grooves in our prototype, meaning that testing our prototype for the effectiveness of these wire grooves gave us a good understanding of the grooves' effectiveness at keeping the wires secured within the plate surface and observing possible issues such as the wires coming loose from the plate (as discussed in parameter analysis section).

Our prototype and final design both use thirty electrodes; thus, during prototype testing we obtained an accurate understanding of the electrodes' effectiveness of picking up a signal from the mucosa. For our prototype we aligned the thirty electrodes in two rows of fifteen, which is the same alignment for our final design. Electrode orientation could affect the plate's compressibility if the wires or electrodes crossed the axis of compression. Also, the electrodes need to be offset so that when the plate is compressed the electrodes from one row will not contact the electrodes on the opposite row. By using the same prototype electrode orientation as our final design during testing, we gained an accurate portrayal of the plate's ability to compress and avoid the aforementioned

issues. Also, we were able to observe the plate's ability to compress into the endoscope's channel during installation and removal from the stomach.

Each electrode in the two rows is separated by 2 mm, which is the same separation in our final design. Since the electrode separation is the same in the prototype and the final design, our prototype testing gave us a good understanding of whether or not there is any signal interference associated with the electrode conduction. The number of clamp holes and the locations of our clamp holes for our prototype are same as our final design. Because there is no discrepancy between the clamp hole quantity or location, our prototype testing will gave us a good understanding of the clamp holes' interaction with the clamps and their combined effectiveness at keeping the device attached to the stomach wall. Along with understanding the effectiveness of keeping the device affixed to the stomach, we also observed the effectiveness of the clamp at maintaining electrode contact with the stomach mucosa lining.

Section 12: Fabrication Plan

The manufacturing of our prototype was very similar to the manufacturing of our final design. We created two molds that used to cast the urethane and silicone compounds. The mold was then milled from a block of Delrin using a CNC mill in the Auto lab. The Solidworks CAD model we have created was converted into a useable format for the CNC mill, and we specified the tool paths required to machine the mold using this converted CAD model. Due to the mold's intricacy, we used several small tooling components to complete the necessary features of the mold. The main cavity was milled using a 1.25 mm diameter two flute end mill at a speed of 5000 rpm. The main body of the primary mold is 0.5 mm thick and the main body of the secondary mold is 1 mm thick. Each mold has six locations for clamps; the four corner holes are 1.5 mm in diameter and the two middle protrusions are 2 mm x 2.502 mm rectangles (see Figures 20, 21, and 22). The four corner holes were formed by inserting four dowel pins into the holes that were removed after the mold finished curing. The two middle holes in the plate are protrusions on the mold which leave rectangular holes in the plate once the mold is removed.

Figure 20: The red area is the cavity that was milled to a depth of 0.5 mm to create the base structure of the primary mold.

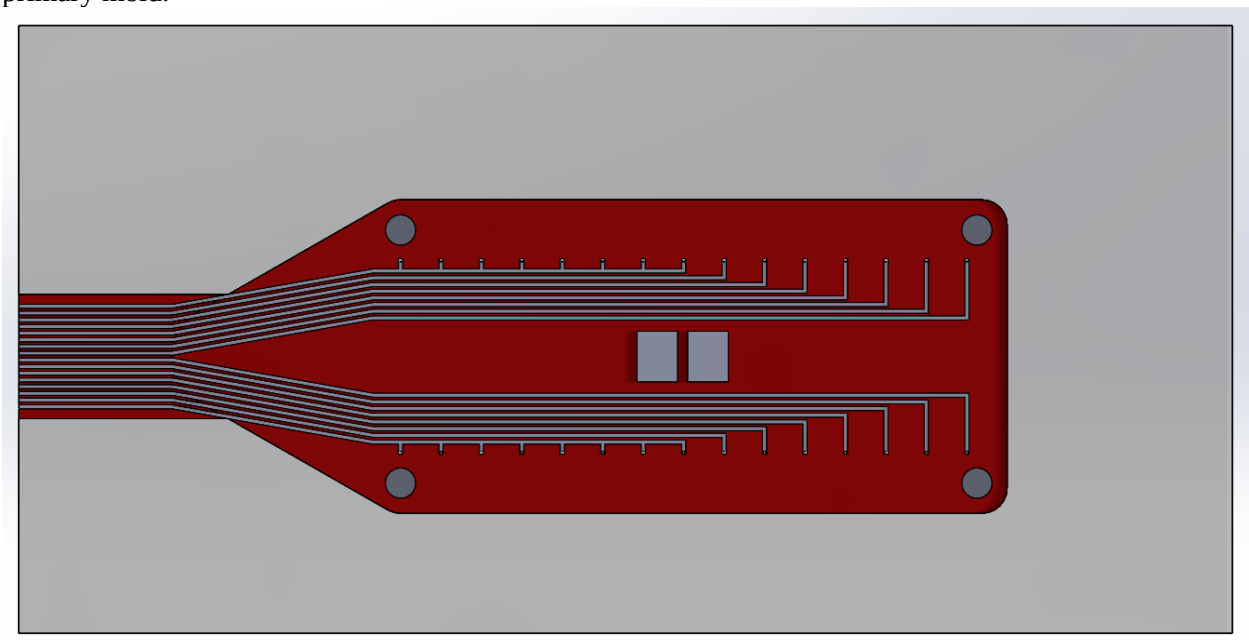


Figure 21: The red area is the cavity that was milled to a depth of 1 mm with a 1.25 mm diameter end mill to create the base structure of the secondary mold.

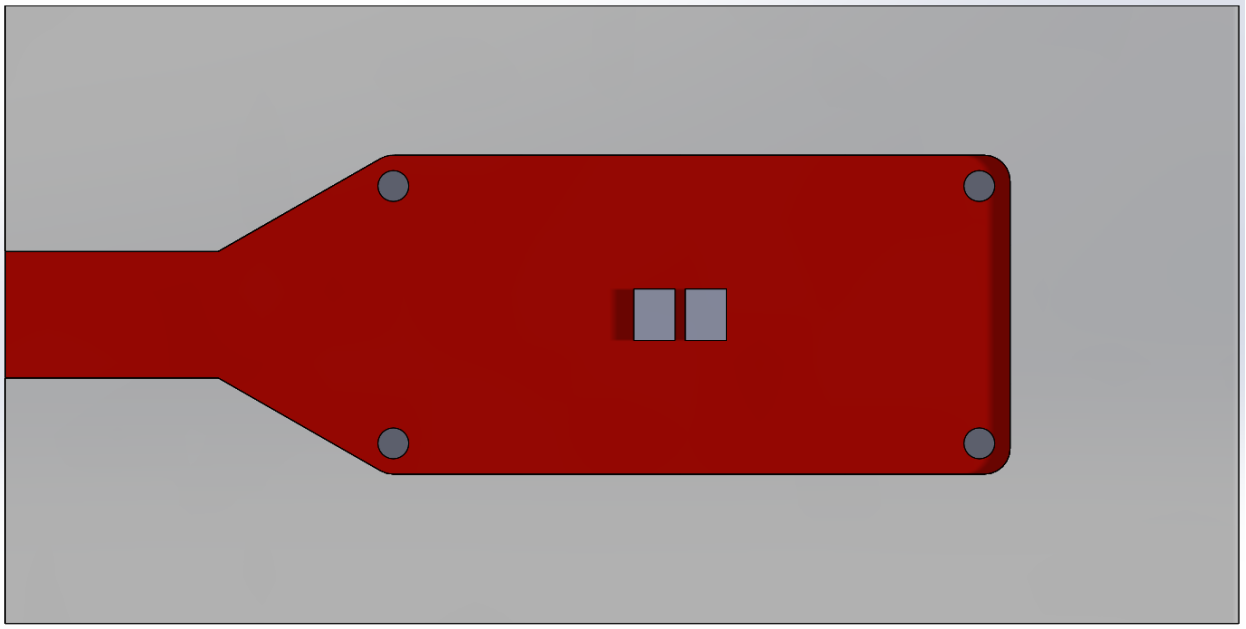
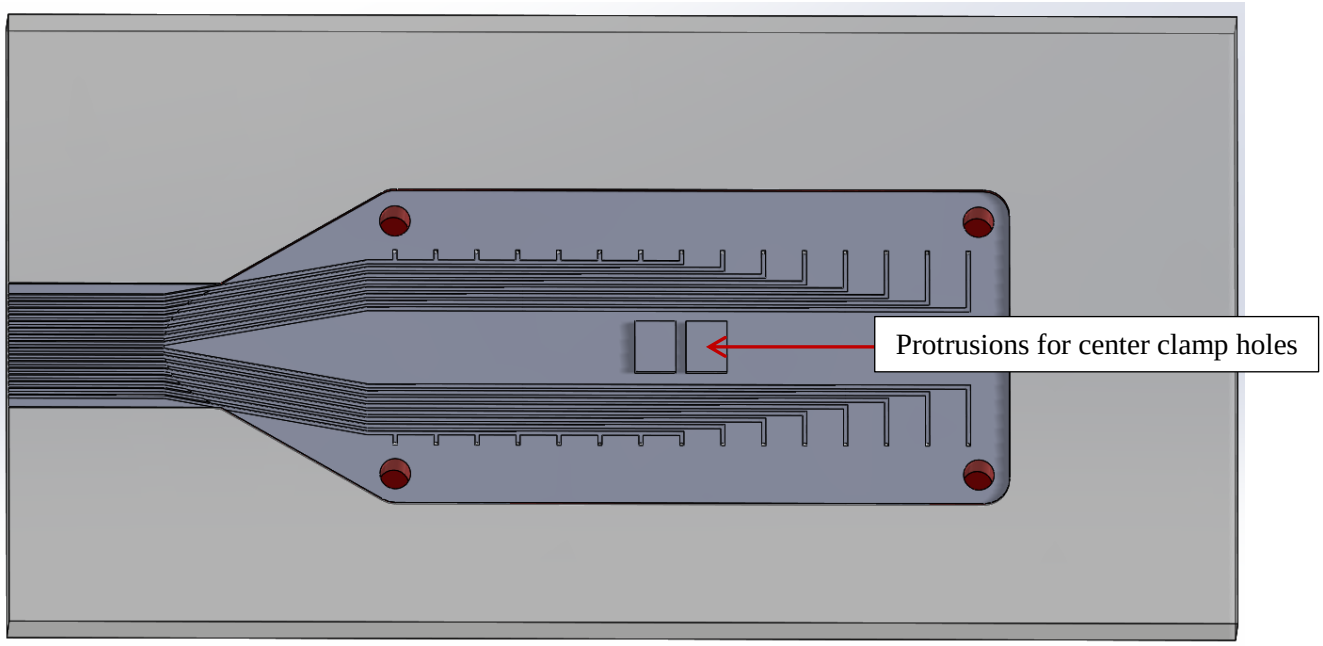
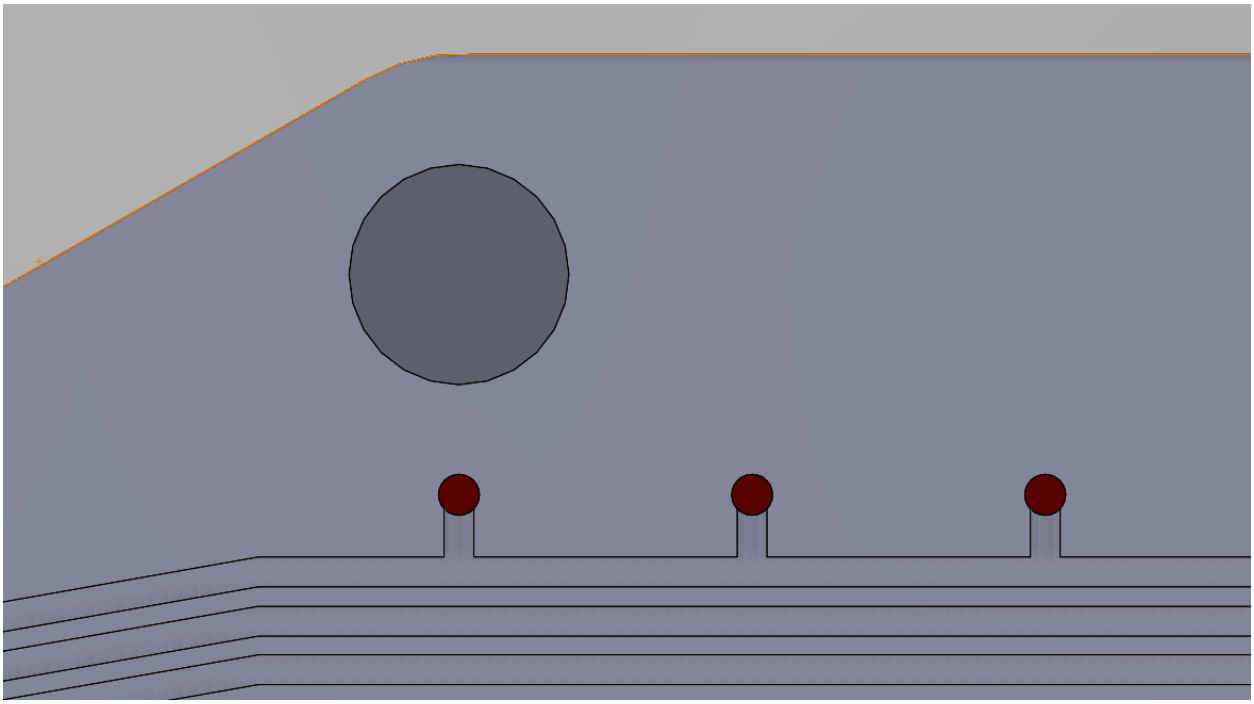


Figure 22: The red area shows the location of the clamp holes, which were drilled through the entire plate with a size 54 drill bit on the CNC mill. The protrusions were milled out of the plate, using a .006" end mill to remove the material between protrusions. Locations for the holes are identical for the primary and secondary molds.



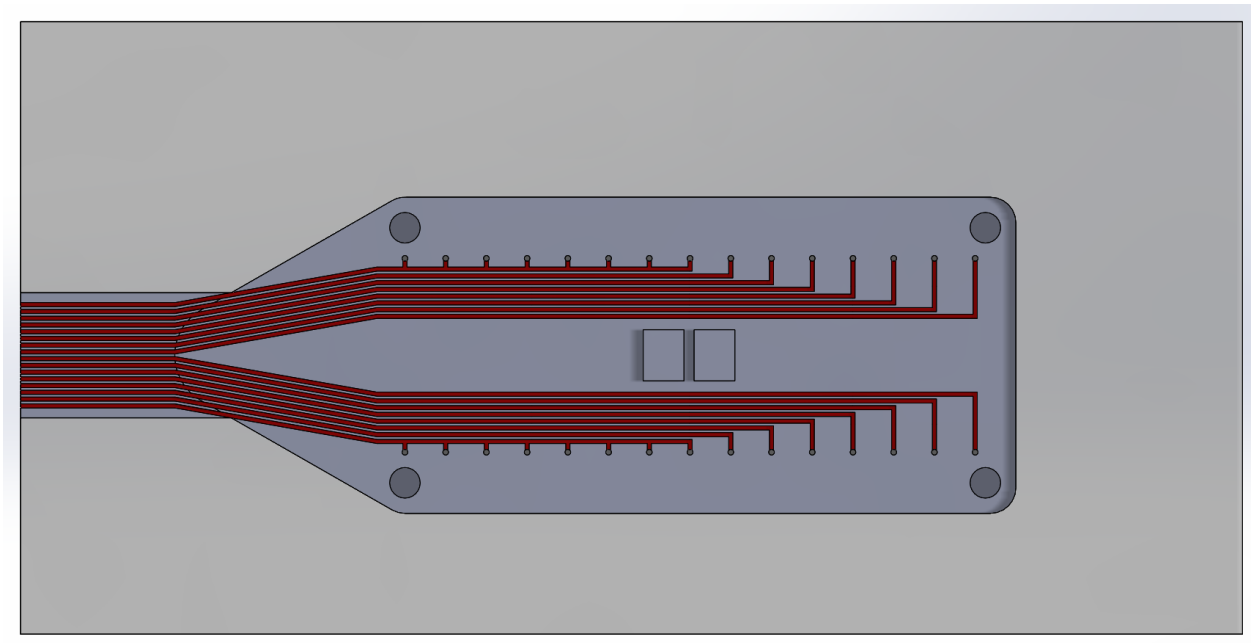
There are thirty holes located in two single row arrays spanning horizontally across the plates. Each hole was drilled through the bottom of the plate with a 0.2794 mm diameter drill bit and spaced 2 mm apart between centers on each row. There are two rows of electrodes that are 9.5 mm apart. The holes in the mold encompass the tips of the wires while the primary mold cures (see Figure 23). There are no holes in the secondary mold.

Figure 23: The red areas are the holes that encompass the electrode wire tips during primary casting. They are loacted 2 mm apart between centers. The holes were drilled on the mill with a .011" drill bit to a depth of 1.5 mm.



There are sixteen groove cuts in the bottom of the primary mold that are the same depth as the diameter of the wires (.006"). We purchased a .006" end mill and used the CNC mill to mill the grooves into the primary mold. Figure 24 shows the wire path grooves.

Figure 24: The red area shows the wire path grooves that are 0.006" in depth and width. These were machined with a .006" end mill on a CNC mill.



The grooves hold the wires in place during the molding process. The wires located closer to the tapered end of the plate lay over the top of the wires in the groove and are located further inside the plate when the mold has cured. Tolerances for machining were extremely precise for all hole placements, hole diameters, and edges of the rectangular section of the plate. Since no critical parts or holes are present in the tapered edge, the end of the taper did not require tolerances as precise as the other features.

