

Physiological Remote Monitoring of Free Tissue Transfer

A Major Qualifying Project
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In partial fulfillment of the requirements for the
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ABET Educational Objectives

An ability to design a system, component, or process to meet desired needs within realistic constraints such as economic, environmental, social, political, ethical, health and safety, manufacturability, and sustainability (ABET Criterion 3c) while incorporating appropriate engineering standards (ABET Criterion 5) (need to assess each of these separately, but since 'or' and "such as" not all need to be met separately).

i) Multiple realistic constraints (economic, environmental, social, political, ethical, health and safety, manufacturability) – pages 26-29 and 72-74

ii) Appropriate engineering standards - pages 62-74

An ability to function on multidisciplinary teams (ABET Criterion 3d) - pages 26-28

An understanding of professional and ethical responsibilities (ABET Criterion 3f)

i) Professional – pages 72-74

ii) Ethical – page 74

An ability to communicate effectively (ABET Criterion 3g). - pages 26-28

The broad education necessary to understand the impact of engineering solutions in a global, economic, environmental, and societal context (3h). (Both economic AND environmental need to be addressed)

i) Economic – page 74

ii) Environmental – page 74

A knowledge of contemporary issues (ABET Criterion 3j) – pages 87-88

Authorship

1 Introduction Editor [Ryan]

Paragraph 1 [Theodore]

Paragraph 2 [Eric]

Paragraph 3 [Theodore/David]

Paragraph 4 [David]

Paragraph 5 [Martin]

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2.2 Tissue Flap Monitoring with Doppler [Theodore]

2.3 Temperature Tissue Flap Monitoring [David]

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5 **Design Verification**

- 5.1 *Artificial Testing [Martin]*

- 5.1.1 Ultrasound Tissue Phantoms
- 5.1.2 Artificial Blood Flow Systems

- 5.2 *Rat Testing [Theodore]*

- 5.3 *Public Demonstration [Theodore]*

- 5.4 *Temperature Test [David]*

6 **Discussion**

- 6.1 *Test Discussion*

- 6.1.1 Rat Test [Theodore]
- 6.1.2 Public Demonstration [Theodore]
- 6.1.3 Temperature Test [David]

- 6.2 *Social Impacts [Theodore]*

- 6.2.1 Economics
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7 **Final Design and Validation**

- 7.1 *Probe*

- 7.1 Thermistor and Ultrasound Transducer [Theodore]
- 7.2 Casing [Ryan]

- 7.2 *Circuitry [David]*

- 7.2.1 Temperature Monitoring Circuitry

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7.3 *Signal Processing [Eric]*

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7.3.2 Signal Acquisition Software

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8 Conclusion and Recommendations

8.1 *Conclusion [Martin]*

8.2 *Future Improvements*

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8.2.4 Mobile Phone Application [David]

1 Introduction

Tissue flap surgery involves the transplant of live tissue from a recipient site to a donor site while maintaining its own blood supply [1]. With a 95% success rate, this is the most effective procedure for many skin defects and reconstructive surgery [2]. Defects include, but are not limited to, severe burns, severe trauma to a particular area of the body and severe infections where the surgery requires extensive skin loss [3]. These procedures can be necessary due to injuries and disease to the skin, fat, muscle, nerves and bone [4]. Free flap transfers can be applied to virtually every extremity of the body. The frequency of free flap transfers varies between hospitals and individual surgeons [5].

Monitoring newly applied free flap transplants is a key part of the overall surgery. Discrepancies between how different surgeons monitor the tissue transplant has impacted patient care for many years. Some physicians check hourly while others check once a day [6]. Currently, the salvage rate for the flaps after a detected failure varies based on the type of flap. How long the issue persisted before detection, and the experience of the surgeon also impacts the salvage rate [2]. A monitoring device that allows for earlier detection and requires less experience is necessary to increase the current salvage rate.

Success of microvasculature surgery has increased with improvements to instrumentation and magnification used during surgical procedures. Complications can have serious impacts on the flap transplant outcome and viability. Recognition of complications early is key to successful interventions. Venous and arterial thrombosis are the main causes of flap failures. In a survey of 1000 microvascular free flap transplants, 68 failures were caused by venous thrombosis. 45 failures were caused by arterial thrombosis [7]. Using current monitoring technology, salvaging flaps with major complications due to loss of blood flow is not easy. In a survey of 378 free flaps, of those requiring re-exploratory surgery to locate thrombosis only 31.8% of flaps were salvaged [8]. Improved monitoring will reduce the risk of these threatening complications.

The ultrasound Doppler probe is the current gold standard for the monitoring of tissue flaps at UMass Memorial Hospital. Surgeons use a combination of different modalities in order to monitor tissue flap transplants. According to one study, 79.4% of surgeons use Doppler probes and 79.4% of surgeons use temperature to monitor the flaps as well. Other methods that are detailed in the table below.

Table 1.1 - Summary of Tissue Flap Monitoring Modalities JH Spiegel [6]

Monitoring Modality	Percent of Surgeons who Utilize the Modality
Flap Color	79.4
Pin Pricks	67.6
Bleeding Rates	67.6
Capillary Refill	61.8
Skin Surface Temperature	11.8
Implantable Doppler Probe	8.8

Post-operative monitoring is necessary in order to increase the salvage rate by detecting vascular occlusions. The non-invasive, ultrasound Doppler probe accomplishes this well. It works by generating electromagnetic waves in the megahertz range, known as ultrasound waves, which propagate through human tissues. If blood is flowing through the vasculature within the monitored flap, then these waves are reflected off of the cells. This is known as 'back scatter' and causes the reflected signal to contain the relative velocity of the blood flow and thus a shift in the reflected frequency. When this wave returns to the transducer, it is processed via circuitry and/or software and produces an audible signal that corresponds to the blood flow of the monitored flap. This method is advantageous over invasive techniques which would require surgery and may subsequently complicate monitoring performance, reliability, and may potentially restrict blood flow. The non-invasive Doppler probe experiences no interference from variations in tissue temperature, density of the flap, nor the viscosity of blood flow. From an economical and engineering standpoint, this device also fulfills low-power consumption standards. It is the non-invasive Doppler probe that sets a high standard of performance for tissue flap monitoring devices.

There are drawbacks to the ultrasonic Doppler probe which keep it from being the best that it can be. According to our clients, Dr. Dunn and Dr. Dowlatshahi, surgeons experience variation in performance between different Doppler probes. Different models will have different end-user experiences that are noted by the surgeons. The handling of the probe and subjective use may also affect the effectiveness of the devices. An improper placement and orientation of the probe may diminish the ultrasound signal or miss the appropriate signal entirely. Also, using the Doppler system keeps doctors limited to monitoring the patient locally within the hospital. The clients have suggested that the device could provide cost savings if patients can be sent home earlier to recover while being monitored by the surgical team. The new remote monitoring app produced within this project, allows surgeons to evaluate flap conditions from afar. This is a pivotal new feature that is missing from all current monitoring technologies. While the gold standard certainly trumps the other existing modalities, these drawbacks and limitations provide a unique opportunity and room for improvement to better the surgeon's monitoring experience as well as save more tissue flaps.

The focus of this project was to design a device to monitor tissue flaps that significantly improves on the current gold standard used by UMass surgeons. The team approached this goal by first identifying the latest technologies in the field that currently monitor tissue flaps. Second, they dove into resources such as medical journals and reached out to medical professionals to utilize their expertise. By cross-comparing the existing modalities, the team decided on a final concept design that became the basis of the first prototype. After receiving client feedback and conducting thorough testing of the prototype, an iterative design process was followed to produce a final product which was evaluated against the project's objectives and constraints. Within the application development phase, various methods were researched and considered. The chosen development platform was selected for its cross-platform capabilities, its minimal learning curve, the testing procedure and the development environment. The end result of the project was a device that monitors ultrasound Doppler and flap temperature, and exports this data to a fully-customized smartphone application, providing the doctors with a new, remote and valuable source of information. This removes many variables from the monitoring process where doctors have direct access to their patient's raw data and is available for their personal interpretation.

2 Background

Before tackling the opportunity presented by the clients, the project required a thorough understanding of several key topics. In the following sections of this chapter you will find information providing a better understanding of various components of our research. These sections include tissue flaps and the transplant process, different methods of monitoring tissue flaps, biomaterials involved, and remote monitoring.

2.1 Tissue Flaps

Tissue flaps are a mass of tissue that requires its own blood supply and may include skin, fat, muscle, nerves and bone. There are four types of tissue flaps: local flaps, regional flaps, free flaps, and composite tissue transplantation. Local flaps are an exact match from the donor site to the recipient site. Regional flaps are tissues taken from a nearby donor site. Free flaps are taken from a donor site that is located on a different part of the body. Composite tissue transplantation is an allograft tissue flap or taken from one individual and transplanted on another [9]. The MQP team will focus on free flaps for our design implementation.

Free flap transfer is a reconstructive plastic surgery procedure where tissue is removed from the donor site and transplanted to the recipient site. Tissue repair that requires a tissue flap transfer is typically from to a traumatic injury [3]. Due to the tissue flap requiring a blood supply to survive, arteries and veins are re-anastomosed through microvascular surgery techniques. Although these surgeries have success rates over 95%, complications exist because of the complexity and nature of the surgery [6].

The most common cause for flap failure is ischemia. Ischemia occurs when blood vessel constriction or obstruction reduces oxygen and nutrient supply to the tissue [10]. Venous and arterial thrombosis, a type of ischemia due to a blood clot, caused 68 flap failures and 45 failures respectively in a retrospective survey of 1000 microvascular free flap transplants [7]. Less than 60% of all tissue flaps that fail are able to be salvaged. For this reason, tissue flaps require physiological monitoring. Different monitoring techniques and technologies are discussed in the following sections.

2.2 Tissue Flap Monitoring with Doppler

For many years the best means of sensing blood flow has been the Doppler Ultrasound probes. These versatile probes are able to detect the blood flow in any vessel of the body. In one study with 150 tissue flap surgeries, the success of the surgery was 96% due to early detection of complications, with major contributions due to the Doppler Ultrasonic units used by the surgeons [2]. They are also used for the diagnosis of pain, swelling, and infection with no known harmful risks known.

Before we go into how the Doppler Ultrasound operates we must discuss the Doppler effect. This is the how the movement of an object alters the wavelength of the wave while the velocity of the signal is not changed. The result is an altered frequency reflected back to the transducer [11]. In this setting, the movement is the arterial and ventricular blood flow causing the distortion of the wave off of the red blood cells. Due to this effect, the medical professional must angle the

transducer at the correct angle in order to retrieve the correct sound wave in noninvasive applications [12]. From the output there are two different means of wave emission: continuous wave emission and pulse wave emission.

Pulse wave Doppler emission and reception is from the same transducer [12]. Pulse wave ultrasound systems are small, compact and allow users to easily move the ultrasound crystal. Its main disadvantage is its inability to measure high blood flow [13]. Continuous wave Doppler emits ultrasonic waves continuously. Separate crystals are used to emit and receive the ultrasound signal, making continuous Doppler probes larger [14]. Continuous sampling prevents aliasing that can occur when using pulse wave emissions. The clarity of continuous wave Doppler is compromised due to the additional red blood cells that reflect ultrasound waves outside of the blood vessel of interest [15]. Based on the characteristics of the audio signal, pitch and amplitude, the surgeons can determine whether the flap has adequate blood flow.

The handheld Doppler probe is typically the monitoring instrument chosen by clinicians. About 80% of surgeons use the Doppler Probe [6]. This is an extremely useful tool for the monitoring of blood flow that have free flap transfers, detecting malignant tumors, as well as warning signs of myocardial infarctions [16]. It detects blood flow utilizing Pulse wave Doppler technology. This allows the surgeon to scan up and down the area of the body that is getting screened [12]. Users say it's so widely utilized because of its noninvasive, reliable, and automatic qualities [17]. Negatives are that it is not continuous, varies from device to device depending on the manufacturer, and is subject to the interpretation of the user.

An improvement in performance is the Cook-Swartz Doppler Probe. This probe utilizes the same pulse Doppler technology, but uses a much smaller probe that is applied directly to the vessel that is being monitored. After a study of 500 flaps over 8 years, the conclusion was that there was an increase to 96% salvage rate with the Cook-Swartz probe compared to the conventional methods 89% salvage rate using all the different methods combined [18]. In a survey of different surgeons that partake in flap monitoring procedure, it was said that only 8% of surgeons utilize this instrument because of its invasive nature [6].

The Laser Doppler detector steps away from the conventional ultrasound technique and goes into the light realm. Light tends to emit the same change in frequency and wavelength as ultrasonic waves do [19]. The light is emitted onto the skin and parts of the original light are reflected while others are refracted. A photodiode then absorbs the reflected light that is now coming back at a different phase. The change in phase is then measured, and this value dictates the success of the surgery [19]. Its appeal is that the light can harmlessly penetrate past the first layers of skin and assess the vessels using a photodetector [20]. The main cause for not utilizing this new technology is the long-term practice of the surgeons with the ultrasonic Doppler probes.

2.3 Temperature Tissue Flap Monitoring

Monitoring free flaps by means of temperature measurement is a useful indication of blood perfusion. As a feature of homeostasis, temperature is regulated to ensure proper function of the bodily systems. This is known as thermoregulation and is controlled via the nervous system. The vascular system is the primary pathway for temperature regulation, where the blood is the vehicle carrying this thermal energy throughout the body [21]. Warm blood travels through arteries to arterioles and finally to capillary beds where much of the heat is diffused to the supporting tissues. Skin tissue is the most superficial tissue to receive the blood's warmth, and this is commonly where temperature monitoring takes place. A greater temperature will be measured if there is more blood flow to the skin and a lesser temperature measured if there is less blood flow. The autonomic nervous system controls this thermoregulation by regulating blood flow and does so by vasoconstriction and vasodilation [22]. Vasoconstriction is the contraction of smooth muscles in the arterial vessels to decrease the vascular radius and thus minimize blood flow. Vasodilation, on the contrary, is the relaxing of smooth muscles to increase vascular radius and allow for greater blood flow. These functions of vasomotion directly control blood perfusion and thus also regulate temperature to the tissues. By monitoring the skin's temperature, blood perfusion is therefore indirectly monitored.

Arterial thrombosis and other vascular occlusions minimize blood flow which can be detected via temperature monitoring. Vascular occlusions within a tissue flap are commonly caused by external pressure on the arterioles or may be due to the clotting known as thrombosis. These obstruct the vessel's pathways simulating a vasoconstriction. An obstruction similarly minimizes the vessel's inner radius and disrupts proper perfusion to the tissue. While measuring temperature of the skin has a direct correlation to autonomic vasomotion, the same relationship is applicable to general vascular occlusions; the presence of an occlusion in a tissue flap results in lesser blood perfusion and thus lower skin temperature. Variable changes in skin temperature due to occlusions are not expected to exceed more than a $\pm 3^{\circ}\text{C}$ change from the patient's core body temperature, based on input from our sponsor Dr. Dowlatshahi. Significant temperature changes would immediately indicate that there is conflict within the flap's perfusion, whereas smaller changes may represent subtle clues towards the flap's progression in perfusion.

Peripheral blood flow in tissue is currently monitored in a number of ways. Temperature probes may be used invasively, however, these are unfavorable in monitoring tissue flaps as only the surface temperature needs monitoring. Non-invasive surface monitoring devices have been used since the invention of the thermometer. Thermometers have been used for centuries to measure temperature of the body and have been reinvented with modern science and engineering to observe the measurand with greater sensitivity. Electrical sensors for monitoring temperature such as thermistors and thermocouples have been designed with extreme precision and are used in conjunction with amplification and filtering circuitry to provide the user with high resolution and high sensitivity measurements. These sensors are placed on the skin's surface to monitor the skin's temperature, however, the weight of these components and the supporting materials may apply too much pressure to the skin of a tissue flap, which could induce vascular occlusions. Safety

precautions must be taken during the design of these devices if they are to be used in medical scenarios where weight must be considered.

An additional method to monitoring surface temperature is through the use of temperature monitoring stickers. These are thin flexible stickers that adhere to the skin. The technology is enclosed within the sticker and utilizes liquid crystal technology. The thermal energy present at the skin's surface modulates the behavior of materials within the sticker. This activity allows for various segments of the material to change color depending on the temperature it is subjected to. These are reasonably sensitive and commonly allow for a resolution of 1 degree Celsius with a response time of approximately 1 second. Monitoring of temperature using this method, however, requires consistent checking of the sticker's display signature which may not be congruent with the agenda of the surgeons or nurses. At best, these stickers may serve as useful indicators of a temperature change of the skin and thus blood perfusion, but are never used as the primary means of detection of vascular occlusions within a free flap.

Infrared light is also used as a viable means in temperature monitoring. In one study, infrared temperature monitors were shown to accurately detect conflict within a healing tissue flap. By detecting the subtle changes in infrared light that surrounds the tissue, temperature is effectively monitored. This infrared light is a quantifiable measure and that correlates to the skin's thermal energy [23]. While this means of monitoring is accurate in its detection of occlusions and perfusion, the receiving transducer requires distance from the patient to acquire an appropriate signal. Currently, these devices are used by a nurse during certain monitoring intervals for a variety of flap locations, while standalone infrared monitors may be placed at a distance from the patient, provided that neither the patient nor the device moves [24].

Another study was conducted in 2009, where 47 microvasculature free flaps were monitored post-operatively via infrared surface temperature [24]. The study was conducted to observe how effective temperature monitoring would be in the detection of flap failure. There were three main temperatures being monitored for each patient; core body temperature, flap temperature, and the skin temperature adjacent to the flap. Flaps that survived ranged from 83.2°F to 100.5°F, whereas failures ranged from 82°F to 95.7°F. The key difference in these two ranges, as the surgeons noted, was that no flaps could survive below a temperature of 83.2°F. Each patient's flap temperature varied within these ranges, so no particular temperature could be considered a tipping point as to indicate there's an occlusion. The flap temperature needed to be monitored in reference to another part of the body. The core body temperature was found to be variable and could not be used as an accurate reference to the flap temperature. If a patient were to lean a certain way and reduce circulation to a limb, then that whole limb would result in a decreased temperature, not just the flap. For this reason, the adjacent skin temperature was found to be useful.

shows these recorded temperature differences throughout the study. Surgeons noted that surviving flaps experienced an maximum average temperature difference of 3.87°F. Failing flaps experienced a minimum average difference of 4.73°F. This data is helpful in the design of a temperature monitoring system that will notify the surgeons when a particular temperature threshold is met.

