Esophageal Mapping and Temperature Regulation for Catheter Ablation

by

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Statement of Disclaimer

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1.0 Executive Summary

The purpose of this document is to provide a development summary for a proposed esophageal temperature mapping device used during catheter ablation. Catheter ablation therapy is performed in the left atria with hot or cold materials to create scar tissue to treat atrial fibrillation. However, utilized temperatures and absorbed energies from the catheter can cause undesired esophageal damage. Therefore, this medical device is designed to monitor esophageal temperature and map its location during catheter ablation. If dangerous temperatures are reached, the device will alarm the surgeon.

This document provides an in-depth overview of the esophageal temperature mapping device's development and contains seven sections: introduction and background, customer requirements and design specifications, stage gate process, description of final prototype design, prototype development, IQ/OQ/PQ, and conclusions and recommendations.

2.0 Introduction and Background

Catheter Ablation Therapy Background

Catheter ablation therapy is performed by cardiologists to treat heart arrhythmias, specifically atrial fibrillation. An arrhythmia is a cardiac problem where the heart beats too fast, too slow, or with an irregular rhythm. Atrial fibrillation is rapid and irregular beating of the atria and is often treated with catheter ablation therapy.

Catheter ablation therapy can utilize hot temperatures, known as radiofrequency catheter ablation, or cold temperatures, known as cryoablation catheter ablation, in the left atrium [1]. In both cases, catheter ablation is performed to create scar tissue in specific areas of the heart to prevent abnormal electrical signals from moving through one's heart [2]. The goal of the procedure is to prevent the propagation of the rapid electrical signal throughout the heart, allowing it to return to a normal beating pattern. Radiofrequency catheter ablation uses a catheter to "emit high frequency radio waves," which are hot in temperature, to create lesions on the abnormal atrial tissue [1]. Cryoablation procedures pass pressurized refrigerant through a catheter to freeze the abnormal tissue and electrical pathways of a particular atrial location [1].

Catheter Ablation Therapy Literature and Issue

The issue that arises with catheter ablation therapy involves the close proximity of the esophagus and the left atria. The mean distance "between the anterior wall of the esophagus and the endocardium [is] 2.6 +/- 0.8 mm [4]." Since there is only a small flap of tissue that separates the left atria from the esophagus, the extreme temperatures experienced during either procedure can cause irreversible damage to the esophagus, often known as left atrial esophageal fistula [3, 4, 7]. Esophageal damage can be difficult to diagnose, but can result in left atrial swelling [3, 7]. Harsh temperature changes experienced in catheter ablation therapy can also result in transmural injury, periesophageal nerve damage, and pulmonary vein damage [5, 6]. **Figure 2.1** displays the temperature issues of catheter ablation therapy due to esophageal anatomical location. Anatomical positioning of the esophagus and thickness of the left atrial wall varies immensely between patients, so tracking esophageal temperature during catheter ablation therapy is critical. Extreme esophagus temperature is an issue experienced by cardiologists who perform catheter ablation, so cardiologists are the desired customer for the following proposed medical device.

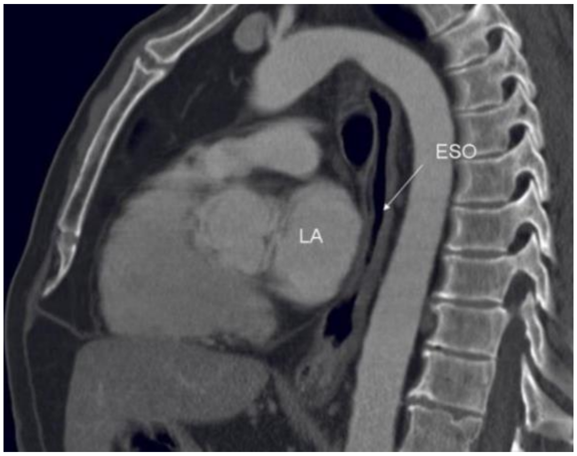


Figure 2.1. Left atria and esophagus anatomical positioning [5].

Current Medical Devices

Two types of medical devices currently exist to assist in esophageal temperature monitoring during catheter ablation; one type is a single-tip temperature probe that can be inserted into the esophagus and the second type utilizes internal bodily mapping technologies to assist in a variety of surgical procedures. However, our aim is to integrate temperature monitoring and mapping into a single device. **Table I** displays current devices on the market. Most devices are capable of either measuring temperatures or mapping the esophagus [8, 9, 10, 11]. Circa Scientific's medical device Circa-S-Cath combines temperature and esophageal mapping, but their device follows an S-shape [12]. This allows the device to only cover two-dimensions of the esophagus (either left and right or front and back depending on how it is positioned), while the device we propose covers all three-dimensions (left and right in combination with front and back). This device also only produces bar graphs to visually depict temperature, not a three-dimensional map. Furthermore, there is no current product on the market that advertises its ability to interface with ablation devices and deliver a power on/off signal when dangerous temperatures are reached within the esophagus. On average, 44,400 catheter ablation procedures are performed annually, so with an esophageal temperature mapping device costing $1500, the anticipated total available market generates $66.6 million [4].

Table I: Current Devices on the Market

Name	Carto Soundstar Catheter	Esophageal Stethoscope	Mon-a-therm Stethoscope	INTELLAMAP ORION	Circa-S-Cath
Company	Biosense-Webster	Medline	Medtronic	Boston Scientific	Circa Scientific
Use	Mapping	Temperature Monitoring	Temperature Monitoring	Mapping	Temperature and Mapping

Current Relevant Patents

In addition to current medical devices on the market, there are patents filed in the United States and France that describe how to monitor temperature and map the esophagus in relation to catheter ablation therapy, **Table II**. Some patents involve esophageal temperature monitoring with position sensors or alarm interruption systems to provide real-time feedback to physicians [13, 14, 15]. Other patents involve the mapping of the esophagus to detect position and damage, either through recording electrical impedance or current and relating those values to heart position [16, 17].

Table II: Relevant Patents

Patent Title	**Patent Number**	**Patent Description**
Esophageal Mapping Catheter	US8224422B2	An esophageal mapping catheter enables a physician to map the location of the esophagus so as to avoid damaging the esophagus during radio frequency (RF) ablation procedures.
Temperature Probe for Insertion into the Esophagus	US7819817B2	Invention containing a temperature probe for insertion into human esophagus onto a catheter and utilizes positioning sensors.
Methods and Systems of Temperature Based Alarms, Esophageal Cooling, and Automatic Interrupt (Shut-Off) during a Cardiac Ablation Procedure	US9033968B1	The computer-based system activates different levels of alarm(s), and initiates ablation energy interrupt based on pre-defined programmed values.
System and Method using Cardiac-Esophageal Impedance Mapping to Predict and Detect Esophageal Injury during Cardiac Ablation Procedure	WO2017151576A1	Apparatus uses assess electrical coupling between an ablative catheter and the esophagus using measurements of electrical impedance to beneficially predict esophageal damage prior to ablation and to detect on-going esophageal damage during ablation.
Esophagus Position Detection by Electrical Mapping	WO2018092070	A method of estimating a spatial relationship between at least a part of a patient esophagus and a heart chamber, including: measuring at least one electric parameter at one or more positions within the heart chamber to obtain measured values; and estimating the spatial relationship based on the measured values.

Medical Device Codes, Standards, and Regulations

It is predicted that our esophageal temperature monitoring and mapping device for catheter ablation therapy will be a class II medical device. The device will be filed under 510(k) requirements and will demonstrate substantial equivalence to Circa Scientific's Circa-S-Cath [18].

Applicable FDA Code of Federal Regulations can be read in **Appendix J**. Some CFR's of note from the list include Quality System Regulation (CFR 820), Medical Device Tracking Requirements (CFR 821), Postmarket Surveillance (CFR 822), Medical Device Classification Procedures (CFR 860), Procedures for Performance Standards Development (CFR 861), Cardiovascular Devices (CFR 870), and Performance Standards for Electronic Products: General (CFR 1010) [19].

Applicable ISO standards include ISO 9001 for Quality Management, ISO 13485 for Medical Device Manufacturing Quality Management, ISO 18001 for Medical Device Risk Mitigation, and ISO 10993 Medical Device Biocompatibility [20].

3.0 Customer Requirements and Design Specifications

3.1 IFU

The Esophageal Temperature Mapping Device is a single-use, minimally-invasive, small digital temperature monitoring device to regulate esophageal internal temperature during catheter ablation procedures. The esophageal probe contains small bead glass thermistors that will send electrical signals to an ADC and ultimately to a Raspberry Pi.

The Raspberry Pi will generate a 3-dimensional cylindrical temperature map from each thermistor temperature signal, interpolating the temperatures in between each sensor. The map will also contain a colored scale, indicating the regions of the esophagus experiencing the harshest temperatures.

Finally, our system will contain an alarm system to the surgeon. If a temperature above 38 °C or below 20 °C is reached, the temperature reading will turn red or blue respectively. This allows the surgeon to determine the next course of action for the catheter ablation procedure and evaluate the region of possible esophageal damage.

The goal of this device is to minimize esophageal tissue damage due to temperature changes during catheter ablation procedures; therefore, it could potentially be implemented in any catheter ablation procedure.

3.2 Product Design Specifications

The current influence driving the design of the device are the customer requirements from Dr. Christopher Porterfield, a local San Luis Obispo cardiac electrophysiologist. Dr. Porterfield's requirements were developed from experience in the O.R. performing catheter ablation on an extensive number of patients. The requirements he has submitted are all intended to enhance doctor visualization of esophageal temperatures, the ease of use during the procedure, and limiting the risk of esophageal damage. These requirements were then converted into engineering metrics to better the design and validate the proposed device. **Table III** outlines the product design specifications to be used for validation of the product. The radius of curvature specification indicates the flexibility of our probe, which must fit through the laryngeal mask airway (LMA) applied by the anesthesiologist.

Table III: Product Design Specifications.

Engineering Characteristic	**Specification**
Esophageal Probe Diameter	6 mm ± 0.5 mm
Vertical Distance between Thermistors	15 mm ± 0.5 mm
Rotation between Thermistors	90° ± 5°
Thermistor Temperature Range	18-40°C (safe between 20°C-38°C)
Thermistor Temperature Accuracy	± 1°C
Temperature Interpolation Accuracy	± 1°C
Radius of Curvature	52.7 mm ± 2 mm

3.3 House of Quality

The House of Quality describes the various design aspects necessary to ensure our device aligns with consumer needs. The completion of this process enabled the prioritization of device characteristics that align with our product's success. Included in the house of quality are our customer requirements, engineering characteristics, engineering characteristics importance rankings, competition comparisons, and category relationships.

Table IV: Customer Requirements.

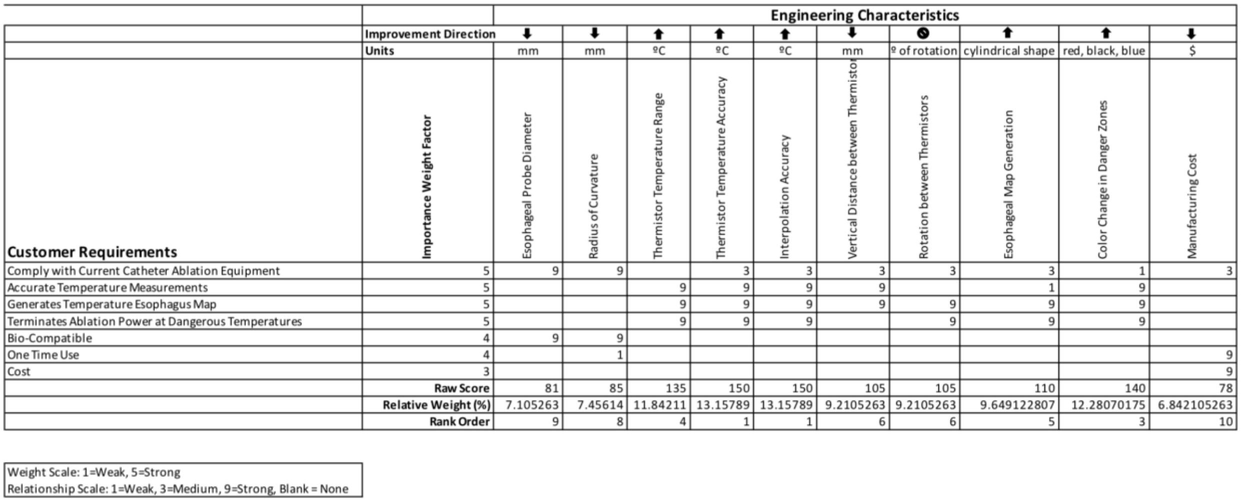
Comply with current catheter ablation equipment
Accurate temperature measurements
Generates temperature esophagus map
Terminates Ablation Power at Dangerous Temperatures
Bio-compatible
One-time use
Cost

Room one of our House of Quality, depicted in **Table IV**, describes the criteria our device must meet in order to satisfy our customer. Our customer is a cardiac surgeon, particularly a cardiac electrophysiologist, who performs cardiac catheter ablation. Therefore, our primary concerns would be in regard to our device's ability to interface with current procedural equipment, its biocompatibility, and its accuracy when measuring temperature along the esophagus. Generation of a real-time, three-dimensional temperature map is important as this function primarily sets our device ahead of those that exist on the market. The inclusion of an alarm system, such as corresponding color changes to dangerous temperatures, is critical for communication with the surgeon during the procedure.

Table V: Engineering Characteristics.

Engineering Characteristic	**Units**
Esophageal Probe Diameter	mm
Radius of Curvature	mm
Thermistor Temperature Range	°C
Thermistor Temperature Accuracy	°C
Interpolation Accuracy	°C
Vertical Distance between Thermistors	mm
Rotation between Thermistors	° of rotation
Esophageal Map Generation	Cylindrical shape
Color Change in Danger Zones	Red, black, blue
Manufacturing Cost	$

Room two of our House of Quality, provided as **Table V**, provides our engineering specifications and their associated units. We decided to include such characteristics as esophageal probe diameter, radius of curvature, and thermistor temperature accuracy and measuring range. By cataloging each of the quantifiable device factors that could be tested, we can guarantee that those considered critical are developed to competitive standards.



		Engineering Characteristics									
	Improvement Direction	⬇	⬇	⬆	⬆	⬆	⬇	⊘	⬆	⬆	⬇
	Units	mm	mm	ºC	ºC	ºC	mm	º of rotation	cylindrical shape	red, black, blue	$
Customer Requirements	**Importance Weight Factor**	Esophageal Probe Diameter	Radius of Curvature	Thermistor Temperature Range	Thermistor Temperature Accuracy	Interpolation Accuracy	Vertical Distance between Thermisto	Rotation between Thermistors	Esophageal Map Generation	Color Change in Danger Zones	Manufacturing Cost
Comply with Current Catheter Ablation Equipment	5	9	9		3	3	3	3	3	1	3
Accurate Temperature Measurements	5			9	9	9	9		1	9	
Generates Temperature Esophagus Map	5			9	9	9	9	9	9	9	
Terminates Ablation Power at Dangerous Temperatures	5			9	9	9		9	9	9	
Bio-Compatible	4	9	9								
One Time Use	4		1								9
Cost	3										9
	Raw Score	81	85	135	150	150	105	105	110	140	78
	Relative Weight (%)	7.105263	7.45614	11.84211	13.15789	13.15789	9.2105263	9.2105263	9.649122807	12.28070175	6.842105263
	Rank Order	9	8	4	1	1	6	6	5	3	10

Weight Scale: 1=Weak, 5=Strong
Relationship Scale: 1=Weak, 3=Medium, 9=Strong, Blank = None

Figure 3.3.1. Customer requirements and engineering characteristics relationships.