To begin the molding process, we stripped the enamel of the copper magnet wire from the last 1 mm of the wire with a razor. Each of the thirty wires was placed into the mold holes, leading with the exposed copper tip. The wires were bent into the grooves individually with the tapered end secured outside of the mold. The seven wires that were closest to the tapered end of the plate lay on top of the walls between the imbedded wires and were secured with a light adhesive. Once the wires were in place, the casting compound was poured into the mold on top of the wires that were previously placed into the mold. We made the plate from a medium-soft fast setting silicone with a shore hardness rating of 40A. The mold was sprayed with mold release and dowel pins were placed in the four clamp holes. The casting compound was mixed and placed into the mold, which was placed on a level surface until the compound hardened. The silicone requires heating to 120°F during the casting process. After the compounds hardened, the plate was extracted from the primary mold and placed upside down in the secondary mold for the bottom coat. The wires were exposed and facing upward when placed in the second mold, and the wire tips were covered with tape to prevent the casting compounds from adhering to them. We then placed another layer of the silicone into the mold. After the second layer cured, the dowel pins were removed and the plate was extracted from the mold.

The circuit consists of thirty operational amplifiers from Texas Instruments (model RC4558IDR). Each amplifier is connected to the bread board by soldering pins onto the surface mount tabs one through five. These pins are then plugged into their own respective rows on the breadboard (shown in Figure 12). The amplifiers are then connected in the orientation shown in the circuit diagram shown in Figure 13. The resistors and capacitors used have wires that have been trimmed to reduce the amount of wire exposed above the surface of the breadboard. The power supply voltages (+15V and -15V) are supplied through the busses on the breadboard and originate from the power supply, which is connected to the 120V A/C wall socket. The green lead wire stemming from the wall outlet cord is secured under the ground screw on the power supply with a Phillips head screwdriver. The black lead is secured under the L tab and the brown lead is secured under the N tab. The green, blue, and black connection wires coming from the breadboard are secured under the V+, V-, and COM tabs respectively. Jumper wires connect the busses of the three breadboards together, and the electrode plate lead wires are gathered and fed through heat shrink tubing that covers from the base of the plate to 30 cm from the end of the wires. Once the wires are completely through the heat shrink tubing, a heat gun is used on the low setting to shrink the tube to the diameter of the group of wires. The lead wires coming from the electrode plate have the tips (last 5 mm) stripped of their enamel coating with a razor blade. After the tips have been stripped, they are placed in breadboard compatible tips and clamped and soldered into place. The complete wires are placed into the input row of the op-amp circuit. Because the electrode plate is meant to be disposable, the amplification circuit that the lead wires are connected to can be reused several times.

For our final plate design, it is critical that the primary mold and secondary mold properly cure together. If the two molds do not properly cure, then the molds will not be properly bonded, which could result in a higher risk of failure due to possible shear stresses. Because the electrodes stick out from the bottom of the mold, it is also important to ensure that the mold has a seal between each electrode so that the electrodes maintain functionality.

After considering the fabrication possibilities in the ME 450 machine shop, we have determined that we are able to manufacture and assemble all parts of our prototype. The advantage of using a mold is that it facilitates the process of creating our electrode plate. Once the secondary mold is cured, we only need to remove the hardened and cured plate from the mold, meaning that no further assembly is required once the molds have been created. The final product of our assembly is plate that is removed from the secondary mold.

Our prototype fabrication process uses manual processes with the exception of the CNC mill. The final product will most likely need a different manufacturing process than our prototype since it will be needed in large scale quantities for diagnostic use in hospitals. The final product if mass produced will have significant changes in the fabrication process. The process will be entirely automated to decrease manufacturing costs and increase the amount of products produced. The electrode plate will most likely be die cast with a similar silicone material. Also, the electrode wires may be printed into the silicone plate with circuit board printing machinery. The amplifiers will also be produced as printed circuit boards, which will decrease the volume of the circuit and also decrease manufacturing costs.

Section 13: Validation Results

To validate our design, we independently tested each device function to prove that each engineering specification was satisfied. We independently tested for each device function because we were unable to conduct a test on a pig stomach due to time constraints for the semester. Our device's individual functionalities were determined based on our engineering specifications. Based on our sponsor's input, material selection was going to be important in the functionality of the device. Before finalizing our material selection, we created samples and allowed our sponsors to make the final decision based on their experience with similar materials. They determined that the silicone compound would be best for our design.

Since the test samples we made for our sponsors were not the exact dimensions of our final design, we still needed to verify that the material would be suitable for our application. By choosing the silicone material, however, we validated that silicone satisfies the following engineering specifications: 1) Inert material, 2) Tensile Modulus between 0 and 5 GPa, and 3) Ability to maintain material properties at 37°C. Although material specifications were met based on the material's characteristics, we needed to verify that the material could withstand tensile forces during the endoscopic procedure and that silicone could satisfy the rest of our engineering specifications.

To ensure that the material would be suitable for our application, we manufactured the device and conducted tests that replicate the mechanical aspects of the endoscopic procedure. To validate that our device can be compressed into the channel of an endoscope, we used a straw with a diameter of 4.5 mm, which is slightly smaller than the instrument channel of an endoscope. Our device successfully compressed along its longitudinal axis and passed through the straw. Since the device successfully passed through the straw, which has a smaller diameter than the endoscope channel, we determined that our device coupled with endoscope is less than 1.5 cm, which is one of our engineering specifications.

From our parameter analysis, we determined that failure of our device would be due to applied tensile loads, and we determined that the silicone material could withstand a tensile load of approximately 4.72 lbs. We used a force gauge to assess how strong 4.72 lbs would be during endoscopic procedure. We attached a force gauge to the copper wire exiting the plate and dragged the plate through the straw 10 times. For each trial, we did not exert a force greater than 1 lb, and the average force required to drag the plate through the straw after 10 trials was 0.78 lbs. Since this average force was approximately 17% of the force to fail the material and that our device is meant to be disposable, we determined that the plate would not fail during removal and installation. We applied a similar test on the wires to ensure that the wires would not be pulled from the plate material. The wires stayed in place after each of the 10 trials, so we determined that the wires would successfully stay in place. Thus, we do not expect the wires to fail after one usage.

Due to the clearance between the clamp holes and edge of the plate, we tested our device to ensure that the plate would not be subject to failure at these locations. Because we were unable to obtain clamps from the endoscopic procedure, we were only able to visually inspect the material in these regions. We observed that no forces were acting in the region between the clamp holes and plate edge, which agrees with our parameter analysis, stating that there should be no forces acting on these clamp holes since they are being constrained by the clamps.

Based on the final prototype, we verified the engineering specifications relating to the physical characteristics of the plate. Our prototype holds 30 electrodes and the plate area is 6.2 cm^2, which satisfies that the plate area must be less than 8 cm^2. Also, our prototype contains six clamp holes; so, our prototype satisfies the specification that our plate must have 4-8 clamp holes. The clamp holes on the plate ensure that the plate will remain affixed to the lining of the mucosa and that the electrodes protruding from the plate will maintain contact with the stomach lining throughout the procedure. Since we were unable to obtain the clamps used in the actual procedure and we were unable to obtain a cadaver stomach to test the effectiveness of the clamps' ability to affix the plate to the mucosa lining, we created a test to simulate the procedure by using a sweatshirt to act as the mucosa lining because we could easily manipulate its shape, which allowed us to observe how the plate would interact along a surface that is changing contour. To model the clamp holes' effectiveness, we inserted safety pins into the clamp holes to ensure that the plate could be affixed to the sweatshirt. As we moved the sweatshirt we were able to observe whether the electrodes were maintaining contact with the sweatshirt. Since we could visibly see the electrodes maintaining contact with the sweatshirt regardless of whether the electrodes were bent flush with the plate. However, we also observed that some of the electrodes were contacting each other, which would contaminate the acquired signal. This observation is not deemed to be a design flaw, but rather a manufacturing flaw. Although we realized that this flaw could inhibit the function of some electrodes, we verified that all of the electrodes would maintain contact with the surface it is affixed to, which satisfied our engineering specification of having 100% of electrodes on the plate maintaining contact with the mucosa lining of the stomach.

Since we were unable to conduct a live test with our sponsors due to time constraints, we were unable to verify that only one tool would be needed for the installation and removal of the device. Although we were unable to verify this engineering specification, we are confident that this specification would be satisfied because all other mechanical aspects of our design fully satisfied their respective engineering specifications; thus, we expect that all of the mechanical aspects of our design will function properly.

After confirming that the mechanical aspects of our design were fully functional, we needed to ensure that our signal acquisition was functional. From our engineering specifications, we needed to provide immediate electrical signal feedback and that the device needed to be powered. Our sponsors indicated that the expected signal strength from the stomach pulses is approximately 0.5- 1 mV. Since this is a very small signal magnitude, we decided that we would need to amplify the signal and eliminate noise from the signal so that our acquired signal could be used for diagnosis. Since we were amplifying our signal, we needed to use a power supply, which allowed us to satisfy our specification of having a powered device. Along with ensuring that noise was reduced for an accurate signal, we also needed to ensure that the signal strength did not diminish while travelling through the length of the wire and that the signals traveling through separate wires were not interacting with each other.

To determine the noise amplitude, we conducted a test with a thermocouple. We used the thermocouple to produce a 1 mV signal by exchanging the thermocouple in different temperature water. Both leads of the thermocouple were soldered into a breadboard, which was simulating the same amplification circuit used in our final design. The only difference between our thermocouple circuit used for testing and our actual prototype circuit is that we used a differential amplifier instead of an inverting amplifier. We need to use a differential amplifier with the thermocouple because there are two inputs from the thermocouple, but the gain and function in both circuits will be the same. Since our final design utilizes the same amplification circuit and gain, repeated thirty times, we decided that if we conducted tests with one of the amplification circuits, then the other circuits would behave the same. By using the thermocouple to generate a 1 mV signal, we were able to simulate a signal with the expected stomach pulse signal strength experienced during the actual procedure. By inputting a voltage of similar amplitude through the exact same length of wire used in our final design and using a known gain, we were able to compare our expected voltage to the actual voltage measured using a Multimeter. We observed that the actual voltage read by the Multimeter was identical to the voltage we expected after amplification. Since the 1 mV signal was able to travel through the same wire length used in the final design and was able to be

amplified after the signal traveled through the wire, we determined that no signal would be lost in the wire during signal transmission.

To observe the noise in our signal, we used LabVIEW to output the signal after amplification. In LabVIEW we applied a low-pass filter, which assisted us in eliminating noise from the signal. By observing the signal as the voltage was being applied from the thermocouple, we determined that we satisfied our engineering specification of providing immediate electrical signal feedback. While observing the signal, we observed that our noise to signal amplitude ratio after amplification was less than 5%. Less than 5% noise allows for a proper diagnosis and ensures that the signal through one wire is accurate. To test whether the wires would be interacting with each other, we grouped the thirty wires together from our final design. Without using our amplification circuit, we used a function generator to drive a 5V DC and a 5VAC signal (a sine wave) through a single wire. While the voltage was being driven through the wire, we were able to ensure that the signal was correct by observing the output on LabVIEW. Once the DC signal was verified, we used a Multimeter to compare the voltage at the end of all the wires that were grouped together versus the wire that was receiving a DC voltage. We did not record a voltage across any of the other wires, meaning that we will not experience any cross contamination of signal between the wires and that the insulation of the wire is adequate for this application. Also, since we used a 5V signal, which is five hundred to one thousand times larger than our expected signal, the likelihood of cross contamination from wire to wire is negligible. By verifying that we could receive immediate electrical feedback and that the signal acquired would be accurate, we verified that the signal acquisition aspect of our design was fully functional.

The only engineering specification we could not test for was whether one tool could be used for removal and installation of our device during endoscopic procedure. The reason we were unable to conduct a test of this specification is that we were unable to schedule a live test with our sponsors due to the time constraints of the semester. Although this specification was not met, this specification is not crucial to the functionality of the device. As previously discussed in the report, this engineering specification scored a 2 in priority level, meaning that this specification is not necessary for device functionality. All of the independent tests conducted show that the design is fully functional. Since all of the functional aspects of our engineering specifications were satisfied, we deemed that our design as well as our prototype is fully functional and valid.

Section 14: Discussion

The tapered edges in our final design were effective at improving the compressibility of the electrode plate during the endoscopic procedure. Since the wires exited through the tapered end, the plate was able to compress to the same diameter as the thirty wires bunched together. Compressibility is essential for our device's functionality since the plate will be inserted into and taken out of an endoscope, which has a diameter of 4.8 mm. With the diameter of the thirty wires exiting the tapered end being less than 4.8 mm, it allows the plate to compress into the instrument channel of the endoscope. Another effective feature our final design utilizes is external amplification, which allows for less electrical components to travel into the patient's stomach. Since we do not have any electrical components traveling to the patient's stomach, we are able to keep the area and width of our plate within the range of our engineering specifications. Also, with electrical components traveling to the patient's stomach there are more chances if components failing. As well as failure, all the electrical components would need to be coated so they would be safe for use in the human body, which could drive up costs and add to manufacturing complexity.

However, because all of the components of our electrode plate are very small, namely the wires and electrodes, manufacturing was an issue due to the significant amount of man hours required to manufacture our plate. Also, since our manufacturing process involved a press mold, with a putty-like compound, some of the wires on the plate did not properly stay in their respective grooves. In addition, we were not able to apply the proper thickness for the secondary mold because the putty-like material would not properly compress into the small depth of the molds. Since a few of the wires were mobile during the molding process some of the electrodes were displaced from their proper locations. With the electrodes not all in their proper locations, some of the

electrodes were close enough to touch, which could be a problem in the future because they will short out the signals. This is only a result of limiting factors in our manufacturing and not a result of flaws in the design itself, though. If the material being molded was in liquid form rather than putty, this would drastically improve the manual manufacturing process. For future improvements though, we would suggest exploring a more automated process that involves the possible use of flexible printed circuit boards. Doing so could reduce the amount of labor required for manufacturing, which would be beneficial for mass production of our device and would negate human manufacturing errors. In addition, since the device is intended to be a single use device, mass manufacturing is going to be a necessary process for future development. Also, for future improvements we would suggest electroplating the exposed copper wire electrodes with silver because silver has a 5.7 % higher electrical conductivity than copper. Electroplating the electrodes with silver would not only improve electrical conductivity but doing so would also improve the rigidity of the electrodes, thus improving the electrodes' ability to maintain contact with the mucosa lining. Improving the rigidity of the electrodes would improve the functionality of the design, because our functioning prototype has issues with the electrodes flattening to be flush with the plate. However, the plate clamping allows for the electrodes to maintain contact with the mucosa lining regardless of electrode orientation. We still think that adding rigidity, as well as improving conductivity, would augment the functionality of the device.

Section 15: Recommendations

For future development of our device, we recommend exploring an automated manufacturing process for making the electrode plate, or using a liquid molding compound. Making the molds on the CNC mill for the mold required a significant amount of labor hours due to the small nature of the components. Along with the time taken to manufacture the molds, we also had trouble manually inserting the wires into the mold, which were the plate electrodes. Using an automated manufacturing process such as printing flexible circuit boards would reduce the manual labor required for making the electrode plate due to an automated manufacturing process inserting the wires into the plate. Since the device is intended to be a single use device, we expect a larger demand for the disposable product in comparison to a reusable product. Because of this larger demand, rapid mass production will be needed to keep an adequate supply. An automated manufacturing process would also eliminate the issue we experienced with the electrodes being displaced from their intended position and slightly contacting each other, which will improve the plate's functionality and possibility of signal contamination.

We also recommend silver-plating the electrodes to improve electrical conductivity. Due to time constraints and a limited budget, we were unable to electroplate our electrodes with silver, so we suggest that our sponsors silver-plate the copper electrodes to not only improve electrical conductivity but also improve electrode rigidity. Improving the rigidity of the electrodes would improve the electrode contact with the mucosa lining, and would also reduce the possibility of signal contamination.

Section 16: Acknowledgements

We would like to thank Kent Pruss for helping us manufacture our molds for the prototype electrode plate production. He helped create our primary and secondary molds on the CNC mill. Also, we would like to thank Professor Alexander Ganago for helping us acquire and amplify an accurate signal and reduce the noise in the signal. He pointed out that a thermocouple could assist in simulating signals with a low voltage and that using capacitors on the Vcc+ and Vcc- terminals of the amplifier would decouple the circuit and result in noise reduction. He also gave us the idea of using a thermocouple to produce the appropriate signal amplitude of 0.5-1 mV. We would like to thank Professor Kevin Pipe for providing the necessary background knowledge of electrodes and how they work. Professor Elijah Kannatey-Asibu made sure that we were on schedule with our project each step of the way, so we would like to thank him for keeping us on track and for his useful input and guidance throughout the semester. We would also like to thank Toby Donajowski for helping us determine the appropriate materials and components necessary for our electrode plate. We also appreciate his help in trouble shooting our circuit during our signal acquisition phase. Finally, we would like to thank our sponsors Dr.

William Hasler and Dr. Radoslav Coleski for supporting our project. This project would not be possible without them, and we would like to thank them for providing the customer requirements for the device and their critique of our electrode plate design throughout the semester

Section 17: Summary and Conclusions

Of all the patients who enter the gastrointestinal unit at University of Michigan Hospital, 95% have unexplained nausea and vomiting. Our sponsors, Dr. William Hasler and Dr. Radoslav Coleski, have developed a three electrode system that records the electrical activity in the stomach generated by stomach pulses. This is a non-invasive procedure capable of measuring differences in electrical activity. Mapping the electrical activity allows for the user to calculate propagation velocity and the direction of the stomach waves, both of which can help diagnose a patient with unexplained nausea and vomiting. This procedure, however, is inaccurate in mapping the electrical activity in the stomach, thereby unable to provide an accurate diagnosis to patients with unexplained nausea and vomiting. Our goal is to build a more accurate multichannel electrode system capable of measuring these differences in electrical activity.