Table 2.1 - Summary of Temperate Information for Flap Monitoring [24]

Last 24 h (4 h block average) °F	1	2	3	4	5	6
Mean temperature difference Failure group (flap-adjacent skin control)	9.56	7.29	6.69	5.43	4.37	5.72
Mean temperature difference Survival group (flap-adjacent skin control)	3.87	3.28	3.16	1.89	1.5	2.48

2.4 Tissue Flap Monitoring with Near Infrared Spectroscopy

The device looks to monitor indicators of successful flap perfusion. Near Infrared Spectrometry (NIS) allows for access of tissue, up to 8 cm, below the surface of the skin. Compared to visible light (450-700 nm), near infrared light (700-1000nm) is able to penetrate through skin relatively unimpeded. NIS satisfies many of the functions required for the project. It is non-invasive, and the parts are readily available for prototyping and design.

The near infrared light can be produced either at the surface of the skin with LED's or by laser diodes that direct it to the surface of the skin. Receivers monitor the reflected light after traversing through the tissue [25]. The distance between the receiver and emitter dictates the depth of tissue monitored. Near Infrared light is absorbed by hemoglobin. The absorptivity of hemoglobin changes depending on whether or not it is oxygenated. As a result, NIS can be used to monitor oxygen perfusion during this project.

Beer Lambert's Law characterizes the concentration of hemoglobin in tissue samples [26].

$$A = \log \left(\frac{I_o}{I} \right) = \alpha * c * d \quad (1)$$

Where, absorption, A , is a logarithmic relationship between the intensity of light input to the sample, I , and the output after traveling through the tissue sample, I_o . Absorption can then be related to the concentration of a given compound within the sample as seen in the second portion of the equation above. Where α is the specific extinction coefficient of the compound ($\text{mol}^{-1} \text{cm}^{-1}$). The extinction coefficient is a constant that describes how strongly a given compound absorbs and holds on to near infrared light. The concentration of a given compound is c , in this case hemoglobin. The distance traveled by the light beam is described by d .

The effectiveness of NIS for monitoring tissue flap transplants was first quantified using porcupine models. A flap was harvested, stitched into a cylindrical configuration, and then reattached to the model pig [27]. The flap was successfully set up on 7 pigs. The surgeons failed to set up the flap on two of the pigs. The arterial input and venous output of the flap was accessed in order to simulate arterial and venous thrombosis with clamps directly applied to vasculature. After applying the clamps, the flap was monitored with NIS.

Figure 2.1 visualizes the response seen with NIS to a venous blockage in the tissue flap. At the time of the occlusion the total amount of Hemoglobin, tHb, begins rising. The concentration of deoxygenated hemoglobin, HHb, also rises. The concentration of oxygenated hemoglobin, O₂Hb, initially rises and then falls. Within the subplot of Fig. 2.1, a plot of the differential hemoglobin value, HbD, is also visualized. The HbD is the difference between O₂Hb and HHb. The venous occlusion produces a clear and significant signal when monitored via NIS. The baseline values of HHb and O₂Hb are seen from time 0 to roughly 550 seconds.

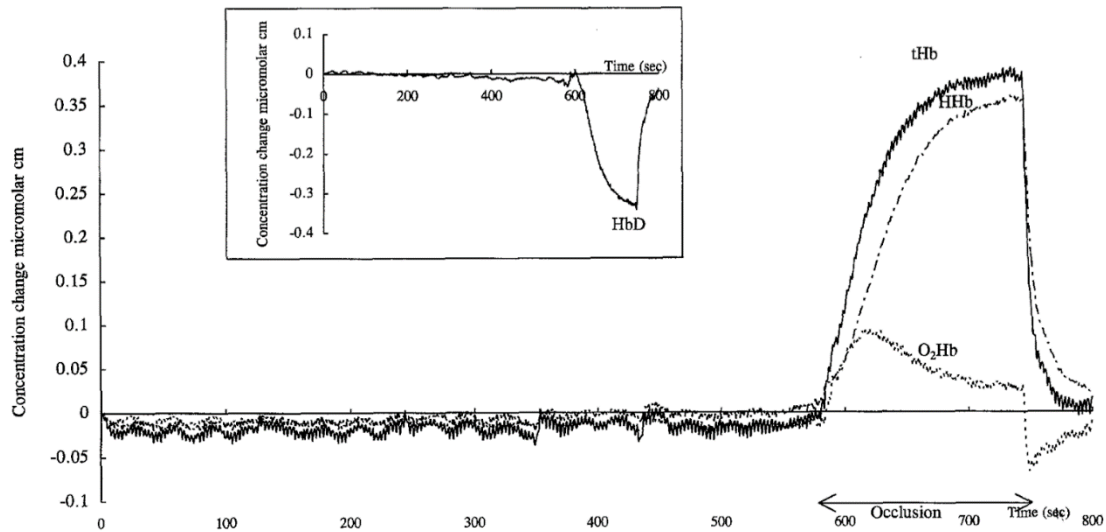


Figure 2.1 - NIS Output during venous thrombosis [27]

Figure 2.2 demonstrates the effect of occluding the arterial input to the flap while monitoring with NIS. In contrast to the venous occlusion, tHb drops after the clamp is put in place. The concentration of O₂Hb drops dramatically, while the concentration of HHb remains relatively constant during the occlusion. A subplot of HbD is again visible in Figure 2.2. After the occlusion is removed, there is a surplus of O₂Hb that become available before all of the hemoglobin values return to normal values. NIS's different responses to arterial and venous occlusions, as illustrated by Figures 2.1-2, allow for reliable independent identification of venous and arterial occlusions.

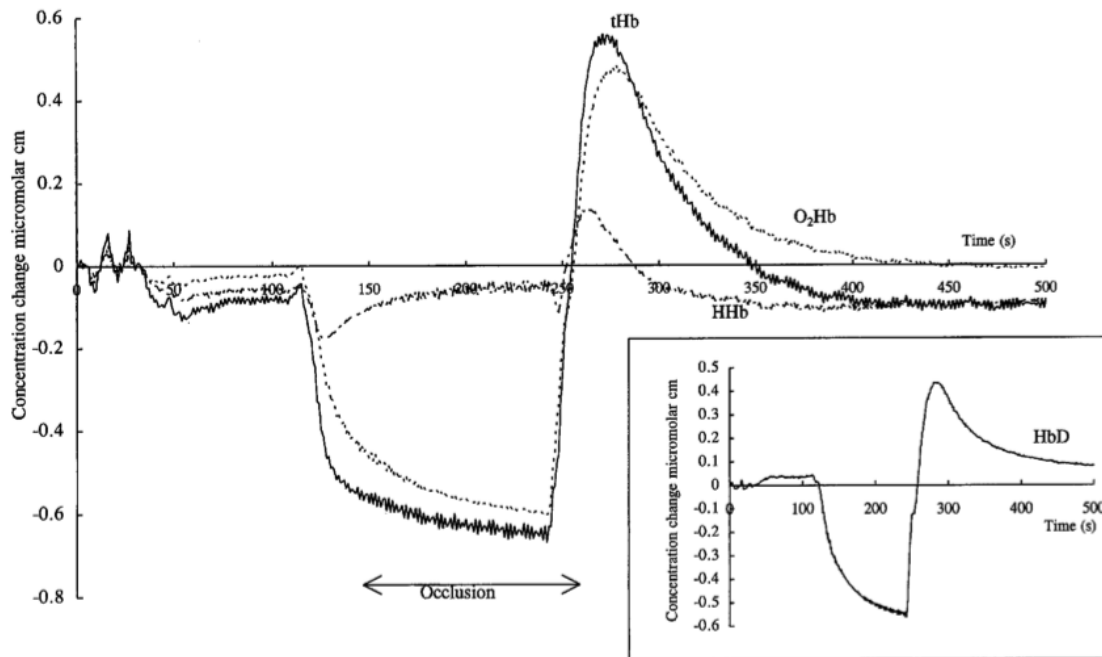


Figure 2.2 - NIS Output During Atrial Thrombosis [27]

2.5 Biomaterials of Tissue Flap Monitoring

When it comes to using a Doppler probe, it is very important that one chooses the appropriate coupling medium. This biomaterial must possess certain properties such as proper adhesion to the skin and probe providing no barrier between them. The probe itself must have a cover made of either latex or an elastomer to protect the probe from bacteria. Some materials may also include an antimicrobial agent to aid in reducing bacterial infections. One of the main purposes of the coupling medium, however, is to reduce the amount of ultrasound energy reflected. When a sound signal is transmitted through this probe-skin interface, the reflection coefficient off of blood flow is close to one therefore most of the sound is reflected [28]. This coupling medium aids in reducing this signal loss while also excluding the small amount of air between the probe and the skin that causes additional impedance.

In addition to these requirements, some other characteristics of an effective coupling medium include being bioinert, conformable, viscous, and capable of sustaining signals close to 1518 m/s. The biomaterial needs to be bioinert so that there is not any degradation of the material on the body causing inflammation of tissue or the probe to fall off the patient over the monitoring period. It must be conformable to various sizes of tissue flaps so that the type of flap does not become a constraint for the user while also providing a convenient method of attaching the probe to the tissue.

Viscosity is important for the medium because the gel needs to have just the right thickness otherwise it won't function properly for the application. A low viscosity may cover a larger area but

tends to be too runny spreading out farther than needed. A high viscosity is convenient for transducers that possess a limited range of movement but is harder to clean up. Therefore, one must choose a medium viscosity material to obtain a well-spread material that is easy to remove and reapply [29]. The coupling medium must also exert minimal pressure on the flap so that it does not cause an occlusion affecting blood flow while also sustaining a sound wave of about 1518 m/s to keep the sound velocity relatively constant with little to no distortion [29].

The various coupling mediums currently being used include silicone, epoxy, plastics, and polyacrylamide and polyethylene glycol. Polyethylene is most commonly used in ultrasound gels. Silicone gels have lower surface tension allowing for wetting to happen very quickly. Low viscosity, high flexibility, low attenuation coefficient, compatible with therapeutic molecules, and an easy removal process make silicone gels strong candidates as coupling mediums. Hydrogels like polyacrylamide have great acoustic properties such as low signal attenuation and are cross-linked, allowing for conformability and durability. They are also very easy to manufacture and relatively inexpensive. Polyethylene glycol also has a very low attenuation coefficient and acoustic impedance close to that of skin [30]. Gels like pHEMA, behave similarly to PAA except they have a higher durability due to their water content as well as a higher attenuation coefficient [31]. Materials like epoxy and plastics have acoustic properties matching silicone with low signal reflection [29].

2.6 Remote Access of Tissue Flap Monitoring

The final component of the design is the remote access capability. Smartphone applications are being widely used for various purposes due to the rising numbers of such devices and their usability. Currently, there are many types of remote monitoring devices on the market that monitor different physiological signals such as heart rate, blood pressure, blood glucose levels, and even body temperature. The project sponsors have informed the team that remote monitoring a patient's blood perfusion via Doppler technology/temperature continuously does not exist in the clinical setting. This device must utilize a programming language such as C++, CSS, HTML5, and/or Javascript to not only communicate results measured over a certain time period via the smartphone application, but also design the application itself. It must also possess capabilities for HTTP requests to a server for data acquisition.

Medical data security is also a concern due to the regulations set forth by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) under the Office for Civil Rights in the United States Department of Health and Human Services. This act controls how private patient medical information is distributed and what security protocols govern such distribution processes. It is governed by the HIPAA Privacy Rule, HIPAA Security Rule, HIPAA Breach Notification Rule, and HIPAA Patient Safety confidentiality provisions. The HIPAA Privacy Rule protects the privacy of individually identifiable health information. The HIPAA Security Rule sets forth national standards for the security of electronic protected health information. The HIPAA Breach Notification Rule requires involved entities and business associates to provide notification following the breach of unsecured protected health information. The HIPAA Patient Safety confidentiality provisions protect identifiable information being used to analyze patient safety events and improve patient safety. Whichever platform we utilize to store temporary patient medical information and transfer to the smartphone application will need to abide by these regulations, certifying HIPAA compliance.

3 Project Strategy

The goal of this project is to design a medical device to monitor the physiological status of post-transplant tissue flaps. It will be completed as a Major Qualifying Project (MQP) during the 2014-2015 academic year. The clients, Dr. Dunn and Dr. Dowlatshahi of UMass Medical, presented the team with an initial problem statement. The project team revised the client statement and formulated objectives and constraints. The device will be safe, biocompatible and adaptable. The following sections will further explain the client statement, objectives, and constraints.

3.1 Initial Client Statement

At the start of this MQP, the team was prompted with the following background and initial client statement:

“Microvascular free tissue transfer represents the transplantation of a body part/organ/tissue from one part of the body to another, within the same individual (autotransplantation), or from one person to another (allograft transplantation) by disconnecting blood vessels from the donor site and re-suturing them at the recipient site. Within the first few days after surgery there is a risk that blood clots may form and lead to failure of the surgery which is usually very lengthy (6h+) and technically demanding. This MQP will define and create a device that will allow for precise tissue monitoring using different technologies (Doppler flow, ultrasound, temperature, etc.) in a remote fashion (e.g. smartphone) in order to detect problems early and prevent failure of these challenging tissue transfer operations.”

The clients expressed their desire and the clinical need for such a device. Further discussion with the clients yielded more explicit expectations for the project. The team quickly learned that the current monitoring technologies exhibit certain difficulties in their use. Through discussions with the clients, the first objectives and constraints were established. The first objective described that the device must be able to locate and provide a correct distinguishable output signal for the smallest detectable vessels. The monitoring results must be easily interpretable for the user.

The client does not want the instrument itself to cause flap failure. Negative outcomes can be prevented by focusing on safety regulation; a primary focus for medical devices that we must acknowledge within the core of the design. There must be minimal pressure or force applied to the flap in order to prevent vessel occlusion. The device must be able to easily adapt to any surface or curvature of the body. Adaptability provides versatility for the device and improves the marketability of the device. The device will also need to monitor the patient for three to five days, during the standard postoperative stay in hospitals for recovering patients.

3.2 Functions

The device is able to acquire multiple signals from the patient’s tissue, process this data in a way that provides a clear signal output, and then export this information to the smartphone application for user interpretation. The project development has been guided by these goals. These features will improve on existing technology and make new sources of data available for the clients.

The device will improve usability in comparison to other monitoring modalities. Surgeons and nurses commonly use the ultrasonic Doppler probe for monitoring tissue flap transplants. Users often struggle with localizing vessels, orienting the probe, and acquiring a strong signal. These difficulties affect the end-user experience and must be accounted for if the device will support long-term, consistent use. The device is simple to handle and convenient to setup without the need for extensive training to use the device.







The clients look to acquire favorable output signals. In order to achieve a high performance, the device must be able to produce reproducible and linear outputs. The device will be sensitive, providing a sufficient resolution as determined by the surgeons. The quality of the signal output has been compared to existing Doppler monitors that the clients use. The clients have reported that the remote monitoring device offers a high fidelity and resolution, when compared to existing monitor setups. Comparisons to existing monitors, and feedback from the clients helped guide development of the remote tissue monitor.

Once the signal is acquired and stored, it will be available for surgeons. Surgeons will be given the opportunity to review the recent history of a patient’s flap. Surgeons and data analysts may also collect data sets for advanced efforts to improve flap salvage rates. Adaptive trends and patterns may be encountered within the sets of the saved data. Future research could be used to improve future algorithms for detecting physiological complications of tissue flaps.

Remote monitoring has produced added value for the device. The client introduced remote monitoring as a key objective for this project. Monitoring a patient’s flap from a remote location provides surgeons with increased flexibility. A single person can now easily monitor a flap staff and surgeons as they discuss a tissue flap’s physiological status.

These functions serve to ease the difficulties of postoperative monitoring of free flap transfers. A summary of the improvements of our device over the current one is shown in Table 3.1. Device functions, as described in this chapter, helped guide design decisions and evaluations. Improved monitoring of tissue flaps will improve flap salvage rates. Re-exploratory surgery and other treatments can be performed before a potential problem threatens flap viability when caught early. This MQP provides the surgeons and operators of this device with a new set of tools for monitoring tissue flaps in a postoperative setting, as detailed in Table 3.1.

Table 3.1 - Functions Summary

Functions	Gold Standard	Our Design
Monitors continuously (3-5 days)		
Produce clearer signal output		
Export data for remote access		

3.3 Objectives and Constraints

Based on the client interviews and background literature review, the team has established a list of objectives and constraints for the overall design of the device. The objectives and constraints are organized in an Objectives Tree as seen in Figure 3.1.

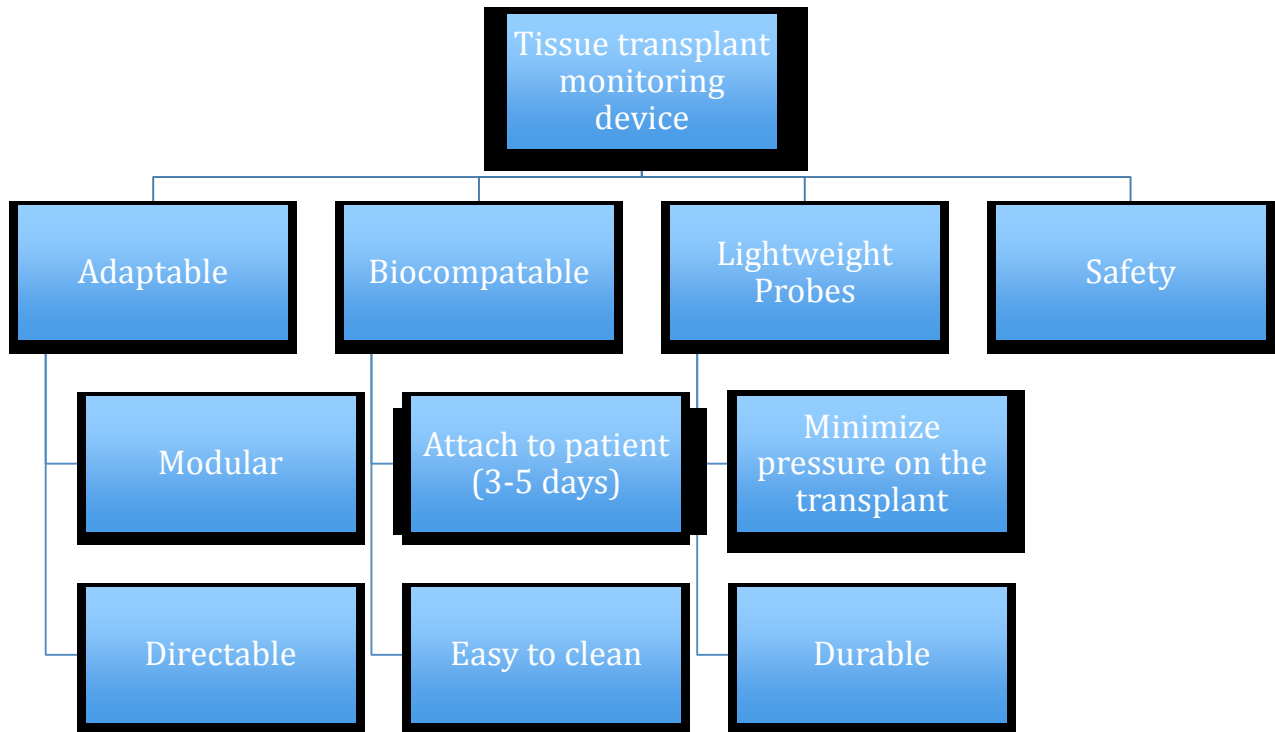


Figure 3.1 - Objectives Tree

After meeting the objectives, the device will be adaptable, biocompatible, lightweight and safe. The device will be constrained by the size and weight limitations, as well as choice of material for its design. The team has evaluated each of these objectives in order to ensure the conceptual designs fulfilled the client's desires. The evaluation was conducted using a pairwise comparison, Table 3.2, using a scale from one vote per member for each comparison. The higher the point total for the objective the more of an impact it would have on our final design. Using the pairwise comparison chart, the team was able to prioritize objectives. The objectives were ranked by the team in the following order: safe, lightweight, biocompatible and adaptable.