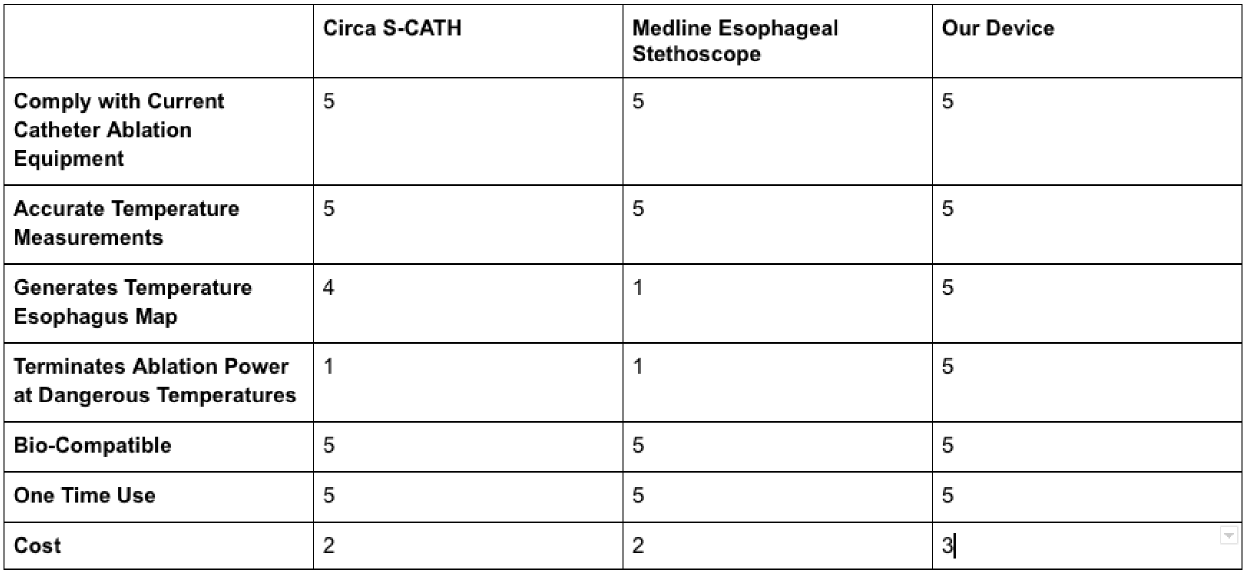
Figure 3.3.1 describes room four of our House of Quality. This section relates customer requirements to engineering characteristics and identifies the strength of the relationship between each pair. We were then able to multiply the number correlating to the strength of relationship between customer requirements and engineering characteristics by the importance weight factor assigned to the customer requirements. Finally, we ranked each engineering characteristic based on the magnitude of their weight factor. Room five, shown in **Table VI**, lists the importance ranking for each engineering metric. Based on our calculations, thermistor temperature accuracy, interpolation accuracy, color change at dangerous temperatures, and thermistor temperature range are the most significant engineering metrics for our team to focus on.

Table VI. Engineering Characteristic Ranking.

Engineering Characteristic	**Importance Ranking**
Esophageal Probe Diameter	9
Radius of Curvature	8
Thermistor Temperature Range	4
Thermistor Temperature Accuracy	1
Interpolation Accuracy	1
Vertical Distance between Thermistors	6
Rotation between Thermistors	6
Esophageal Map Generation	5
Color Change in Danger Zones	3
Manufacturing Cost	10

Room six, presented in **Table VII**, evaluates our device and the competitive devices on market against our consumer requirements. We used a scale of 1-5, with 5 being the most desirable and 1 being the least. Based on our comparison, our device best complies with customer requirements when analyzed against the competition.

Table VII. Competitive Advantage Matrix.



	Circa S-CATH	**Medline Esophageal Stethoscope**	**Our Device**
Comply with Current Catheter Ablation Equipment	5	5	5
Accurate Temperature Measurements	5	5	5
Generates Temperature Esophagus Map	4	1	5
Terminates Ablation Power at Dangerous Temperatures	1	1	5
Bio-Compatible	5	5	5
One Time Use	5	5	5
Cost	2	2	3

4.0 Stage Gate Process

4.1 Concept Review

Figure 4.1.1. LMA visual.

In order to create our designs, we shadowed multiple catheter ablation therapies performed by Dr. Porterfield to observe current temperature monitoring adjacent to the procedure in action. We learned that the device must be deployable by the anesthesiologist and travel through a Laryngeal Mask Airway (LMA) to sit in the esophagus, **Figure 4.1.1**. Additionally, the device must have a length of at least 3 inches in anterior esophagus articulation to cover all catheter locations experienced in the left atrium during the procedure.

As an overview of the device, it will include three parts. The first part includes the esophageal probe that sends temperature input from thermistors to a Raspberry Pi. The second part includes the Raspberry Pi receiving temperature input and building a 3D esophageal, cylindrical shaped map. Finally, the last part includes a color change in thermistor point values, along with an interpolated color map, to alarm the surgeon at dangerous temperatures (less than 20°C or greater than 38°C). **Figure 4.1.2** provides a circuit diagram overview for how each part of the device system integrates.

For the programming of the Raspberry Pi, its collection software will be organized into three main functions. First, the Raspberry Pi will be coded to collect the thermistor voltage readings, which will then be written to a temporary file to be converted into resistance and interpolated into temperature values. Finally, the temperature values for each thermistor will be brought into the mapping function where the values will be plotted in a 3-D space with a corresponding color map. These aspects are all visually summarized in **Figure 4.1.3.**

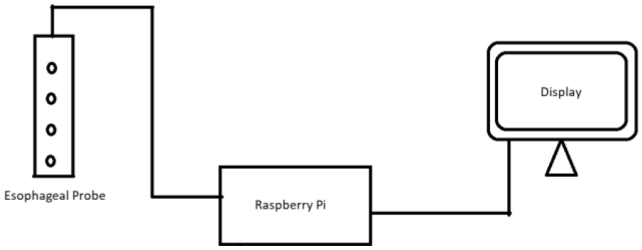


Figure 4.1.2. Summary circuit diagram.

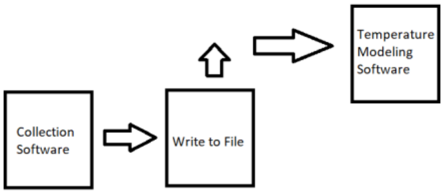


Figure 4.1.3. Summary software diagram.

In regard to the design review process, three designs were proposed to determine which would fit best for the esophageal probe. **Figure 4.1.4A** displays the first esophageal probe design, Design A, which follows a helical shape and aims for esophageal articulation over all surfaces. The probe will be shape set into the helical shape, ideally constructed out of nitinol, with single-point thermistors placed along the helical pattern of the probe.

The second design, Design B, involves a small, cylindrical shape esophageal temperature monitoring and mapping probe. The design will include single glass-bead thermistors following a ring-shaped pattern, spaced apart vertically by 10 m. **Figure 4.1.4B**, displays a SOLIDWORKS rendering of Design B.

The last design, Design C, will not include a physical prototype and instead be an entirely software-based approach to modeling and predicting heat transfer from the ablating catheter in the left atrium to the esophageal anterior wall. CT scans will be used to gather initial geometries of the heart and esophagus. From there, real time measurements of the ablation catheter could be used to predict the heat transfer into the esophagus utilizing the heat transfer equation and varying the heat transfer coefficient. If dangerous temperatures are reached, the software would warn the surgeon.

Figure 4.1.4A: Design A.

Figure 4.1.4B: Design B.

Appendix H displays the Pugh Chart for Designs A, B, and C each as datums. The criteria for design evaluation include the engineering characteristics from Room 4 of the house of quality. The Pugh Chart, using Design A as the datum, results in a net positive (Number of pluses - Number of minuses) of +4 for Design B and +3 for Design C. Using design B as datum, Design A receives a net positive of -3 and Design C receives a net positive of +3. Finally, using Design C as datum, Designs A and B both received net positive scores of -3.

4.2 Design Freeze

Figure 4.2.1: Rendering of the design freeze for the temperature-sensing section of the probe body. The rest of the body includes non-modified tubing to house the wiring and connect to the circuit board.

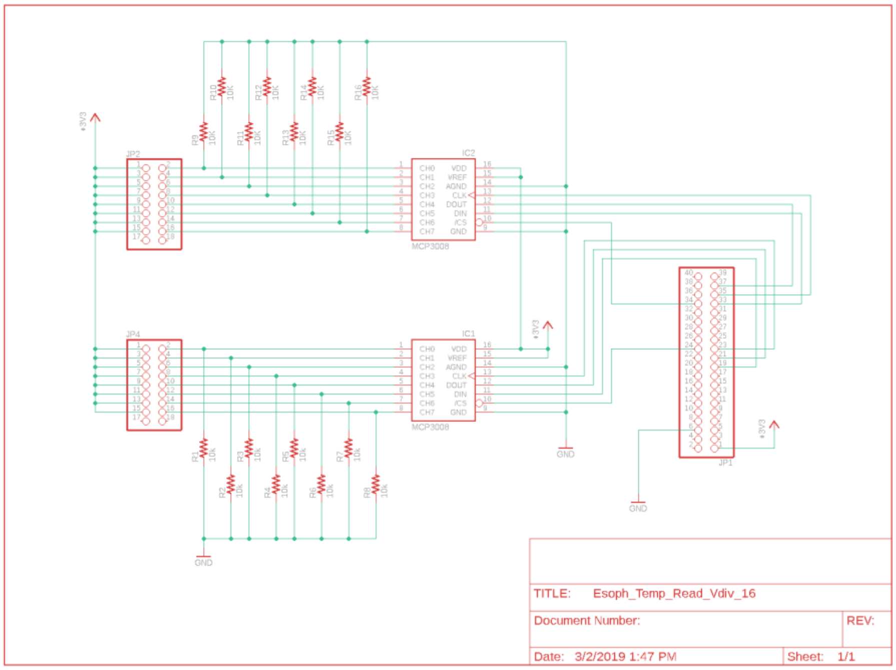


Figure 4.2.2: The schematic for the electrical hardware to interpret and transmit the thermistor signal to the Raspberry Pi. The schematic displays the use of voltage dividers to interpret the change in resistance change caused by the temperature change in the esophagus.

4.3 Design Review

Ultimately, the design front-runner is Design B, the cylindrical-shaped esophageal probe. Design C was eliminated because physicians insisted upon a physical device for each surgical procedure. Between Designs A and B, Design B scored higher in its net positive scores in the Pugh Chart. Design B appeals to the customer requirements and engineering specifications because it places little pressure on the esophagus by maintaining its cylindrical shape. Additionally, its cylindrical shape allows for the probe to fit through the LMA via anesthesiologist delivery. This design generates a maximum surface area contact with the anterior esophageal surface in comparison to the spiral shape in Design A. Finally, the design utilizes single-bead thermistors to generate point temperatures in the x-direction.

The software will generate a three-dimensional map in the shape of a cylinder with the same dimensions of the esophageal probe. The cylinder will contain 8 scatter points representing the x, y, z location of each thermistor. Each point will have a temperature displayed, representing the current esophageal temperature and updated every 1 second. The cylinder will also be plotted with a color map to interpolate the temperature between points based off a color scale. The final aspect to the software design will include a visual alarm that will alert the surgeon if temperatures above 40 °C (red color) or below 20 °C (blue color) are recorded. All safe temperatures will be black. All software will be coded in Python 3 utilizing special libraries such as Matplotlib, Numpy, Circuit Python, Scipy and adafruit.MCP3XXX for calculations and display functions.

The electrical hardware for the final Design includes a Raspberry Pi as the main processing unit, an ADC for converting the analog signal of the thermistors to a digital signal, and 8 thermistors for reading temperatures. Various electrical components, such as resistors and wires, are included. For prototyping purposes, the circuit will be constructed on a breadboard.

5.0 Description of Final Prototype

5.1 Overview

We decided to pursue a second iteration of our design, as it allows for a simplified MPI and provides a more cohesive product overall. 8 thermistors were oriented in a helical design along the first 105 mm of the probe body. Thermistors were spaced 15 mm longitudinally, at a 90° rotation clockwise from each previous thermistor. To hold the thermistors in this set position, a 105 mm fixture split into two halves was 3D printed with the thermistor holes already designed into the body as seen in **Figure 5.1.1**. Thermistors were then epoxied into their specified holes and their wires threaded up through the remainder of the printed tube. The two halves were then epoxied to one another, and the entire device, along with the wires, was encapsulated in heat shrink. Additionally, the breadboard circuit proved to be an excellent tool for testing the circuit, but a custom PCB was designed and implemented into the final electrical prototype for ease of use, **Figure 5.1.2** and **Figure 5.1.3**. Finally, the software was written in Python 3 and the Matplotlib, Numpy, Scipy, Circuit Python and MCP3XXX libraries were utilized for calculations, visualization, matrix mathematics and interfacing between the Raspberry Pi and the thermistors. An up-to-date repository of the code can be found here. The code used during the time of publishing this report can be viewed in **Appendix O**.

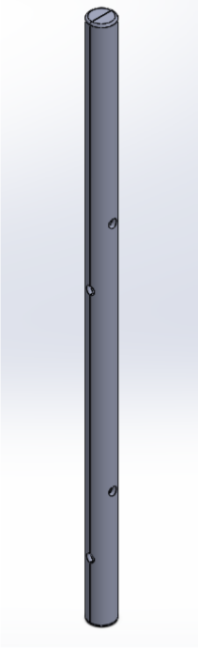


Figure 5.1.1A: Assembled rendering of the probe body housing 8 thermistors.

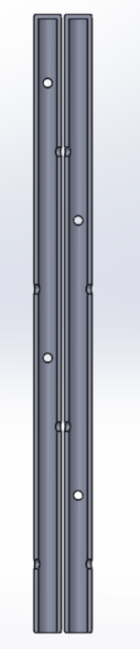


Figure 5.1.1B: Two halves of the probe body adjacent to each other.

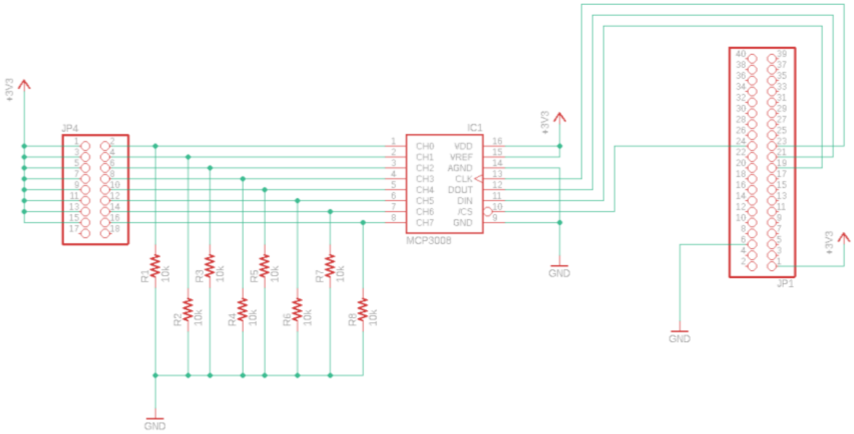


Figure 5.1.2: Updated schematic for the 8-thermistor probe design with the intention to interface with Raspberry Pi headers and JSC connectors.

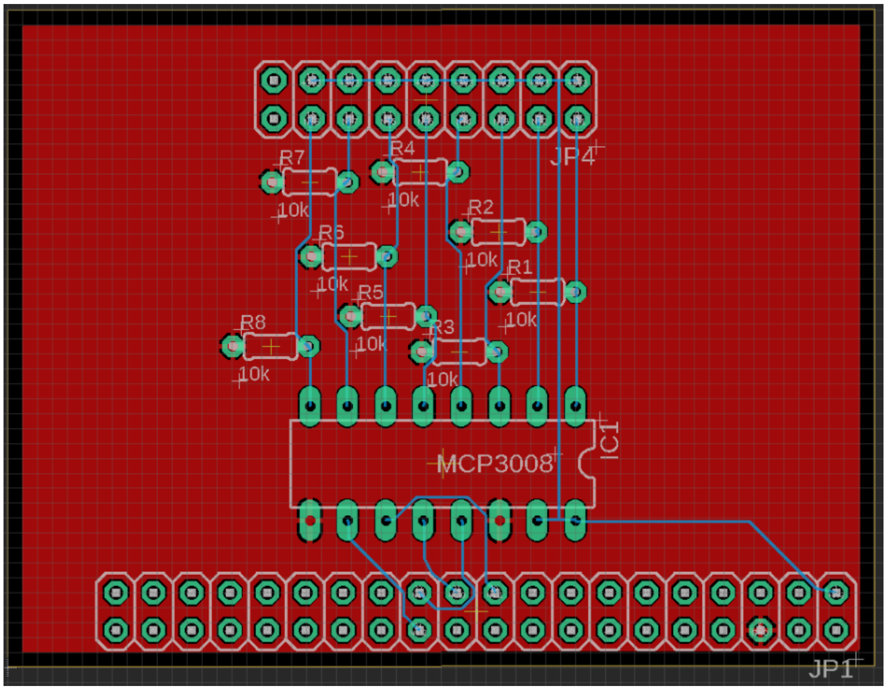


Figure 5.1.3: Rendering of the custom Raspberry Pi shield to serve as an interface between the Raspberry Pi and the thermistors.

5.2 Design Justification

We decided the helical orientation of the thermistors was important to optimize the esophageal tissue that articulates with the probe's thermistors because it ensures at least two are in contact with the esophageal wall at all times. This allows for a more accurate temperature to be mapped. The 3D printed portion of the probe provided a rigid, mostly enclosed section to support the thermistors, while the wiring harness has been encapsulated in heat shrink to provide the flexibility, length, and protection from the environment that is advantageous for probe movement through an LMA. The number of thermistors were decreased from 16 to 8 to simplify the device, minimize cost, and reduce the housing size. Additionally, the PCB circuit board, instead of a breadboard circuit, guarantees stronger connections and easier assembly. It allows the end user to be more mobile with the device and decreases the amount of effort to construct the electrical hardware. For the software, Python 3 was chosen due to its ease of use, robustness across platforms, and broad range of resources available for the language. The Matplotlib library was used due its open source nature and its capability to plot in 3-dimensions with updated data.