Our final design uses thirty .006" diameter magnet wires used as electrodes. The magnet wires made of copper are placed in wire grooves on the plate, and the electrodes are aligned in two rows of fifteen to maximize plate compressibility. The plate is made of a silicone compound and contains a tapered end which also improves plate compressibility when going through the endoscope channel. There are four holes on the corners of the plate for the clamps and two center clamp holes, which are protrusions also used to help the clamps attach the plate to the stomach lining.

To create the electrode plate, we made a primary mold and secondary mold both made of Delrin. We placed the silicone compound in the primary mold, which contains all of the grooves and clamp holes, and cured it with the secondary mold laying over it, which contains the four corner clamp holes. Another layer of silicone was added when placed in the secondary mold, and the wire tips were covered with tape to avoid casting compounds adhering to the tips. Once the second layer cured, the plate was extracted from the mold.

The expected amplitude of the signals in the stomach is 0.5-1 mV. Because this amplitude is very small, we used an external amplifier to amplify this signal for analysis. We built a custom circuit that utilizes bread boards for mounting the circuits. This custom circuit involves the use of 30 separate inverting amplifiers to amplify the signals along with a low pass filter transfer function and capacitor decoupling to reduce the noise. The circuit was repeated thirty times to account for each electrode. We generated amplified signals through LabVIEW, inputting the transfer function for a low-pass filter to help reduce the noise in the signal.

The use of a silicone compound for the electrode plate satisfies the following engineering specifications: 1) Inert material, 2) Tensile modulus between 0 and 5 GPa, and 3) Ability to maintain properties at 37°C. We inserted our device through a straw of diameter 4.5 mm to determine if our device could compress enough through the endoscope's 4.8 mm diameter channel. Our device successfully passed through the straw, so we determined that it would also pass through the endoscope since the endoscope's diameter is greater than the straw's diameter. We used a thermocouple to produce the applied voltage of 0.5-1 mV and tested this signal in LabVIEW to determine if we could provide immediate electrical feedback. The noise to amplitude ratio after amplification was less than 5%, meaning that we are providing an accurate signal for diagnosis. We checked for signal interference from the wires by applying a DC voltage through one wire and grounding the wires that were not receiving a voltage. We found that there was no voltage drop across the wires, meaning that our signal was not being contaminated by cross-talk among the wires. We were unable to test if one tool could be used through the endoscope for installation and removal of our device, but we are confident that this specification would be satisfied because all of the other specifications were satisfied through testing. This specification is not necessary for device functionality, so we are confident that our device is fully functional and valid for use.

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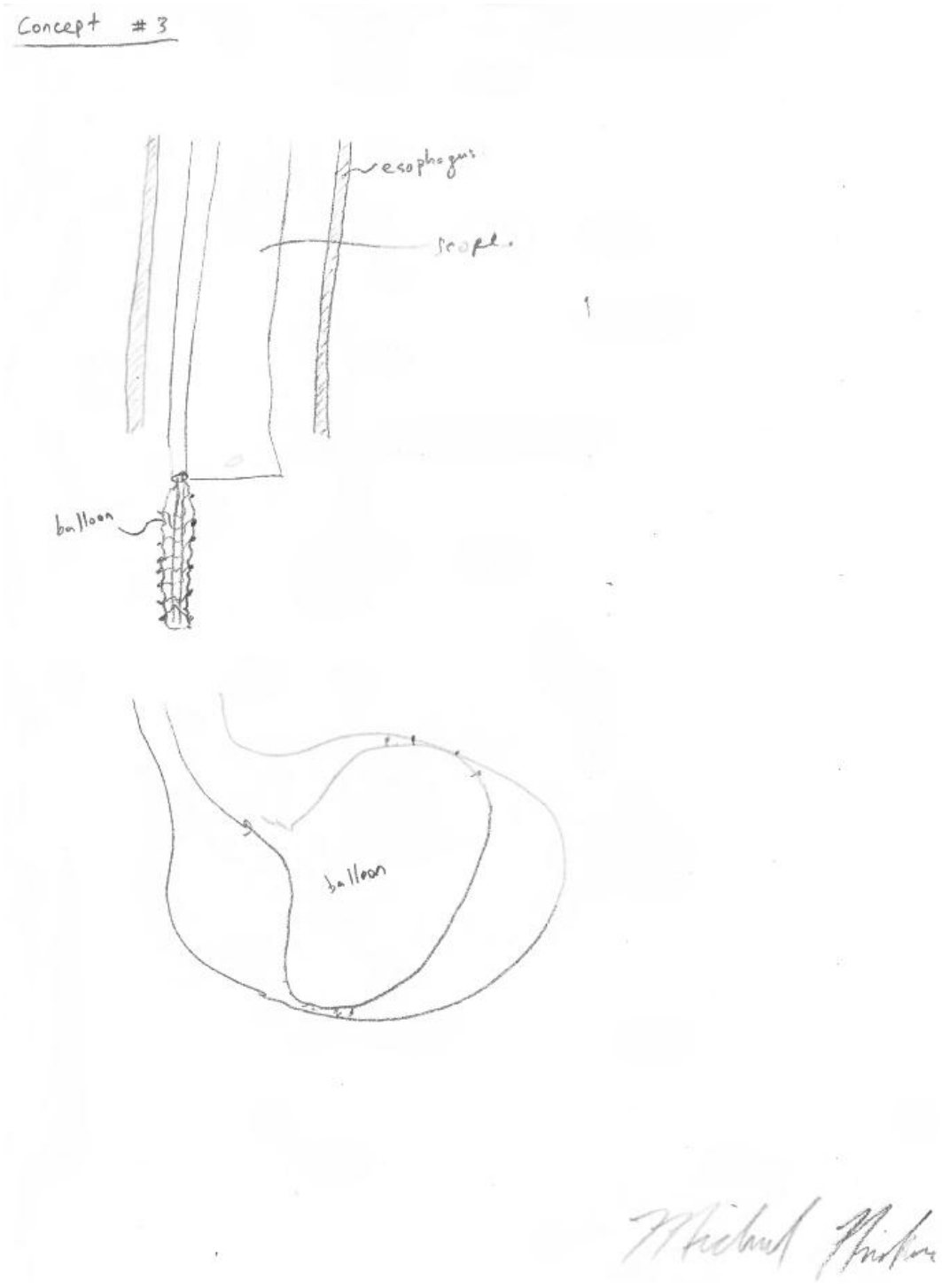
APPENDIX A: CONCEPTUAL DESIGNS

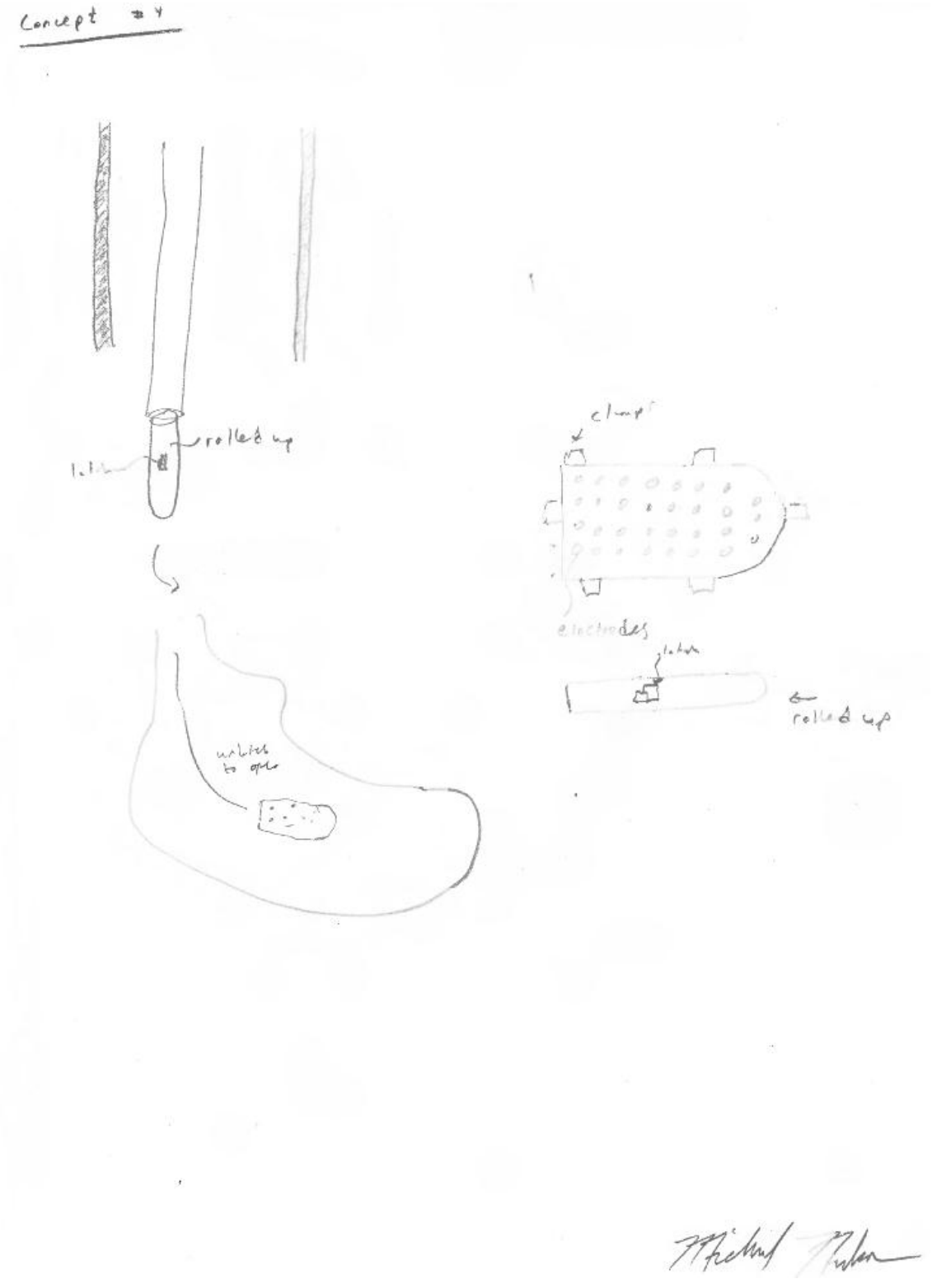
A.1: Concept 3

This concept uses an inflatable balloon to mount the electrodes. The deflated balloon has internal wiring with electrodes protruding through the balloon wall. Once the balloon is passed into the stomach, the balloon is inflated to push the electrodes against the wall of the stomach. For removal, simply deflate the balloon and retract the device.



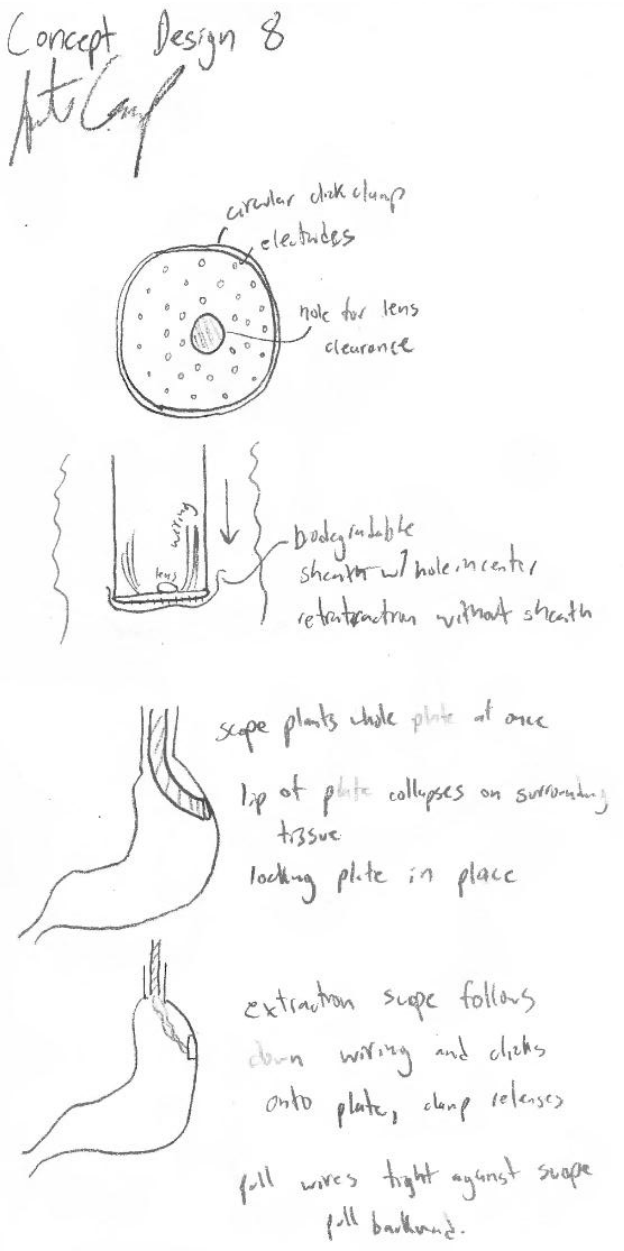
A.2: Concept 4

This concept uses a flexible plate that can be rolled tight to fit inside the delivery tube. Once inside the stomach the plate will unroll, exposing the electrodes. The plate resembles a rectangle with one rounded end. The rounded end is to make the roll more streamlined when travelling through the esophagus. Six clamps along the exterior of the plate affix the device to the stomach lining. For removal, the clamps are removed individually and the plate is repacked into the delivery tube.



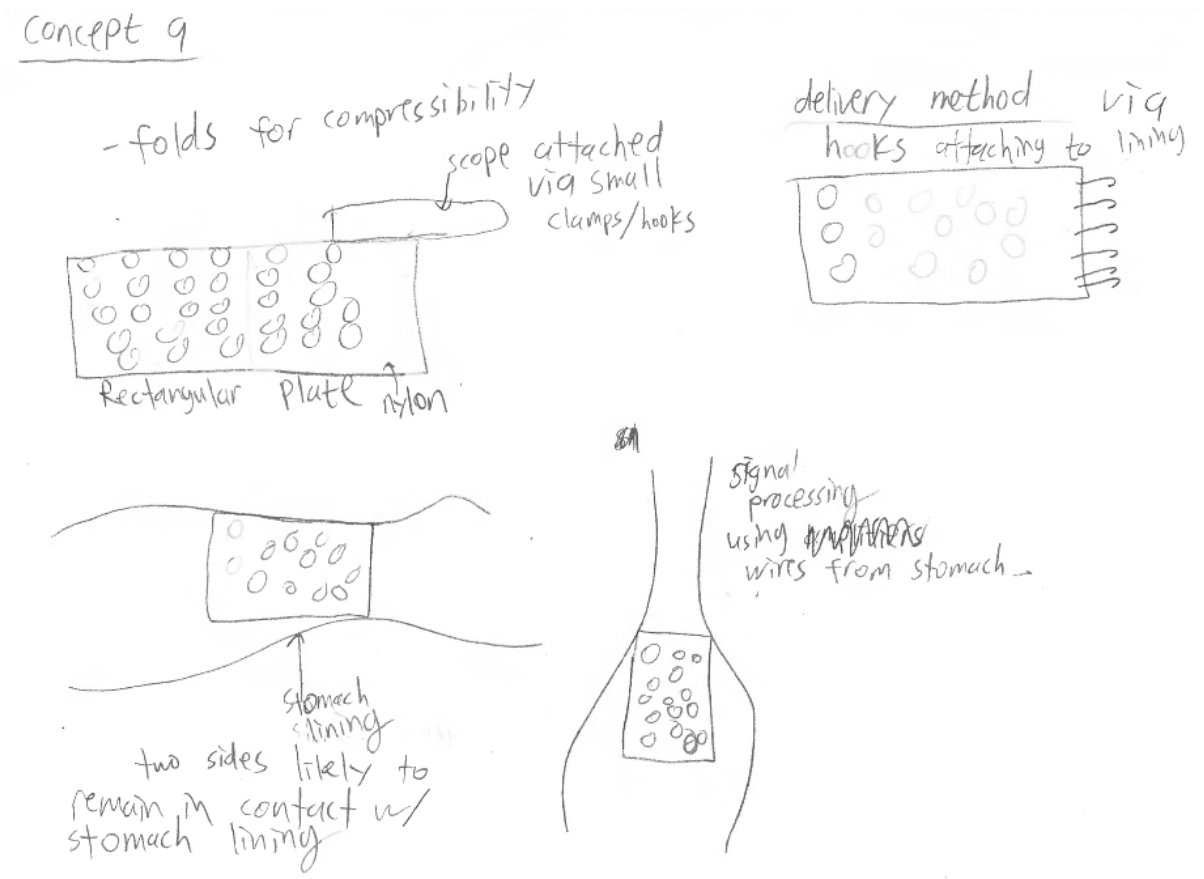
A.3: Concept 8

This concept consists of a flexible circular plate with a hole in the center. The hole is present to allow the lens of the endoscope to have an unobstructed view. There is a biodegradable flap that covers the electrodes as the device passes through the esophagus. Once it reaches the stomach, the flap will drop into the stomach and dissolve. There is a circular suction cup like clamping mechanism that clicks into place when pressed against the stomach lining. To remove, detach the clamp and pull the wires tight so the plate is up against the end of the scope and keep the electrodes from the edges of the esophagus.