Table 3.2 - Pairwise Comparison Chart Completed by the Team

	Safe	Biocompatible	Lightweight	Adaptable	Total
Safe	X	5	3	4	12
Biocompatible	0	X	1	4	5
Lightweight Probes	2	4	X	4	10
Adaptable	1	1	1	X	3

A copy of the pairwise comparison chart was also presented to the clients, as shown in Table 3.3. The client utilized a different scoring system, in which he used one to four points per comparison rather than one to five scale that the group utilized. His ranking is as follows: safe, biocompatible, lightweight, and adaptable. The final concept design was created with the team's and client's objectives rankings in mind.

Table 3.3 - Pairwise Comparison Chart Completed by the Clients

	Safe	Biocompatible	Lightweight	Adaptable	Total
Safe	X	4	3	4	11
Biocompatible	1	X	3	3	7
Lightweight Probes	2	2	X	2	6
Adaptable	1	2	3	X	6

3.3.1 Safety

Safety must be considered in all phases of the monitor design in order to insure immediate and long-term success of the device. Without proper safety considerations, the device will not gain support from doctors or the larger medical device industry. The Food and Drug Administration (FDA) details many safety requirements that are required for all medical devices. Requirements for the 510(k) “premarket notification” will provide guidance for safety considerations while designing this tissue-monitoring device. Of particular concern during the design phase of our project is the “Electromagnetic Compatibility and Electrical Safety.” While designing the monitor, steps must be taken to minimize the risk it poses to patients and the surrounding medical environment.

The ISO standard 14974 is used to analyze potential risks in a medical device. ISO-14974 categorizes medical devices by the potential risk they pose to patients. Appropriate means of protection (MOP) are recommended for each category of medical devices. Likely, MOP will involve isolating circuitry that comes into contact with patients from potential outside electrical sources. The FDA uses the International Electrotechnical Commission (IEC) standard 60601-1 in order to confirm MOP perform adequately and minimize risk to the patient. Outside testing houses, such as TÜV Rheinland, are utilized in order to confirm medical devices meet the IEC 60601-1 standard. Before sending a new medical device to a testing company, often bench tests are performed in-house. Safety bench tests for our monitor device will involve High Potential and Continuity testing. A High Potential test provides a high voltage signal to the power input, usually in the magnitude of thousands of volts.

The monitor will have to isolate the patient circuitry from the high voltage input. This test confirms that a high voltage input, such as a surge, will not cause a potentially dangerous current to traveling to the patient from the device. Continuity testing measures the resistivity of ground at various points of the circuit in order to confirm there is not a threatening voltage build up. Considering safety during all phases of design and implementation is key to producing a successful device.

3.3.2 Probe weight

One of the most important objectives for the project is designing the device in order to be lightweight and minimize patient impact. This pertains to the probe itself because this is the only component that directly attached to the patient. The device will be minimally invasive, durable, and not place significant pressure on the flap. These characteristics will be kept in mind throughout the design of the project.

Although there are invasive solutions to the proposed problem, the client has indicated they would like a non-invasive device for tissue flap monitoring. An invasive device will increase the risks to a patient and challenges during the design process. For an invasive device, there are more considerations required for safety and materials used inside the body. FDA clearance is more heavily regulated for an invasive medical device. The design team will define their device as minimally invasive instead of non-invasive, because the surgeons will use sutures to most effectively attach the device to the patient.

The device must be durable to continue to operate successfully over its lifespan in a clinical setting. There are numerous design considerations to include when designing for durability. The designed product must be robust to withstand above normal wear and tear. This can be achieved with a strong design of the hardware to protect the working parts of the product. The device must be able to withstand exposure to bodily fluids it will encounter during practice. Material selection and the physical design will be considered to maximize durability.

The amount of pressure the device places on the tissue needs to be minimized to ensure the device does not cause harm to the flap. Pressure on the flap may cause an occlusion of blood vessels thus obstructing arterial and venous flow. The device will look to minimize its pressure applied to the flap through two design considerations: flexibility and lightweight. A flexible device will allow it to conform to various surface shapes of body. If the device was rigid, it could cause pressure points on a curved surface possibly increasing the pressure on the flap past a harmful limit. The device will be designed to be lightweight. If the device is too heavy, it may apply too much pressure on the flap. Increased pressure on the flap may also cause a different signal output as well as harm to the tissue.

3.3.3 Biocompatibility

Biocompatibility describes what the device is made of and how it interacts with a patient's body. In terms of the device's interaction with the body, the material it is made from must be completely bioinert so the device remains intact on the patient without degrading or causing any foreign body response. The device needs to be able to monitor the patient without any disruption to the signal such as biodegradation. Any biodegradation of the device poses serious risks to the devices functionality and the patient's safety. If the device is made of a degrading material, this could

potentially provide risk to the patient in terms of inflammation and possibly tissue damage if the material is absorbed into the body.

It is also very important for the device to strongly adhere to the tissue flap/coupling medium for long-term attachment. This is significant so that it does not fall off and lose the signal from the tissue flap. A need of our client is that the device stays attached to the patient's tissue flap for at least three to five days to ensure there are no post-operative complications.

3.3.4 Adaptability

Adaptability of the device is a quality that cannot be overlooked during the design process. The group defined adaptability as the device's modular and adjustable abilities. The design must be flexible enough to conform to different surfaces of the body while also accurately monitoring the venous and arterial blood flow through these regions.

This objective is significant because it widens the marketability of the device. The more adaptable the design, the more surgeries that it can be fit for, and the more patients it can help, leading to an increase in the potential sales market. This objective did receive the lowest amount of votes in our Pairwise Comparison Chart. The team aims to first create a successful and accurate device before making any adjustments to the design to maximize adaptability.

3.3.5 Constraints

The major constraints the team will face while designing this device are the size and weight of the device, and the materials used to make the device. The size and weight of the device is a major constraint to our design because the device cannot apply too much pressure to the flap, which may cause occlusions or interfere with the tissue monitoring. Capillaries refill at a pressure of 32 mmHg [32]. The device must exert less than 32 mmHg in order to insure proper blood flow. Another constraint for the design is the coupling medium material

The material used for the coupling medium must have a low-absorption coefficient, an acoustic impedance similar to the tissues being monitored, low cost, and general acceptability by the body [30]. Coupling media serve to attenuate the signal that is lost through the skin-air-probe interface, making them a vital component of the design. They may also serve as the adhesive material connecting the device to the skin. In order to adhere to the patient, the coupling medium must have a good wetting behavior, low viscosity, creep resistance, and a "debonding" ability, in order to support a quick and painless peel release procedure [33].

3.4 Revised Client Statement

After careful consideration of the client's concerns and developing an understanding of our objectives and constraints, the team generated the following revised client statement:

*This MQP will design a device that **monitors** the **anastomotic perfusion** of post-transplant tissue flaps. The device will **safely** interface with the patient for three to five days to **detect** ischemia. The output will be **remotely accessible**.*

3.5 Project Approach

In this section, we will discuss the project approach for each of the three components of the device. The three components are the sensing device, signal processing, and remote monitoring. Each portion of the overall device may be broken down into different features to clarify the design approach.

3.5.1 Sensing Device

One of the first phases of this project is the design and construction of the sensing device. The component must stay on the patient for 72 to 96 hours and sample physiological signals for monitoring. The sensing device is composed of the ultrasonic transducers for Doppler and thermistors for temperature monitoring, as well as the interface circuitry and casing structure holding these parts. The ultrasonic transducer used must have a small enough aperture to distinguish signals from individual blood vessels, while also having a suitable frequency to penetrate to the proper depth of the tissue for our application. The ultrasound monitoring console by Parks Medical is a continuous wave (CW) Doppler system which requires the team's utilization of a CW probe. The ultrasonic transducer will contain separate crystals for the transmitter and receiver. The thermistor will be selected for its high sensitivity to temperature variation and smallness in size. The thermistor must show little delay in relaying the apparent temperature of its local environment.

These sensors are brought together via the interface circuitry, which connects the sensors with the microprocessor and Doppler console. Since more than one ultrasound probe is being used and there is only one probe jack on the console, a multiplexing circuit must be used to decide which of the probes will be monitored at any given time. This may be done using various types of switch transistors or relays capable of passing the 9.3 MHz signal. When one of the probes is monitored, the corresponding switching component is turned on while the others are turned off. Each of the electronic switches is controlled by an output pin on the microprocessor that is either high (3.3V) or low (0V). The coding scheme written to the microprocessor will cycle through these output pins with only one pin set high at a time to ensure only one probe is powered and monitored and signals are kept independent. Finally, the auditory output of the Doppler console is passed to the microprocessor for digital signal processing. Figure 3.2 below is a block diagram depicting the connection between the probes, sensors, microprocessor, and Doppler console via the interface circuitry.

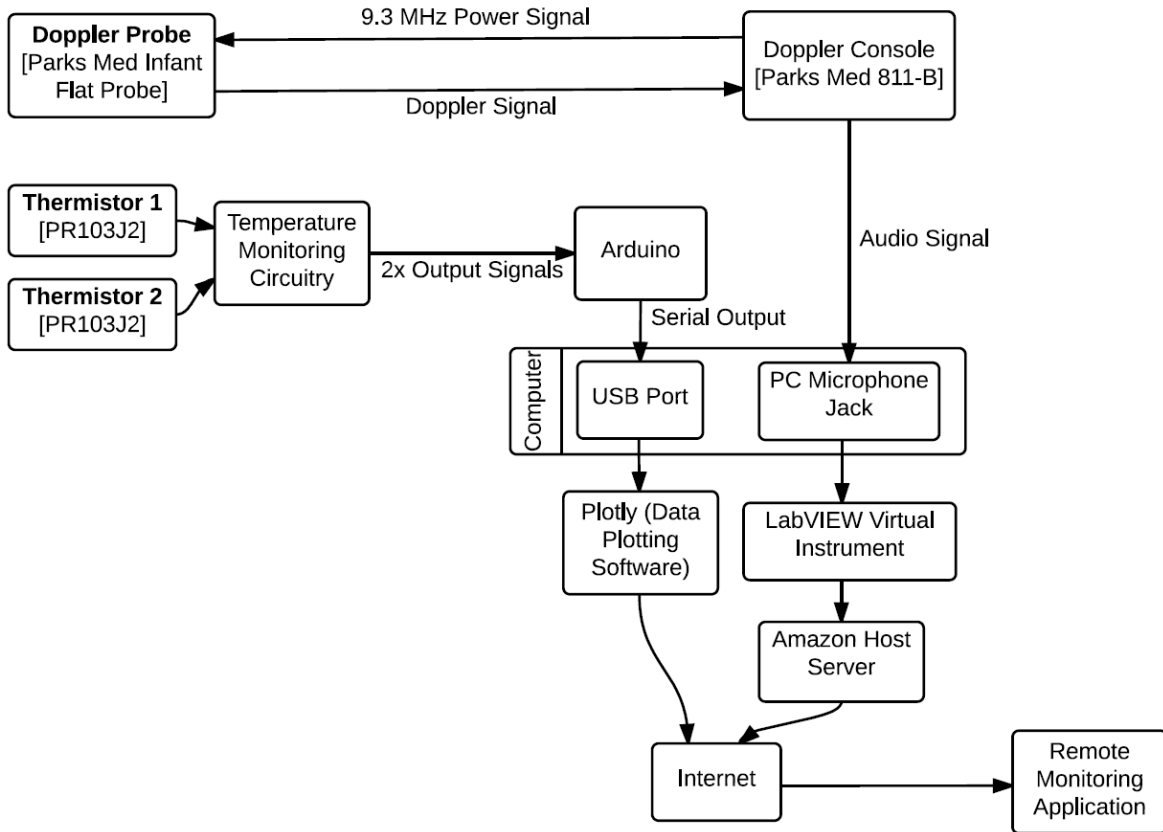


Figure 3.2 - System Diagram Overview

A similar multiplexing technique is also used in switching between which thermistor will be monitored. Figure 3.3 shows this thermistor multiplexing circuit. Each thermistor is set in series with a transistor to make a sensor and switch pair. These pairs are then set parallel to each other while only one transistor is active such that current only flows through one circuit path. The parallel circuitry is used within a Wheatstone bridge in order to supply a differential voltage used for amplification. The thermistor multiplexing circuit is shown below with the nodes labeled Pin 1 and Pin 2 representing the microprocessor's output pins to control the multiplexing feature, allowing the user to compare the temperature of the flap with the temperature of the skin that was not operated on. Rth1 and Rth2 represent the two thermistors, and the nodes Va and Vb used for the differential voltage.

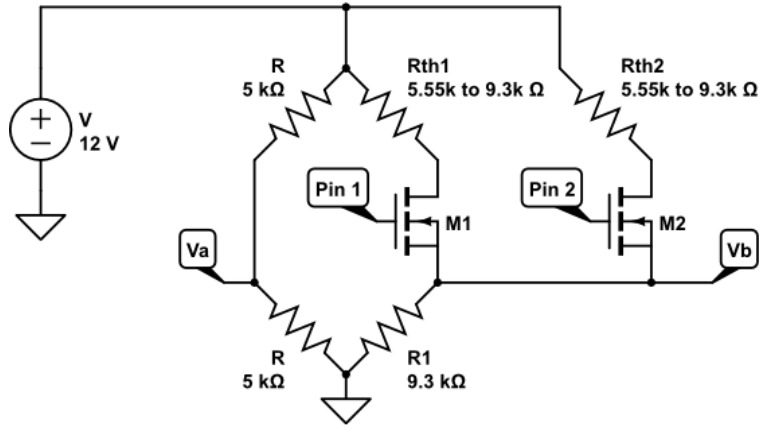


Figure 3.3 - Thermistor Multiplexing Circuit

The schematic shown in Figure 3.4 below is the differential amplifier circuit used to amplify the voltage difference of the Wheatstone bridge nodes Va and Vb. The amplifier works to scale the output voltage to a range of 0V - 5V that is compatible with microprocessor analog input pins.

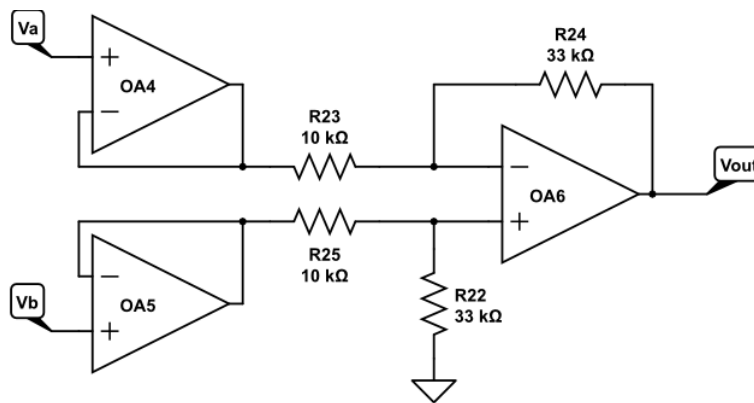


Figure 3.4 - Differential Amplifier Circuit

The project team will design a casing structure to house both the Doppler probe and thermistor. The design will meet the objectives that were established between the MQP team and the sponsors. Material properties will be greatly considered to ensure a flexible construct and biocompatibility with the tissue. Features such as loop hooks will be added to allow the doctor to stitch the housing to the skin. The housing is designed in Solidworks™ and prototypes are 3-D printed at Worcester Polytechnic Insistute's main campus.

3.5.2 Data Acquisition

Data acquisition is key to the backend of the remote monitoring app that is accessed by the surgeons. The data from the Doppler and temperature probes must be recorded and saved to a cloud server where it can be accessed by the remote app. The Doppler and temperature signals are recorded simultaneously. The Doppler signal is sampled at 44.1 kHz by a desktop computer's sound card. That sampling rate was chosen in order to preserve the fidelity of the audible Doppler signal that is recorded from the Park Med Ultrasound Doppler device. At the same time, temperature is

recorded using two analog inputs on an Arduino. The temperature is sampled at 100 Hz. Due to the relatively slow changing nature of tissue flaps temperature and client feedback, it was determined that 100 Hz would provide more than sufficient resolution for the device's temperature probe.

The Doppler and temperature signals are then saved to two different cloud locations. The Doppler signal is recorded using Labview. Within Labview the recordings are time stamped and segmented into 30 second segments. Each segment is then uploaded to Amazon's S3 cloud storage service. The S3 server is then made available through the app for the doctors. The temperature signals are recorded using an Arduino then uploaded to Plotly, a visualization service. Plotly produces an HTML snippet of the temperature probes plots to be embedded in the mobile app. In two stages, the data acquisition portion of the project records then saves the data streams in order to make them available for the remote app.

3.5.3 Remote Monitoring

The front end of the smartphone application, or the user interface, needed to be user-friendly for the doctor to easily and quickly access patient information on the go. The software needed to be able to access information from outside the application and display it directly on the screen for the user to monitor. For these purposes, the group researched multiple ways of developing the code for the application that were time efficient, effective for the group's needs, and relatively easy to learn with no previous knowledge of programming smartphone applications. These methods included using the Apple tutorials and development tools, developing JavaScript code using Eclipse, and using an online software program called AppGyver. Although Apple's website information on smartphone application development would enable the group to make an application directly for the type of phone our user possessed, it was very difficult for one person to learn especially based on the time constraint and the lack of experience. The tutorials were also very vague, often assuming that the reader knew much of the lingo in advance. Eclipse, would have been used to develop the application for the Android smartphone while also structuring the application based on our needs. However, the group would need to program massive amounts of code from scratch while also prototyping and testing our code. This process was not practical with our time constraint.