5.3 Analysis

The chosen design was successfully implemented as it meets all design requirements set by Dr. Porterfield. Its diameter of 0.7 mm is smaller than the esophageal access tube in the LMA and a comparable diameter to the current single-temperature probe. Therefore, with lubricant during the procedure, it will fit through the LMA when deployed by the anesthesiologist. Additionally, the total vertical height of tissue measured by the thermistors is 105 mm (> 4 inches), greater than the need to capture 3 inches of the esophagus. Finally, our design incorporates thermistors on all four quadrants of the cylindrical probe, ensuring that at least two thermistors will be fully articulating with the esophagus during catheter ablation. This removes much of the variability associated with probe insertion into the esophagus.

5.4 Cost Breakdown

Table VIII: Manufacturing Cost Breakdown.

3D Print of Probe Body in PLA	$0.30
Loctite Medical-Grade Epoxy	$0.97
30-gauge red wire	$4.86
30-gauge black wire	$4.86
Thermistors	$25.36
MCP3008 ADC	$7.50

Raspberry Pi Model B+	$35.00
PCB	$13.20
PCB Headers	$6.00
Heat Shrink Tubing	$2.37
Heat Shrink Tip	$1.22

Using the final MPI, the total cost of manufacturing per device is $101.64.

5.5 Safety Considerations

Since our device is a class II special consideration, the potential safety and hazards were analyzed. These hazards included the risk of damage to the device during surgery due to misuse, exposure to a corrosive environment, or misinterpretation of the device output. Other safety considerations include the safety of the patient and the surgeon including an electrical shock or possible radiation exposure. A full hazards and risks assessment can be seen in **Appendix D**.

6.0 Prototype Development

6.1 Model Analysis

The design we chose to pursue involves a small, cylindrically shaped, esophageal temperature monitoring and mapping catheter. The design will include single glass-bead thermistors following helical shaped pattern with thermistors separated by a z-height of 15 mm.

We selected this design because it provides the most accurate temperature readings while minimizing the number of components required. This design allows for maximum probe articulation with the anterior surface of the esophagus, placing little pressure on the esophagus by maintaining its cylindrical shape. Additionally, this design possesses the geometries necessary to fit through the LMA in the anesthesiologist’s delivery system. The probe data generates a three-dimensional temperature map of the esophagus on a monitor display to allow the surgeon full procedural visualization. Finally, the incorporation of a color-coded alarm system will further the communication between surgeon and device to decrease the risk of esophageal damage during the catheter ablation procedure.

There are no existing devices on market that integrate a 3D dimensional, color coded, temperature map for monitoring esophageal temperatures during catheter ablation. For a more detailed comparison of existing devices and our chosen design against our consumer requirements, reference **Figure 3.3.5**.

6.2 Evolution of Prototypes

Currently, a SOLIDWORKS rendering has been generated for the running prototype of our device, **Appendix C**. Initially, we planned on creating our esophageal probe with plastic tubing, drilling holes into the tubing at each thermistor location. The thermistors were then epoxied into place and wires threaded up the length of the tubing. However, this process was individually taxing and not sufficient for large-scale manufacturing. Therefore, our final prototype changed to include two, 3D printed halves for easy attachment of each thermistor head. Additionally, the 3D printed body and wires were easily encapsulated in heat shrink.

Another change to our prototype included our change from a breadboard circuit to a PCB. Although both generated temperature readings that were communicated to the Raspberry Pi, it was difficult to secure all pins in the breadboard. This created a sensitive prototype, impractical for use in the operating room. By creating a custom PCB and using a wiring harness, the device decreased in size of components while increasing ease of assembly and use.

6.3 Manufacturing Process

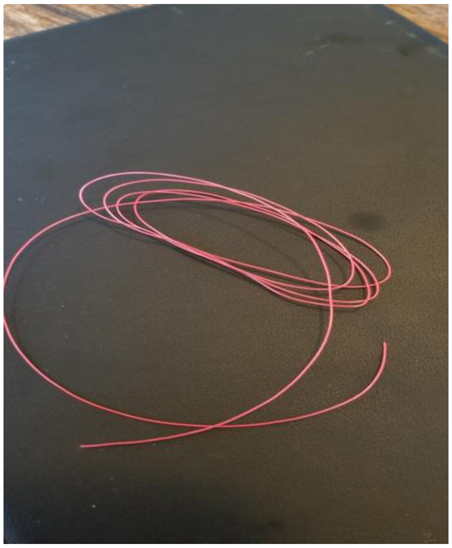
An overview of the manufacturing process is as follows:

1. 3D print probe body using an STL file generated from the CAD model.
2. Solder one red and one white wire to each terminal of the eight thermistors respectively.
3. Glue each thermistor into its respective position within the 3D printed probe body.
4. Combine the two halves of the probe body and secure using epoxy.
5. Place black heat shrink tip over the end of the probe body.
6. Place clear heat shrink tubing over the entire probe body and wiring harness.
7. Heat and shrink all heat shrink to a 1 cm diameter.
8. Connect the custom PCB to the Raspberry Pi.
9. Connect a mouse, keyboard and monitor to the Raspberry Pi.
10. Load the necessary code onto the Raspberry Pi.
11. Connect each thermistor wire to a corresponding female header.
12. Connect each pair of thermistor headers to their corresponding male header on the custom PCB.

A detailed manufacturing process contains explanations of each step and visual aids is as follows:

1. The probe body is to be 3D printed by exporting the SOLIDWORKS files, “Thermistor Body 1” and “Thermistor Body 2”, as STLs before being sent to an FDM 3D printer printing with PLA filament with a layer height of 0.075 mm, print speed of 50 mm/s and a travel speed of 70 mm/s. The probe body prints should be oriented longitudinally flat on the bed as shown in the image below.

2. Measure out 3 feet of red and white 30 AWG wire before stripping both ends of the wire. Ensure one end of the wire is stripped no more than 5 mm to limit the amount of heat shrink required for insulating the wire. Solder one red and one white wire to the two terminals on the thermistor. Cut heat shrink into 10mm pieces before sliding the heat shrink over the exposed solder joint and heat to insulate.

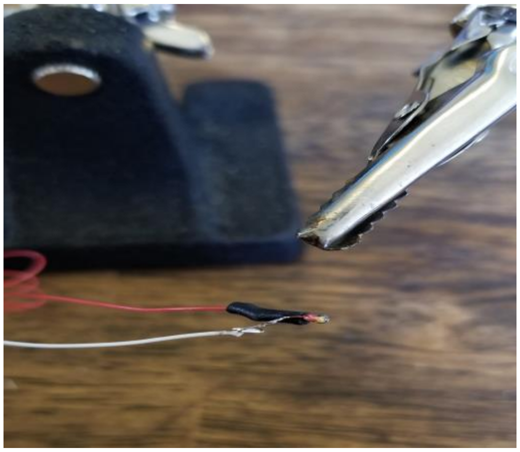


3 feet of red 30 AWG wire.

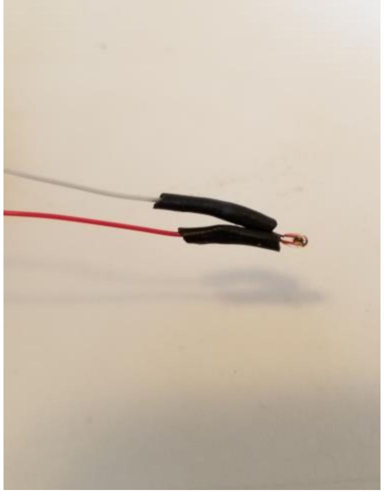
Wire stripped down approximately 5mm.

Heat shrink cut down to 10mm each.

Thermistor cut down and folded in for easier soldering.

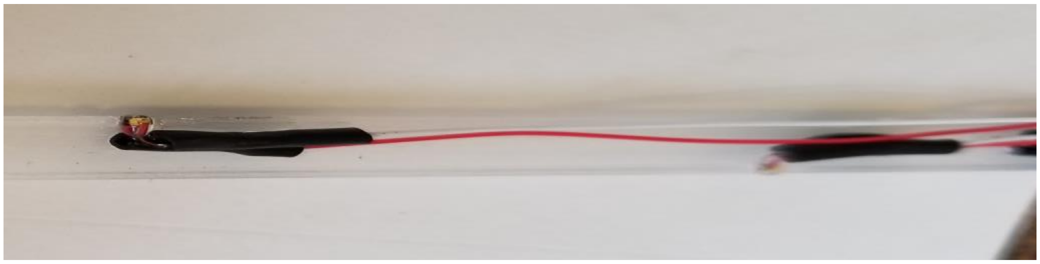


Thermistor soldered to the white and red wire.

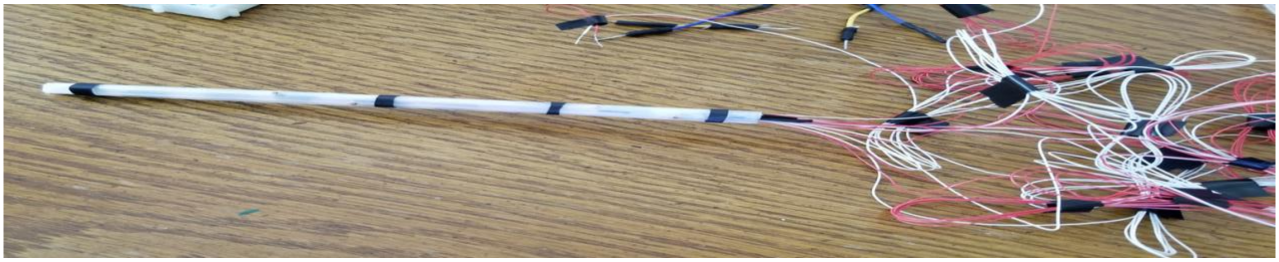


Completed wired thermistor with heat shrink.

3. Using the Loctite 4011, secure the thermistors to each half of the 3D printed body. Ensure each thermistor is glued at the head and between the wire and probe body. These two points of gluing are necessary to limit the amount of mechanical stress experienced by the thermistor and reduce the probability failure. Ensure each thermistor glass head is fully inserted into its corresponding hole. Repeat steps for each thermistor in both bodies until all eight thermistors are attached to their respective half body.



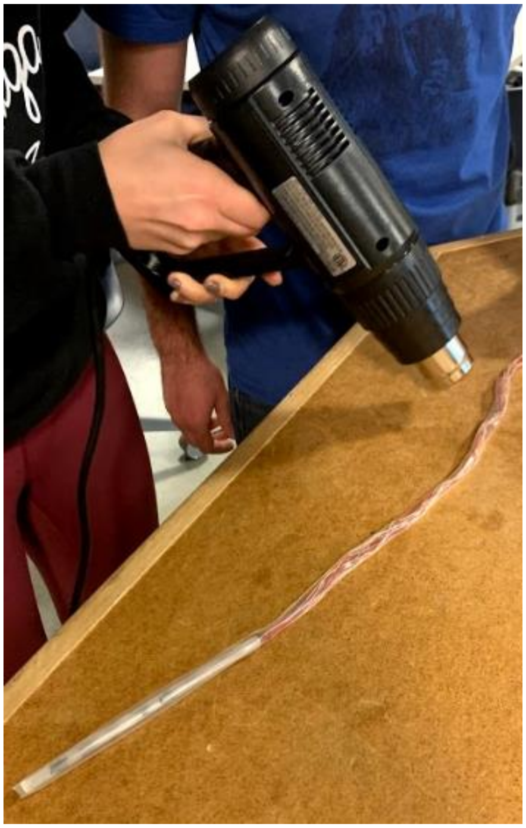
4. Place the Loctite 4011 along the edge of one probe body and then carefully press the two body halves together to form a complete probe body. Work slowly to ensure the alignment of the two probe body halves is correct. Hold the two probe bodies together for 2 minutes to ensure the adhesive has dried correctly, then allow the body to rest for 24 hours to reach the glues maximum strength. Keep indoors at temperatures over 50 °F and below 90 °F.



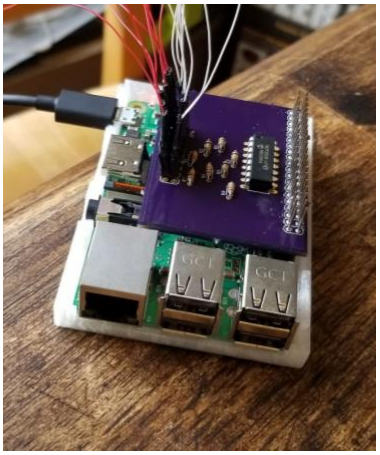
5. Cut the clear heat shrink to 2 feet long before sliding it over the wiring harness and fully covering the probe body.

6. Apply a light coating of adhesive to the black heat shrink tip before placing it over the inferior end of the probe body. Ensure the black tip overlaps with the clear heat shrink wrap.

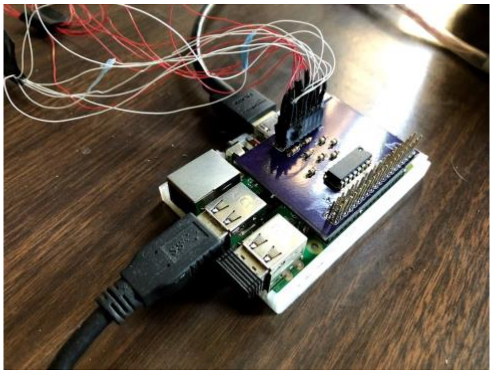
7. Apply a constant heat of approximately 250 °F to shrink the black and clear heat shrink down to their minimum sizes. Be sure not to exceed temperatures over 300 °F as damage to the probe body may occur. Be sure to evenly distribute the heat and not concentrating the heat in one spot for more than a few seconds.



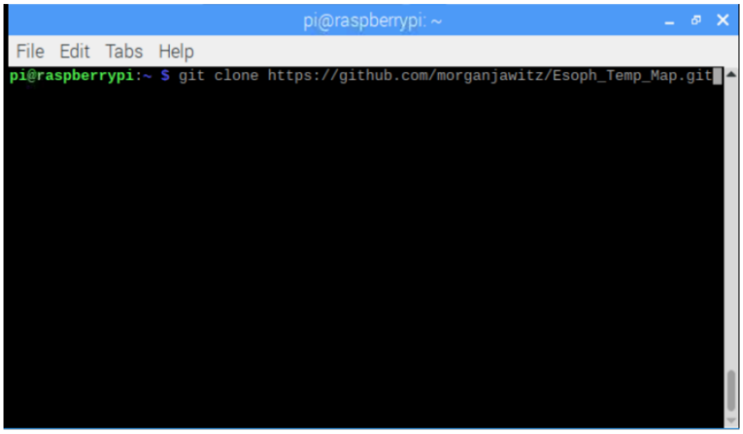
8. Align the 40-pin female header on the custom PCB with the 40-pin male and gently connect the two boards together. Ensure no pins are misaligned, bent or broken.



9. Plug in a mouse and keyboard to USB ports on the Raspberry Pi before connecting a monitor to the HDMI port.

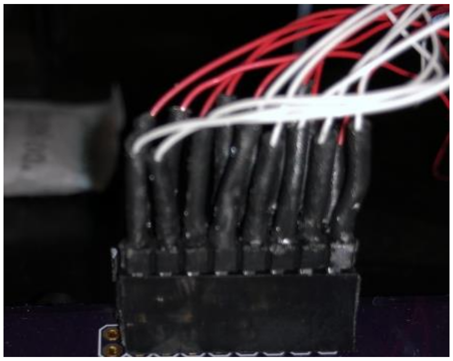


10. Plug in the power supply and boot into the Linux OS. Navigate to the terminal and run the following command to download and install the GitHub repository. All necessary files will be downloaded, and a folder will be created on the Desktop to launch the python program.
    a. Several python libraries are necessary for the Map Generation code to run, Matplotlib, Numpy, SciPy, Circuit Python, ATLAS and adafruit.MCP3XXX. See hyperlinks for installation details.

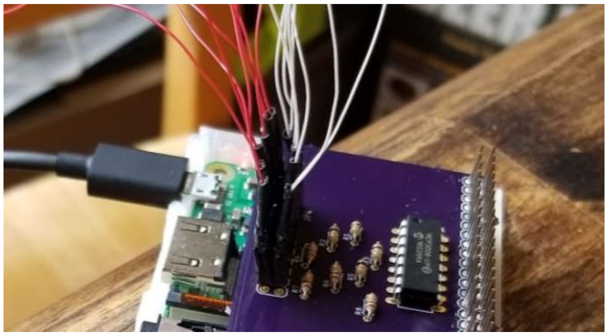


```
pi@raspberrypi:~ $ git clone https://github.com/morganjawitz/Esoph_Temp_Map.git
```

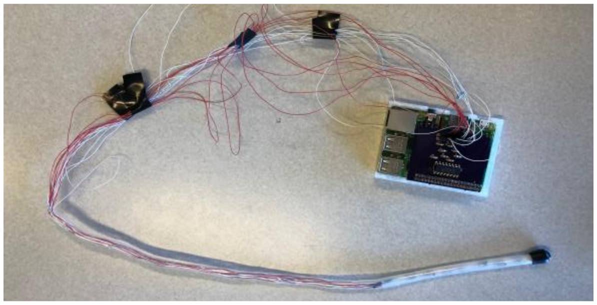
11. Retrieving the probe body once again, attach female headers to the end of each thermistors 30 AWG stripped wire.