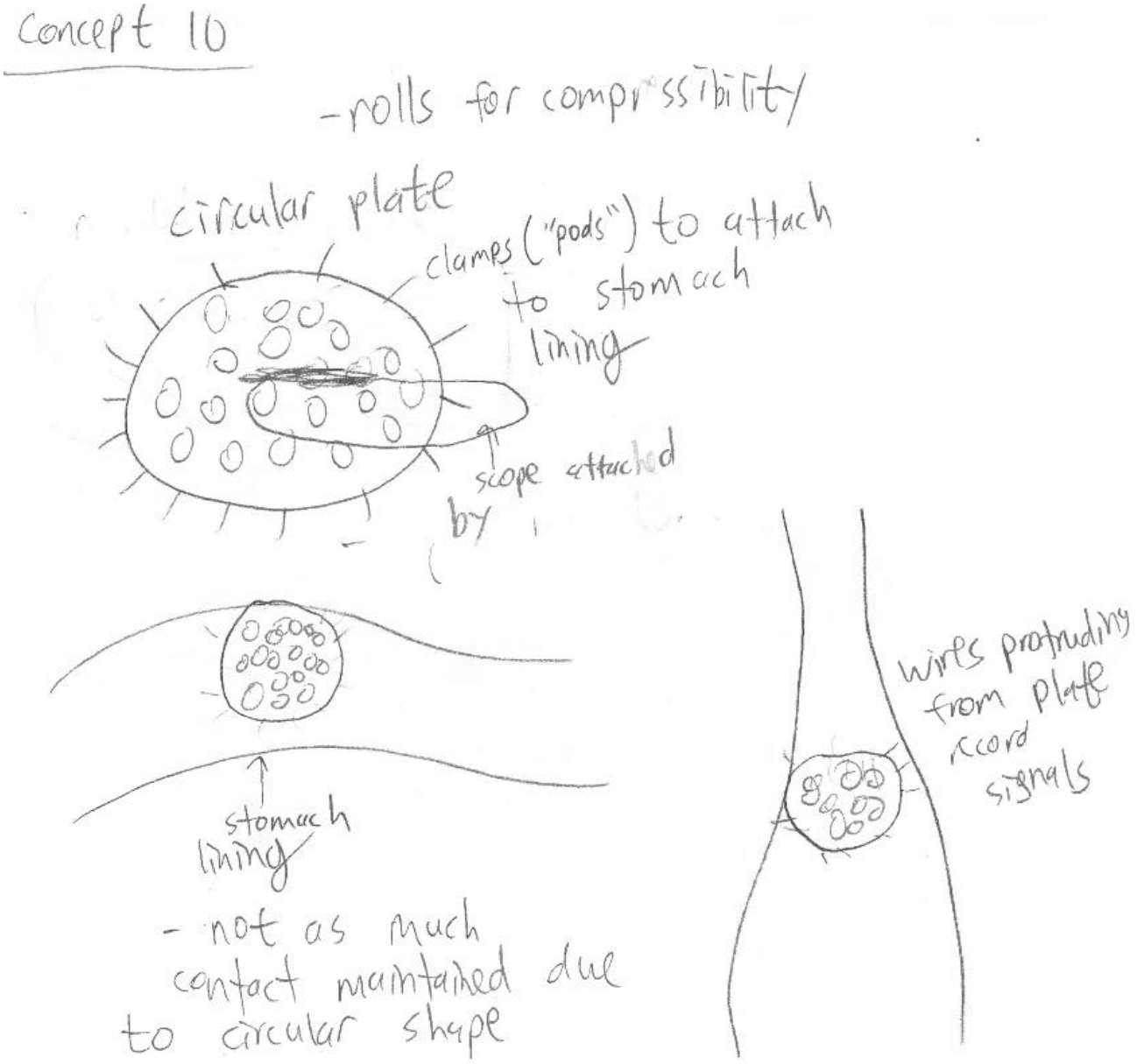
A.4: Concept 9

This concept uses a rectangular plate made of a nylon material with the electrodes placed in five rows of 6. The plate is able to roll up for compressibility, and the scope is attached to the plate via clamps or hooks. There are also several hooks at the end of the plate that are used to attach to the stomach lining. The rectangular shape should have several sides attach to the lining at all times. Also, gauge wires are used to process the signal for display.



A.5: Concept 10

This concept uses a circular plate which can be compressed by being rolled up. There are also several clamps around the plate to attach to the stomach lining and the electrodes are dispersed throughout the plate. The purpose of using a large amount of clamps is to ensure that the plate is securely attached to the stomach lining. However, the disadvantage to using a circular shape is that the plate may have difficulties fitting in between the stomach folds of the mucosa. Gauge wires will be used to record the signals from the electrodes.



APPENDIX B: STRESS ANALYSIS

Copper Wire

Tensile strength: $\sigma_y = 2.9x10^4$ psi [13]

Area of one wire: $A=\pi r^2, = \pi(.006)^2 = 1.13x10^{-4}$ in^2

Area of thirty wires: $A_{30} = 30 \times 1.13x10^{-4} = .003393\ in^2$

Force to failure (tensile): $F = \sigma_y \times A_{30}$

$$\boldsymbol{F = 24.6\ lbs.}$$

Shore 20A Urethane

Tensile strength, tear strength: $\sigma_y = 549$ psi, $T = 120$ pli [12]

Area: $A = t \times w = .03937$ in x $.4528$ in

$A = .01783$ in^2

Force to failure (tensile): $F = \sigma_y \times A$

$$\boldsymbol{F = 9.79}\ \textbf{lbs.}$$

Force to failure (tear): $F_t = T \times t$

$$\boldsymbol{F_t = 4.72}\ \textbf{lbs.}$$

Shore 40A Urethane

Tensile strength, tear strength: $\sigma_y = 950$ psi, $T = 120$ pli [11]

Area: $A = t \times w = .03937$ in x $.4528$ in

$A = .01783$ in^2

Force to failure (tensile): $F = \sigma_y \times A$

$$\boldsymbol{F = 16.9}\ \textbf{lbs.}$$

Force to failure (tear): $F_t = T \times t$

$$\boldsymbol{F_t = 4.72}\ \textbf{lbs.}$$

Shore 40A Silicone

Tensile strength, tear strength: $\sigma_y = 550$ psi, $T = 120$ pli [10]

Area: $A = t \times w = .03937$ in x $.4528$ in

$A = .01783$ in^2

Force to failure (tensile): $F = \sigma_y \times A$

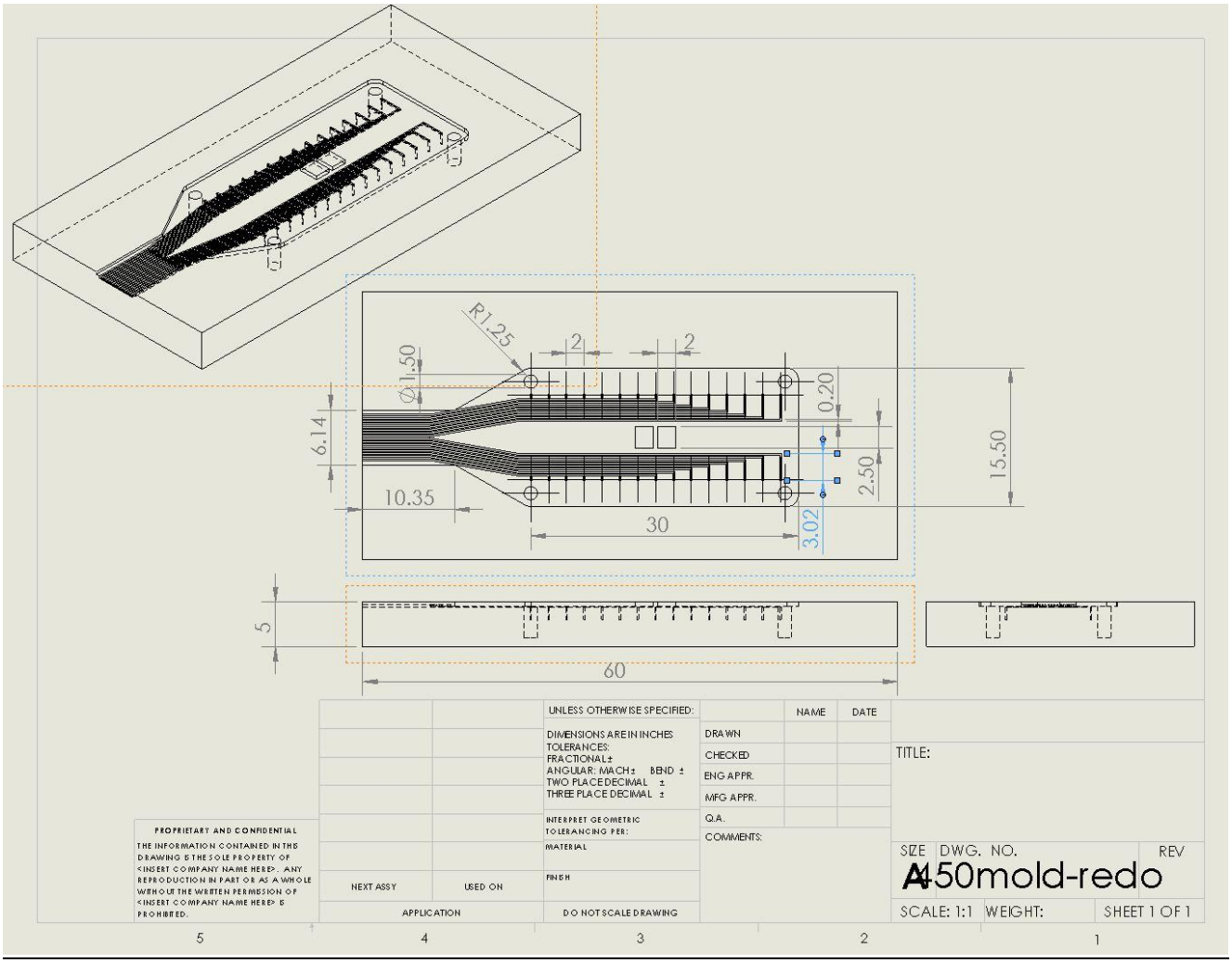
$$\boldsymbol{F = 9.80}\ \textbf{lbs.}$$

Force to failure (tear): $F_t = T \times t$

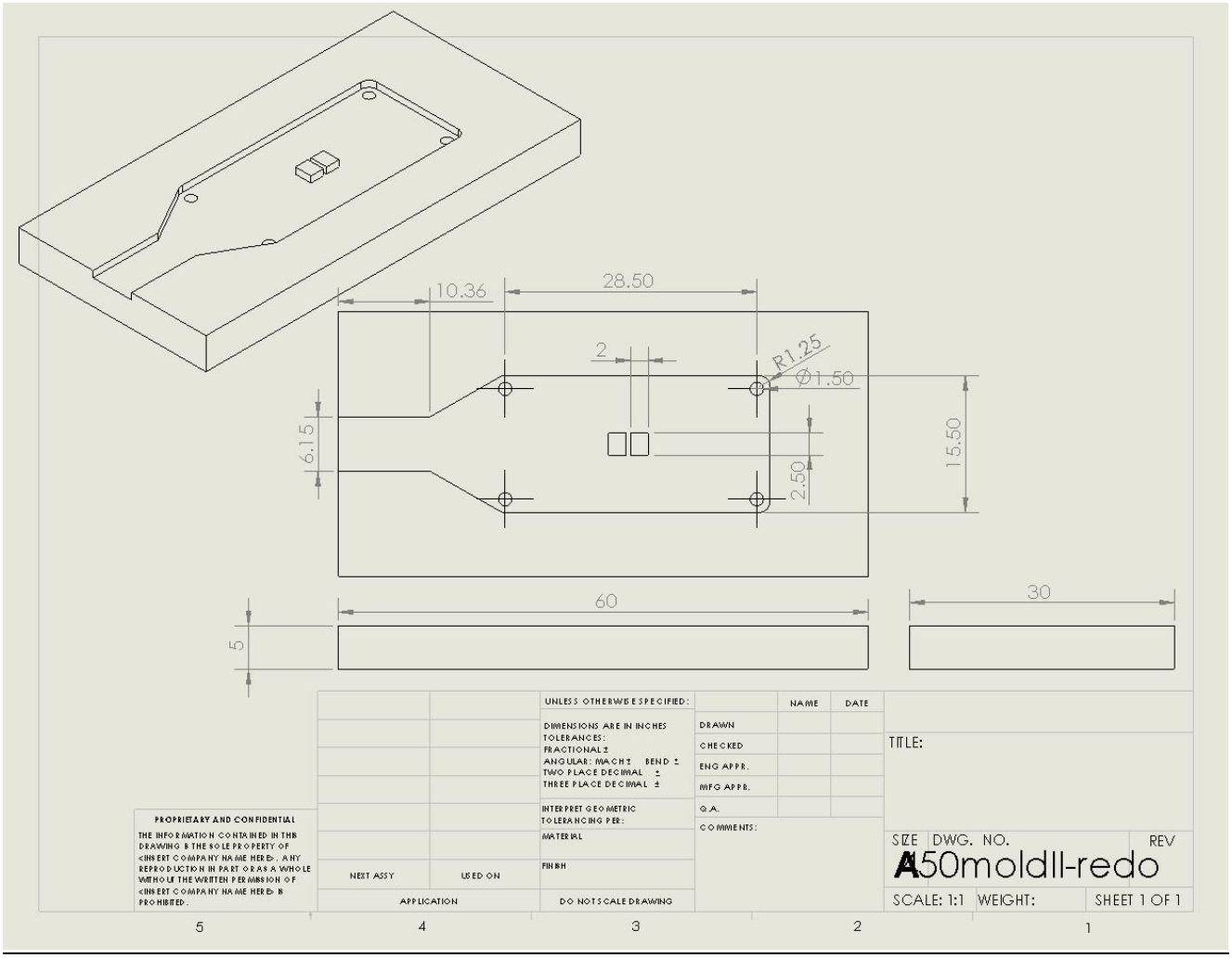
$$\boldsymbol{F_t = 4.72}\ \textbf{lbs.}$$

APPENDIX C: FABRICATION DRAWINGS

C.1: Front view and top view of primary mold



C.2: Top view and front view of the secondary mold



APPENDIX D: SAFETY REPORT

Executive Summary

This report contains our manufacturing, assembly, and assessment of our final design using DesignSafe. Our manufacturing plan involves using a CNC mill to fabricate two molds, a primary mold and a secondary mold. We need to use the CNC mill to fabricate these molds because of the scale and intricate nature of our design. Once the molds have been manufactured, we will use our purchased liquid compounds (General Purpose Urethane – Shore 20A and 40A and a silicone compound Shore 40A) to make test samples. Once we, along with our sponsor, determine which material is best for our application based on its physical properties, we will lay our magnet wire into the grooves of the primary mold and pour our selected material compound into the mold and let it harden. Once the material has hardened we will transfer it to the secondary mold, where will pour another layer of the compound, and then let the mold cure at room temperature. Using DesignSafe, we were able to assess that our design has low risks for every aspect. Our independent analysis also indicates that we low risks associated with our design. Our device would be most likely fail in tension if it were to fail. The failure could be in tension itself or it could be in tear, which is along the direction perpendicular to the tensile load. This failure would occur at forces that we believe will far exceed the forces that are expected during the removal of our device; the only time our device will experience any loading. We are planning to collect data in the mechatronics lab to verify the functionality of our design. Our device is used to conduct very weak signals (0.5-1 mV), so we will be looking to generate a signal comparable to this. At this point, we will need to refine our data collection by filtering out unwanted signals, which will involve computer programming. We are hoping to test our device on a pig stomach at the University of Michigan Hospital, which will be facilitated by our sponsor Dr. Radoslav Coleski. If this will be possible we will be able to test the physical functionality of the device in a controlled environment. At the point of testing, we will have our signal acquisition completed and refined so we can also test this aspect of our designs functionality.

Experimentation

We plan to experiment with a live pig stomach to validate our engineering specifications. All experiments will be conducted with a finished prototype, and we plan to make arrangements with Professor Asibu to conduct the first tests of our prototype. We expect the first tests to occur in the next couple of weeks.

A recording monitor will need to be powered with a power supply for our device to operate. We will analyze the device's ability to pick up a signal by measuring the voltage when the electrode plate makes contact with the stomach mucosa. As the voltage is measured, we will also measure the signal's duration to determine whether our device can record up to 3-4 hours of stomach electrical activity. We will also determine whether all electrodes maintain contact with the mucosa lining electrically by analyzing the output to see if there are any irregularities caused by an electrode not maintaining contact. We plan to confirm electrode contact visually using the lens on the endoscope to observe the plate inside the stomach. Additionally, the plate needs to maintain shape along the stomach lining. So, we will observe the plate's ability to fit between the folds of the stomach mucosa. We also plan to observe the clamps' ability to keep the device attached to the stomach, which will help us determine if the electrode plate can affix to the stomach lining. Also, we will attempt to use forceps through the endoscope to determine if our device is easy to remove and install during endoscopic procedure. If we can remove and install our device using one tool (forceps), then our device has successfully satisfied this customer requirement.

If a live pig stomach is unavailable for testing, then we will clamp our device to a sweatshirt or another inanimate object to observe whether the electrodes are maintaining contact with the shirt and whether the plate is able to conform to the shirt while attached. To determine the electrodes' ability to pick up a signal, we plan to attach the plate to the exterior of the human body with the assistance of a conductive solution. Although the

signal strength will not accurately depict the signal strength from the inside of the stomach, this experiment will nonetheless determine whether our device provides immediate electrical feedback.