These methods led the team to use the online program AppGyver. This program allows one to structure the application based on the user's preference, orient buttons and icons freely, and then design features such as information logging for multiple patient usage. AppGyver's Composer feature allowed the group to structure the app and download the code it developed so that we could export and modify the project whenever we needed to fix minor flaws. Another advantage was the ability for both Android and iPhone smartphones to quickly obtain the app using a QR code that could be scanned with the AppGyver application (downloaded from the Application Store on each phone for free). This prevented our application from being restricted to one operating system. The AppGyver software also enabled the programmer to scan the application with his own smartphone so that it could readily be tested. This allowed for the programmer to change the code through either Composer or the project folder and have this change instantly updated for viewing on the smartphone. In order for multiple people to modify the code, a single AppGyver account was created, and the project folder was created in Google Drive.

4 Alternative Designs

In this section of the paper we will discuss the steps taken to reach our final design. Development was broken down by project sector. The probe, temperature and Doppler circuitry, signal acquisition, and the mobile app followed their own separate development paths. This chapter will detail the design process for each sector of the project.

4.1 Evaluated Monitoring Modalities

As part of the design process the team explored many solutions that are available to help meet the client's needs. The team considered several different technologies to ensure that the design offered the best solution for the sponsors. These included skin color (oxygenation), turgor (pressure), near infrared spectrometry (oxygenation), dye monitoring (blood flow), Doppler (blood flow), surface temperature, and pH. Some monitoring modalities were evaluated (skin color, turgor, dye monitoring) but ultimately deemed unsuitable for this project due to limited published research and experimentation into them or them being too invasive for our purposes. Alternative monitoring modalities are evaluated in the following sections.

4.1.1 pH Monitoring

One of the first alternative technologies explored by the team was pH monitoring. Although pH measurements offered a promising relationship for failing tissue flaps, it was ruled not feasible for the desired design. In order to measure the pH levels of the flap, the sensor would have to be invasive, which goes against the minimally invasive objective of the project. The non-invasive option for measuring pH does not calculate tissue pH but rather skin pH, which does not have the same correlation with ischemic tissue. In addition, the size of the skin sensing probes are too large for our application because they require a reference electrode in contact with a known fluid. It is for these reasons that pH was determined not feasible in the design.

4.1.2 NIR (Near Infrared) Spectroscopy

As described in Section 2.4 NIR was considered as a potential means for evaluating blood flow in tissue flap transplants. NIR had several benefits which initially made it an attractive option for this project. NIR could measure hemoglobin levels at different depths, uses relatively low cost parts, and would be easy to prototype. Ultimately, NIR was discarded as a means for measurement for several reasons. NIR has only been used in a limited number of applications for monitoring oxygenation. Past applications involve using NIR on the hand or head, where the subcutaneous structure is relatively uniform and free of large muscles.

In contrast, many locations on the body have significant amounts of myoglobin in the tissue. Myoglobin in muscles absorbs NIR like hemoglobin, interfering with measurements to determine oxygen levels in a tissue sample. Variations in the tissue structure could also produce unexpected absorption patterns of NIR. If the project utilized NIR as a means of detection it would not be robust enough to work on variety of different flaps on different parts of a patient's body. Doctors are also reluctant to work with NIR after poor experiences with NIR based pulse-oximeters. For the described reasons, NIR was discarded as a potential means of measuring blood flow in tissue flap transplants.

4.1.3 Doppler (Direct Monitoring Approach)

Within the first 10 weeks of the project, the team began to assess the existing ultrasound Doppler technologies. UMass Memorial Hospital, uses the Parks Medical 811-B model ultrasound console for monitoring the patient flaps. The device was dismantled to observe and test the internal circuitry along with looking at the provided schematic of the device. The team's initial and predominant idea for moving forward with the Doppler technology was to redesign a similar circuit. The new circuit would use more contemporary components on a PCB (printed circuit board) to utilize SMD (surface mount device) components, allowing the physical size of the circuit board to decrease substantially and maintain greater control over the high frequency operation of the device.

The circuit by Parks Medical (as shown in Appendices 6.1) uses discrete components to construct a number of sub-circuit systems which are cascaded to give the device its full functionality. A high frequency oscillator circuit is used to generate a 9.3MHz signal which also powers the ultrasound probe's transducer. The reflected signal that is received by the probe is passed to a circuit that demodulates the Doppler effect within the signal. Both the high frequency oscillator and demodulating circuitry requires an advanced knowledge of microelectronics and high frequency circuits in order to fully understand the workings of the Parks Medical Doppler console. The team estimated that it would require too much time to learn and apply the knowledge necessary to construct a similar design. This would be a major setback and would ultimately require advanced PCB design skills to handle the MHz frequencies without acting as an antenna for other ambient electromagnetic waves. The team confidently decided to move past this initial approach for these limiting reasons and advanced towards the simpler approach of monitoring the audio signal that is the output of the Doppler console. This signal is the already demodulated content of the reflected ultrasound signal. The audio monitoring approach is already documented in Chapter 3.4 Project Approach.

4.2 Probe Casing Designs

This section discusses the alternative designs, compares different biomaterials and shows the preliminary designs and data of the probe casing.

4.2.1 Alternative Designs

The group's "Christmas Light" Model is seen in Figure 4.1. It is made up of male and female jacks at the top and bottom of the probe that fit into one another. This concept would allow the probe to become part of an array across the flap. This is similar to the series nature of Christmas lights. The probe would be packaged in strips of these probes, allowing maximum efficiency in delivery. One of the faces of the probe would have been the sensors that we have chosen while the opposite side would be the input to the cord connected to the Doppler power circuit.

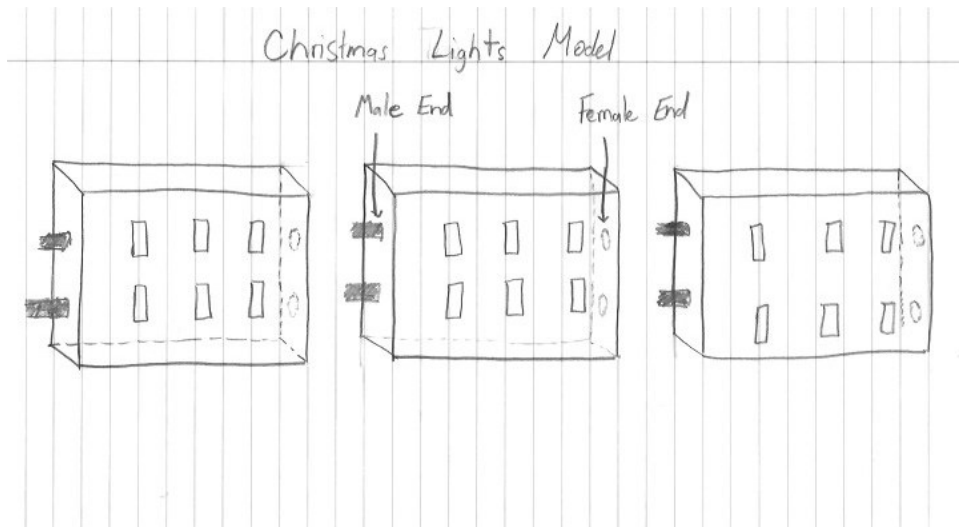


Figure 4.1 - "Christmas Light" Model

Figure 4.2 is our "Tape" Model Probe. It is categorized with a flat face that would cover the flap surface. The areas without a sensor exposed would have an adhesive coating that would allow the probe to stay connected to the patient. On this flat interface would be an array of sensors with a break in the center of the probe to test the capillary refill of the vessels. This probe would also be connected in series with the other probes. The array would be torn or separated at designated spots in order to allow the surgeons to select the proper size array for any flap.

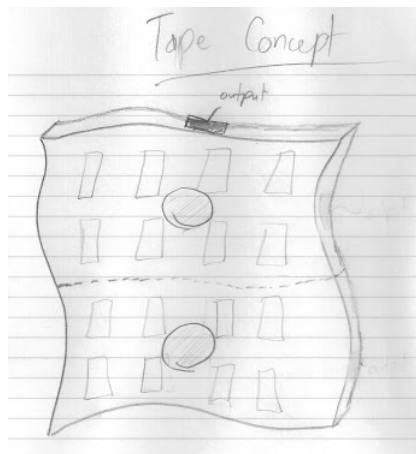


Figure 4.2 - Tape Model

The "Netting" Model, Figure 4.3, utilizes an array of sensors. This probe design having has the different probes on a mesh-like fitting that would be able to pick up their particular bio-signal hold the Doppler sensors in place. This combats the issue of adhesion to the surface of the flap. The netting helps adhere the sensors to the skin without occluding the surface of the skin.

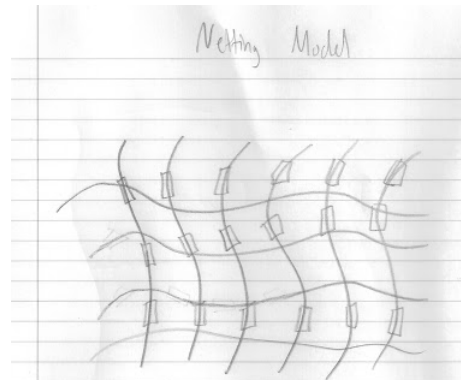


Figure 4.3 - Netting Model

The final concept design was the "fixture model" as seen in Figure 4.4. This design was a casing that contained the Doppler probe as well as any additional probes we wanted to adhere to the skin. This model had loophole features that would allow the device to suture to the skin.

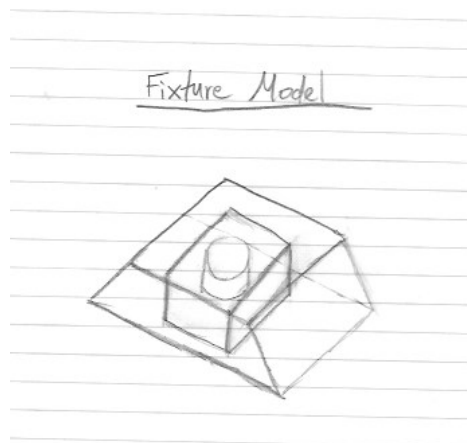


Figure 4.4 - Fixture Model

4.2.2 Biomaterial Comparison

After doing research on the materials in Table 4.5, we determined that the most viable option that fulfills the design needs is silicone. It is a great adhesive on tissue, matches the impedance of skin very closely, is bio-inert so it won't cause any inflammation or allergic reactions, and is viscous enough that it can be easily peeled while also keeping the probe attached to the tissue.

Polyacrylamide is found to be a possible neurotoxin and can penetrate the blood over time. Epoxy is too permanent preventing the doctor/surgeon from adjusting the probe location. PEG is not very adhesive to the tissue and also has the potential of penetrating the skin. Therefore, silicone will most likely be used in the final design to attach the probe to the skin. A summary of biomaterial attributes is included in Table 4.1.

Table 4.1 - Biomedical Comparison

Biomaterial	Tissue Adhesion	Acoustics	Biocompatibility	Viscosity
Polyacrylamide	Good	Low attenuation	Blood penetrable, Neurotoxin	Medium
Silicone	Good (Up to seven days)	Low attenuation	Bio inert (Low chemical reactivity)	Medium
Epoxy	Very strong (Permanent)	Low attenuation	Possible Allergic reaction	Variable
Polyethylene Glycol	Not adhesive, Skin penetration	Impedance Close to skin	No skin toxicity	Medium

4.2.3 Needs Analysis

The casing of the probe has a few basic needs that it needs to follow. The material needs to be able to conform to the skin of the patient while keeping the transducer and thermistor in the proper location. In order to do this the stiffness of the material must be low, so bending around the flap takes place. Next, there were concerns about heat emitted by the ultrasonic transducer affecting the thermistor. This made thermal conductivity an issue to be overcome as well. The final consideration was the ability to stick to the skin. This was the first obstacle overcome because Dr. Dowlatshahi wanted to suture the probe in place.

4.2.4 Conceptual Designs

Each one of the probes that were previously discussed has been considered for our final design of the probe. One common issue for all of these models is the price of the ultrasound transducers as well as the thermistors that are being used. The cost of these two components is staggering and would limit the number of sensors that the team could use in an array.

The first probe, the “Christmas Light” Model has a variety of design flaws. The rectangular and sharp nature of the design would make it difficult for adhesion to the skin for three to five days. This would also increase the necessity of the medical professionals to add an increasing amount of ultrasonic gel in order to maintain a strong signal. However, it would be effective in the short term and would adapt to the surface that it’s being applied to as well.

The next probe to be discussed is the “Tape” Model. This model is flat to the skin, and addresses the problem of adhesion to the skin with the adhesive layer. However, the conductive gel may interfere with the effectiveness of the adhesive layer. The surgeons believe discharge from the flap itself would also interfere with the adhesive layer. The flexible nature of the covering would allow for the probe to match the curves of the flap perfectly. Also, the spaces where there are no covering of the flap allow the doctors to monitor the flap based off of its color and cap refill. Because the model is so thin and will be subject to wear, it may not be safe for repetitive movement.

The third model that was considered is the “Netting” Model. This model is similar to the previous one in addressing the problem by combating the adhesion to the flap. However, the ultrasonic gel would also be a problem because it would seep through the open areas. Applying such a large array

while ensure the sensors are placed on blood vessels with strong signals becomes very challenging. The team has opted to investigate designs that incorporate more features in order to improve ease of use.

For this reason our final design would need to take the positive aspects of all these models and combine them. The leading model is the "fixture model." A version of the "fixture model within Solidworks can be seen in Figure 4.5.

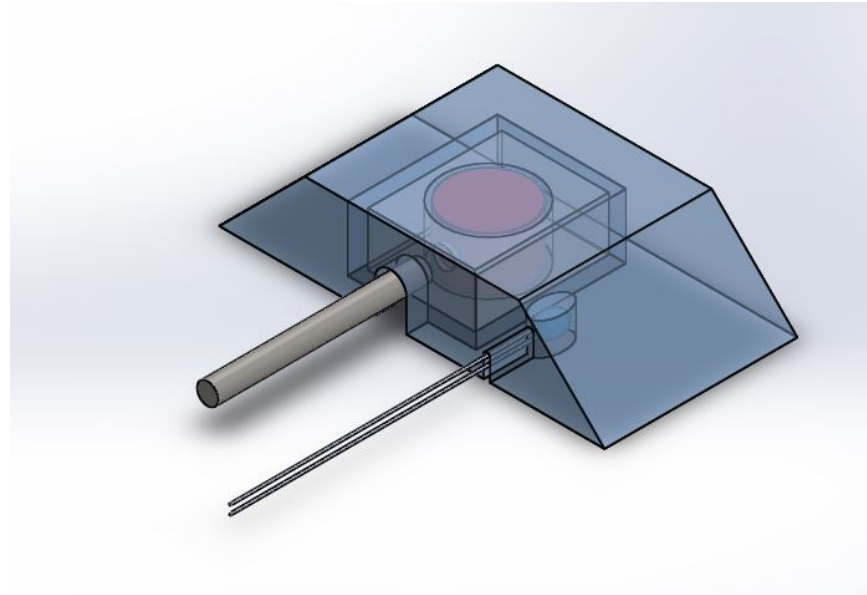


Figure 4.5 - Solidworks Sketch of the Fixture Model

The probe needs to connect to the skin while housing one or two transducers. The probe is as flat to the surface as possible while still having room for the transducers and the gel. The probe adhesion will be maintained by suturing the sides down on the surface of the flap. A comparison of different probe designs can be seen in Table 4.2.

Table 4.2 - Probe Design Evaluation Matrix

	Effective	Clear Signal Output	Safety	Minimal Patient Impact	Biocompatible	Adaptability	Total
Tape				X	X	X	3
Christmas Lights	X					X	2
Netting			X	X		X	3
Fixture	X	X	X	X	X		5

4.2.5 Preliminary Designs

The probe is of two main aspects, the thermistor and the ultrasound transducer. There were many different possibilities that were considered for the probe enclosure. Originally, the probe was going to have two probes for both ultrasound and temperature in order to gather a reference signal. The probe design in Figure 4.6 contains one sensor for both applications.

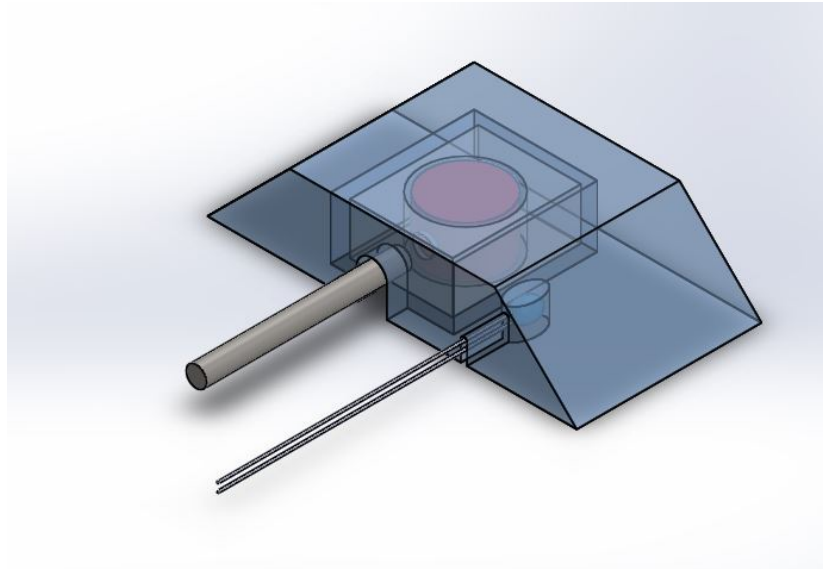


Figure 4.6 - The Original Probe Casing

This casing encloses the two probes in a three dimensional trapezoidal configuration. Within the enclosure there are openings that allow the probes to be nested in the housing unit. The angled edges allows for it to be taped to the skin surface. Upon presenting this model to our clients, suturing holes were requested. The design in Figure 4.7 was the updated design.