12. Plug the female header terminal ends of each thermistor into their respective ports on the custom PCB as seen in the



13. Probe is assembled.



Design History Record for Working Prototype

Table IX: Initial DHR.

Date	**Task**	**Quantity Manufactured**	**Performed By**	**Comments**	**Signature**
2/7/2019	Manufacturing: Solder the Thermistors	8	Morgan	N/A	Morgan Jawitz
2/10/2019	Manufacturing: 3D Print Probe Body	2	Madi and Morgan	N/a	Madi Keith Morgan Jawitz
2/15/2019	Manufacturing: Probe Epoxy	1	Madi and Sarah	N/A	Madi Keith Sarah Sanders
2/22/2019	Manufacturing: Heat Shrink Body	1	Madi and Morgan	N/A	Madi Keith Morgan Jawitz

1/20/2019 - 2/25/2019	Manufacturing: Electrical Assembly	1	Morgan	Currently using voltage dividers, investigating use of op-amps	Morgan Jawitz
1/7/19 - 2/25/19	Manufacturing: Software/Code	1	Madi and Morgan	N/A	Madi Keith Morgan Jawitz

6.4 Divergence Between Final Design and Final Functional Prototype

Several modifications were made between the final design and the final functional prototype. A key difference begins with the design of the body, originally the body was designed to incorporate 16 thermistors into a single 2.5-foot-long clear tubing. The functional prototype now contains a separate, two halved, body piece that was 3D printed and is sealed using clear heat shrink. This modification was made to ease the manufacturing process while still maintaining the design requirements. The new body design also allowed for increased precision in thermistor location. The quantity of thermistors was decreased to 8 to limit the amount of electronic hardware required. A new spiral pattern was therefore developed to maximize the amount of surface area read by the 8 thermistors. With the decrease in thermistor quantity, the electric circuit was modified to include only 8 voltage dividers inputting into a single ADC. With this new, smaller, circuit design, a custom PCB was designed oppose to the utilization of a breadboard for the final functional prototype. The use of PCB creates a more stable final product that also increases the ease of manufacturing.

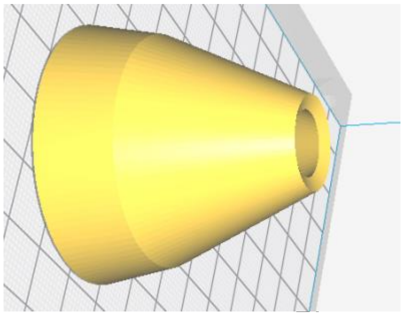
7.0 IQ/OQ/PQ

7.1 DOE

In order to ensure our product is accurately achieving its intended use, a Design of Experiments (DOE) was developed. The DOE assigns engineering metrics to each product specification and explains the testing methods to verify each metric. A complete list of DOEs have been generated and can be found in **Appendix I** and all procedures below.

7.1.1. Pre-Test to Validate Heat Gun

1.) Obtain calibrated thermometer.
2.) Obtain heat gun and attach the three dimensionally printed conical fixture (depicted at right) for the tip.
3.) Bring heat gun to a temperature setting of 20°C, 30°C, and 40°C.

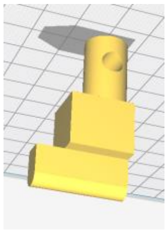


4.) Hold the calibrated thermometer to the working end of the heat gun for 30 seconds and ensure each thermometer reading matches the heat gun setting +/- 1°C.

7.1.2. Temperature Accuracy

1.) Calibrate a thermometer.
2.) Plug in a hot plate and heat to 20°C (ensure temperature with digital thermometer).
3.) Place probe on hot plate with one thermistor directly interfacing with the hot plate.
4.) Record the temperature measurements for both the thermometer and each thermistor.
5.) Repeat recordings for all eight thermistors at a specific temperature.
6.) Bring the thermometer and probe back to room temperature.
7.) Change hot plate to 22°C.
8.) Repeat thermometer and probe reading comparisons.
9.) Repeat for 24°C, 26°C, 28°C, 30°C, 32°C, 34°C, 36°C, and 38°C.
10.) Calculate average absolute mean difference for all eight thermistors. Run ANOVA test to observe if $p<0.05$.

7.1.3. Flexible Modulus



1.) Insert 3D printed Instron arm attachment (depicted at right).
2.) Assemble esophageal probe with heat shrink but without thermistors.
3.) Place probe on top of lower U-shaped attachment and tape into place.
4.) Measure cord length of probe.
5.) Set Instron to run a bending test, moving at 75mm/min and stopping when there is a 40% decrease in force, signaling failure.
6.) Run test.
7.) Repeat for four more specimens.

7.1.4. Temperature Range

1.) Assemble a validated heat gun and the esophageal probe.
2.) Use heat gun at temperatures ranging from 20 to 38 °C in two-degree temperature steps to test each thermistor on the probe.
3.) Calculate average absolute difference for all eight thermistors at each temperature measurement compared to heat gun reading and the overall temperature range.

7.1.5. Temperature Map Generation

1.) Set-up software and connect wiring in probe and monitor to Raspberry Pi.
2.) Bring the environment to a temperature between 20 and 38 °C.
3.) Temperature readings should display in black at the safe range, and a cylindrical map should be generated with the eight thermistors in their specified regions.
4.) Ensure temperature applied matches color key.

7.1.6. Alarm Test

1.) Set-up software and connect wiring in probe and monitor to raspberry pi.
2.) Use a heat gun or ambient environment to generate a temperature of 18°C at one thermistor.
3.) Record color of number of appropriate thermistors. Blue color should be observed below 20°C, black color for 20-38°C, and red color above 38°C.
4.) Repeat at 30 and 40°C.

7.1.7. Accurate Interpolation

1.) Set-up software and connect wiring in probe and monitor to Raspberry Pi.
2.) Use a heat gun or ambient environment to generate a temperature between 20-38°C at Point 1.
3.) Record the thermistor temperature at point 1.
4.) Record the thermometer temperature at point 1.
5.) Perform 5 trials.
6.) Repeat steps 1-5 for Point 2.
    a.) Point 1: (2.12, 2.12, 7.00)
    b.) Point 2: (-2.12, -2.12, 53.00)

7.1.7. Testing Bill of Materials

Table X: Testing BOM.

Item #	**Description**	**Purpose**	**Vendor**	**Item Number**	**Quantity**
1	Calibrated Thermometer	Temperature measurement to compare against thermistors	Target	20594	1
2	Temperature-Sensitive Heat Gun	Soldering Iron Validation, Temperature Accuracy, Temperature Range, Accurate Interpolation Tests	Ace Hardware	N/A	1

7.2 Verification and Validation

Design specifications were all met as provided in the testing data compiled below. Both test plans and resultant data has created a foundation of evidence that instills confidence in our final prototype.

7.1.1. Pre-Test to Validate Heat Gun

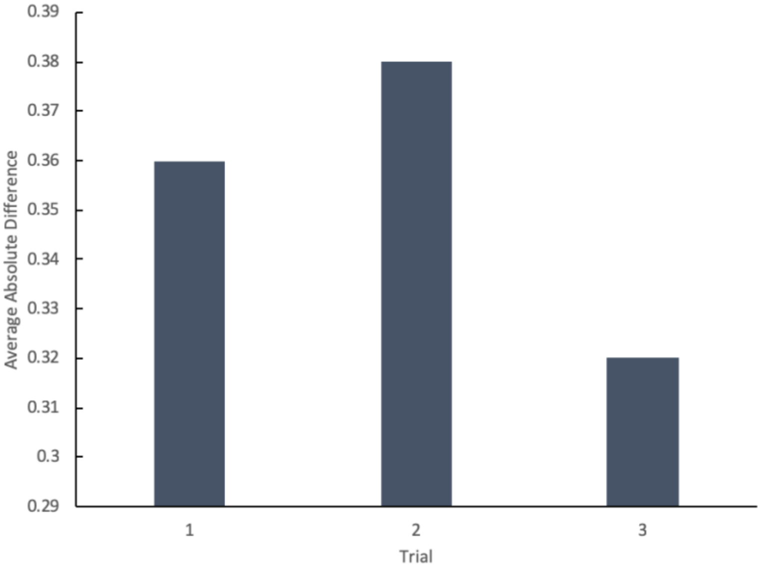
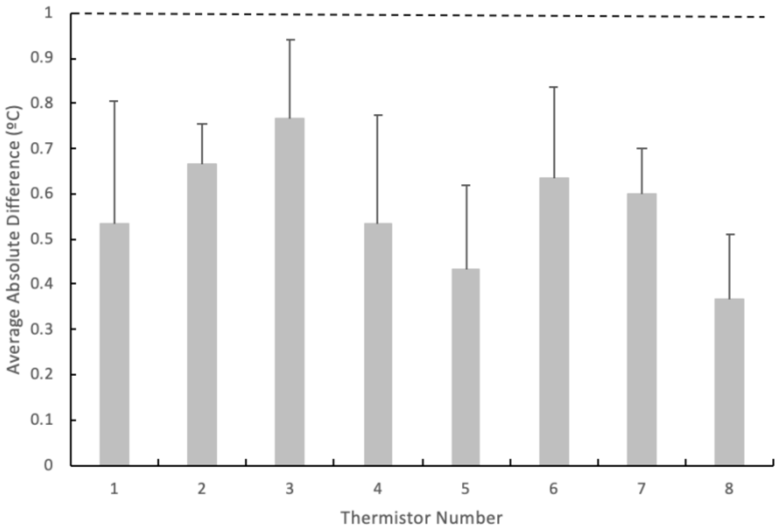
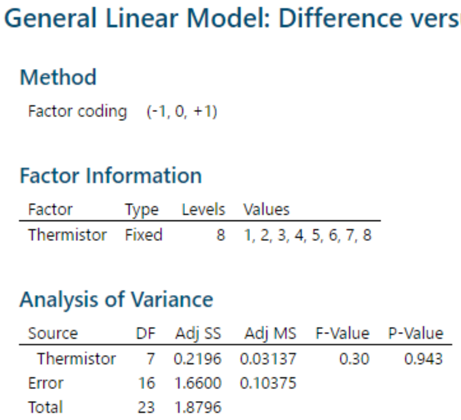


Figure 7.1.1. Average absolute difference between heat gun setting and validated thermometer. Specification restricted heat gun temperature setting accuracy to within one degree of the validated thermometer measurement. Results support that specification was met.

7.1.2. Temperature Accuracy





General Linear Model: Difference versus Thermistor

Method

Factor coding (-1, 0, +1)

Factor Information

Factor	Type	Levels	Values
Thermistor	Fixed	8	1, 2, 3, 4, 5, 6, 7, 8

Analysis of Variance

Source	DF	Adj SS	Adj MS	F-Value	P-Value
Thermistor	7	0.2196	0.03137	0.30	0.943
Error	16	1.6600	0.10375		
Total	23	1.8796			

Figure 7.1.2. Average absolute difference between individual thermistor temperature measurement and validated thermometer temperature measurement, along with the associated statistical data. Specification restricted average variance to within one degree of the validated thermometer measurement. Results support that the specification was met.

7.1.3. Radius of Curvature

Extension at Maximum Load (mm)	**Radius of Curvature (mm)**
10.25	42.02
7.63	53.37
10.25	42.02
8.25	49.96
7.25	55.78
Average	48.63

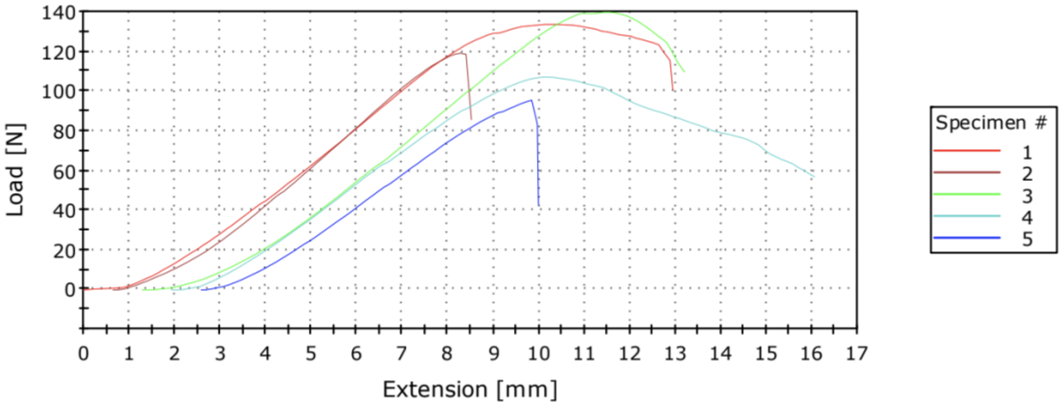


Figure 7.1.3. a.) Extension at maximum load (load to failure) and the resulting radius of curvature calculated. b.) Load vs extension of each specimen that underwent testing. Specification stated that the device radius of curvature was to be smaller in magnitude than the LMA radius of curvature, 52.7mm. Average radius of curvature at failure was 48.63 mm. Two individual tests failed according to our specification. Three of the five tests passed, as well as the average device radius of curvature. Results support that the specification was conditionally met.

7.1.4. Temperature Range

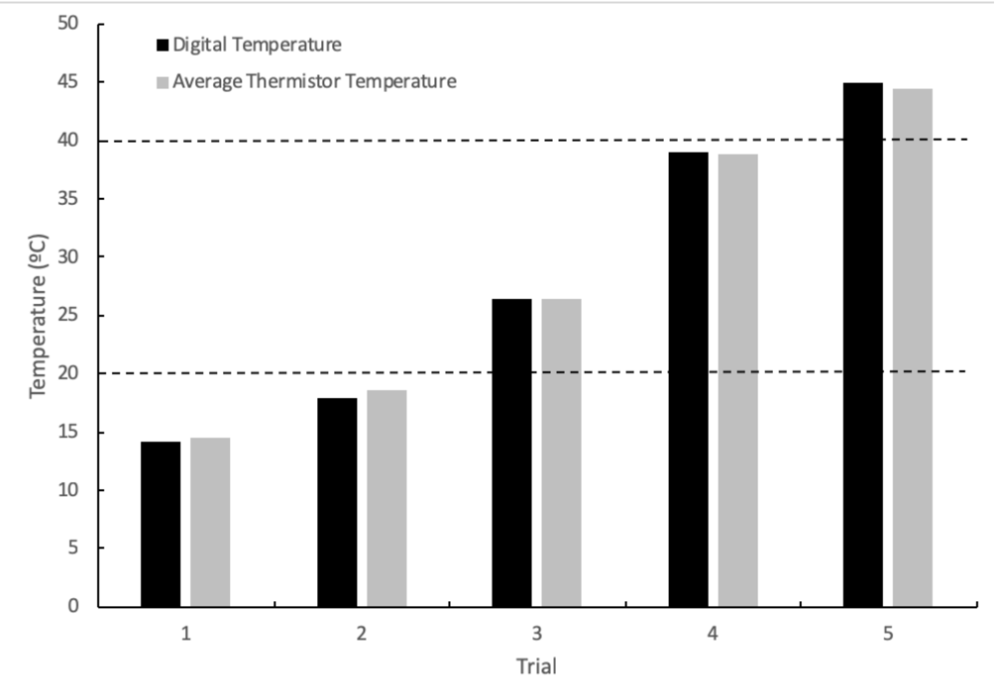


Figure 7.1.4. Average absolute thermistor temperature vs. digital temperature spanning beyond the range specified. Results prove accurate device measurement across all temperatures it is exposed to *in vivo*.

7.1.5. Temperature Map Generation

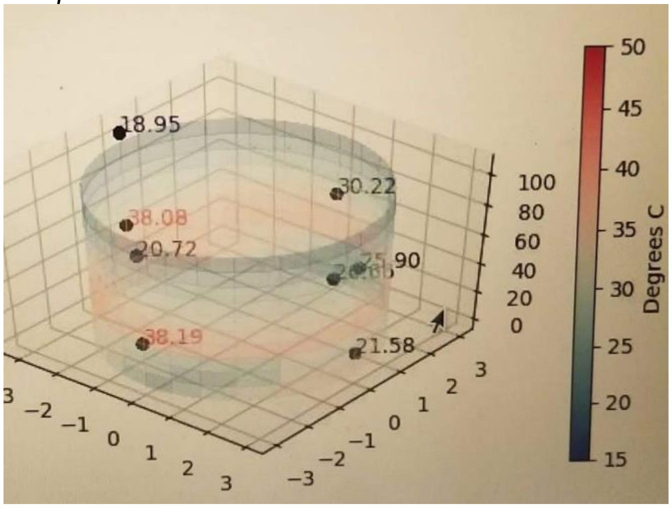


Figure 7.1.5. Temperature map generation justified our claim that an accurate temperature map of the esophagus could be displayed on a monitor in real time.