FMEA Analysis

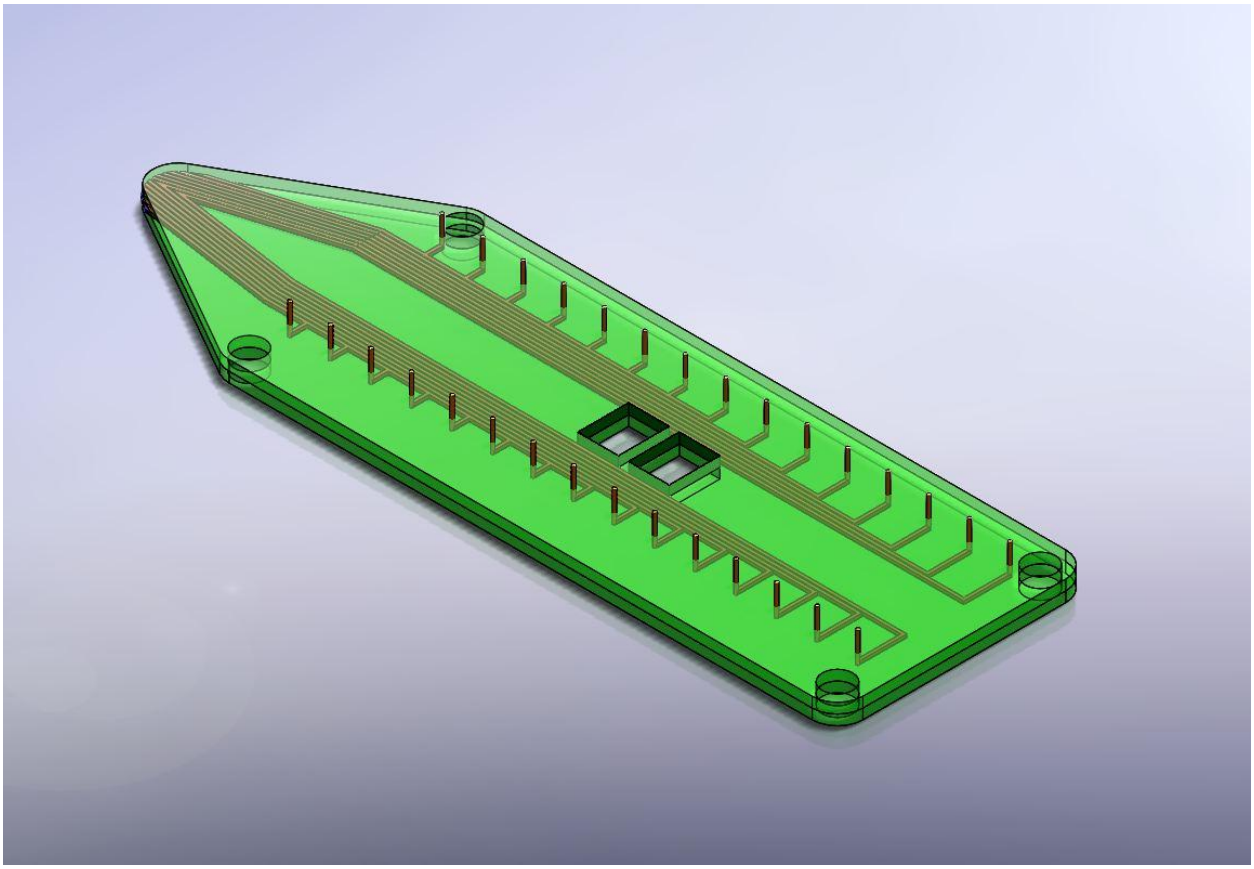
We purchased the following materials that could potentially be selected for our plate: 1) General Purpose Urethane 20A, 2) General Purpose Urethane 40A, and 3) Silicone 40A. All three of these materials will serve as the plate casting compound. Also, we purchased a square end mill to mill the mold and we purchased magnet wire as our electrodes. The drill bit will be used to drill the holes for the electrodes and the captive pins purchased will fill the clamp holes as the compound cures.

The table found in Appendix A summarizes our FMEA (failure mode and effects analysis) of all of our purchased materials. All of our plate casting compounds will experience the same failure modes, namely potential air bubbles and improper curing. Such failure could result in the material failing due to tension and/or tear, which would be caused by improper handling of the liquid compound and manufacturing defects. To avoid these failures, we will place each compound at room temperature since all three materials cure at room temperature and we will use a scale to ensure that we are accurately mixing the proportions of each compound. However, we feel that these failures are unlikely to occur, and should any failure occur, we are confident we will detect the failure quickly. Also, the square end mill and drill bit could both experience fracture due to breakage. Fracture of the square end mill could be caused by making a pass that is too deep or running the mill at a slow speed. While we feel that this will be a minor issue, we will specify the tool path on the CNC machine to make shallow, frequent cuts, and we will run the machine at the highest speed. The same applies for the drill bit except the only potential cause of failure is running the drill bit too slow. The magnet wires could fracture due to a significant tensile load. However, we do not feel that this is a major concern, but nonetheless we will make sure to avoid this failure by avoiding subjecting the wire to large tensile loads. Also, because the mold base and captive pins will not be subject to any external forces, we determined that there are no possible modes of failure.

DesignSafe Analysis

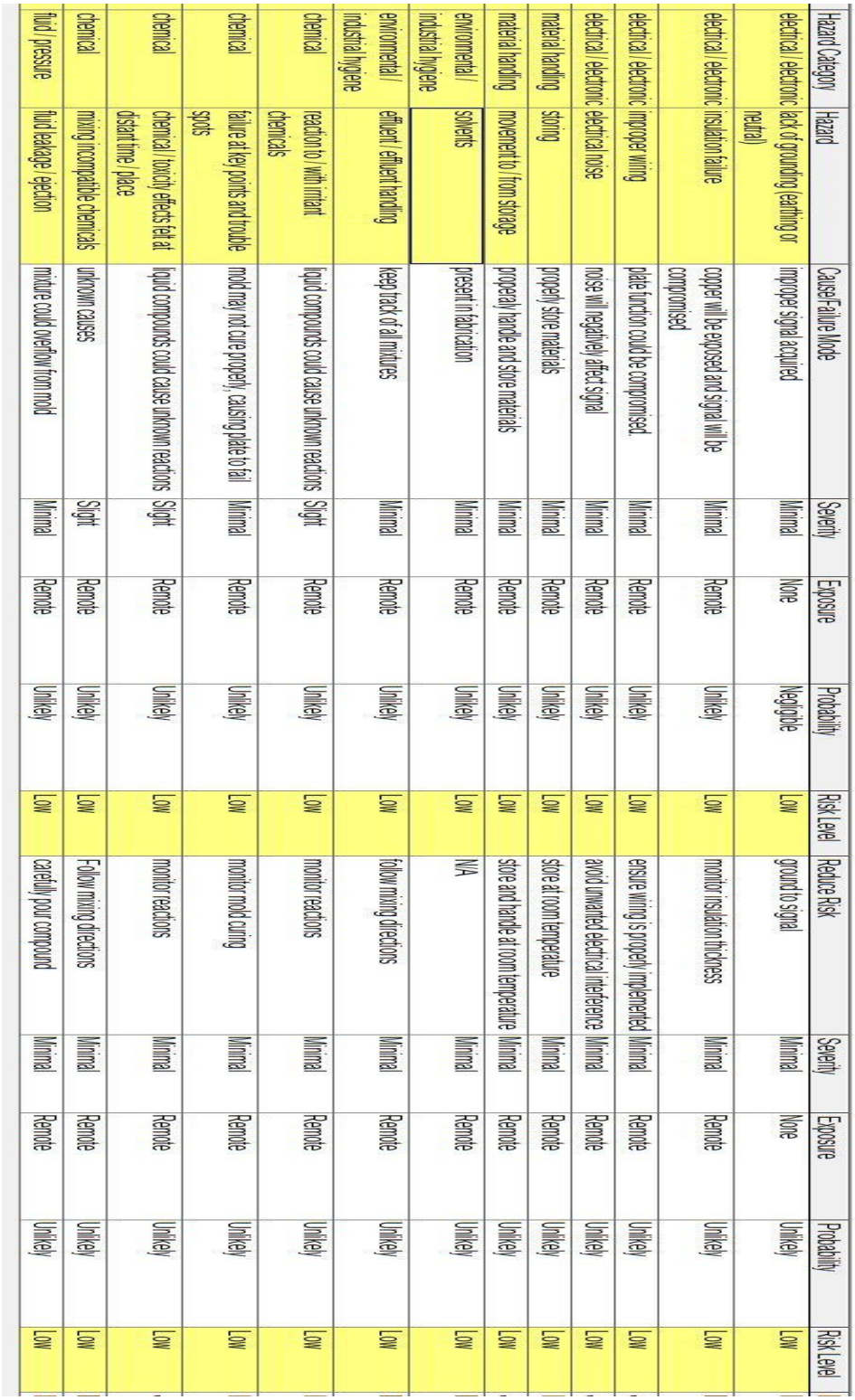
Figure D1 on the next page is an isometric view of the SolidWorks model of our electrode plate.

Figure D1: Isometric view of our electrode plate. We plan to fully manufacture this model.



After analyzing our final design, we determined that a lack of grounding could be due to improper wiring and that insulation failure could compromise the quality of the electrical signal. We will need to pay attention to the insulation thickness to prevent this problem from happening. As we mix the compounds, we will also need to ensure that we follow the mixing directions to avoid the compound overflowing from the mold. Additionally, we will need to carefully monitor curing because improper curing could cause the plate to fail. When storing and handling the materials, we will need to ensure that the materials are stored at room temperature for proper curing. However, after analyzing the output from DesignSafe, we concluded that all of the aforementioned issues are negligible and are unlikely to occur. Therefore, we feel confident that our electrode plate is safe to manufacture. Figure D2 on the next page shows our DesignSafe output.

Figure D2: The figure below shows our DesignSafe output. All possible hazards were deemed low risks.



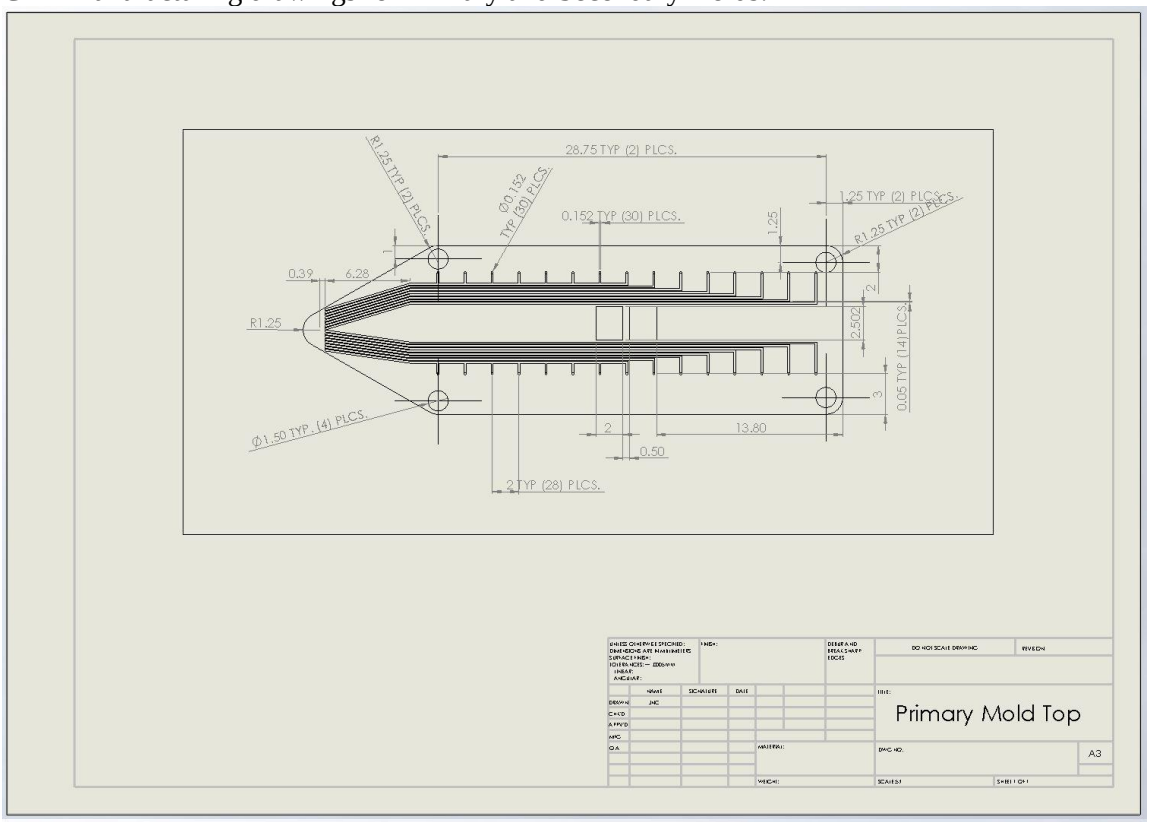
Hazard Category	Hazard	Cause/Failure Mode	Severity	Exposure	Probability	Risk Level	Reduce Risk	Severity	Exposure	Probability	Risk Level
electrical / electronic	lack of grounding (earthing or neutral)	improper signal acquired	Minimal	None	Negligible	Low	ground to signal	Minimal	None	Unlikely	Low
electrical / electronic	insulation failure	copper will be exposed and signal will be compromised	Minimal	Remote	Unlikely	Low	monitor insulation thickness	Minimal	Remote	Unlikely	Low
electrical / electronic	improper wiring	plate function could be compromised.	Minimal	Remote	Unlikely	Low	ensure wiring is properly implemented	Minimal	Remote	Unlikely	Low
electrical / electronic	electrical noise	noise will negatively affect signal	Minimal	Remote	Unlikely	Low	avoid unwanted electrical interference	Minimal	Remote	Unlikely	Low
material handling	storing	properly store materials	Minimal	Remote	Unlikely	Low	store at room temperature	Minimal	Remote	Unlikely	Low
material handling	movement to / from storage	properly handle and store materials	Minimal	Remote	Unlikely	Low	store and handle at room temperature	Minimal	Remote	Unlikely	Low
environmental / industrial hygiene	solvents	present in fabrication	Minimal	Remote	Unlikely	Low	N/A	Minimal	Remote	Unlikely	Low
environmental / industrial hygiene	effluent / effluent handling	keep track of all mixtures	Minimal	Remote	Unlikely	Low	follow mixing directions	Minimal	Remote	Unlikely	Low
chemical	reaction to / with irritant chemicals	liquid compounds could cause unknown reactions	Slight	Remote	Unlikely	Low	monitor reactions	Minimal	Remote	Unlikely	Low
chemical	failure at key points and trouble spots	mold may not cure properly, causing plate to fail	Minimal	Remote	Unlikely	Low	monitor mold curing	Minimal	Remote	Unlikely	Low
chemical	chemical / toxicity effects felt at distant time / place	liquid compounds could cause unknown reactions	Slight	Remote	Unlikely	Low	monitor reactions	Minimal	Remote	Unlikely	Low
chemical	mixing incompatible chemicals	unknown causes	Slight	Remote	Unlikely	Low	Follow mixing directions	Minimal	Remote	Unlikely	Low
fluid / pressure	fluid leakage / ejection	mixture could overflow from mold	Minimal	Remote	Unlikely	Low	carefully pour compound	Minimal	Remote	Unlikely	Low