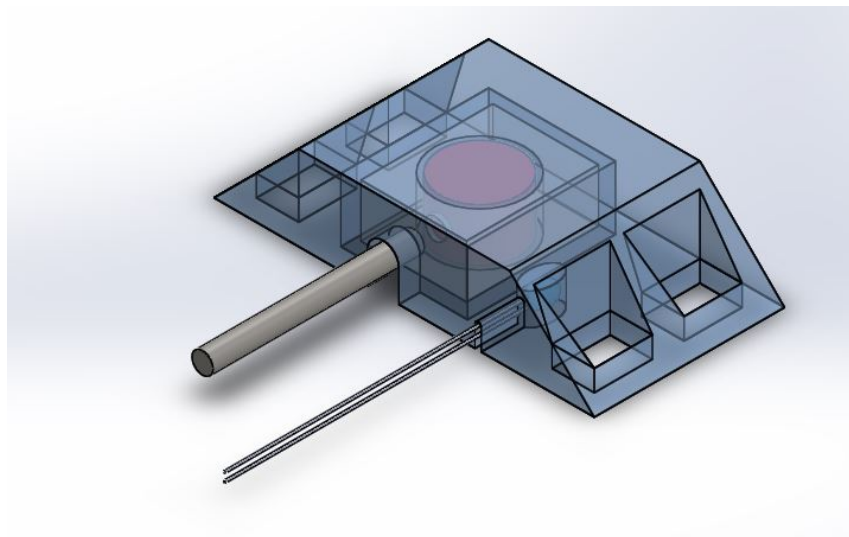


Figure 4.7 - Angled View of the Original Probe

This model resembles our former design and now has the openings on the angled ends of the casing. These holes allow the doctor to suture the probe on to the patient flap. This casing was printed in the rapid-prototype machine located at WPI and used in our live animal test.

4.2.6 Preliminary Data

The live animal test exposed many improvements that needed to be made to the probe casing. As a team and with notes from our clients we determined several problems of the probe housing. First the suturing holes were too large, and too few. Second we would need reduce the size of the probe housing. This probe used 0.38 cubic inches of printed material. Third the edges of the probe casing were too sharp. Fourth the probes were too deep in the casing and lost contact with the skin. Finally wire management needed to be improved.

4.3 Circuitry

This section explores the design processes of temperature monitoring and Doppler ultrasound monitoring. For each monitoring modality, the needs, concept designs, alternative designs and preliminary testing are discussed.

4.3.1 Temperature Monitoring

4.3.1.1 Needs Analysis

In order for the temperature monitoring circuitry to be effective, there are three main criteria it must fulfill. The circuit must operate and be able to monitor the appropriate temperature range of 80°F to 102°F (26.7°C to 38.9°C). There must be two temperature probes in order to monitor the difference between two temperatures. Finally, the output voltage of the circuit must range from 0-5V to correspond with the input temperature range (0V at 80°F and 5V at 102°F). There are a number of ways this circuit may be designed and constructed, but they must fit these needs for the system to function correctly.

4.3.1.2 Functions and Specifications

The necessary requirements for temperature monitoring and the specifications of the temperature probe thermistors must be understood for the design and development of the temperature circuitry. The most appropriate thermistor found for this project's application was PR103J2 NTC-type thermistor available from Digi-Key. This component is documented to be functional within a -55°C to 80°C range and is accurate to within 0.05°C. The plot in Figure 4.8 shows the thermistor resistance versus temperature within the temperature range being monitored. The data set was acquired from the specification sheet for the thermistor available on the Digi-Key website.

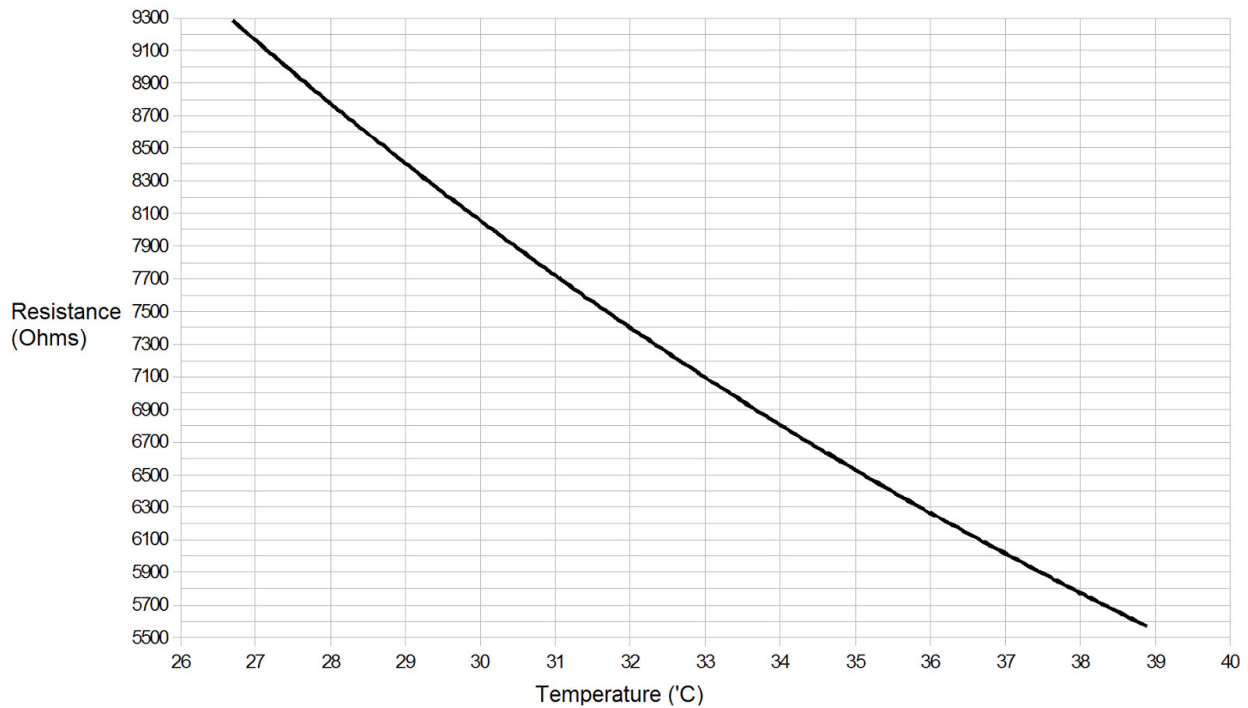


Figure 4.8 - PR103J3 Resistance vs. Temperature [34]

The thermistor measures a resistance of 9.285k Ω at the highest monitored temperature of 38.9°C and measures 5.568k Ω at 26.7°C. For more simple calculation purposes, the circuit is designed using the thermistor resistance values of 5.5k Ω and 9.3k Ω for the peak high and low temperatures monitored respectively. By using these values, a slightly greater temperature range may be monitored, however, the difference in range is of little significance in the final operation and output range of the circuit.

4.3.1.3 Conceptual Designs

There are many different circuits that may be designed for this temperature monitoring application, however, the conceptual design remains consistent throughout. Over the monitored temperature range of 80°F to 102°F, the thermistors experience a resistance ranging 9.3k Ω to 5.5k Ω , respectfully. Conceptually, the circuit is to output 0V when this resistance is 9.3k Ω and output 5V when measuring 5.5k Ω . Figure 4.9 shows the relationship between these three variables where output voltage is dependent on thermistor resistance which is dependent on temperature.

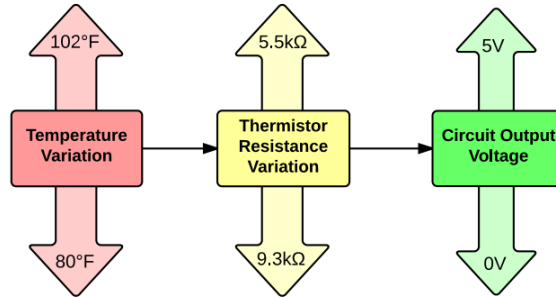


Figure 4.9 - Conceptual relationship between variables in temperature monitoring circuitry

Since the observable output of the circuit is a voltage, the variable thermistor resistance must be converted to a corresponding variable voltage. This is easily done by using a voltage divider. A resistor placed in series with the thermistor, both connected to a voltage source allows the voltage node between the two resistors to fluctuate with the resistance change. This basic voltage divider is shown in Figure 4.10.

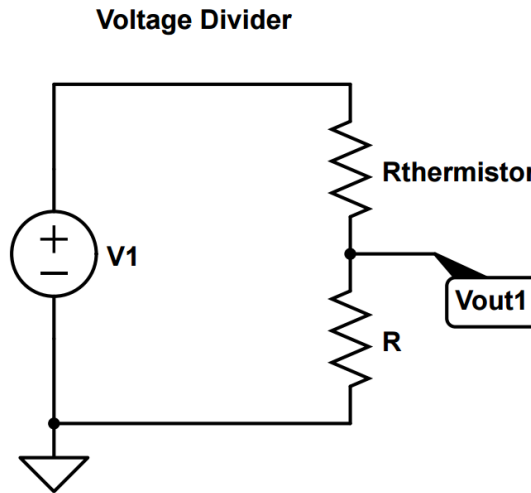


Figure 4.10 - Basic voltage divider for concept circuit

This output voltage from the voltage divider will have a certain voltage range based on the source voltage and the resistance of the paired resistor, but is not the desired output voltage that ranges from 0V to 5V. The output must be scaled and offset in order to achieve the 0V to 5V range. This is done with an amplifier circuit. The voltage divider output serves as an input to the amplifier which outputs the desired voltage range based on the resistor values used to set the gain and the offset voltage. Figure 4.11 shows the basic non-inverting operational amplifier circuit whose gain is $(1+R2/R1)$. If the input V_{in} ranges 0V to 1V, then this must be amplified or multiplied by a gain of 5 to achieve 0V to 5V. This gain may be set using an $R2/R1$ ratio equal to 4.

Non-Inverting Amplifier Circuit

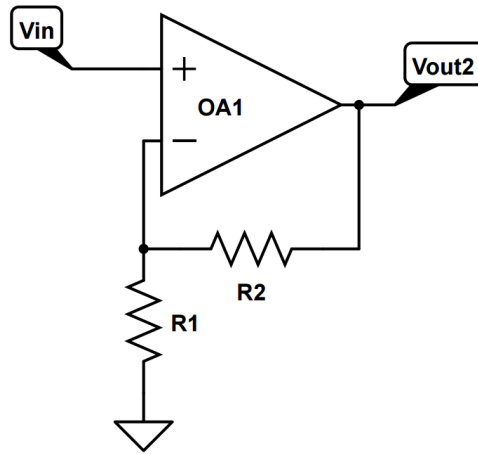


Figure 4.11 - Basic non-inverting amplifier for conceptual circuit

The combination of voltage dividers and amplifiers achieve the requirements and specifications for the temperature circuitry. The preliminary and alternative designs investigate several designs that attempt to implement this concept.

4.3.1.4 Preliminary/ Alternative Designs

The preliminary design for this circuit incorporates a Wheatstone bridge, MOSFET switches and an instrumentation amplifier. The bridge creates two voltage dividers, one of which would maintain a fixed voltage as a reference point and the other contains the thermistor such that the voltage fluctuates with a change in temperature. These two voltages from these dividers would each be passed to buffer amplifiers as to not load the voltage dividers. The buffered voltages serve as inputs to the differential amplifier which scales the difference between the two voltages and output the desired range in reference to a set offset voltage. Figure 4.12 shows this preliminary design circuit.

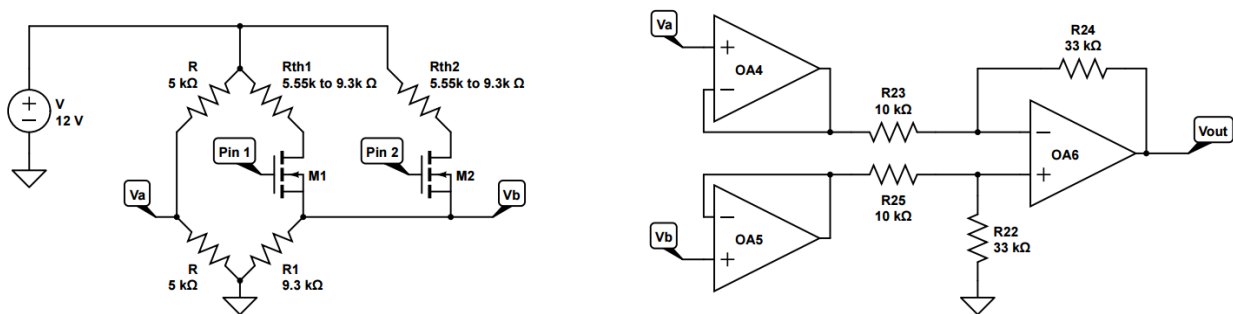


Figure 4.12 - First temperature monitoring circuit concept

The Wheatstone bridge portion is shown to the left in the figure where both 'R' resistors generate a fixed 6V point, V_a , that is half of the 12V source voltage. Node V_b of bridge is controlled by the switching between thermistors via MOSFETS M_1 and M_2 . When M_1 is on and M_2 is off, the thermistor R_{th1} is being monitored and the R_{th2} when the transistors are controlled opposite. The transistors are controlled via their gate pins, noted as Pin 1 and Pin 2. The multiplexing, or switching between

thermistors was originally considered to be necessary due to the belief that only one probe could be monitored at a time. This multiplexing feature is held for several of the alternative design circuits.

When monitored at the low temperature point, the thermistors are to measure about 9.3kOhms which in series with R_1 generates 6V at V_b . At the high temperature point, a voltage divider of the thermistor's 5.5kOhms in series with the R_1 would generate 7.52V at V_b . This difference of 1.52V requires amplification by the differential amplifier with a gain or scale factor of 3.3 in order to exhibit the desired output range of 5V necessary to maximize usage of the Arduino's ADC, analog-digital-converter. The gain is set by using an R_2 of 10k and an R_3 of 33k, a ratio of 3.3.

Preliminary Design Testing

In testing this preliminary design, the op-amp had output the appropriate 5V at the high temperature point, but could not decrease to 0V at the low temperature point. The op-amps cannot output voltages too close to their rail supply voltages, thus leaving the lowest possible output to be 1.3V instead of 0V. This characteristic was not immediately considered in the design. In addition to this issue, the MOSFET control would not work as initially thought; the transistor required a voltage differential between the gate and source pins. The source pins of M_1 and M_2 are connected to V_b which is not an appropriate reference point to drive a voltage from. This would require the Arduino's ground being referenced to V_b which is setup to float with relation to temperature. These issues were assessed carefully and the preliminary circuit was redesigned as an alternative solution.

Secondary Alternative Design

This alternative design is an attempt to rectify the issues of the initial, preliminary design. Figure 4.13 shows this particular circuit design.

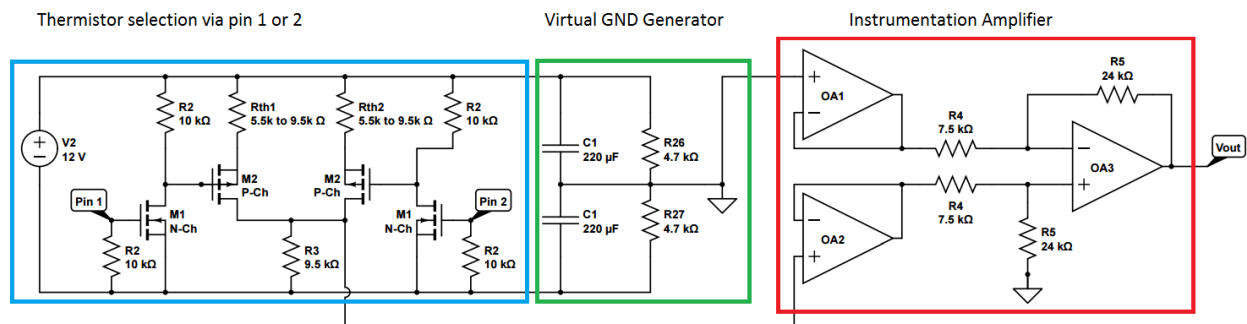


Figure 4.13 - Second Alternative Design Temperature Monitoring Circuit

The addition of the P-Channel MOSFETS M_2 in the above circuit are used to correct the previous control issue. When Pin 1 is controlled with a 5V input, the adjacent N-Ch transistor is active such that its drain pin is brought to 0V. This connects the corresponding P-Ch transistor's gate to the 0V and makes it active, reducing the drain-source resistance to less than 1mOhm. This allows monitoring of R_{th1} and will switch to monitoring R_{th2} when Pin 1 is low and Pin 2 is high. Connection to the Arduino is made possible by connecting the digital output pins to Pin 1 and Pin 2 while the

Arduino's ground may be directly connected to the circuit ground instead of a floating reference point.

To solve the issue of the differential amplifier's inability to generate the 0-5V range (an issue from the preliminary design), the amplifier is instead referenced to a different offset point. This point is shown with the inverted triangle symbol in the above circuit diagram and is intended to represent a virtual ground. This virtual ground point is generated using the voltage divider in the middle of the diagram containing R_{26} and R_{27} . By referencing this point, the op-amp output would appear to be able to range from -6 to +6V as the 12V supply is split by the voltage divider. The capacitors C_1 were added to absorb fluctuation in the 12V supply voltage and to offer current to the loading circuit when demanded.

Second Alternative Design Testing & Preliminary Data

This circuit was tested by individually testing the switching function of the transistors. After this was found to be operational, one of the thermistors was placed in a beaker of hot water which would be slowly cooled to the lower temperature point. A digital thermometer was also placed in the beaker to observe the temperature through another measuring device. Figure 4.14 below shows the resultant data. Obtaining a precise temperature of the water is difficult and there is no guarantee the thermistor would experience the same temperature as the digital thermometer. The plot shows the temperature shown by the thermometer and the output voltage of the circuit for one of the thermistors.