7.1.6. Alarm Test

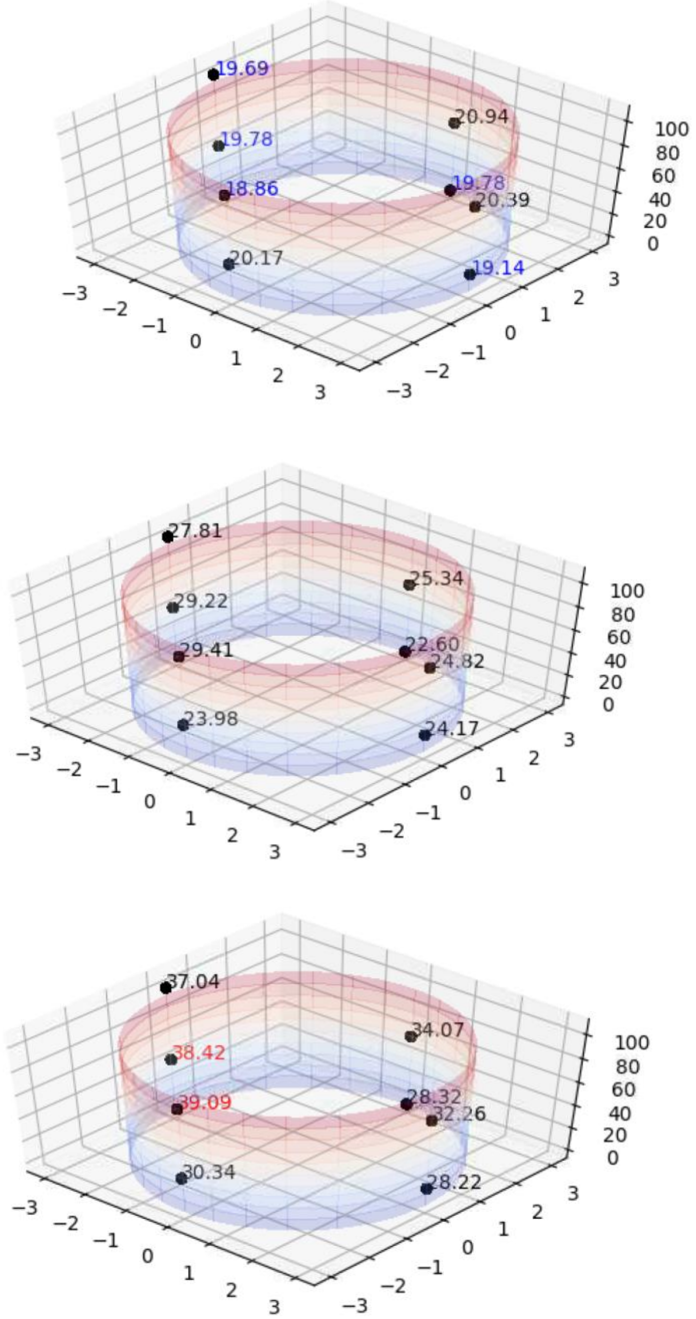


Figure 7.1.6. Alarm test proved that the temperature map generated also alerted its viewer to dangerous surface temperatures (less than 20°C and greater than 38°C) through color coded numerical displays at the thermistor location. The blue and red temperature readings were displayed in response to appropriate environmental stimuli, and so our specification was met.

7.1.7. Accurate Interpolation

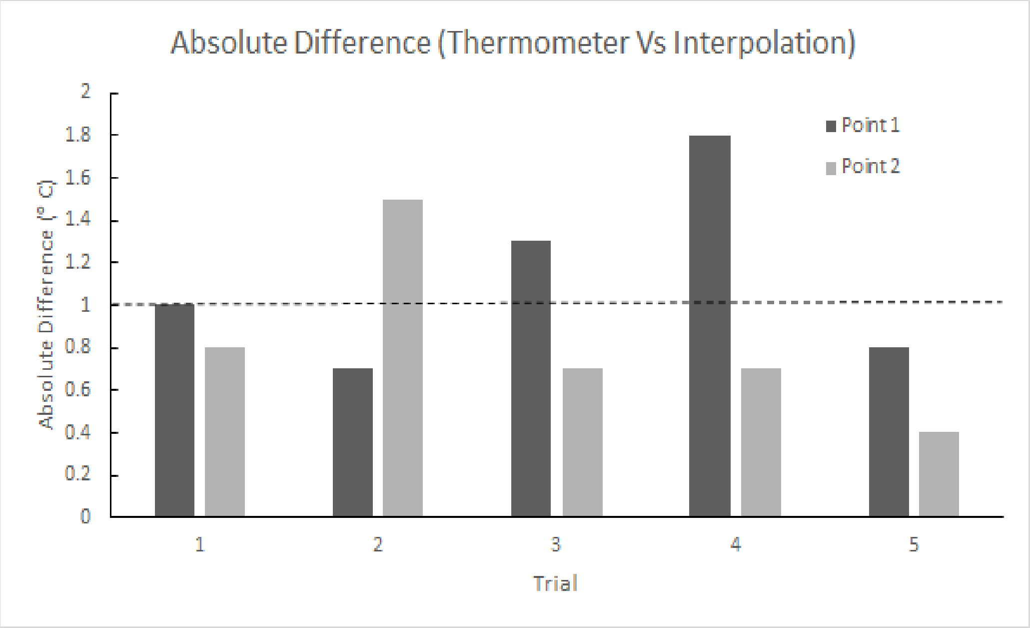


Figure 7.1.7. This test justified that the temperature map interpolated accurate temperatures values at specified random points between thermistors. The data from the two points was then compared with the thermometer measurement and a plot of the absolute difference was generated. Our specification (less than ± 1°C) was met based on the average absolute difference in data (± 0.97°C).

8.0 Conclusions and Recommendations

After two quarters of senior project, we were able to successfully create an esophageal probe that measures real-time esophageal temperatures during catheter ablation and produces a three-dimensional color-coded map. If dangerous temperatures are reached, the surgeon will be alarmed by this color coding, allowing them to move to a different left atrial position or pause during the procedure.

Moving forward to a second iterative design, there are changes that can be made to the device to improve its design and function. For this project, we were unable to incorporate a power termination portion due to the confidential instrumentation of hospital medical equipment. Ideally, this device would be developed in partnership with a medical device companies, such as Abbott Laboratories or Medtronic, to incorporate power termination to the catheter. This would remove the element of surgeon dependency on the alarm system. Another improvement to the device is utilizing an op amp circuit instead of a voltage divider circuit to increase the resolution of temperature readings and decrease the PCB component count. Additionally, the bottom portion of the esophageal probe should be injection molded rather than three-dimensional printed to ensure precise shapes of the device and utilize a rubber-like compound to increase the flexure modules. Finally, the heat shrink should be sized in a controlled environment, such as an oven, rather than with the movement of a heat gun.

9.0 Acknowledgments

As a senior project group, we would like to thank Dr. Porterfield for the idea of the device, guidance on its development, and shadowing of his procedures. We strongly believe this device addresses a large market in the medical device industry. Sarah Griess from Abbott Laboratories also provided valuable input to device background and manufacturing.

Additionally, thank you to the Biomedical Engineering Department at California Polytechnic State University for giving us the knowledge, laboratory space, and funds to complete our senior project. The development of this document and device was not possible without the guidance of Drs. Heylman and Whitt. We would also like to thank the Hannah Forbes committee for selecting our project for extra funding.

10.0 Appendices

Please refer to Appendix C for updated CAD drawings

Please refer to Appendix D for the Failure Modes and Error Analysis

Please refer to Appendix F for vendor Information and traceability

Please refer to Appendix G for the Budget/BOM

Project notebooks are available upon request

10.1 Appendix A: References

[1] “Types of Ablation Therapy for Arrhythmias.” *UChicago Medicine*, 2018.

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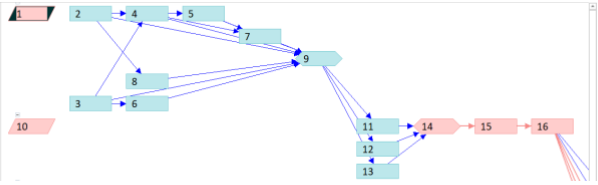
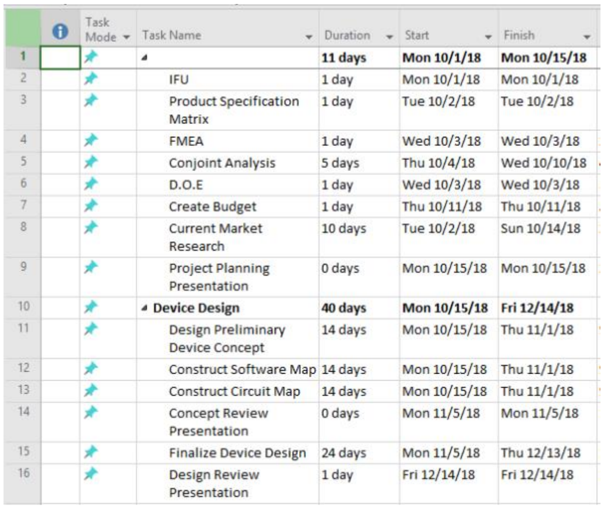
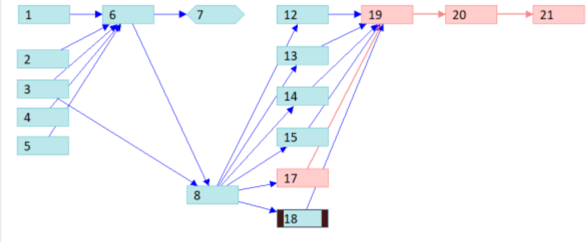
10.2 Appendix B: Project Plan (PERT Chart)

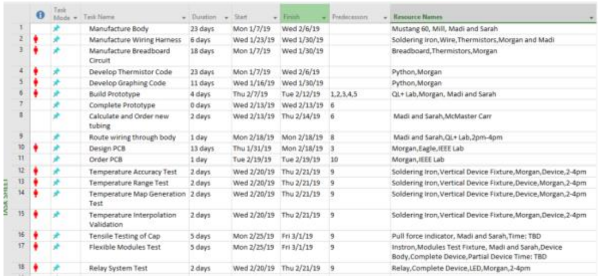




	ⓘ	Task Mode	Task Name	Duration	Start	Finish
1		📌	◢	**11 days**	**Mon 10/1/18**	**Mon 10/15/18**
2		📌	IFU	1 day	Mon 10/1/18	Mon 10/1/18
3		📌	Product Specification Matrix	1 day	Tue 10/2/18	Tue 10/2/18
4		📌	FMEA	1 day	Wed 10/3/18	Wed 10/3/18
5		📌	Conjoint Analysis	5 days	Thu 10/4/18	Wed 10/10/18
6		📌	D.O.E	1 day	Wed 10/3/18	Wed 10/3/18
7		📌	Create Budget	1 day	Thu 10/11/18	Thu 10/11/18
8		📌	Current Market Research	10 days	Tue 10/2/18	Sun 10/14/18
9		📌	Project Planning Presentation	0 days	Mon 10/15/18	Mon 10/15/18
10		📌	◢ **Device Design**	**40 days**	**Mon 10/15/18**	**Fri 12/14/18**
11		📌	Design Preliminary Device Concept	14 days	Mon 10/15/18	Thu 11/1/18
12		📌	Construct Software Map	14 days	Mon 10/15/18	Thu 11/1/18
13		📌	Construct Circuit Map	14 days	Mon 10/15/18	Thu 11/1/18
14		📌	Concept Review Presentation	0 days	Mon 11/5/18	Mon 11/5/18
15		📌	Finalize Device Design	24 days	Mon 11/5/18	Thu 12/13/18
16		📌	Design Review Presentation	1 day	Fri 12/14/18	Fri 12/14/18

Figure 10.2.1. Showing the project pert chart for fall quarter of 2018. The critical path is highlighted in red. The table on the right shows the corresponding task to the numbered boxes.





	ⓘ	Task Mode	Task Name	Duration	Start	Finish	Predecessors	Resource Names
1		📌	Manufacture Body	23 days	Mon 1/7/19	Wed 2/6/19		Mustang 60, Mill, Madi and Sarah
2	♦	📌	Manufacture Wiring Harness	6 days	Wed 1/23/19	Wed 1/30/19		Soldering Iron,Wire,Thermistors,Morgan and Madi
3	♦	📌	Manufacture Breadboard Circuit	18 days	Mon 1/7/19	Wed 1/30/19		Breadboard,Thermistors,Morgan
4	♦	📌	Develop Thermistor Code	23 days	Mon 1/7/19	Wed 2/6/19		Python,Morgan
5	♦	📌	Develop Graphing Code	11 days	Wed 1/16/19	Wed 1/30/19		Python,Morgan
6	♦	📌	Build Prototype	4 days	Thu 2/7/19	Tue 2/12/19	1,2,3,4,5	QL+ Lab,Morgan, Madi and Sarah
7		📌	Complete Prototype	0 days	Wed 2/13/19	Wed 2/13/19	6	
8		📌	Calculate and Order new tubing	2 days	Wed 2/13/19	Thu 2/14/19	6	Madi and Sarah,McMaster Carr
9		📌	Route wiring through body	1 day	Mon 2/18/19	Mon 2/18/19	8	Madi and Sarah,QL+ Lab,2pm-4pm
10	♦	📌	Design PCB	13 days	Thu 1/31/19	Mon 2/18/19	3	Morgan,Eagle,IEEE Lab
11		📌	Order PCB	1 day	Tue 2/19/19	Tue 2/19/19	10	Morgan,IEEE Lab
12	♦	📌	Temperature Accuracy Test	2 days	Wed 2/20/19	Thu 2/21/19	9	Soldering Iron,Vertical Device Fixture,Morgan,Device,2-4pm
13	♦	📌	Temperature Range Test	2 days	Wed 2/20/19	Thu 2/21/19	9	Soldering Iron,Vertical Device Fixture,Device,Morgan,2-4pm
14	♦	📌	Temperature Map Generation Test	2 days	Wed 2/20/19	Thu 2/21/19	9	Soldering Iron,Vertical Device Fixture,Device,Morgan,2-4pm
15	♦	📌	Temperature Interpolation Validation	2 days	Wed 2/20/19	Thu 2/21/19	9	Soldering Iron,Vertical Device Fixture,Morgan,Device,2-4pm
16	♦	📌	Tensile Testing of Cap	5 days	Mon 2/25/19	Fri 3/1/19	9	Pull force indicator, Madi and Sarah,Time: TBD
17	♦	📌	Flexible Modules Test	5 days	Mon 2/25/19	Fri 3/1/19	9	Instron,Modules Test Fixture, Madi and Sarah,Device Body,Complete Device,Partial Device Time: TBD
18	♦	📌	Relay System Test	2 days	Wed 2/20/19	Thu 2/21/19	9	Relay,Complete Device,LED,Morgan,2-4pm

Figure 10.2.2. Showing the project pert chart for winter quarter of 2019. The critical path is highlighted in red. The table on the right shows the corresponding task to the numbered boxes.

10.3 Appendix C: CAD Drawings

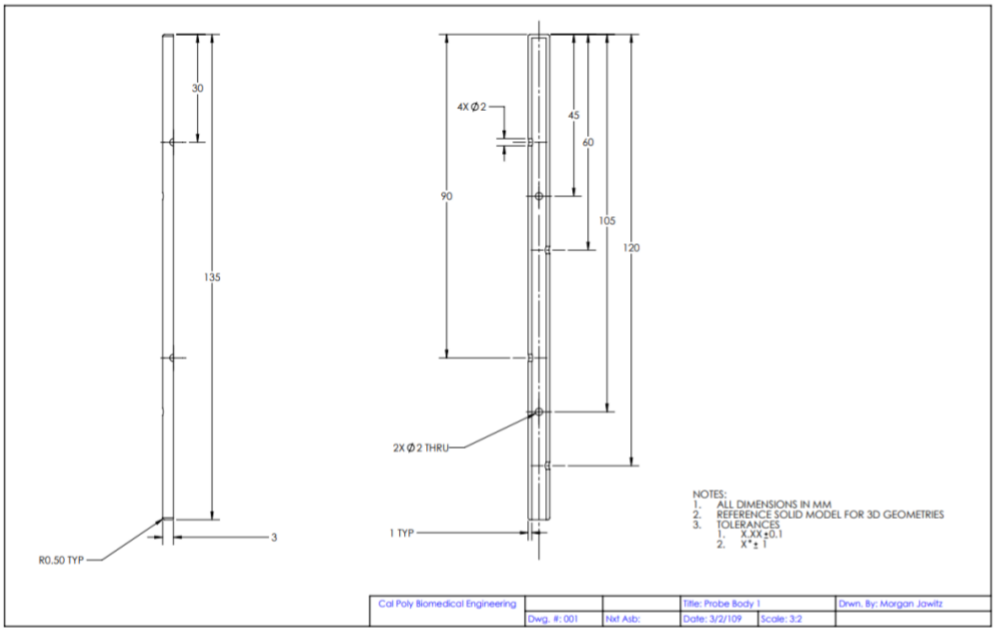


Figure 10.3.1: Technical drawing for Probe Body 1.