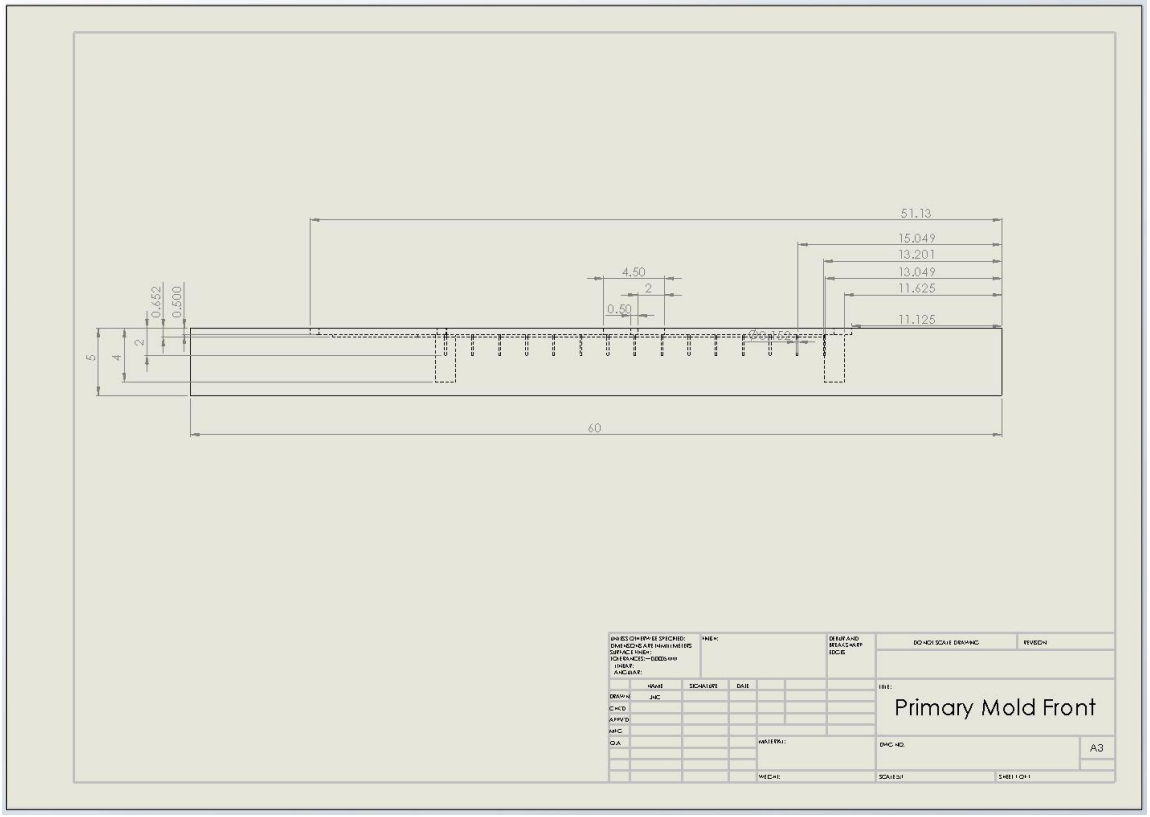
Fabrication

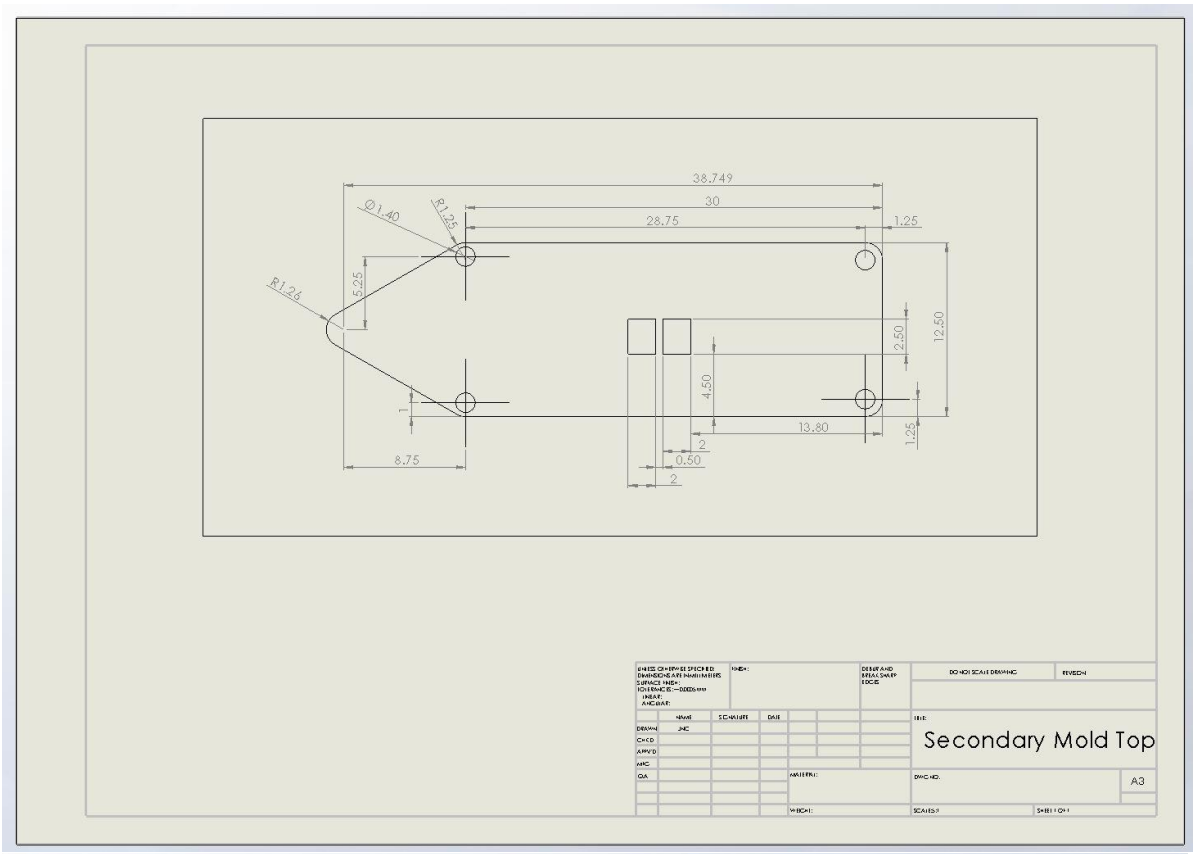
5. The following is a list of our fabrication and manufacturing activities:

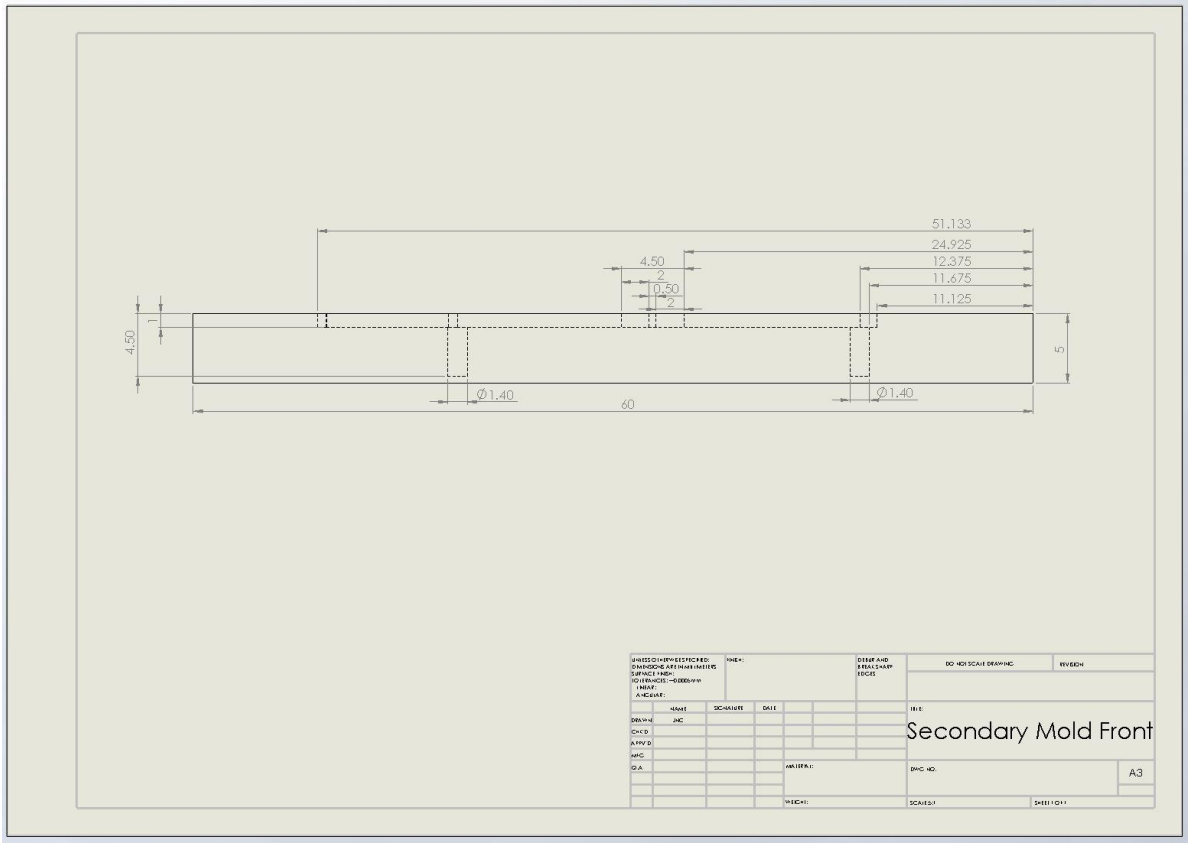
a. Material Specimen Mold x3
    i. Mill 1mm deep into Delran block with 12.5mm end mill for 40mm (3000 rpm)
    ii. Mix casting compounds and pour into mold
    iii. Remove material specimen after curing
b. Primary Mold
    i. Convert CAD model to tool path files for CNC mill
    ii. CNC mill 0.5 mm depth of plate contour with 2.5mm end mill (3000 rpm)(1 inch/min)
    iii. CNC mill space between rectangular protrusions with 0.152mm end mill (3000 rpm) (1 inch/min)
    iv. CNC drill clamp holes to depth of 4mm with 1.5mm drill bit (3000 rpm) in Delran
    v. CNC drill electrode holes to depth of 1.5mm with .152mm drill bit (3000 rpm)
    vi. CNC mill wire path grooves with .152mm end mill to depth of .006" (3000 rpm) (1 inch/min)(.002" depth per pass)
c. Secondary Mold
    i. Convert CAD model to tool path files for CNC mill
    ii. CNC mill 1mm depth of plate contour with 2.5mm end mill (3000 rpm) in Delran
    iii. CNC mill space between rectangular protrusions with .152mm end mill (3000 rpm)
    iv. CNC drill clamp holes to depth of 4mm with 1.5mm drill bit (3000 rpm)
d. Wire Prep
    i. Cut .006" copper magnet wire to length of 2m
    ii. Strip 1mm from end of wire with razor blade
e. Mold Casting
    i. Spray mold with mold release
    ii. Place electrode tips in holes and wire path grooves by hand
    iii. Mix casting compound
    iv. Pour compound in mold until material reaches top edge
    v. Allow mold to harden
    vi. Remove mold and place inverted in secondary mold
    vii. Cover electrode tips with tape
    viii. Mix casting compound
    ix. Pour compound in mold until material reaches top edge
    x. Allow mold to cure
    xi. Remove cured plate

CAD manufacturing drawings for Primary and Secondary molds:






38.749
30
28.75
1.25
Ø1.40
R1.25
R1.26
5.25
2.50
12.50
4.50
13.80
1.25
1
2
0.50
2
8.75
DO NOT SCALE DRAWING
REVISION
Secondary Mold Top
A3


51.133
24.925
12.375
11.675
11.125
4.50
2
0.50
2
1
4.50
5
Ø1.40
Ø1.40
60
DO NOT SCALE DRAWING
REVISION
Secondary Mold Front
A3

6. The components will be assembled using the manufacturing instructions above. Molds will be manufactured in either the GG Brown machine shop with the help of Bob Coury to operate the CNC mill or in the Auto Lab with the help of Kent Pruss and Marv Cressey to operate the CNC mill. The assembly consists of setting the electrode wires into the primary mold, placing clamp hole dowels in the slip fit holes, and pouring the casting compounds in the mold. After the primary mold has hardened we will remove the plate, invert it, and place it in the secondary mold with clamp hole dowels for the second application of the casting compound. Our assembly is very simple and does not have many opportunities for failure. The assembly has been analyzed mathematically and will not fail unless the plate or wires experience a tensile load much greater than the material limit. It is unlikely that the plate or wires will be exposed to such large loads before, during, and after use. The forces applied to the plate during installation result from rolling the plate into the endoscope channel, pulling the plate from the channel once inside the stomach, and the application of clamps to the clamp holes present on the plate. During the procedure, the forces on the plate are the result of the stomach contractions moving the stomach wall. All forces applied at these times are minimal and will not result in failure of the design. The largest loads applied are during extraction when the wires are pulled and the plate experienced a tensile force as it is pulled back up through the esophagus. The analysis we have done on the plate material properties and estimated forces leads us to believe that the plate will perform without failure.

7. We plan to test our device on a live pig stomach. We will be working with our sponsors at the University of Michigan hospital. We will be testing the materials by creating the material specimen molds. This is the only testing we will do during the manufacturing process. Once we have finished the prototype, we will validate all functions in a single test on the live pig. The electrodes will be evaluated based on the feedback received by the monitoring equipment. The clamp hole and clamping mechanisms will be evaluated by observing the ability to maintain contact with the stomach lining. The flexibility of the plate will also be evaluated by watching the movement of the plate during a stomach contraction via the endoscope lens. We have arranged for a cognizant individual to be present during our first major test. This individual will be our sponsors, Dr. Coleski and Dr. Hasler from the university of Michigan hospital. We expect this testing period to take place a few weeks after we start the fabrication process. However, this testing period is based on the availability of our sponsors and the resources needed to conduct the experimentation.

MSDS

The following link provides the material safety data sheet for the Delrin we plan to use. However, we were unable to find material safety data sheets for the following materials: 1) General Purpose Urethane 20A, 2) General Purpose Urethane 40A, and 3) Silicone 40A. These materials were all purchased from McMaster-Carr and they do not have attainable MSDS's for any of the three specified materials.

http://siri.org/msds/f2/bxs/bxspq.html

D.1: FMEA Results

Table D1 below displays our FMEA results along with severity, occurrence, and detection ratings. We determined that all possible failures had a low risk and that any failure would be detected quickly.

Table D1: The table below summarizes the possible failures and recommended courses of action for our purchased materials.

Part Number, Name, & Function	Potential Failure Mode	Potential Effects of Failure	**Severity (S)**	Potential Causes/Mechanisms of Failure	**Occurrence (O)**	Current Design Controls/Tests	**Detection (D)**	Recommended Actions	**RPN (= S x O x D)**
# 8644K51: Urethane 20A. Plate casting compound	Air bubbles, improper curing	Material failure (tension/tear)	2	Improper handling of liquid compound (mixing/curing directions), manufacturing defects	2	Visually inspect air bubbles. Measure mixing proportions. Place compound in controlled environment (regulate curing temperature)	2	Place compound at room temperature. Check mixing proportions for accuracy using scale.	8
# 8644K53: Urethane 40A. Plate casting compound	Air bubbles, improper curing	Material failure (tension/tear)	2	Improper handling of liquid compound (mixing/curing directions), manufacturing defects	2	Visually inspect air bubbles. Measure mixing proportions. Place compound in controlled environment (regulate curing temperature)	2	Place compound at room temperature. Check mixing proportions for accuracy using scale.	8
# 8595K12: Silicone 40A. Plate casting compound	Air bubbles, improper curing	Material failure (tension/tear)	2	Improper handling of liquid compound (mixing/curing directions), manufacturing defects	2	Visually inspect air bubbles. Measure mixing proportions. Place compound in controlled environment (regulate curing temperature)	2	Place compound at room temperature. Check mixing proportions for accuracy using scale.	8
#8823A379: Square End Mill. Mill the mold	Fracture. End mill breaks.	Flying debris	3	Making pass that is too deep with end mill. Running end mill too slow.	2	Use shallower passes. Increase run speed.	1	Specify tool path to make shallower, more frequent cuts with end mill. Run at highest speed.	6
#7588K27: Magnet Wire. Electrodes	Fracture	Parts separate	2	Too much wire tension.	2	Visually inspect wires.	1	Avoid subjecting wire to significant tensile loads	4
# 8739K95: Mold Base. Mold for plate	No failure modes	No effects	0	No mechanisms of failure.	0	N/A	0	N/A	0
#2901A229: Drill Bit. Drill electrode holes	Fracture. Drill bit breaks.	Flying debris	3	Running drill bit too slow.	1	Increase run speed.	1	Run at highest speed.	3
#95648A290: Captive pins. Fill clamp holes	No failure modes	No effects	0	No mechanisms of failure.	0	N/A	0	N/A	0

APPENDIX E: BILL OF MATERIALS

E.1: Off-the-Shelf Materials

The following is a bill of materials listing all of the off-the-shelf parts we have ordered and plan to order.

Part #	Part Name	Qty	Material	Color/Finish	Size	Amount	Cost	Function
2951A12	Drill Bit	1	Steel	Black	.0063" Dia	3	$9.56	Drill electrode hols
8595K12	Silicone (40A)	1	fast-setting	green	4 in^3	90g	$12.31	plate casting compound
8823A379	Square End Mill	3	TiAlN carbide	purple	.05"Dia, .075"L	1	$21.86	mill the mold
7588K27	Magnet Wire	1	copper	clear	.006" Dia	6,150ft	$16.59	electrodes
8739K95	Mold base	1	delrin	white	1/8"x2.5"x12"	5	$4.65	mold for plate
2901A229	Drill Bit	5	Black oxide	black	54	1	$1.51	drill dowel holes
95648A290	Captive pins	1	metal	grey	8mm(L), 1.5mm(D)	25 pins	$10.04	fill clamp holes
RC4558IDR	Op-Amps	1	silicone	black	364 x 364 x 27 mm	30	$7.09	Amplify signals

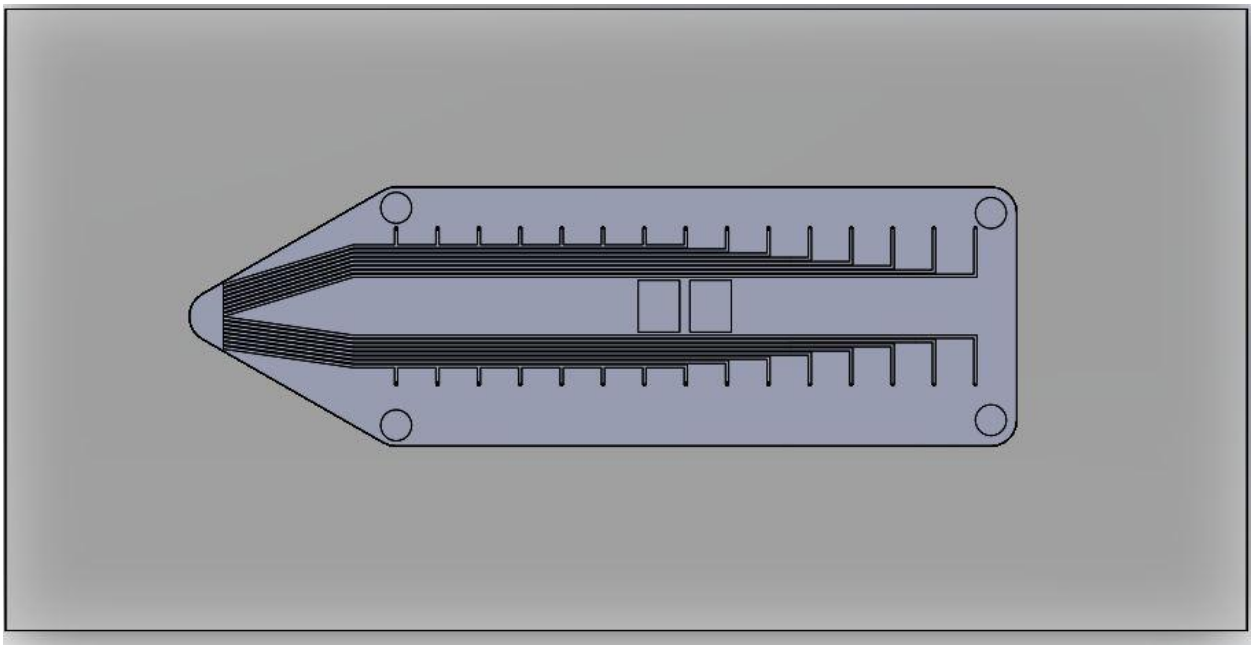
E.2: In-house Materials

We obtained Delrin from the machine shop and used a mold release, which is an aerosol adhesive resistant compound. Mold release was found in the assembly area and machine shop. We constructed amplification circuits using sixty 22 µF capacitors, thirty 1.1 kΩ resistors, and sixty 1.1 MΩ resistors, all of which can be found in the mechatronics room. Electrodes were created using magnet wire and we created a primary mold and secondary mold. For the primary mold, we milled the plate design using a Delrin block with the square end mill at a depth of 0.5 mm, and thirty holes for electrode placement were drilled using 36 gauge drill bits. Each drilled hole has an associated groove cut into the mold for us to route the magnet wire. The secondary mold was manufactured similar to the primary mold with the exception that the secondary mold is 1 mm deep and does not have the thirty holes drilled for electrodes nor does have the grooves cut for wire routing. For our final product, we followed these steps in the following order: 1) place wires and electrodes in the primary mold, 2) cast the silicone compound, 3) place the primary molded compound in the secondary mold, 4) cast the second layer of the silicone compound, 5) build the amplification circuit, and 6) connect electrodes to amplifiers.