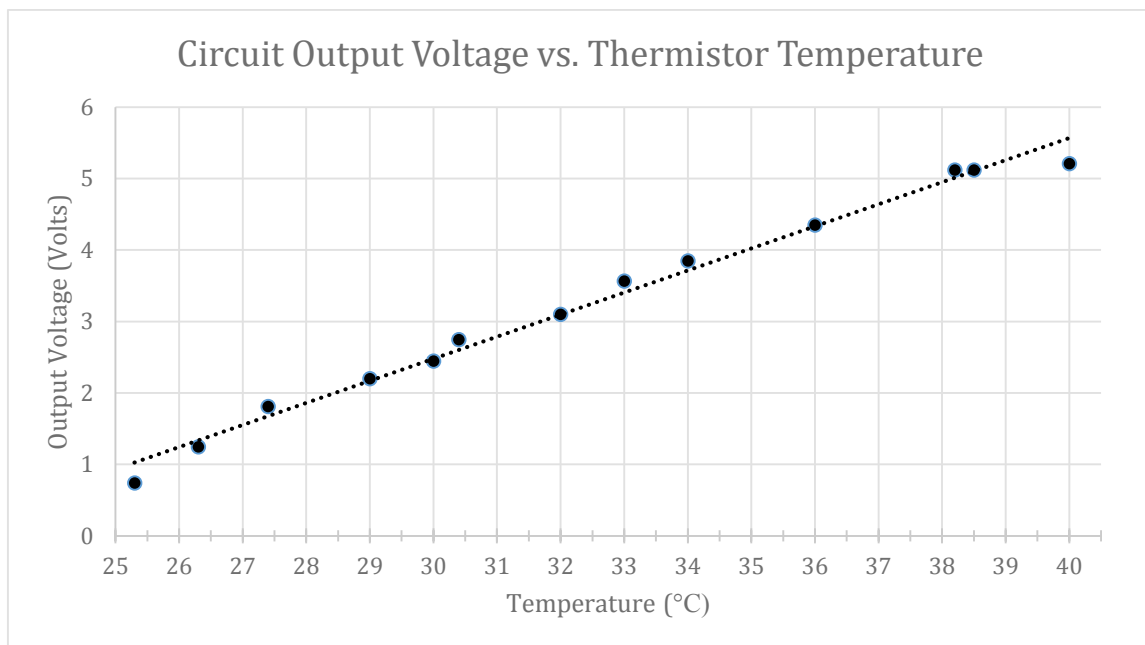


Figure 4.14 - Circuit Output Voltage v Temperature

While the circuit showed reliable operation, it was discovered that this circuit was still inadequate for control via the Arduino. The digital control pins would control the transistor gates Pin 1 and Pin 2, and the Arduino would be connected to the circuit ground. The output of the circuit would serve

as input to an analog pin, however, the output voltage required being measured from the virtual reference point which was 6V. The circuit needed to be redesigned such that the Arduino ground was the reference point for the transistor control voltage and also as the reference for the circuit output. These issues required an additional alternative design attempt to allow Arduino control synchronization.

Third Alternative Design

In resolving the issues of the secondary alternative design, opto-isolators were used to isolate the Arduino from the circuit's power supply. The circuit below in Figure 4.15 shows the updated schematic with their use.

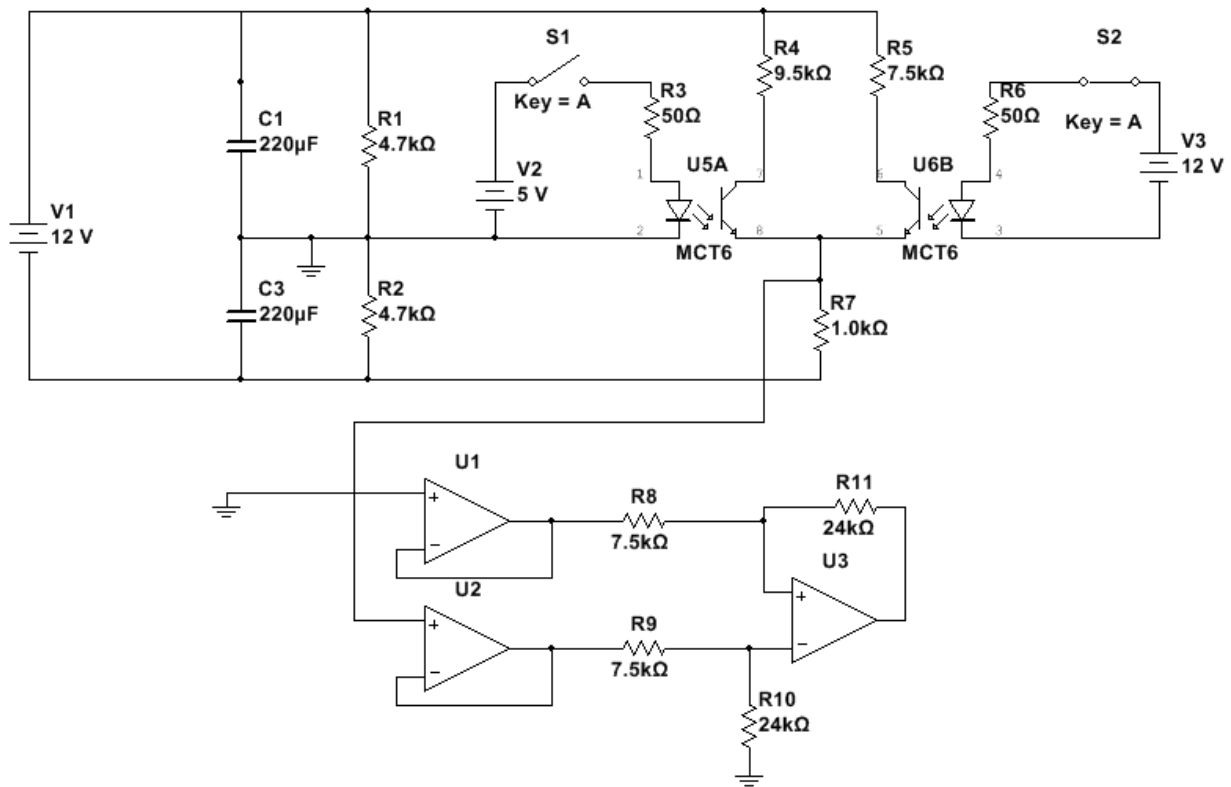


Figure 4.15 - Simulation schematic for use with opto-isolators

The upper left portion of the schematic shows the virtual reference point as indicated by the actual circuit ground symbol. This generates a +6V and -6V dual supply for powering the op-amps. The Arduino ground would be connected to this circuit ground and the digital control pins would power the opto-isolators as the indicated 5V voltage sources V_2 and V_3 . The opto-isolators exhibit low impedance when turned on and a theoretical infinite impedance when turned off. By placing them each in series with their corresponding thermistor and then in parallel with each other, it allows either one thermistor to be monitored, neither to be monitored (both opto-isolators are off), or both opto-isolators are on and the thermistor resistances are placed in parallel (not an appropriate use for this circuit). The voltage divider circuit containing the thermistors passes its voltage to the instrumentation amplifier whose reference is to the circuit and Arduino ground.

This circuit was simulated in MultiSim and tested in the lab, both exhibiting proper function. As shown in the simulation, switch S_1 is closed which turns on the adjacent opto-isolator U_4 and thus allows monitoring of thermistor R_1 which measures 5.5k Ω (corresponds to high temperature point). The output of the circuit in this configuration is 5V with reference to ground which is the desired output for the high temperature point. This behavior was replicated on the breadboard circuit, however, consultation with project advisors pointed towards simplification of the circuitry. The simplified final design is referred to in the design verification section of this report.

4.3.2 Doppler Ultrasound Monitoring

The following section discusses the needs analysis, functions conceptual designs and preliminary results regarding to Doppler ultrasound.

4.3.2.1 Needs Analysis

Dr. Dowlatshahi presented the idea of using two ultrasound probes for monitoring a patient. This is a novel idea that could provide more useful data to surgeons. The circuitry for this concept began development, however, in the halfway through the design and construction of an alternative design, the concept was referred to Dr. Dunn who was unaware of this potential feature. His reaction to this idea was that it could have potential in the future, but it is not currently practical within their monitoring practice.

4.3.2.2 Functions (Specifications)

In order to design this system properly, the Parks Medical 811-B Doppler console needs to be understood. The frequency used by the probes and console is 9.3MHz. All components used in the design of this circuitry needs to be usable in a range containing this frequency. The magnitude of the power signal at its maximum is 5V. The console can only power one probe and receive a signal from one probe at a time. Circuitry would need to be developed to interface the two probes with the uni-probe console.

4.3.2.3 Conceptual Designs

The dual probe to single probe interface requires circuitry that selects and switches between two probes. This is known as multiplexing, where one probe would be selected to be powered by the Doppler console, monitor the tissue, and output the Doppler signal to the console. The concept diagram in Figure 4.16 shows this feature with the Arduino representing the digital control input for the multiplexing circuitry that would control which probe is being monitored.

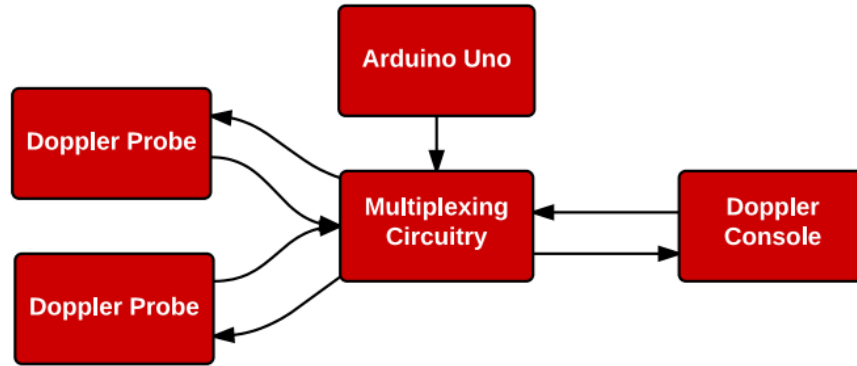


Figure 4.16 - Concept diagram for Doppler probe switching circuitry

4.3.2.4 Preliminary/ Alternative Designs

The initial circuit concept for this switching function was thought possible by using MOSFETs. The schematic below in Figure 4.17 shows this concept utilizing N-Channel MOSFETs that are cascaded to open or close the paths of the 9.3 MHz signal (the probe's input power signal) and the corresponding Doppler signal (the probe's output signal).

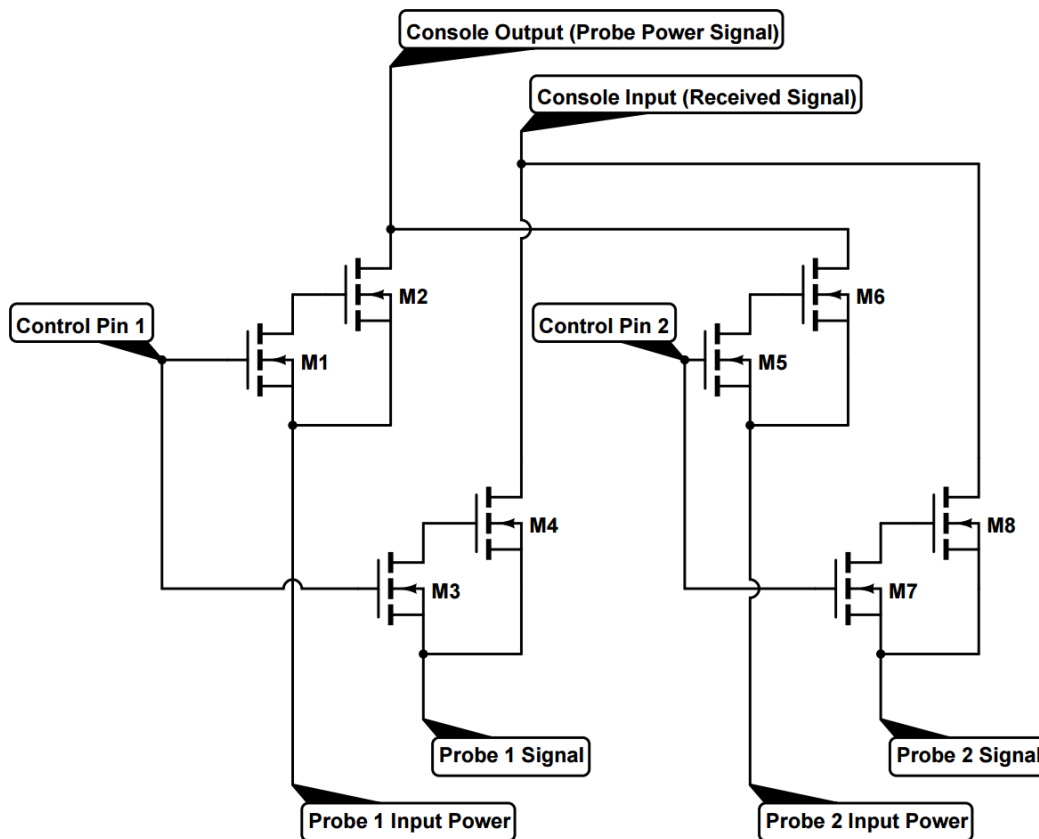
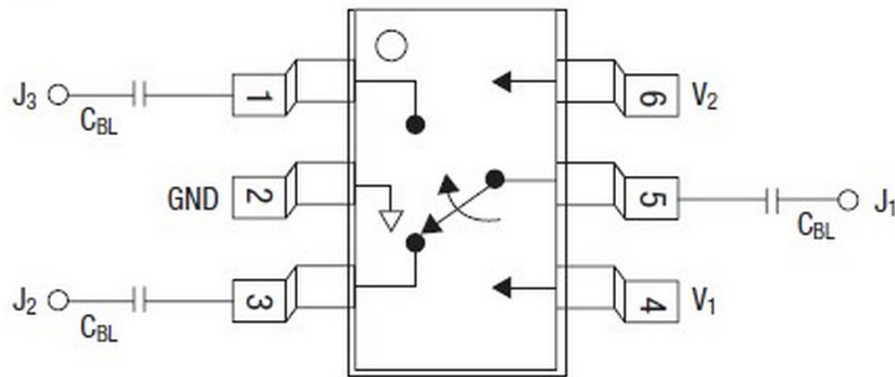


Figure 4.17 - Initial Doppler Multiplexing Circuit Concept with MOSFETs

Control Pins 1 and 2 would be controlled by the Arduino's digital output pins with a low, 0V signal or a high, 5V signal. These digital signals would turn the corresponding transistors on or off at the

transistor gates which would turn them on or off, low or high resistance respectively. The cascaded transistors are setup similar to a Darlington Pair BJT combination. The secondary transistors require that their gate and source pins are connected in order for them to be considered on or active. In the active state, the drain to source resistance is minimal, however, this is only for DC resistance. This was not taken into account during this initial design. More research was required in to understand switching AC signals on and off. Consultation of WPI's Professor Gene Bogdanov lead towards considering RF switches. The switch chosen is manufactured by Skyworks Solutions Inc. as Part #AS169-73LF costing only \$0.62 each. The documentation for this part shows that it has a VSWR of ~ 1.15 at a signal frequency of 1 GHz. This means there is very little reflection of the signal. This component is also capable of handling the very low wattage ($< 680\text{mW}$) of the Doppler console's 9.3 MHz signal. The internal mapping of the part is shown in the pinout below in Figure 4.18. This figure is taken from the part's specification sheet and enlarged, albeit blurry.

Pin Out



DC blocking capacitors (C_{BL}) must be supplied externally for positive voltage operation.
 $C_{BL} = 100\text{ pF}$ for operation $> 500\text{ MHz}$.

Figure 4.18 - Skyworks Solutions Inc. RF Switch AS169-73LF Pinout [35]

The multiplexing circuit was updated replacing the transistors with the RF switches. Figure 4.19 below shows this circuit.

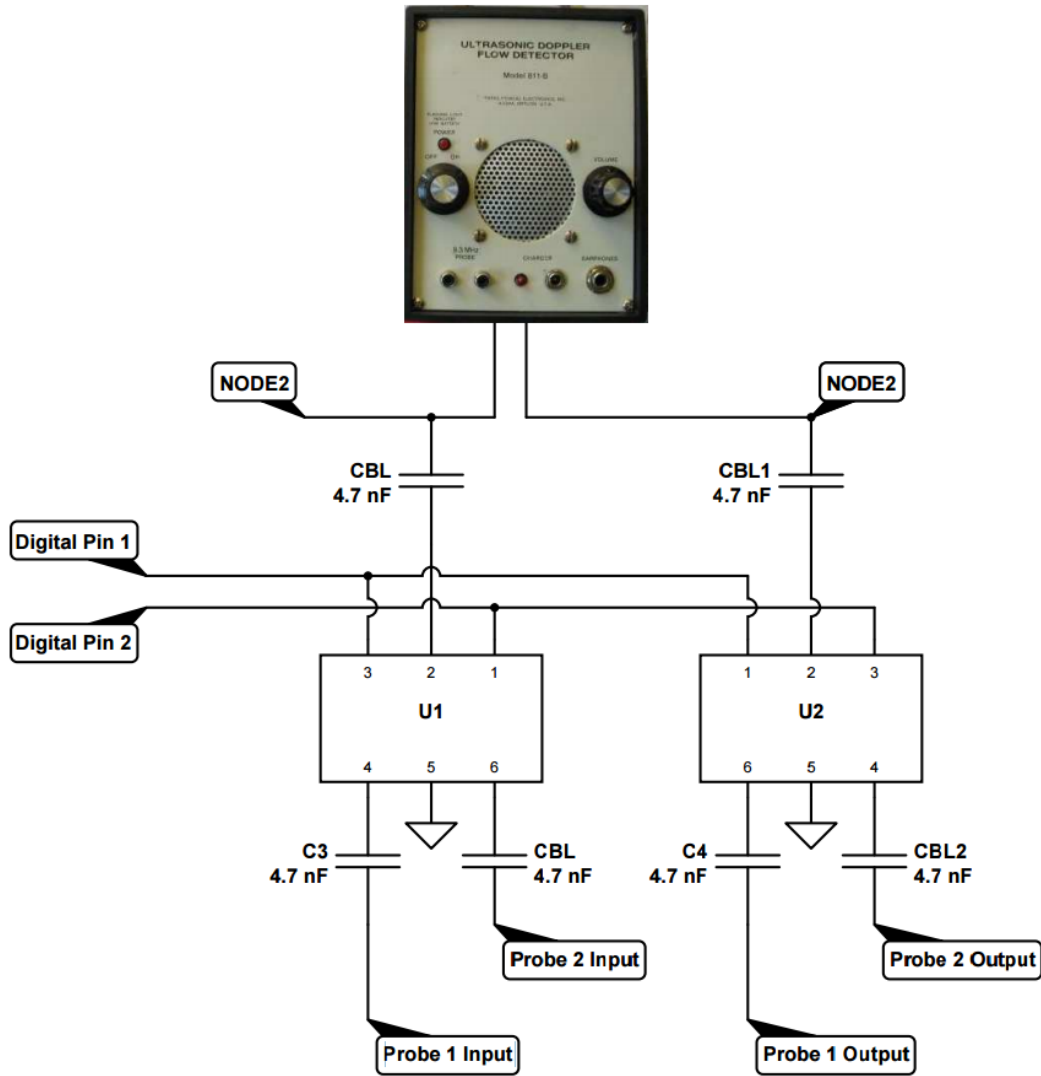


Figure 4.19 - Doppler Multiplexing Circuit Concept

Following the pinout of the component, the above schematic is used to transmit the 9.3MHz power signal to the selected probe via RF switch U₁ and then the reflected Doppler signal is passed to U₂ as either Probe 1 or Probe 2 Output. The capacitors are used to block DC voltage as suggested by the component documentation. A probe is selected using the digital pin nodes shown in the diagram. One of the pins must be high (5V) while the other must be low (0V). The Arduino would be used for this control.