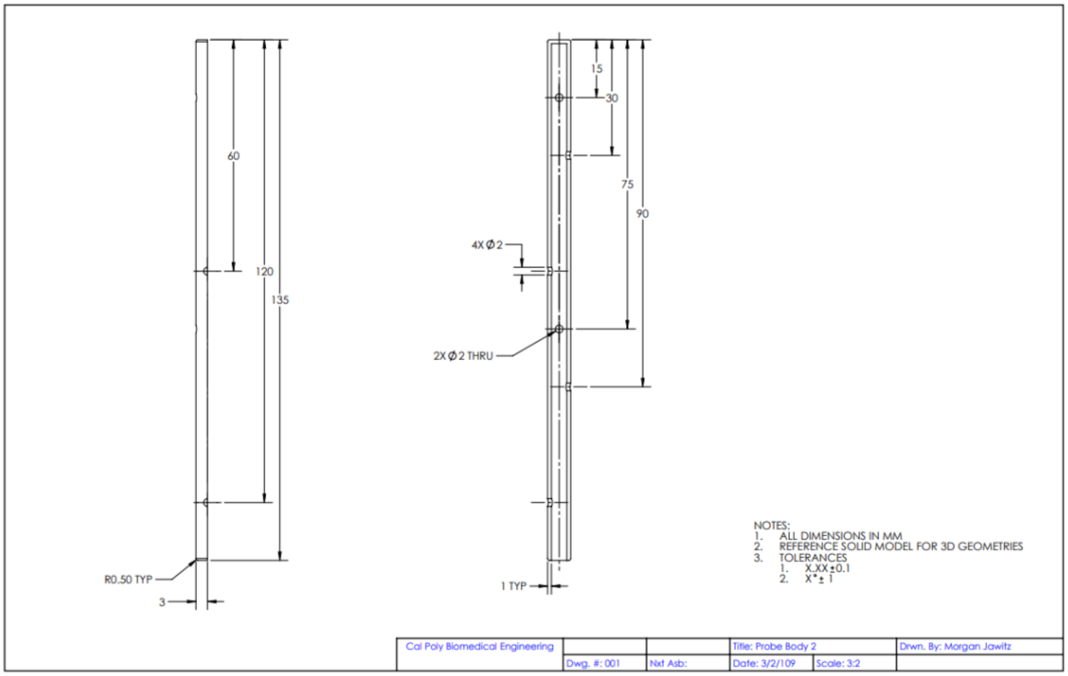


Figure 10.3.2: Technical drawing for Probe Body 2.

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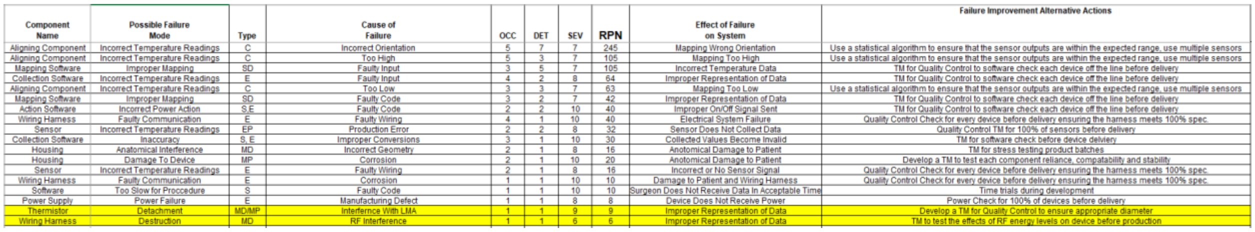
10.4 Appendix D: FMEA, Hazard & Risk Assessment



Component Name	Possible Failure Mode	Type	Cause of Failure	OCC	DET	SEV	RPN	Effect of Failure on System	Failure Improvement Alternative Actions
Aligning Component	Incorrect Temperature Readings	C	Incorrect Orientation	5	7	7	245	Mapping Wrong Orientation	Use a statistical algorithm to ensure that the sensor outputs are within the expected range, use multiple sensors
Aligning Component	Incorrect Temperature Readings	C	Too High	5	3	7	105	Mapping Too High	Use a statistical algorithm to ensure that the sensor outputs are within the expected range, use multiple sensors
Mapping Software	Improper Mapping	SD	Faulty Input	3	5	7	105	Incorrect Temperature Data	TM for Quality Control to software check each device off the line before delivery
Collection Software	Incorrect Temperature Readings	E	Faulty Input	4	2	8	64	Improper Representation of Data	TM for Quality Control to software check each device off the line before delivery
Aligning Component	Incorrect Temperature Readings	C	Too Low	3	3	7	63	Mapping Too Low	Use a statistical algorithm to ensure that the sensor outputs are within the expected range, use multiple sensors
Mapping Software	Improper Mapping	SD	Faulty Code	3	2	7	42	Improper Representation of Data	TM for Quality Control to software check each device off the line before delivery
Action Software	Incorrect Power Action	S,E	Faulty Code	2	2	10	40	Improper On/Off Signal Sent	TM for Quality Control to software check each device off the line before delivery
Wiring Harness	Faulty Communication	E	Faulty Wiring	4	1	10	40	Electrical System Failure	Quality Control Check for every device before delivery ensuring the harness meets 100% spec.
Sensor	Incorrect Temperature Readings	EP	Production Error	2	2	8	32	Sensor Does Not Collect Data	Quality Control TM for 100% of sensors before delivery
Collection Software	Inaccuracy	S, E	Improper Conversions	3	1	10	30	Collected Values Become Invalid	TM for software check before device delviery
Housing	Anatomical Interference	MD	Incorrect Geometry	2	1	8	16	Anotomical Damage to Patient	TM for stress testing product batches
Housing	Damage To Device	MP	Corrosion	2	1	10	20	Anotomical Damage to Patient	Develop a TM to test each component reliance, compatability and stability
Sensor	Incorrect Temperature Readings	E	Faulty Wiring	2	1	8	16	Incorrect or No Sensor Signal	Quality Control Check for every device before delivery ensuring the harness meets 100% spec.
Wiring Harness	Faulty Communication	E	Corrosion	1	1	10	10	Damage to Patient and Wiring Harness	Quality Control Check for every device before delivery ensuring the harness meets 100% spec.
Software	Too Slow for Proccedure	S	Faulty Code	1	1	10	10	Surgeon Does Not Receive Data In Acceptable Time	Time trials during development
Power Supply	Power Failure	E	Manufacturing Defect	1	1	8	8	Device Does Not Receive Power	Power Check for 100% of devices before delivery
Thermistor	Detachment	MD/MP	Interfernce With LMA	1	1	9	9	Improper Representation of Data	Develop a TM for Quality Control to ensure appropriate diameter
Wiring Harness	Destruction	MD	RF Interference	1	1	6	6	Improper Representation of Data	TM to test the effects of RF energy levels on device before production

Figure 10.4.1. Shows the most recent FMEA table with highlighted updates/revisions.

Table 10.4.2. Risk and Hazards Assessment.

Description of Hazard	Planned Corrective Action
Special knowledge of device will be necessary for use	Train the surgeons using the device accordingly, include a detailed manual with the device
The device will be exposed to extreme conditions as it is to be use inside of the esophagus. Conditions include: humidity, temperature changes, and a specialized chemical environment	When choosing materials for the device, ensure that they are biocompatible with the conditions of the esophagus. Additionally, choose materials that resist corrosion.
There is potential for the device to be used in an unsafe manner—specifically its incorrect placement in the esophagus.	Build in an aligning tool for the device to mitigate the risk associated with surgeon placement errors.
Device is connected to a power supply. Voltage may pose a risk to the surgeon or patient.	Ensure surgeons wear protective gear, ground all circuits accordingly, and ensure that the power supply is not exposed to moisture.
Radiation exposure due to tracking of device in surgery	Lead vests during operation, ensure device appears under imaging technologies

10.5 Appendix E: Pugh Chart

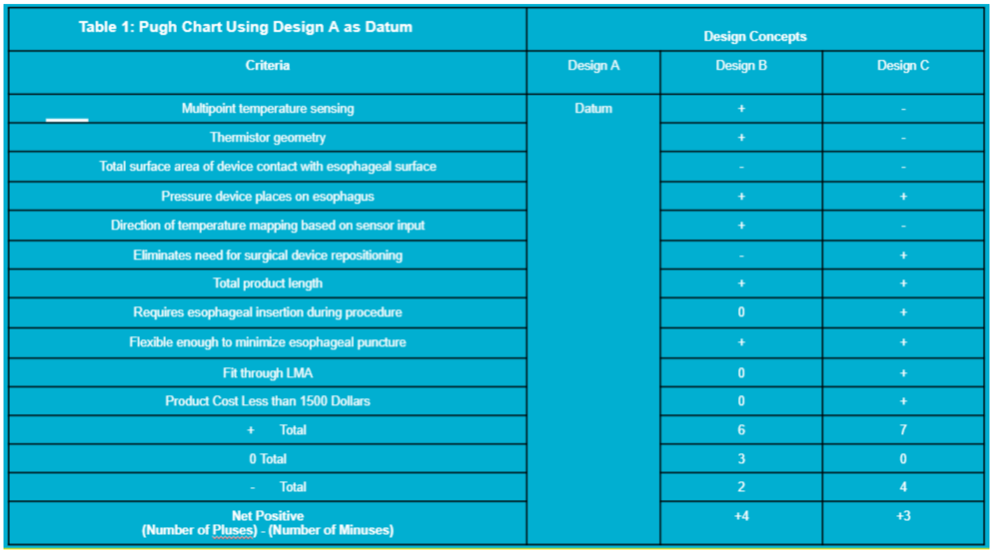


Table 1: Pugh Chart Using Design A as Datum	Design Concepts		
Criteria	Design A	Design B	Design C
Multipoint temperature sensing	Datum	+	-
Thermistor geometry		+	-
Total surface area of device contact with esophageal surface		-	-
Pressure device places on esophagus		+	+
Direction of temperature mapping based on sensor input		+	-
Eliminates need for surgical device repositioning		-	+
Total product length		+	+
Requires esophageal insertion during procedure		0	+
Flexible enough to minimize esophageal puncture		+	+
Fit through LMA		0	+
Product Cost Less than 1500 Dollars		0	+
+ Total		6	7
0 Total		3	0
- Total		2	4
Net Positive (Number of Pluses) - (Number of Minuses)		+4	+3

Figure 10.5.1. Displaying the Pugh chart for Design A being the datum for comparing the varying criteria.

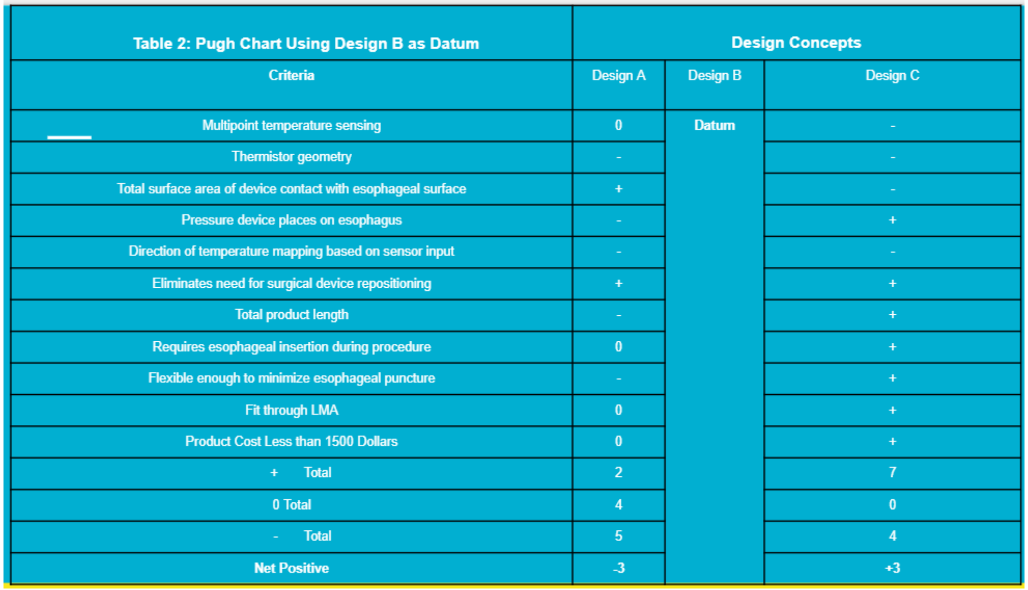


Table 2: Pugh Chart Using Design B as Datum	Design Concepts		
Criteria	Design A	Design B	Design C
Multipoint temperature sensing	0	Datum	-
Thermistor geometry	-		-
Total surface area of device contact with esophageal surface	+		-
Pressure device places on esophagus	-		+
Direction of temperature mapping based on sensor input	-		-
Eliminates need for surgical device repositioning	+		+
Total product length	-		+
Requires esophageal insertion during procedure	0		+
Flexible enough to minimize esophageal puncture	-		+
Fit through LMA	0		+
Product Cost Less than 1500 Dollars	0		+
+ Total	2		7
0 Total	4		0
- Total	5		4
Net Positive	-3		+3

Figure 10.5.2. Displaying the Pugh chart for Design B being the datum for comparing the varying criteria.

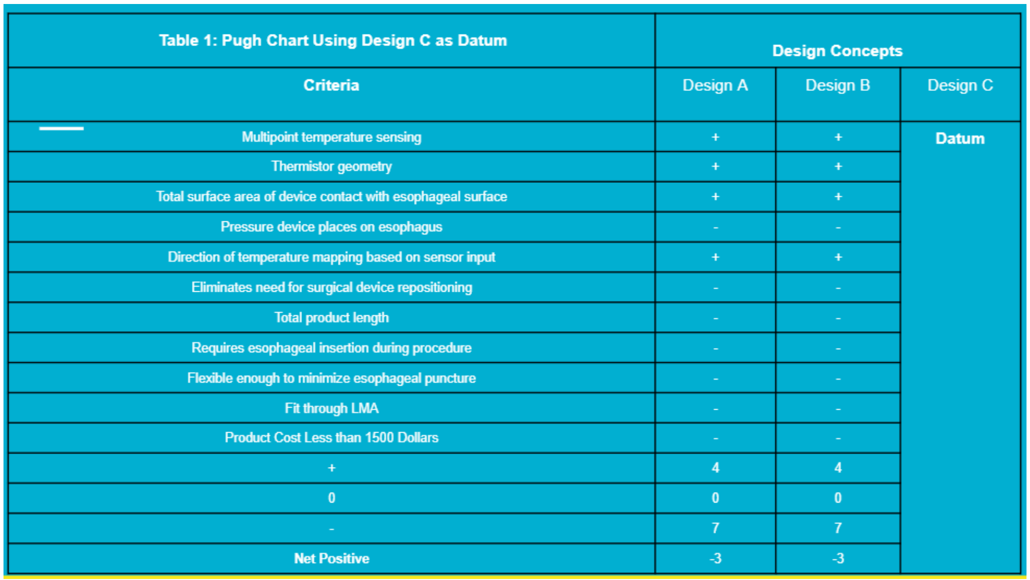


Table 1: Pugh Chart Using Design C as Datum	Design Concepts		
Criteria	Design A	Design B	Design C
Multipoint temperature sensing	+	+	Datum
Thermistor geometry	+	+	
Total surface area of device contact with esophageal surface	+	+	
Pressure device places on esophagus	-	-	
Direction of temperature mapping based on sensor input	+	+	
Eliminates need for surgical device repositioning	-	-	
Total product length	-	-	
Requires esophageal insertion during procedure	-	-	
Flexible enough to minimize esophageal puncture	-	-	
Fit through LMA	-	-	
Product Cost Less than 1500 Dollars	-	-	
+	4	4	
0	0	0	
-	7	7	
Net Positive	-3	-3	

Figure 10.5.3. Displaying the Pugh chart for Design C being the datum for comparing the varying criteria.

10.6 Appendix F: Vendor Information, Specifications, and Data Sheet

Table I.F. Vendor information.

Vendor	Website	Physical Location
Adafruit	www.adafruit.com/about	150 Varick St, New York, NY 10013
Amazon	www.amazon.com/about	Amazon.com, Inc. Customer Service PO Box 81226 Seattle, WA 98108-1226
McMaster Carr	www.mcmaster.com/about	9630 Norwalk Blvd. Santa Fe Springs, CA 90670-2932

Table II.F. Datasheets.