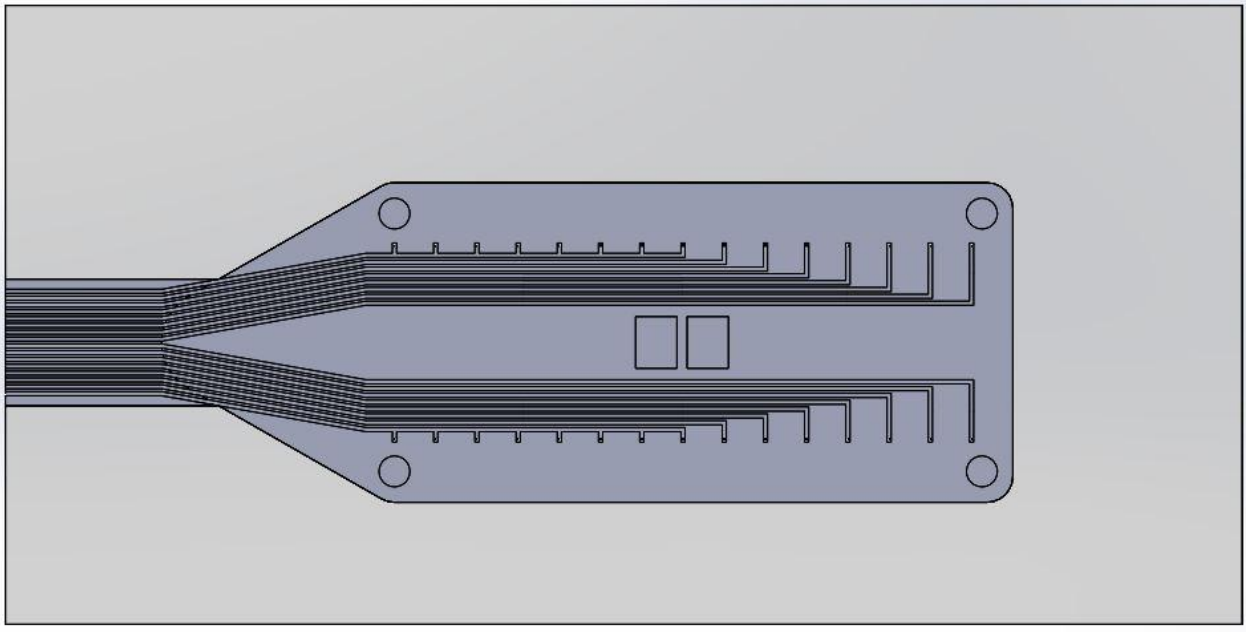
APPENDIX F: ENGINEERING CHANGES SINCE DR #3

This section explains the engineering changes that were made from Design Review #3 along with corresponding before and after figures.

Before:



After:



We increased the width of each groove and the thickness of the wall due to the collet not being true during manufacturing. The cut varies by 0.001.” To account for this manufacturing limitation, the groove width was increased from 0.006” to 0.008.” Also, the wall thickness was increased to 0.005.” By making these changes, the wires will stay in place as they are being fitted into the grooves. We also extended the taper so that the wires can reach the end of the plate without bending.

APPENDIX G: DESIGN ANALYSIS ASSIGNMENT

This section explains the material selection assignment for functional and environmental performance and the manufacturing process selection assignment.

G.1: Functional Performance

The first major component is the electrode plate. The purpose of the plate is to keep the electrodes in a fixed position during endoscopic procedure. The plate must be flexible enough to maneuver along the folds of the stomach mucosa but also rigid enough to maintain its shape during travel. The chosen material needs to maintain a balance between flexibility and rigidity but also must easily mold onto the plate's previously determined dimensions, namely width, length, and thickness. Ideally, the material needs to also minimize cost since we are constrained to a $400 budget. Also, because the material will be subject to a tensile load when the plate is removed from the esophagus, the chosen material must not fail due to this tensile load.

We then created material indices based on these constraints, functions, and objectives. For the plate, we determined that tensile strength would be the appropriate material index for determining the best material. Tensile strength is governed by equation 1

We plotted Young's modulus vs. density, specifying ranges for both variables based on sponsors' input and prior research. Our sponsors indicated that a urethane or silicone material could be the most suitable material for the electrode plate. So, we determined that a Young's modulus range of 5-8 MPa and a density range of 0-0.05 lb/in^3 would be acceptable ranges for our plot since these value ranges encompass both urethane and silicone materials. After inputting these ranges, we then narrowed down the materials based on tensile strength since the chosen material needs to have a high enough tensile strength to withstand a tensile load during removal from the esophagus. We narrowed down our material selection by selecting the five materials with the highest tensile strengths, which yielded the following results: 1) Silicone (VMQ, heat cured), 2) Butyl/Halobutyl rubber, 3) Polysulphide rubber, 4) Epichlorohydrin copolymer, and 5) Ethylene propylene (diene). Although Epichlorohydrin copolymer and Butyl/Halobutyl rubber have the two highest tensile strengths, we found that silicone is the most readily available material of the five possible materials. Because silicone satisfies our objectives, functions, and constraints, silicone is the best material choice due to its availability. Figure G1 shows the CES EduPack plot for the electrode plate material:

The second major component is the electrodes, whose purpose is to conduct a signal from pulses generated in the stomach. The electrodes need to be made of a material with a high electrical conductivity so that the electrodes conduct a strong signal from the stomach pulses. The electrodes also need to be extruded into the shape of a wire and the chosen material needs to maximize tensile strength since the electrodes will be subject to tensile loads. Because electrical conductivity needs to be maximized, we determined that electrical resistivity needs to be minimized, which is governed by the following equation:

$$R = \rho \frac{L}{A} \qquad \text{(Eq. G1)}$$

where R is electrical resistivity, ρ is density, L is the length of the material, and A is the cross-sectional area of the material. Conductivity is defined as the inverse of density, so minimizing density will minimize electrical resistivity, which will consequently maximize electrical conductivity. After talking with our sponsors, we found that silver and copper would be good materials for the electrode. Based on this knowledge, we determined ranges for Young's modulus and density that included silver and copper. We determined a Young's modulus range of 9-25 GPa and a density range of 0.061-0.41 lb/in^3 since both of these ranges encompass copper and silver [17,18]. After inputting these ranges, we narrowed down our material selection to the following materials: 1) Copper alloy, 2) Silver, 3) Aluminum alloy, 4) Titanium alloy, and 5) Zinc alloy. Similar to the electrode plate material, we need to minimize cost when selecting our electrode material. So, we eliminated zinc alloy,

titanium alloy, and silver. Our sponsors have previously used copper for the electrodes in their three electrode system, we decided that copper would be the best electrode material since we know that copper is a safe material for use inside a patient's body and it has been successfully used for an electrode material in the past. Figure G2 shows the CES EduPack plot for the electrode material.

Figure G1: From the plot below of Young's modulus vs. density, the top five materials previously discussed are shown for the electrode plate. We input various material properties based on a discussion with our sponsors.

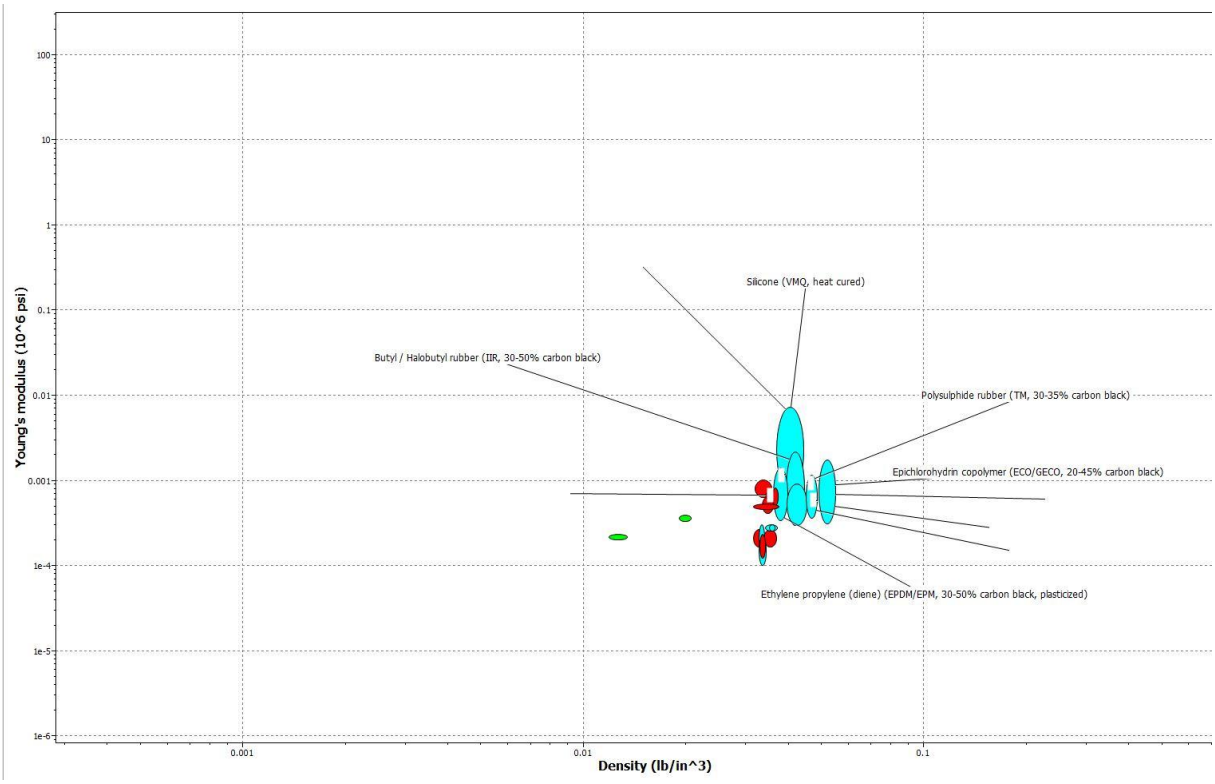
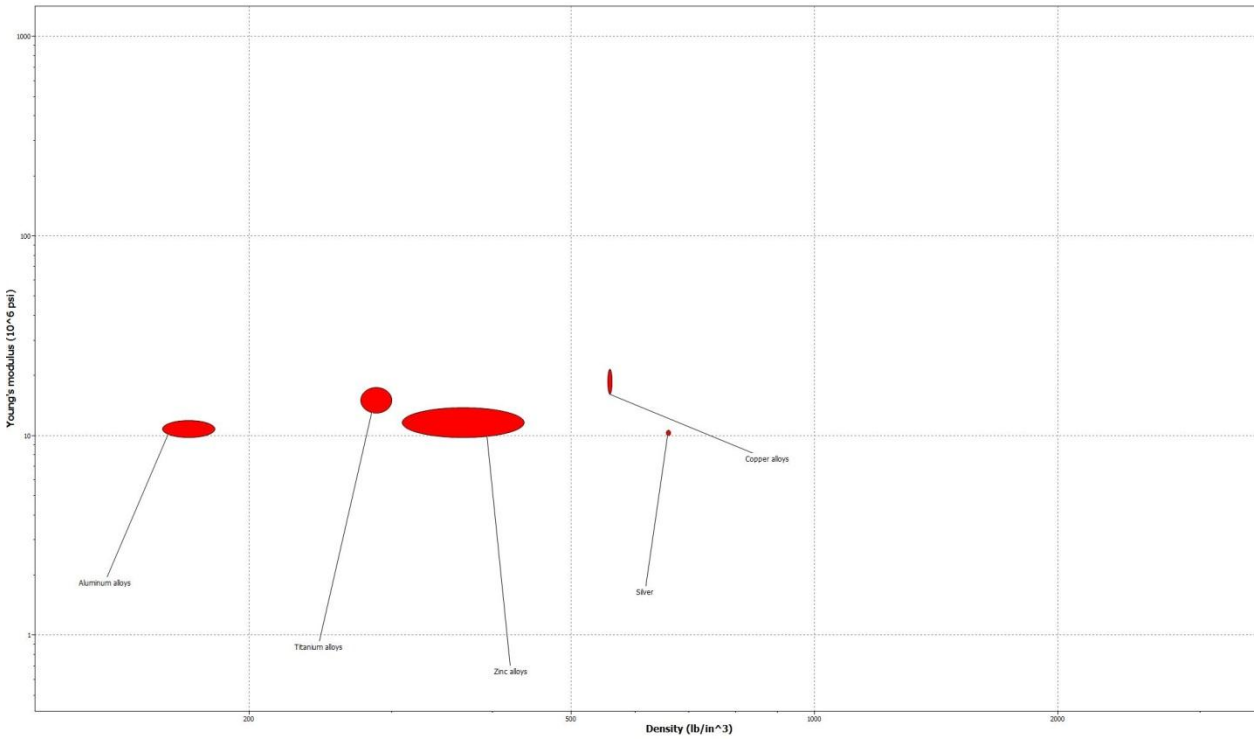


Figure G2: After inputting ranges for density and Young's modulus, we narrowed down our material selection to five materials. Copper alloy was determined to be the best since it has been used by our sponsors for their three electrode system.



G.2: Environmental Performance

After selecting our two materials, we used SimaPro software to determine the environmental impact each material would have. We first determined the masses required for each material by multiplying the materials' respective densities by the volume of their component. For copper, the component volume is the thirty wires and the component volume is the electrode plate for Polybutadiene E, which was the closest material we could fine on SimaPro. Using SimaPro, we calculated the total mass of air emissions, water emissions, raw materials, waste materials, and soil waste for Polybutadiene E and copper. A plot of these emissions can be seen in Figure G3. From the plot, we expect that copper will produce significantly more emissions from Polybutadiene E and that the majority of these wastes will come from water wastes.

We then used SimaPro to plot the damage assessment of each material to gain a better understanding of the impact each material will have on the environment. This plot can be seen in Figure G4. As seen in the plot, copper has a much higher damage assessment number than Polybutadiene E in every category. So, we determined that copper would have a much bigger impact on the environment in each of these categories. Next, we plotted a normalization of these damage categories to gain a better understanding of the importance of each damage category. A plot of this normalization can be seen in Figure G5. From the figure, carcinogens received the highest normalization score. This means that when considering material selection for our two major components of our design, we will have to keep this in mind since carcinogens directly affect human health. Because our project deals with patients in hospitals, it is especially crucial that we pay close attention to how our materials could affect human health.

After determining that human health would be the most important damage category, we used SimaPro to create a plot of the "single score" of copper and Butadiene E to determine which material will have a bigger impact over the span of a full life cycle. A plot of this single score can be found in Figure G6. Because the amount of

copper used in our project is significantly higher than Polybutadiene E (.0986 g vs. .00930 g), copper will have a bigger impact on the environment. Given a full life cycle, the only way Polybutadiene E could be equally as important as copper is if the mass of Polybutadiene E was similar in magnitude compared to that of copper's.

From our analysis of SimaPro, we concluded that copper would be the best choice for our electrode material. Although other metals may have been suitable, each metal would have a similar impact on the environment as copper, so regardless of the chosen electrode material, we will have to consider the same environmental impacts. Also, copper is an electrode material that is commonly used in other applications, so we decided that copper would be the best choice for our electrode plate. Silver is the only metal that has a higher electrical conductivity than copper, but silver is significantly more expensive than copper. Since cost needs to be minimized, this is another reason why copper is a suitable electrode material.

For the electrode material, we determined that there are better choices than Polybutadiene E. Each of the possible electrode plate materials will have the same environmental impacts as Polybutadiene E. A silicone compound or urethane material would be the best material choice for the electrode plate. Our sponsors indicated that a silicone material could work well for the electrode plate, and since silicone was our top choice from our CES EduPack analysis, we decided that using a silicone compound would be the best material choice since any polymer or urethane material chosen would have the same environmental impact.

Figure G3: From the plot below, copper will produce more emissions than Polybutadiene E, meaning that it will have a bigger impact on the environment overall.