This circuit was tested using a sample 9.3 MHz signal from a frequency generator and was shown to work effectively in switching the signal. The circuit was then connected directly to the Doppler console for use with the actual power signal and the Doppler probes. When selecting one of the

probes, the signal passed perfectly to the probe and then back to the console where the resultant audio signal could be heard. The second probe would not fully transmit the signal, however, and using the oscilloscope to probe the circuit for debugging only introduced noise. It was thought that the wiring of the circuit could have introduced an antenna-like effect. The circuit was tested once more with a frequency generator test signal and was found to be working properly. The conclusion was that each RF switch should only be used per probe. This concept was implemented in the final design of the circuit shown in the design verification section.

4.4 Data Acquisition

The following section discusses the data acquisition of the device.

4.4.1 Needs Analysis

The hardware necessary for signal acquisition went through many different configuration changes. A combination of hardware elements was required to meet the design requirements for the project. The final hardware setup is required to sample the Doppler signal at a minimum of 10 kHz and two temperature sensors simultaneously. Sampling for the Doppler closer to 44.1kHz is preferable in order to preserve all the auditory details that the surgeons would normally hear from the Doppler monitor. Dr. Dowlatshahi proved invaluable while evaluating recording means. His experience using many different Doppler ultrasounds provided valuable feedback during the design process. The data acquisition must also minimize noise introduced to the signal.

The software required to sample the Doppler and Temperature signals faced many challenges during project. Sampling the temperature signals proved to be relatively straightforward due to their low sampling rate. The Doppler signal proved to be more difficult. Labview was utilized in order to sample the Doppler signal. The Labview program had to perform several key features. Labview had to sample the sound card for 30 seconds, segment the recording into separate recordings, then save them to an Amazon S3 cloud server. The Labview implementation tackled each requirement separately, building from the simplest to more complex process. Labview development involved bridging the signal acquisition with the cell phone application.

4.4.2 Conceptual Designs

A National Instruments DAQ USB 6008, Arduino and the computers built in sound card were evaluated for use in the project. The Arduino provided a flexible platform for prototyping. It is relatively inexpensive and is available with shields such as the Ethernet shield, which expands its functionality. There is extensive documentation for the Arduino to assist in many different projects. The main limiting factor of the Arduino is its Analog to Digital Converter (ADC), with a sampling rate of about 10 KHz. Though not a great platform the Doppler signal, during early proof of concept designs, the Arduino worked well for the temperature data.

The NI DAQ originally appeared to be a promising solution for the project. The NI DAQ was ultimately disqualified because it could not sample all three data streams at a sufficient rate. The Arduino was similarly disqualified because it could not sample the The Labview software limits multiple channels to the same channel. When split in three equal parts, the NI DAQ's max sampling rate of 10 kHz was not sufficient for the Doppler signal. It was determined that acquiring a single

DAQ with the required sampling rate would be cost prohibitive. Instead, the data stream was split into two separate parts. The Doppler would be sampled separately from the temperature signals.

Labview supports sampling an audio signal through the sound card on a computer. Build in sound cards allow the device to sample the Doppler signal at 44.1 kHz, a considerable improvement over the NI DAQ board. Considerations had to be taken to minimize noise introduced into the Doppler signal. It was found that a combined headphone and microphone jack, such as those found on laptops, can introduce noise and feedback into the Doppler signal. UMass IS has agreed to provide a desktop for deployment of our device. When setting up the device care has to be taken to insure that a separate line in jack is available on the computer used to deploy the device.

4.4.3 Feasibility Study

During the design process the device was built and evaluated piecewise. The systems for acquiring a Doppler and temperature signal were tested independently. Proof of concept experiments provided useful information when they went well and when they went poorly. The temperature probe was first tested using the described Arduino setup. A single temperature probe was used during this early experiment. Data was collected on the Arduino, and sent directly to Plotly via an Ethernet connection.

The Doppler acquisition system was tested during a number of different scenarios, as it proved more difficult to acquire. The first Doppler recordings were made using an audio recorder that was plugged directly into the Doppler monitor. These first recordings provided a quality baseline for future development. The Doppler was then sampled using the NI DAQ. The signal was sampled at 10kHz and it was the only process running on the NI DAQ at that time. The headphone output from the Doppler monitor was connected directly to one of the NI DAQ's analog inputs.

4.4.4 Preliminary Results

The Doppler was originally tested with the NI DAQ as a proof of concept. The audio signal was sampled at 10 kHz. The analog input on the NI DAQ was connected directly to the audio output of the Doppler monitor during this test. Results of the Doppler tests can be seen plotted in Figure 4.20. The peaks in the signal correspond to changes in blood flow as a patient's heart beats. A single peak, or cycle, is highlighted in red in Figure 4.20.

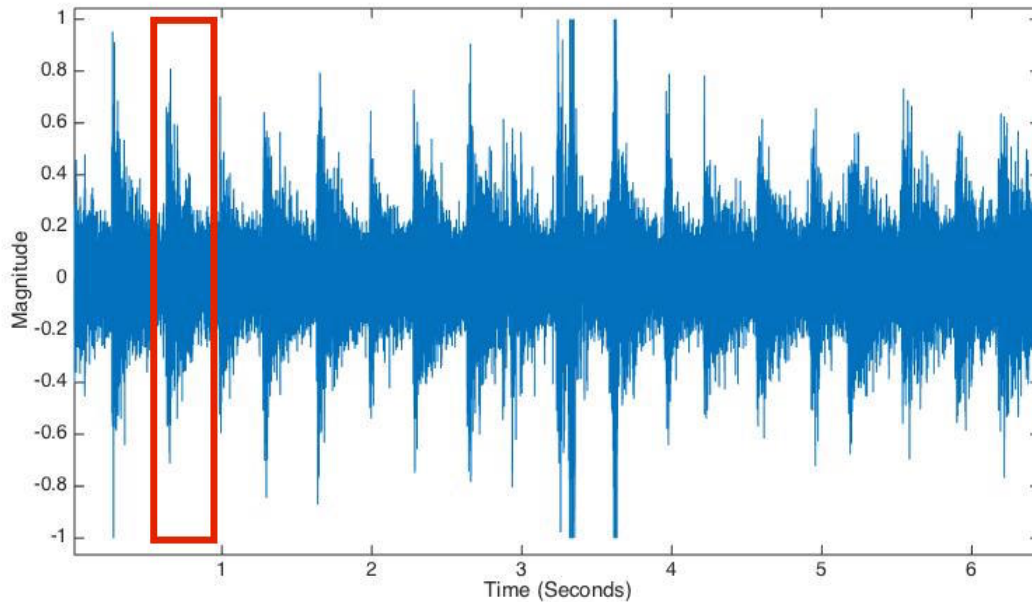


Figure 4.20 - Doppler Signal from Proof of Concept Setup. Blood flow corresponding to a single heartbeat is highlighted in red.

This original proof of concept setup for the Doppler signal acquisition system provided useful feedback for future development. The signal quality and bandwidth was improved when sound cards were implemented to sample the Doppler signal.

Once complete, the temperature circuit was connected to an Arduino in order to demonstrate that the device could get temperature data from the sensor to mobile app. The raw signal from the Arduino's analog to digital converter was plotted online using Plotly. Figure 4.21 illustrates what the raw temperature signal looked like as seen on Plotly's web service.

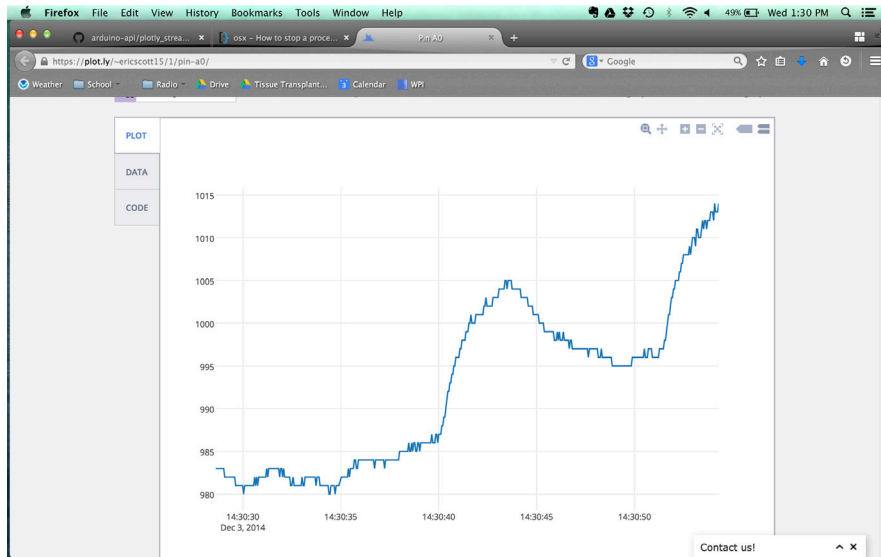


Figure 4.21 - Temperature Signal from Proof of Concept Setup

4.5 Mobile Phone Application

The mobile phone application has many individual components that need to be addressed by the Appgyver software for the application to be commercially used in the medical industry. The most important factors include the functionality of the applications, security of medical information, and for the application distribution to be as efficient as possible.

4.5.1 Alternative Designs

This was the first rendition of the first page of the app, as seen in Figure 4.22. The team knew that it would want the capabilities of monitoring a current patient or checking a past recording. The color scheme was chosen in order to make the Welcome page stand out and make certain buttons and wording easy to read.

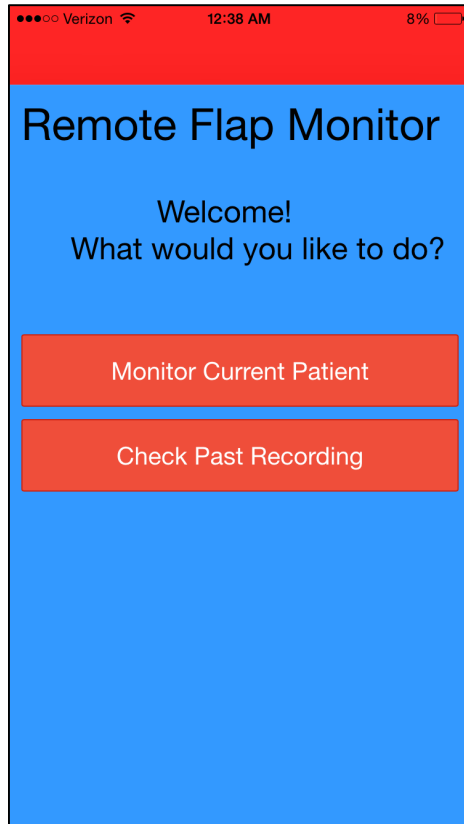


Figure 4.22 - First Welcome Page

The preceding pages that the user would see after clicking, “monitor current patient” are visualized in Figure 4.23 and Figure 4.24.

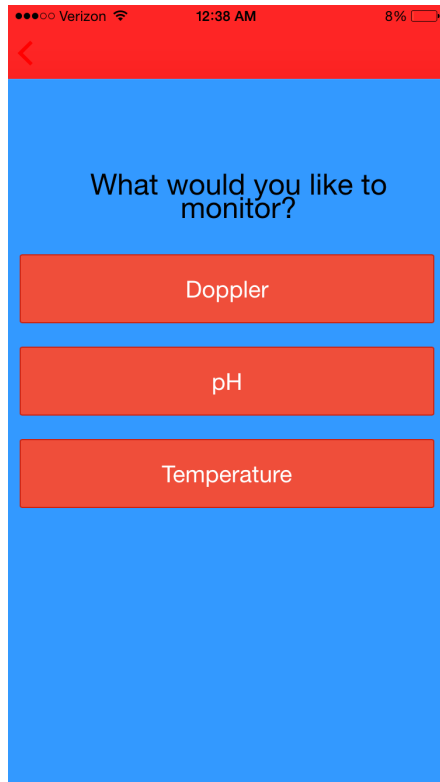


Figure 4.23 - Monitoring Selection

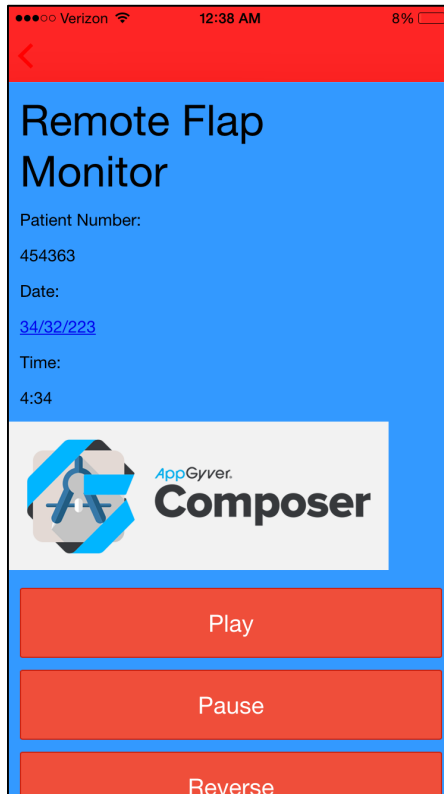


Figure 4.24 - Doppler Page

Figure 4.25 one draft of the app structure keeping all functionality in mind but also making it easy to navigate. This included a Welcome Screen moving on directly to the sensing selection page, probe selection page, and then a time selection page. After a time was chosen, the app would display the data requested by the doctor.

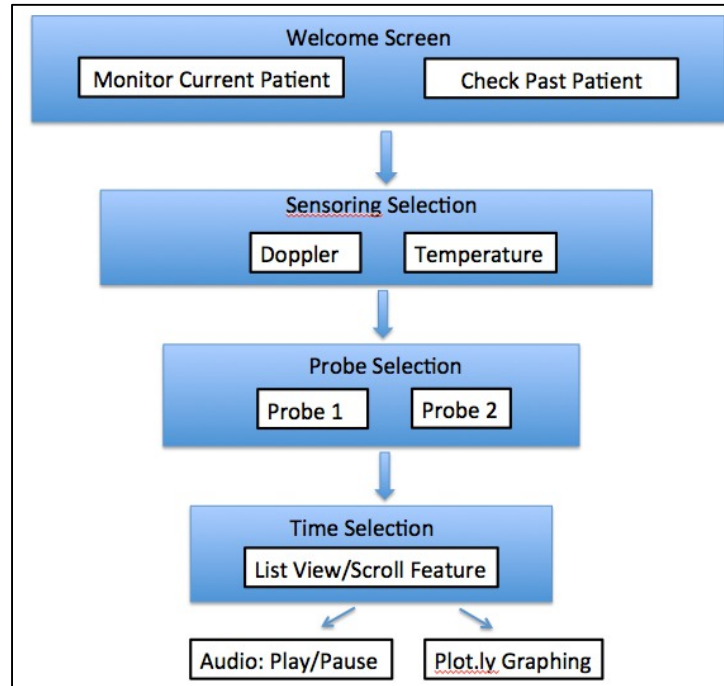


Figure 4.25 - App Structure Draft

4.5.2 Needs Analysis

Based on the designs above, the team knew that there needed to be a revision to the color scheme based on the client's input from a meeting. The team also realized that checking a past recording was a feature that was not feasible for how much time was given for the project. Time selection also needed to be incorporated in a different way than simply inputting a time on a page. The doctor would never know which times were recorded yet unless he kept typing times until a recording appeared.

4.5.3 Functions and Specifications

The team knew that the application needed to convey data in a fashion that was easy to manipulate and very clear to understand. Doppler information was needed to be played through the app, having features such as pause, rewind, and fast forward. Temperature information needed to be graphed continuously while also allowing the user to check past temperatures. All information was required to be secure in some data storage that the app was able to extract from with ease and display quickly to the user. The application also required a method of notifying the doctor of any abnormal signals such as a drop in temperature of the tissue flap.

4.5.4 Feasibility Study

Through various experiments, the app seemed to function well. It was always able to play audio but not always rewind or fast forward through data. Also, it became challenging to determine whether or not the application was malfunctioning or it simply lost a connection to the Internet, which was required in order for the app to run smoothly and effectively. Temperature also seemed to not format properly on the application, often not showing the entire graph or scaling it incorrectly. Doppler was also challenging due to the whole concept of databasing and categorizing audio files in a manner that was easy to understand by the user as well as interpretable by the app. In many experiments, audio files were often saved incorrectly, recorded for a short time, or not saved at all. However, based on many test runs of the app, the team knew that the application had potential. It was capable of acquiring an audio file that was saved on another server securely. It was also capable of providing a live visual graph of temperature information directly on the screen despite formatting issues.

4.5.5 Functionality

The ability for the application to convey the information that is gathered from the other components of the system is a crucial component of the project. This is the first part of the application that needs to be completed in order to progress to the security and the distribution. The sequence the application would need to progress in order to see the right means of monitoring would be as follows: the welcome page with the choice of active monitoring, the sensor page showing the choice of which modality to monitor, and the different screens depending on what modality was chosen: the Doppler page would convey an audio signal while the temperature page would show a line graph of flap temperature being monitored.

There were several reasons why the initial design of this application was modified. First, the decision to drop pH monitoring was made. pH monitoring would sacrifice the minimally invasive quality of the of system. Next, the team determined that the layout is not aesthetically pleasing based on client's input. Another modification included the removal of the past recordings button on the welcome page. This decision was made based on research into database such as SQL and PHP. Due to our team's limited knowledge in computer science and databasing, the idea of storing live data was not plausible in our time frame. It seemed much more feasible to simply show the live recordings to the user. The ultrasound and temperature signal playback were also changed so that they are called upon from different sources and are not visible/audible to the client simultaneously. Based on the client's requests, we determined that it is more logical for the doctor to be able to monitor each signal separately to eliminate multi-tasking and concentrate on one modality.

Some minor modifications to the page layout was the addition of a probe selection page allowing the user to be able to choose which Doppler/temperature probe he/she would like to monitor at that time, as well as a time selection page, allowing the user to input a time to monitor that chosen modality. However, this was quickly removed due to the realization that we would be storing all data files on a cloud server. The cloud server would simply list all files that had been recorded since the probe started recording. It would also include a filing system for files that were recorded using Probe 1 or Probe 2. We also decided not to utilize the time selection page because the user could never know if the most recent time had been recorded unless he tried inputting it. Rather than

inputting the time, it would be more efficient for the user to quickly access the page that showed all files that had been recorded up to that time.