Component	Vendor	Item Number	Link
Thermistor	Digikey	495-5820-ND	https://media.digikey.com/pdf/Data%20Sheets/Epcos%20PDFs/B57550G1_Rev_Jan2016.pdf
Raspberry Pi	Adafruit	3775	https://cdn-shop.adafruit.com/product-files/3775/Raspberry-Pi-Model-B-Plus-Product-Brief.pdf
ADC	Adafruit	856	https://cdn-shop.adafruit.com/datasheets/MCP3008.pdf
Adafruit METRO M0 Express	Adafruit	3505	https://www.adafruit.com/product/3505

10.7 **Appendix G:** Budget

Items	Vendor	Part Number	Quantity	Total Cost	Person	Purpose
Loctite Medical-Grade Epoxy	Amazon	18680 4011	1	$48.79	Amazon	Probe Body
Small Tubing	McMaster-Carr	52335K32	3	$39.00	Madi	Probe Body
1.2 mm drill bits	McMaster-Carr	30565A12	4	$14.82	Madi	Probe Body
Sillicone Rubber Caps	McMaster-Carr	92805K8	1	$23.68	Madi	Probe Body
Steel Rod	McMaster-Carr	8890K117	2	$22.03	Madi	Probe Body
Large Tubing	McMaster-Carr	50405K36	1	$16.86	Madi	Probe Body
Wood Rod	McMaster-Carr	9683K12	1	$16.75	Madi	Probe Body
1.5mm drill bit	McMaster-Carr	30565A222	3	$5.37	Morgan	Probe Body
1.6mm drill bit	McMaster-Carr	30565A224	3	$5.37	Morgan	Probe Body
1.7mm dril bit	McMaster-Carr	30565A226	3	$5.43	Morgan	Probe Body
30 guage red wire (50 ft)	Radioshack	8369H7	1	$4.86	Morgan	Electrical
30 gauge black wire (50 ft)	Radioshack	8369H8	1	$4.86	Morgan	Electrical
Thermistors	Digi-Key	495-5820-ND	34	$107.78	Morgan	Electrical
MCP3008 ADC	Adafruit	856	2	$7.50	Morgan	Electrical
Raspberry Pi Model B+	Adafruit	3775	1	$35.00	Morgan	Electrical
Breadboard	Adafruit	3314	1	$9.95	Morgan	Electrical
PCB	OSH	tovndCbK	1	$46.30	Morgan	Electrical
Heat Shrink Cap	McMaster-Carr	7856K76	5	$6.10	Morgan	Probe Body
Heat Shrink Tubing (25ft)	McMaster-Carr	72855K24	1	$23.73	Morgan	Probe Body
10K, 1/8 Watt Resistors	Radioshack	8847R4	16	$8.67	Morgan	Electrical
Wooden Dowels	Michaels	4810334887	1	$8.37	Sarah	Probe Body
Gelatin	Target	261080037	3	$8.45	Sarah	Testing
Heat Gun	Miners Ace Hardware	1087760	1	$47.08	Sarah	Testing
Thermometer	Target	70050944	1	$15.50	Sarah	Testing
Wax Paper	Target	253010953	1	$2.00	Sarah	Testing
	Total			$534.25		

Figure 10.7.1. Current budget for the project, including prototyping and testing materials.

10.8 Appendix H: DHF

		Engineering Characteristics									
	Improvement Direction	⬇	⬇	⬆	⬆	⬆	⬇	⊘	⬆	⬆	⬇
	Units	mm	mm	ºC	ºC	ºC	mm	º of rotation	cylindrical shape	red, black, blue	$
Customer Requirements	**Importance Weight Factor**	Esophageal Probe Diameter	Radius of Curvature	Thermistor Temperature Range	Thermistor Temperature Accuracy	Interpolation Accuracy	Vertical Distance between Thermistor	Rotation between Thermistors	Esophageal Map Generation	Color Change in Danger Zones	Manufacturing Cost
Comply with Current Catheter Ablation Equipment	5	9	9		3	3	3	3	3	1	3
Accurate Temperature Measurements	5			9	9	9	9		1	9	
Generates Temperature Esophagus Map	5			9	9	9	9	9	9	9	
Terminates Ablation Power at Dangerous Temperatures	5			9	9	9		9	9	9	
Bio-Compatible	4	9	9								
One Time Use	4		1								9
Cost	3										9
	Raw Score	81	85	135	150	150	105	105	110	140	78
	Relative Weight (%)	7.105263	7.45614	11.84211	13.15789	13.15789	9.2105263	9.2105263	9.649122807	12.28070175	6.842105263
	Rank Order	9	8	4	1	1	6	6	5	3	10

Weight Scale: 1=Weak, 5=Strong
Relationship Scale: 1=Weak, 3=Medium, 9=Strong, Blank = None

Figure 10.8.1. Customer requirements and engineering characteristics relationship (same as **Figure 3.3.1)**.

Table I.H: Product Design Specifications.

Engineering Characteristic	**Specification**
Esophageal Probe Diameter	6 mm ± 0.5 mm
Vertical Distance between Thermistors	15 mm ± 0.5 mm
Rotation between Thermistors	90° ± 5°
Thermistor Temperature Range	18-40°C (safe between 20°C-38°C)
Thermistor Temperature Accuracy	± 1°C
Temperature Interpolation Accuracy	± 1°C
Radius of Curvature	52.7 mm ± 2 mm

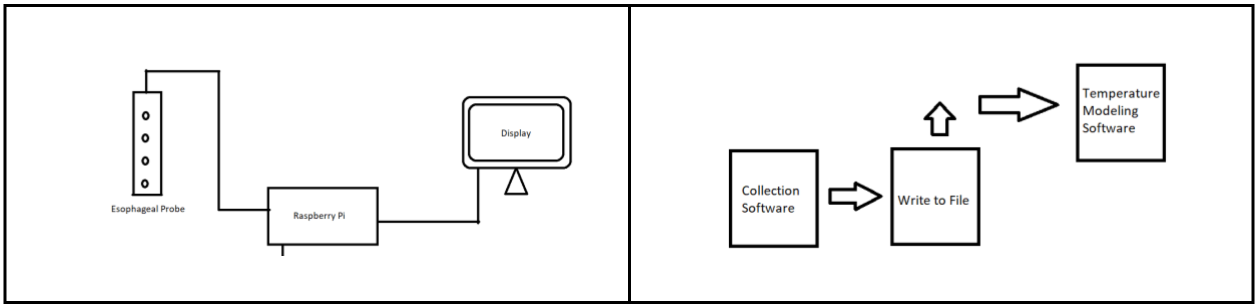


Figure 10.8.2. Circuit diagram and software diagram.

10.9 Appendix I: DOE

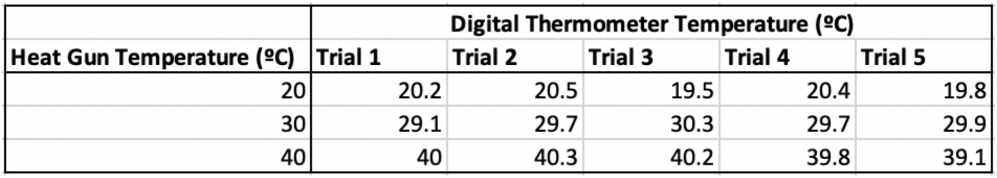
Engineering Metric	**Specification**	**Test Method**	**Location**	**Training**	**Sample Size**	**Pass/Fail Criteria**
Validate Heat Gun	±1°C	Absolute difference with calibrated thermometer	BMED Wet Lab (192-328)	N/A	15	Mean absolute difference less than 1°C
Thermistor Temperature Accuracy	±1°C	Absolute difference with calibrated thermometer	BMED Wet Lab (192-328)	N/A	24	Mean absolute difference less than 1°C and ANOVA p-value less than 0.05
Temperature Range	20-38°C	Absolute difference with calibrated thermometer throughout range	BMED Wet Lab (192-328)	N/A	40	Mean absolute difference less than 1°C throughout range
Radius of Curvature	52.7 mm	Instron bend testing to failure	BMED Wet Lab (192-328)	Completed with trained ISA Austin Roberts	5	Mean radius of curvature more than LMA radius of curvature
Temperature Map Generation	Pass/Fail	Observation	BMED Wet Lab (192-328)	N/A	1	Cylindrical shape with displayed temperatures
Alarm Test	Color change outside 20-38°C	Compare colors at 3 temperatures	BMED Wet Lab (192-328)	N/A	3	Blue below 20°C, black between 20-38°C, red above 38°C
Interpolation Test	±1°C	Absolute difference between thermistor and 90° turn.	BMED Wet Lab (192-328)	N/A	5	Mean absolute difference less than 1°C

Figure 10.9.1. A chart representing the DOE for the product demonstrating how engineering metrics will be verified.

10.10 Appendix J: Applicable Code of Federal Regulations

- CFR 800 General
- CFR 803 Medical Device Reporting
- CFR 806 Medical Devices - Reports of Corrections and Removals
- CFR 814 Premarket Approval of Medical Devices
- CFR 820 Quality System Regulation
- CFR 821 Medical Device Tracking Requirements
- CFR 822 Postmarket Surveillance
- CFR 860 Medical Device Classification Procedures
- CFR 861 Procedures for Performance Standards Development
- CFR 870 Cardiovascular Devices
- CFR 1002 Records and Reports
- CFR 1004 Repurchase, Repairs, or Replacement of Electronic Products
- CFR 1005 Importation of Electronic Products
- CFR 1010 Performance Standards for Electronic Products: General
- CFR 1030 Performance Standards for Microwave and Radio Frequency Emitting Products

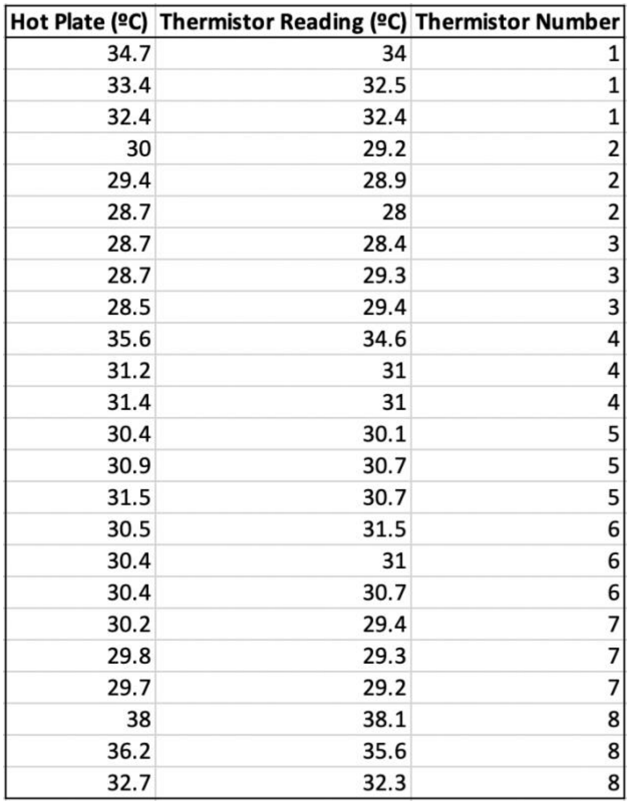
10.11 Appendix K: Heat Gun Validation Raw Data



	Digital Thermometer Temperature (ºC)				
Heat Gun Temperature (ºC)	**Trial 1**	**Trial 2**	**Trial 3**	**Trial 4**	**Trial 5**
20	20.2	20.5	19.5	20.4	19.8
30	29.1	29.7	30.3	29.7	29.9
40	40	40.3	40.2	39.8	39.1

Figure 10.11. Heat gun validation raw data.

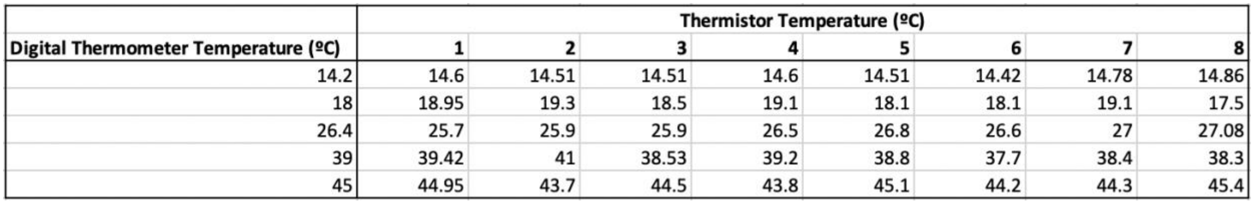
10.12 Appendix L: Temperature Accuracy Raw Data



Hot Plate (ºC)	Thermistor Reading (ºC)	Thermistor Number
34.7	34	1
33.4	32.5	1
32.4	32.4	1
30	29.2	2
29.4	28.9	2
28.7	28	2
28.7	28.4	3
28.7	29.3	3
28.5	29.4	3
35.6	34.6	4
31.2	31	4
31.4	31	4
30.4	30.1	5
30.9	30.7	5
31.5	30.7	5
30.5	31.5	6
30.4	31	6
30.4	30.7	6
30.2	29.4	7
29.8	29.3	7
29.7	29.2	7
38	38.1	8
36.2	35.6	8
32.7	32.3	8

Figure 10.12. Temperature accuracy raw data.

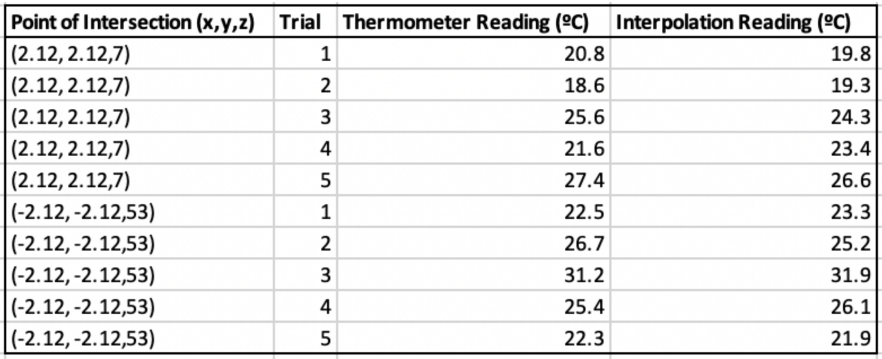
10.13 Appendix M: Temperature Range Raw Data



	Thermistor Temperature (ºC)							
Digital Thermometer Temperature (ºC)	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
14.2	14.6	14.51	14.51	14.6	14.51	14.42	14.78	14.86
18	18.95	19.3	18.5	19.1	18.1	18.1	19.1	17.5
26.4	25.7	25.9	25.9	26.5	26.8	26.6	27	27.08
39	39.42	41	38.53	39.2	38.8	37.7	38.4	38.3
45	44.95	43.7	44.5	43.8	45.1	44.2	44.3	45.4

Figure 10.13. Temperature range raw data.

10.14 Appendix N: Temperature Interpolation Raw Data

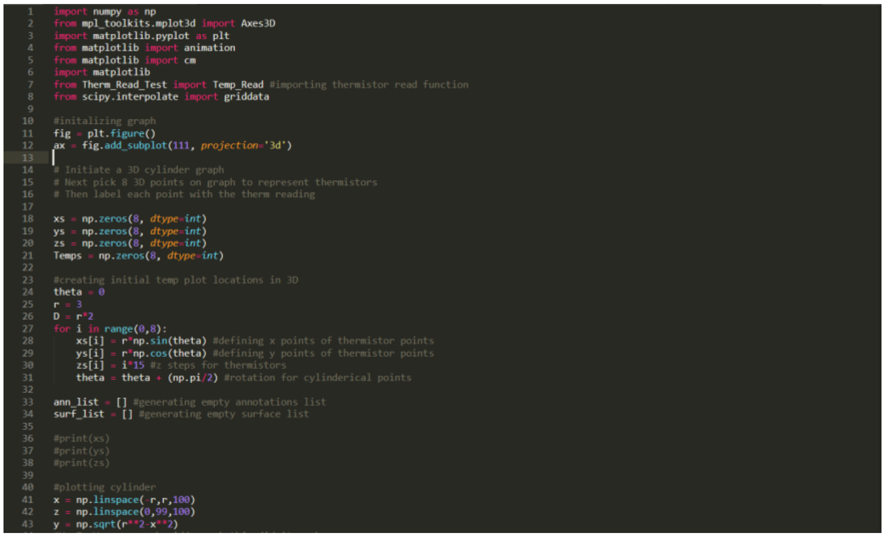


Point of Intersection (x,y,z)	Trial	Thermometer Reading (ºC)	Interpolation Reading (ºC)
(2.12, 2.12,7)	1	20.8	19.8
(2.12, 2.12,7)	2	18.6	19.3
(2.12, 2.12,7)	3	25.6	24.3
(2.12, 2.12,7)	4	21.6	23.4
(2.12, 2.12,7)	5	27.4	26.6
(-2.12, -2.12,53)	1	22.5	23.3
(-2.12, -2.12,53)	2	26.7	25.2
(-2.12, -2.12,53)	3	31.2	31.9
(-2.12, -2.12,53)	4	25.4	26.1
(-2.12, -2.12,53)	5	22.3	21.9

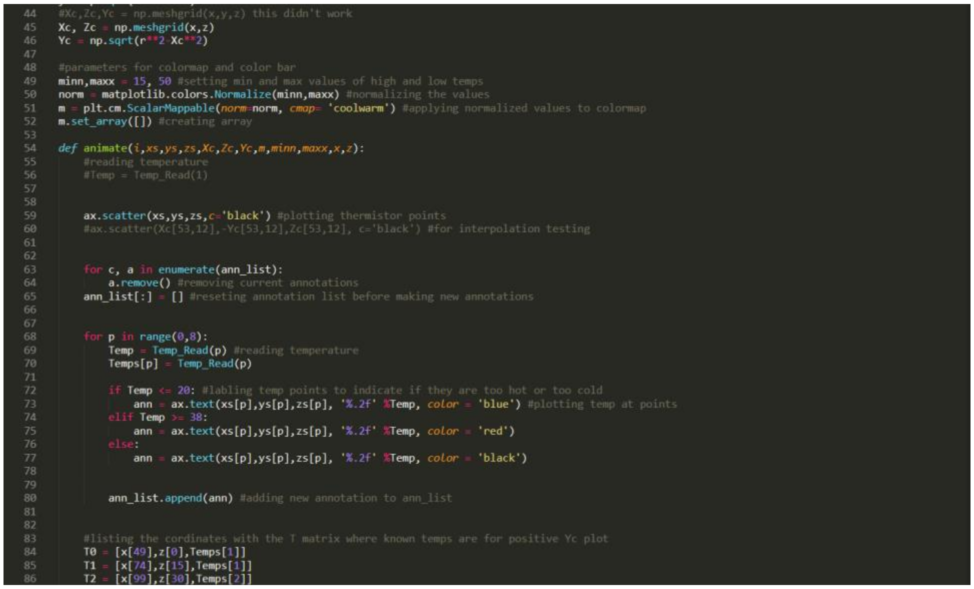
Figure 10.14. Temperature interpolation raw data.