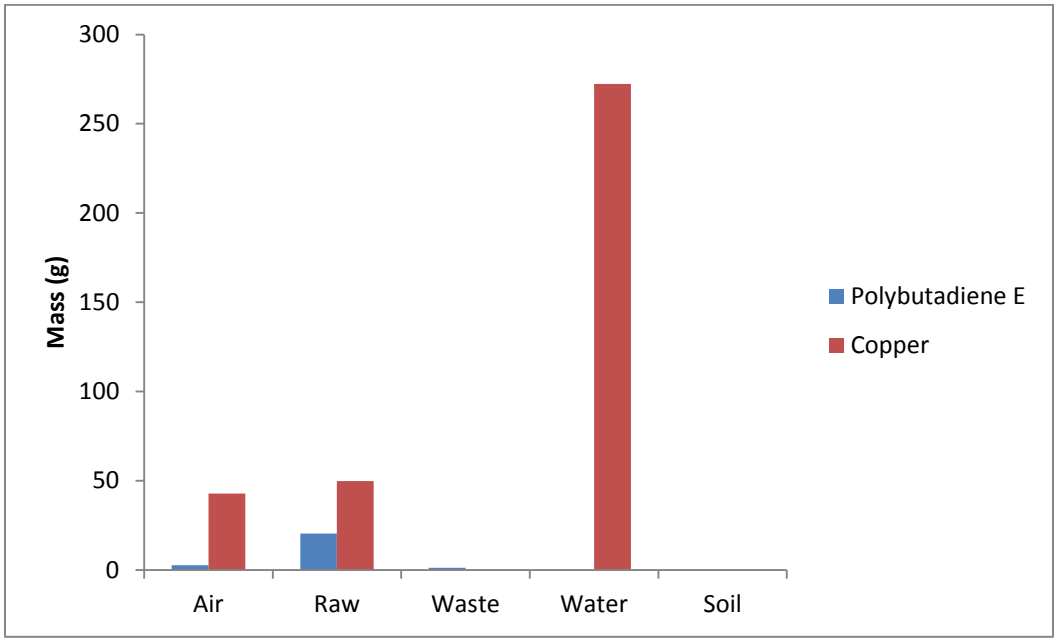


Figure G4: The plot below shows that copper (shown in red) will have a much bigger impact on the environment than Polybutadiene E because copper has a significantly higher damage assessment in each of the displayed categories.

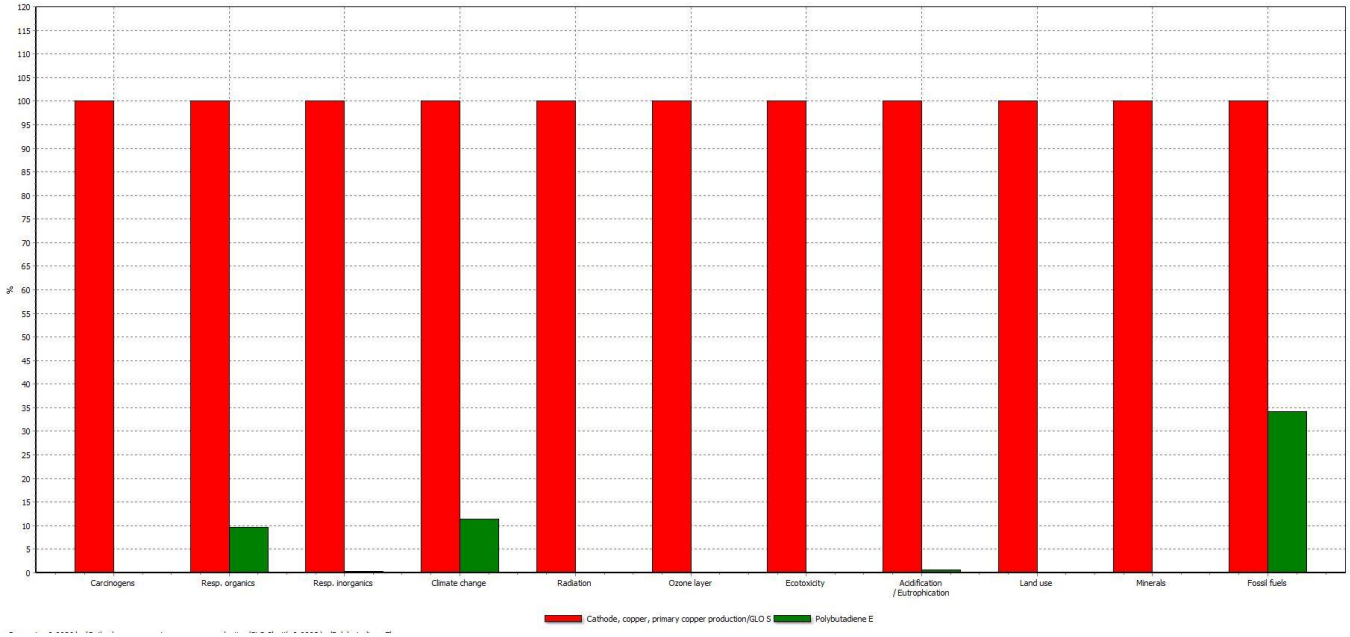


Figure G5: The figure below shows that carcinogens will be most important in the damage assessment. A significant amount of carcinogens can be harmful for human health, so it is most likely that human health will be the most important damage assessment to consider for our material selections.

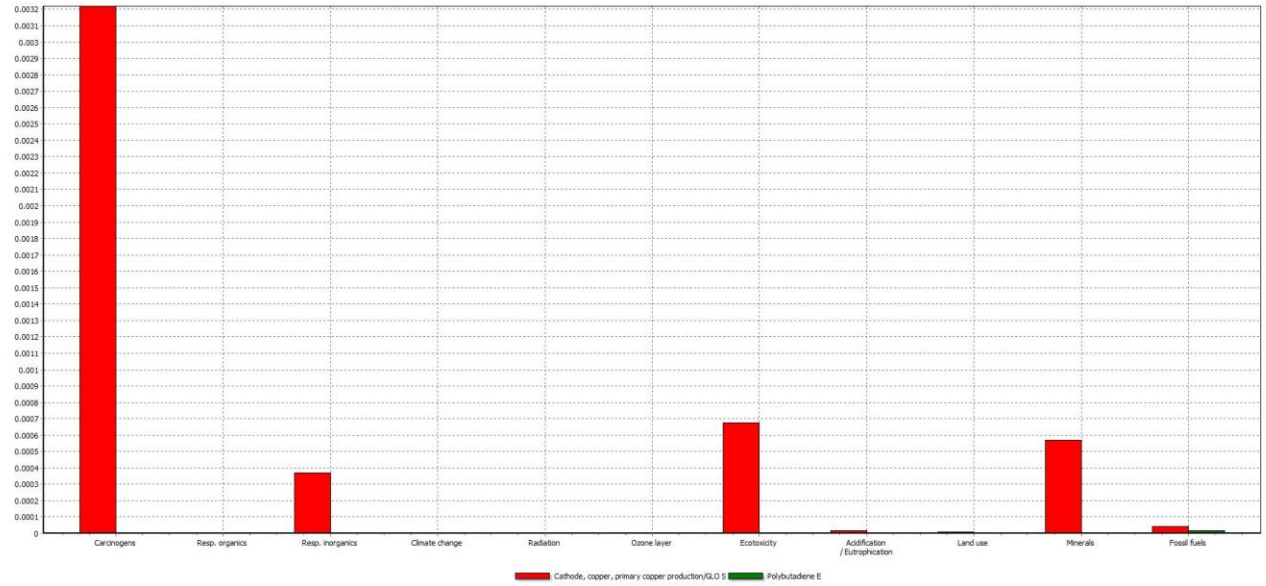


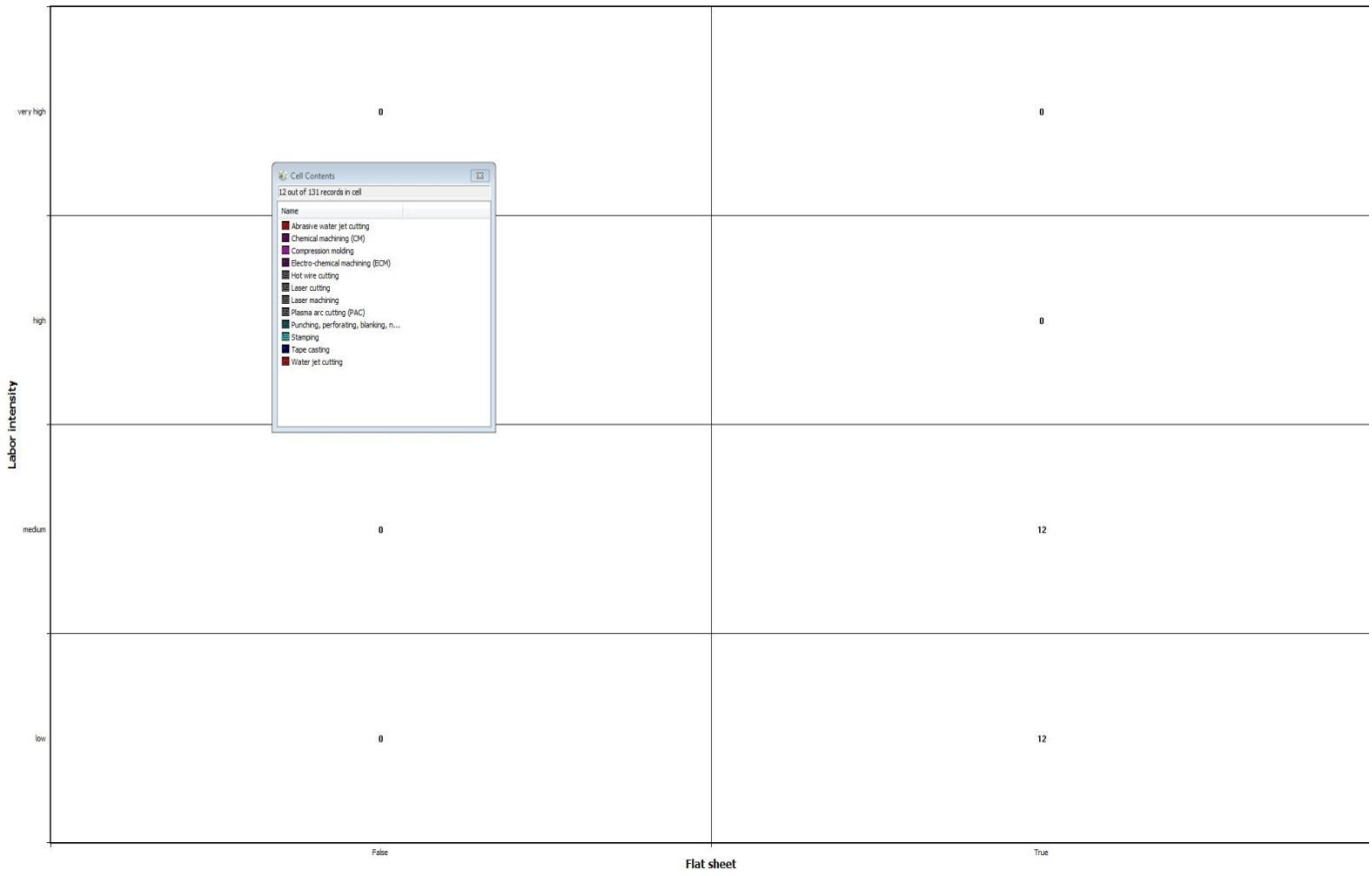
Figure G6: From the figure below, copper received the higher single score. However, over a full life cycle, it is possible that Polybutadiene E could be equally as important as copper, but the only way for Polybutadiene E to have an equally strong impact as copper is if the two masses used were of similar magnitude.

While we only produced one prototype for this course, we considered the possibilities of our device being produced in the real world. If our device were to be used in real life applications, it is likely that our device would need to be produced by millions since it would need to be used in all hospitals that use endoscopic procedures. While each hospital unit might differ from another, we would have to manufacture a significant amount of electrode plates because the device is meant to be disposable. Because we are unsure of how frequent endoscopic procedures take place in hospitals globally, we would prepare for possible scenarios by mass producing millions of our device. We project that we would have to produce at least 1 million electrode plates for hospitals to use not only in the US but also around the world.

G.3: Manufacturing Process Selection

To mass manufacture our device, we used CES EduPack to determine the best manufacturing processes for our two major components, namely the electrode plate and electrode material. For electrode plate material, we plotted labor intensity vs. flat sheet since labor intensity is important to consider when mass producing a device and the electrode plate material would be ordered in many flat sheets. Figure G7 shows this plot.

Figure G7: From the plot, the most reasonable manufacturing process for our electrode plate is to use stamping. The box shown indicates that stamping would be most practical because the rest of the manufacturing processes listed do not make practical sense for our application. Also, stamping is labeled under low labor intensity, which is another reason why stamping would be the best manufacturing process.



To manufacture the electrode material, we used CES EduPack to help determine the best processes by inputting ranges for costs and tolerances and ranges of mass used. A description of the chosen manufacturing process can be seen in Figure G8.

Figure G8: Our EduPack analysis led us to the conclusion that it is best to use extrusion for making the .006" electrode copper wires. Since these wires are very thin, it would not make sense to use any process other than extrusion.

Description

The process

The process of squeezing toothpaste from its tube is one of extrusion. The gooey toothpaste - or the gooey polymer or metal in the industrial process - is forced by pressure to flow through a shaped die, taking up the profile of the die orifice. In co-extrusion two materials are extruded at the same time and bond together - a trick used in toothpaste to create colored stripes in it.

Process schematic

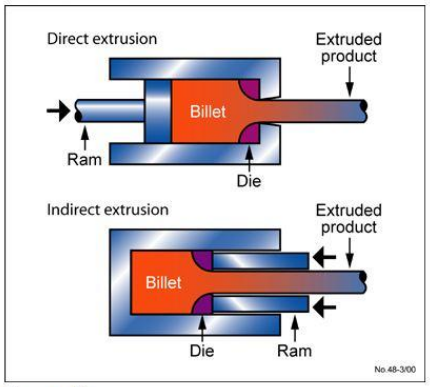


Figure caption

Extrusion and back, or indirect, extrusion

Shape

Circular prismatic	✓
Non-circular prismatic	✓

Physical attributes

Mass range	2.2	-	2.2e3	lb
Range of section thickness	39.4	-	3.54e4	mil
Surface roughness (A=v. smooth)	B			
Tolerance	0.984	-	19.7	mil

Economic attributes

Relative tooling cost	high
Relative equipment cost	high
Labor intensity	low

Supporting information

Typical uses

Tubing, window frame sections, building and automotive trim, aircraft structural parts, railings, rods, channels, plastic-coated wire, seals, filaments, film, sheet, pellets, bricks.

Links

Reference	...
MaterialUniverse	...

Values marked * are estimates.
Granta Design provides no warranty for the accuracy of this data

APPENDIX H: BIOS

Section H.1: Eric Lhymn

I was born in Conneaut, Ohio and raised in Erie, PA. I have two older sisters and an older brother. I was raised by a family of engineers. My dad is a retired materials science professor and my oldest sister and brother graduated with Bachelor of Science degrees in chemical engineering and mechanical engineering, respectively. Ever since high school, I knew that I was going to major in engineering. It wasn't until after my freshman year in college that I decided to major in mechanical engineering. Mechanical engineering is a broad field with many possibilities for future employment after college, which is what appealed to me the most about mechanical engineering.

I played 4 years of varsity tennis in high school and I sang in chorus for 3 years in high school. I also played the piano for my high school chorus occasionally. I started playing tennis and piano when I was 8 years old. I quit taking piano lessons as a junior in high school and I quit taking tennis lessons after graduating high school. I expect to graduate in May 2013 and I hope to obtain a full-time job upon graduation. Later in my career I plan to go into a management type of position, which might involve getting an MBA in the future.

For the past two summers, I interned with Air Liquide USA LLC, and I hope to work full-time for Air Liquide or another industrial gas company such as Air Products & Chemicals, Inc. The past two summers helped me realize that I am not only passionate about this particular industry but also that I have the skillset to excel in an industrial gas company such as Air Liquide.

Section H.2: Michael Nimkar

I was born in Beverly, Massachusetts and grew up in Swampscott, MA. Swampscott is a suburb of Boston and is about 20 miles outside of the city. I played a lot of sports growing up including football, basketball, and baseball. I continued to play these sports throughout my high school career. In high school, I was always best in my math and science classes. My father is a Mechanical Engineer and my older brother, of 2 years, is a Mechanical Engineer as well. Growing up I always looked up to my father and my brother, and have aspired to be an engineer my whole life. My older brother came to Michigan and graduated with a degree in Mechanical Engineering. I feel like it is fitting that I followed in his footsteps, as he has gone on to be successful. I chose to do Mechanical mainly because it is the broadest field of engineering. I would be able to learn and work in many different fields of engineering with a background in Mechanical.

After my sophomore year of college, I worked in a research lab with Professor Epureanu. Professor Epureanu's lab dealt a lot with turbomachinery, which sparked my interest in this field. This led me to being an engineering intern at Williams International. Williams International is a small turbine engine company that designs and manufactures turbine engines for military and commercial applications. I worked in the research and development department and was involved with engine testing and Pro/E solid modeling/drawings of engine parts. I have the opportunity to work full time for Williams International, and plan to enter industry when I graduate. I would also like to go back to school after a year or so in industry to pursue a Master's Degree in engineering and possibly an MBA.

Section H.3: Justin Croop

I was born and raised in Cincinnati, Ohio. Growing up I always had a dominant interest in large industrial equipment (Contstruction and Demolition equipment in particular). Dump trucks, back hoes, and dynamite were a few of my favorites. I have a fascination for learning how mechanical objects operate. I always take things apart and check out the inner workings. In school, math and science were always my best and favorite subjects, never English (I was horrible). My interests pushed me in the direction of engineering and once I got to college I instantly was attracted to the field. I like Mechanical Engineering because the area of study is so broad that I

can apply course material to almost anything. After graduation I am seeking employment for a few years and hope to later return to earn an MBA and possibly another degree in engineering.

This past summer I worked for Intelligrated, an industrial conveyor company north of Cincinnati. I was a mechanical engineering intern that started off working in Field Service Engineering. I travelled to rebuild and installation sites across the US to lend a hand in assembling the conveyors and adjusting the As-Built Auto-CAD drawings to match. I mainly worked on sortation units. About halfway through the summer I moved to the headquarters to help design the layout of new distribution centers for Lowe's, Kohl's, and Nike. I did hanger beam load calculations, horse power requirements for conveyor motors, and designed the air piping from the compressor to the pneumatic switches throughout the system.