10.15 Appendix O: Code

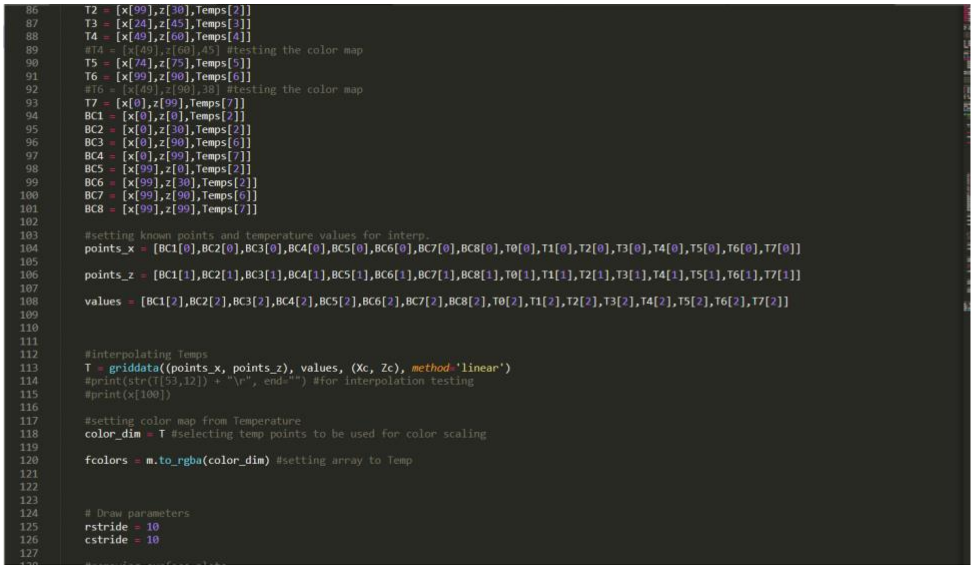
Map_Gen.py



```python
import numpy as np
from mpl_toolkits.mplot3d import Axes3D
import matplotlib.pyplot as plt
from matplotlib import animation
from matplotlib import cm
import matplotlib
from Therm_Read_Test import Temp_Read #importing thermistor read function
from scipy.interpolate import griddata

#initalizing graph
fig = plt.figure()
ax = fig.add_subplot(111, projection='3d')

# Initiate a 3D cylinder graph
# Next pick 8 3D points on graph to represent thermistors
# Then label each point with the therm reading

xs = np.zeros(8, dtype=int)
ys = np.zeros(8, dtype=int)
zs = np.zeros(8, dtype=int)
Temps = np.zeros(8, dtype=int)

#creating initial temp plot locations in 3D
theta = 0
r = 3
D = r*2
for i in range(0,8):
    xs[i] = r*np.sin(theta) #defining x points of thermistor points
    ys[i] = r*np.cos(theta) #defining y points of thermistor points
    zs[i] = i*15 #z steps for thermistors
    theta = theta + (np.pi/2) #rotation for cylinderical points

ann_list = [] #generating empty annotations list
surf_list = [] #generating empty surface list

#print(xs)
#print(ys)
#print(zs)

#plotting cylinder
x = np.linspace(-r,r,100)
z = np.linspace(0,99,100)
y = np.sqrt(r**2-x**2)
```



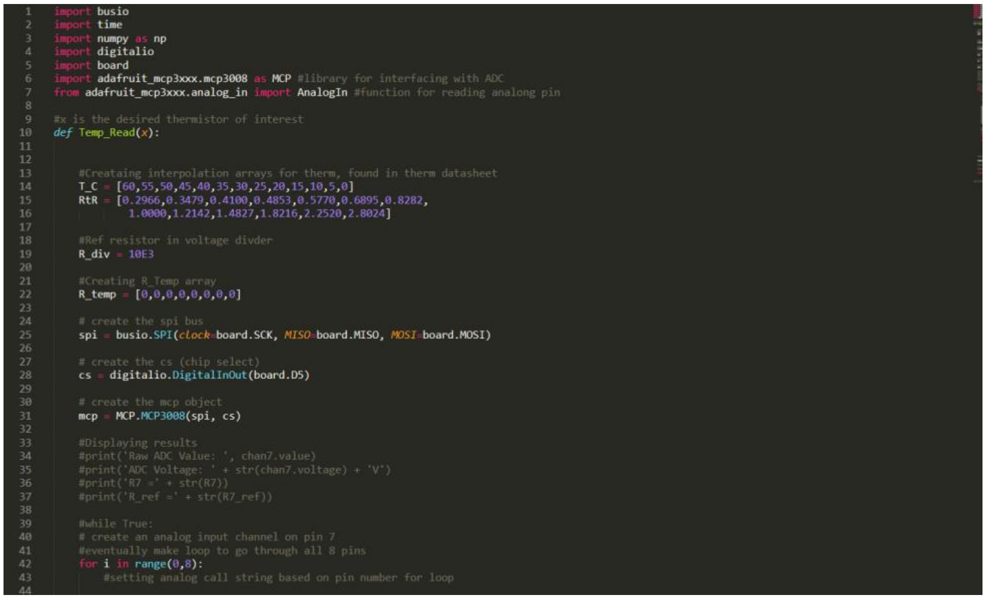
```
#Xc,Zc,Yc = np.meshgrid(x,y,z) this didn't work
Xc, Zc = np.meshgrid(x,z)
Yc = np.sqrt(r**2-Xc**2)

#parameters for colormap and color bar
minn,maxx = 15, 50 #setting min and max values of high and low temps
norm = matplotlib.colors.Normalize(minn,maxx) #normalizing the values
m = plt.cm.ScalarMappable(norm=norm, cmap= 'coolwarm') #applying normalized values to colormap
m.set_array([]) #creating array

def animate(i,xs,ys,zs,Xc,Zc,Yc,m,minn,maxx,x,z):
    #reading temperature
    #Temp = Temp_Read(1)


    ax.scatter(xs,ys,zs,c='black') #plotting thermistor points
    #ax.scatter(Xc[53,12],-Yc[53,12],Zc[53,12], c='black') #for interpolation testing


    for c, a in enumerate(ann_list):
        a.remove() #removing current annotations
    ann_list[:] = [] #reseting annotation list before making new annotations


    for p in range(0,8):
        Temp = Temp_Read(p) #reading temperature
        Temps[p] = Temp_Read(p)

        if Temp <= 20: #labling temp points to indicate if they are too hot or too cold
            ann = ax.text(xs[p],ys[p],zs[p], '%.2f' %Temp, color = 'blue') #plotting temp at points
        elif Temp >= 38:
            ann = ax.text(xs[p],ys[p],zs[p], '%.2f' %Temp, color = 'red')
        else:
            ann = ax.text(xs[p],ys[p],zs[p], '%.2f' %Temp, color = 'black')


        ann_list.append(ann) #adding new annotation to ann_list


    #listing the cordinates with the T matrix where known temps are for positive Yc plot
    T0 = [x[49],z[0],Temps[1]]
    T1 = [x[74],z[15],Temps[1]]
    T2 = [x[99],z[30],Temps[2]]
```



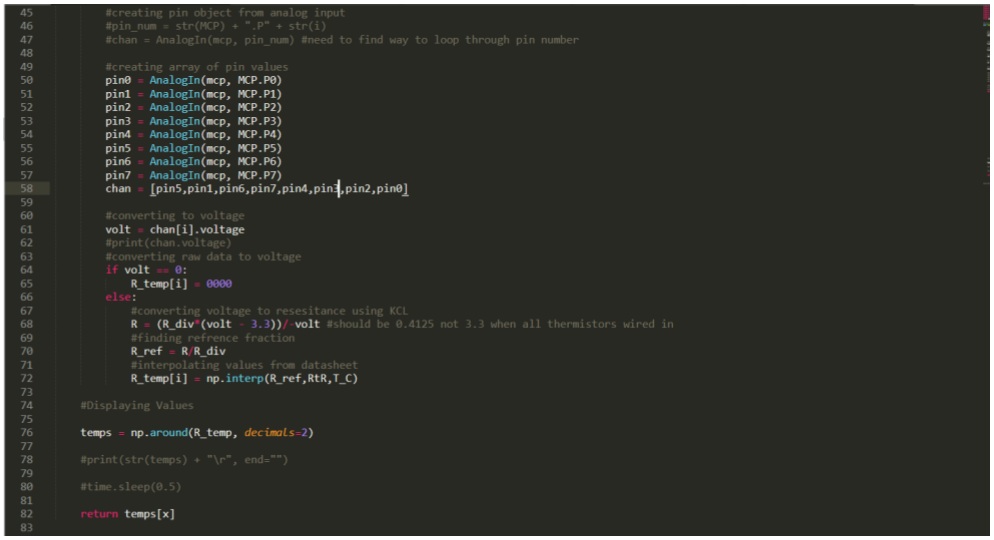
```
    T2 = [x[99],z[30],Temps[2]]
    T3 = [x[24],z[45],Temps[3]]
    T4 = [x[49],z[60],Temps[4]]
    #T4 = [x[49],z[60],45] #testing the color map
    T5 = [x[74],z[75],Temps[5]]
    T6 = [x[99],z[90],Temps[6]]
    #T6 = [x[49],z[90],38] #testing the color map
    T7 = [x[0],z[99],Temps[7]]
    BC1 = [x[0],z[0],Temps[2]]
    BC2 = [x[0],z[30],Temps[2]]
    BC3 = [x[0],z[90],Temps[6]]
    BC4 = [x[0],z[99],Temps[7]]
    BC5 = [x[99],z[0],Temps[2]]
    BC6 = [x[99],z[30],Temps[2]]
    BC7 = [x[99],z[90],Temps[6]]
    BC8 = [x[99],z[99],Temps[7]]

    #setting known points and temperature values for interp.
    points_x = [BC1[0],BC2[0],BC3[0],BC4[0],BC5[0],BC6[0],BC7[0],BC8[0],T0[0],T1[0],T2[0],T3[0],T4[0],T5[0],T6[0],T7[0]]

    points_z = [BC1[1],BC2[1],BC3[1],BC4[1],BC5[1],BC6[1],BC7[1],BC8[1],T0[1],T1[1],T2[1],T3[1],T4[1],T5[1],T6[1],T7[1]]

    values = [BC1[2],BC2[2],BC3[2],BC4[2],BC5[2],BC6[2],BC7[2],BC8[2],T0[2],T1[2],T2[2],T3[2],T4[2],T5[2],T6[2],T7[2]]



    #interpolating Temps
    T = griddata((points_x, points_z), values, (Xc, Zc), method='linear')
    #print(str(T[53,12]) + "\r", end="") #for interpolation testing
    #print(x[100])

    #setting color map from Temperature
    color_dim = T #selecting temp points to be used for color scaling

    fcolors = m.to_rgba(color_dim) #setting array to Temp



    # Draw parameters
    rstride = 10
    cstride = 10

```

```
    # Draw parameters
    rstride = 10
    cstride = 10

    #removing surface plots
    for c, s in enumerate(surf_list):
        s.remove() #removing the surfs from the plot
    surf_list[:] = [] #clearing surf_list to make room for new surfs



    #plot the surface with new colors, adding new elements to surf_list to be plotted
    surf1 = ax.plot_surface(Xc, Yc, Zc, alpha=0.4, rstride=rstride, cstride=cstride, facecolors = fcolors, vmin=minn, vmax=maxx, shade=False, Line
    surf2 = ax.plot_surface(Xc, -Yc, Zc, alpha=0.4, rstride=rstride, cstride=cstride, facecolors = fcolors, vmin=minn, vmax=maxx, shade=False, Lin

    #adding the new surf plots to surf_list
    surf_list.append(surf1)
    surf_list.append(surf2)




#set up plot to call animate() function periodically
ani = animation.FuncAnimation(fig, animate, fargs = (xs, ys, zs, Xc, Zc, Yc, m, minn, maxx, x, z), interval=1000)
cbar = plt.colorbar(m, ax=ax) #plotting the color bar based off the color map array
cbar.ax.set_ylabel('Degrees C')
plt.show()


```

Therm_Read_Test.py



```python
import busio
import time
import numpy as np
import digitalio
import board
import adafruit_mcp3xxx.mcp3008 as MCP #library for interfacing with ADC
from adafruit_mcp3xxx.analog_in import AnalogIn #function for reading analong pin

#x is the desired thermistor of interest
def Temp_Read(x):


    #Creataing interpolation arrays for therm, found in therm datasheet
    T_C = [60,55,50,45,40,35,30,25,20,15,10,5,0]
    RtR = [0.2966,0.3479,0.4100,0.4853,0.5770,0.6895,0.8282,
            1.0000,1.2142,1.4827,1.8216,2.2520,2.8024]

    #Ref resistor in voltage divder
    R_div = 10E3

    #Creating R_Temp array
    R_temp = [0,0,0,0,0,0,0,0]

    # create the spi bus
    spi = busio.SPI(clock=board.SCK, MISO=board.MISO, MOSI=board.MOSI)

    # create the cs (chip select)
    cs = digitalio.DigitalInOut(board.D5)

    # create the mcp object
    mcp = MCP.MCP3008(spi, cs)

    #Displaying results
    #print('Raw ADC Value: ', chan7.value)
    #print('ADC Voltage: ' + str(chan7.voltage) + 'V')
    #print('R7 =' + str(R7))
    #print('R_ref =' + str(R7_ref))

    #while True:
    # create an analog input channel on pin 7
    #eventually make loop to go through all 8 pins
    for i in range(0,8):
        #setting analog call string based on pin number for loop

```



```python
        #creating pin object from analog input
        #pin_num = str(MCP) + ".P" + str(i)
        #chan = AnalogIn(mcp, pin_num) #need to find way to loop through pin number

        #creating array of pin values
        pin0 = AnalogIn(mcp, MCP.P0)
        pin1 = AnalogIn(mcp, MCP.P1)
        pin2 = AnalogIn(mcp, MCP.P2)
        pin3 = AnalogIn(mcp, MCP.P3)
        pin4 = AnalogIn(mcp, MCP.P4)
        pin5 = AnalogIn(mcp, MCP.P5)
        pin6 = AnalogIn(mcp, MCP.P6)
        pin7 = AnalogIn(mcp, MCP.P7)
        chan = [pin5,pin1,pin6,pin7,pin4,pin3,pin2,pin0]

        #converting to voltage
        volt = chan[i].voltage
        #print(chan.voltage)
        #converting raw data to voltage
        if volt == 0:
            R_temp[i] = 0000
        else:
            #converting voltage to resesitance using KCL
            R = (R_div*(volt - 3.3))/-volt #should be 0.4125 not 3.3 when all thermistors wired in
            #finding refrence fraction
            R_ref = R/R_div
            #interpolating values from datasheet
            R_temp[i] = np.interp(R_ref,RtR,T_C)

    #Displaying Values

    temps = np.around(R_temp, decimals=2)

    #print(str(temps) + "\r", end="")

    #time.sleep(0.5)

    return temps[x]

```