Many cloud servers were looked into for our purposes including Built.io, a backend that Appgyver is familiar with, the WPI network drive, a storage drive given to all students, as well as the usage of UMass Medical School's cloud server for storage. Built.io was a possible choice but was challenging to implement especially with audio files and live streams for temperature. The WPI network drive was thought to be another option, however, it was not practical for future reiterations of this project. The network drive would have needed to be installed under a student account, which would have most likely been deactivated once the student left WPI. UMass Medical School's cloud server was an option because they are the clients and should be the only people that had possession of any medical information. However, we would have needed to bypass their firewall in order to upload files as well as included file encryption. Again, this was impractical given our limited knowledge of network security and computer science. It was also illogical given our time frame. Therefore, the most logical alternative was Amazon Web Services. Amazon would have allowed the team to create a free account allowing the full usage of their cloud. Amazon's cloud server, Amazon S3, allows for complete manipulation of file folders, data uploads/downloads, as well as sharing to other users.

4.5.6 Security

There are major concerns with the distribution of the application. The information that is broadcasted needs to comply with the patient-doctor confidentiality. Patient-doctor confidentiality is regulated by the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). As stated in Chapter 2, this act regulates only those who have permission to view the medical files of an individual. With the first draft of the application, this issue was not addressed very well. However, Amazon S3 does have the capability of limiting permissions to who could access the file folders. The hospital's information technology and security team would potentially control permissions. Amazon S3 was also chosen due to its HIPAA compliance.

4.5.7 Distribution

The current means of distribution is strictly for the development of the application, to make troubleshooting easier. Currently, you must either download the Appgyver software via your smartphone, and the QR code is then sent to you via Appgyver's Composer program, or run your computer's command line interface and deploy the application through that outlet. Either way allows for the immediate download of that iteration of the application using the QR code supplied by Appgyver through a web page. The app then instantly gets uploaded and saved to your phone. Currently, this is an efficient way of accessing the application for development purposes. However, the app is only available locally for anyone on that wireless network. Once the app is ready for user testing, it can be deployed to the cloud and a link is supplied to the developer directing one to a webpage displaying the QR code for the app. This link can be given to anyone and can be tested by anyone. The iOS Developer program has been purchased to account for further development and deployment to the App Store in the future.

5 Design Verification

The following discloses how we verified our results with Doppler testing on a live animal, cross national broadcasting and temperature testing. This section also conducts why artificial testing was not feasible for this application.

5.1 Artificial Testing

Thorough artificial testing research was conducted on the topics of ultrasound tissue phantoms and artificial blood flow systems in order to provide a proof-of-concept for our design as well as design modification purposes.

5.1.1 Ultrasound Tissue Phantoms

There exists many variations of ultrasound tissue phantoms currently on the market. These phantoms are utilized for medical teaching purposes as well as product development testing purposes in companies such as Blue Phantom, Supertech-to-go, and Medical Device Depot, Inc., as shown below, and many more. These devices exceed the project budget, however, and could no longer be considered possible means for testing our device. The phantom from Medical Device Depot costs \$3,039, while the Supertech-to-go's costs \$4,542 and Blue Phantom's costs \$1,499.



Figure 5.1 - Medical Device Depot testing phantom



Figure 5.2 - Supertech-To-Go testing phantom



Figure 5.3 - Testing phantom from Blue Phantom

The team had a very limited budget and these prices were way out of the team's range. When this was discovered, the team decided to move on to creating their own testing system.

5.1.2 Artificial Blood Flow Systems

Research into artificial blood flow systems broke the matter down into three main components. These included a system consisting of a tissue mimic, blood mimicking fluid, and a circulating system. There has been much research on different formulations for a tissue mimicking material that could simulate the acoustic properties of skin. Some articles simply use tubing made from materials like polyethylene that simulate these acoustic properties while others attempt to use a wall-less vessel phantom (container with an empty space surrounded by tissue mimic) to account for the hardship of matching the skin impedance. The polyethylene tubing does not demonstrate the flexibility of skin, which most likely flawed the experiment's results [36]. The wall-less vessel phantom experiment was close but their intentions were to eliminate noise and scattering complications instead of obtain accurate readings of blood flow [37]. A diagram of a wall-less vessel phantom can be seen in Figure 5.4.

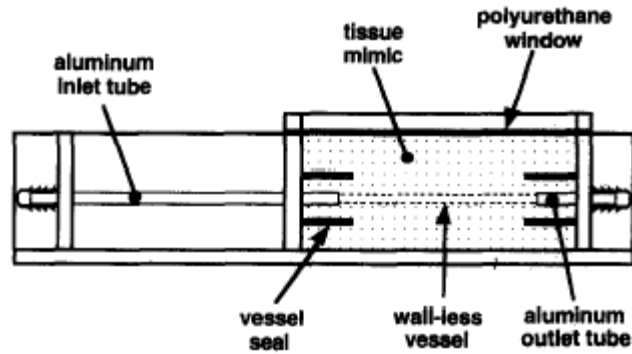


Figure 5.4 - Wall-less Vessel Phantom [37]

Blood mimicking fluid varies across articles as well but usually consists of some sort of scattering particle such as Orgasol (to simulate red blood cells), distilled water, and either glycerol or another fluid such as machine cutting fluid. The circulating system is also important due to the complexity of the body's microvasculature. Both articles failed to address the concern (one of them randomly tying a knot in the tube to simulate the architecture "in some form of a cluster") and thus flawed their results. The flow must also be controlled due to the variations in arterial and venous flow. This flow is dependent upon the pump used in the system as well as the material diameter used to simulate the blood vessel wall.

As stated in Ericksson et al., "...there have been no satisfactory phantoms mimicking microcirculation". This article was able to simulate blood at a range of 1.3mm/s, while the average flow velocity in the capillaries under resting conditions is around .3mm/s. They obtained close measurements but also disregarded many concerns. In addition many things involved in both of these experiments including equipment and materials for certain tissue mimic and blood mimic formulations that are sold by vendors all around the world. Therefore, the team decided that due to our limited time for testing as well as our limited budget, it was more logical to proceed with something more realistic and physiological such as animal testing.

5.2 Doppler Testing

The live animal experiment was the first time the group saw quantifiable data for Doppler ultrasound monitoring. This was the first time that the group ever was in a surgical setting with the device to be tested on a live animal. The original procedure was as follows: first to located the artery in the right leg, next find the location where the most clear signal could be acquired and suture the transducer to this location. Figure 5.5 visualizes the signal that that was acquired when the team recorded the undisturbed artery with a sedated rat.

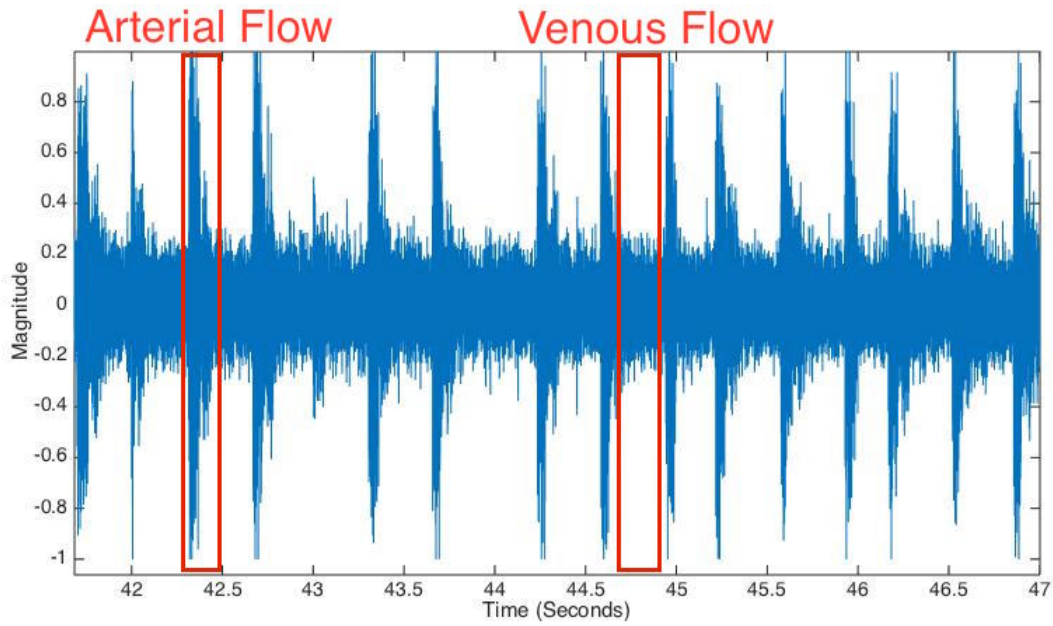


Figure 5.5 - Doppler Signal of the Femoral Artery. Arterial flow and venous flow are annotated in red.

The doctors then started to clamp down on the artery to occlude it. The resulting signal can be seen in Figure 5.6.

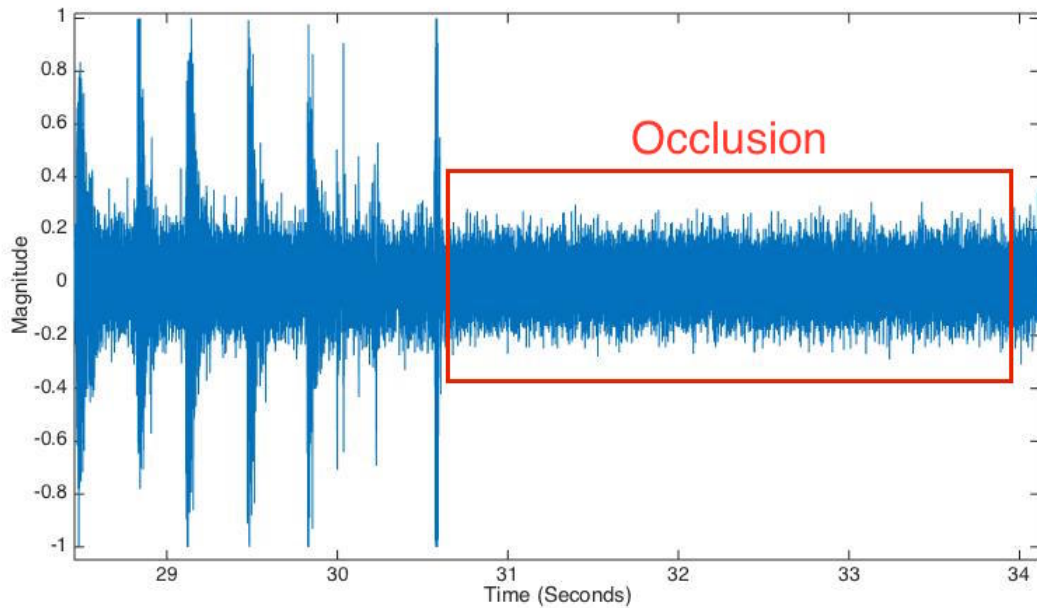


Figure 5.6 - Signal of occluded femoral artery. The decrease in peaks corresponds to the start of the occlusion.

Figure 5.7 is the resulting waveform after the repair of the severed artery.

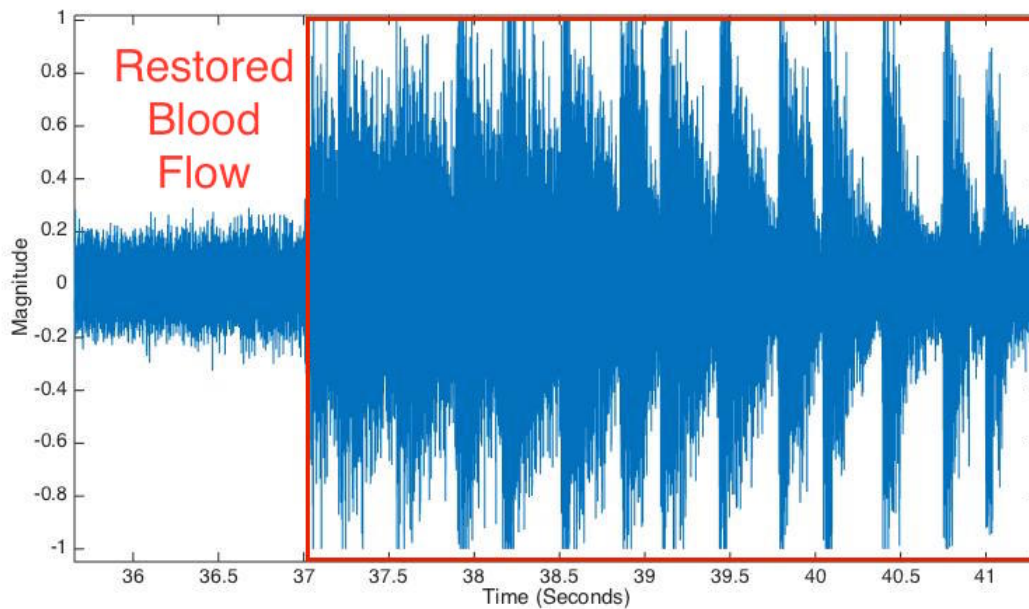


Figure 5.7 - Signal of repaired femoral artery. An initial rush of blood is visible at about 37 seconds into the recording when the clamp on the artery was released. Eventually it stabilized to the characteristic blood flow.

Figure 5.8 details the time-frequency relationship of an occluded artery. A shift in the frequency distribution of the signal can be seen as the artery is occluded at about 9 seconds into the recording. The spectrogram above was produced using Short Time Fourier Transforms. A Hanning function was applied to each window of 256 samples. Each window was then overlapped 50%. The signal was originally recorded at 10 kHz.

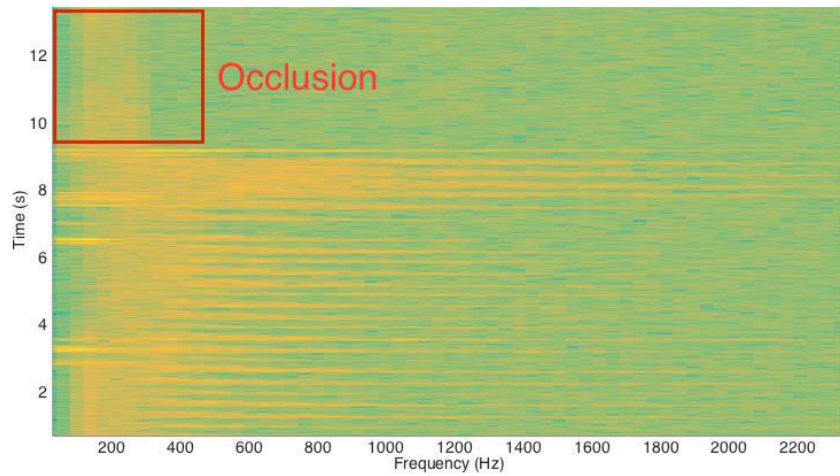


Figure 5.8 - Spectrogram of occluded artery. A shift in the frequencies heard is seen as the artery is occluded as highlighted in red.

Figure 5.9 visualizes frequency information about the Doppler signal over time. A shift in the frequency components of the signal from venous flow can be seen 24 seconds into the recording as venous flow is restored. In comparison to arterial flow, venous flow is much harder to detect. Venous flow oscillates at a lower frequency. The projects sponsors describe the sound that venous flow produces, as similar to the sound that waves at a beach make. The venous spectrogram was produced using the window size and characteristics as the arterial spectrogram.

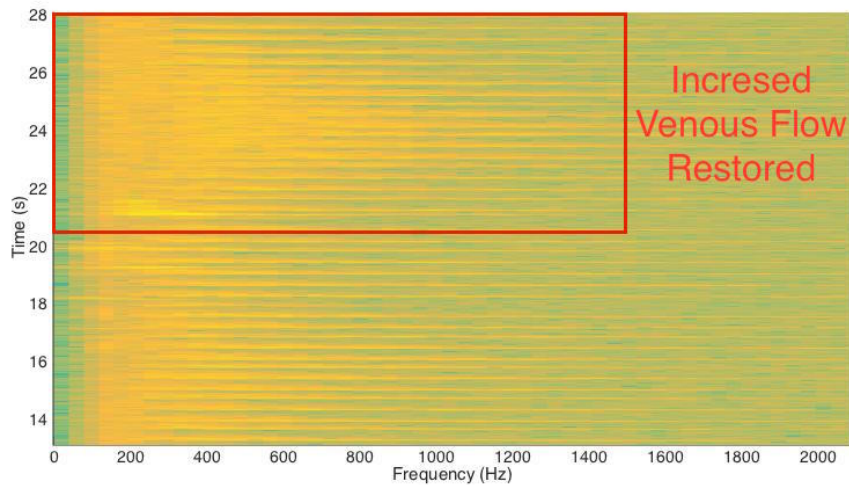


Figure 5.9 - Spectrogram of Venous Flow. Restoration of venous flow is highlighted in red.

5.3 Temperature Test

Temperature monitoring was control tested using beakers of water heated to various temperatures. One beaker is filled with water that is 92.5°F and the other is 95°F. The probes are both placed in the 92.5°F water for a short while. Probe 1 is then placed in a 95°F bath while Probe

2 is removed from the heated water and exposed to room temperature (about 75°F). In Figure 5.10 below, the two curves are visualized.

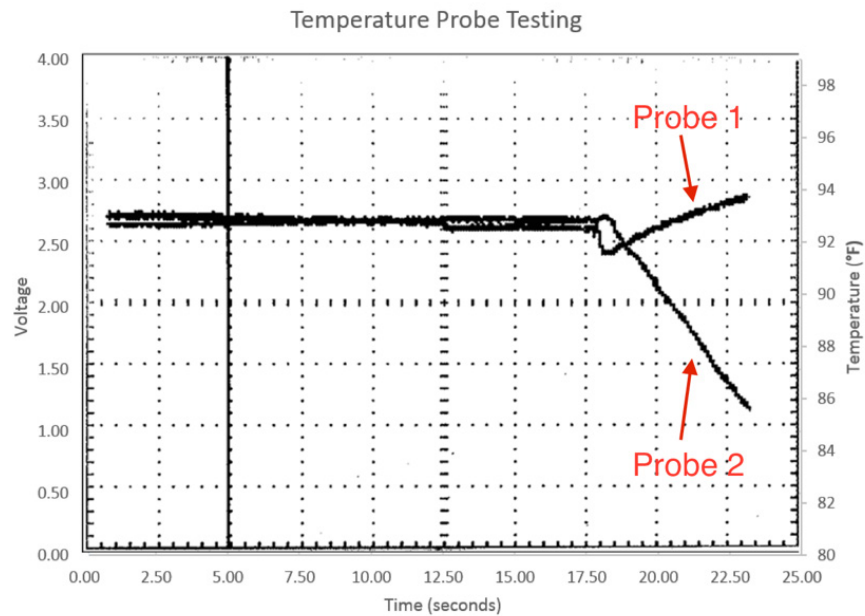


Figure 5.10 - Temperature testing as a simulation for live flap testing. Probe 1 is the reference probe, Probe 2 would be attached to the tissue flap itself.

The left vertical scale depicts the output voltage of the circuit and the right vertical scale shows the corresponding temperature in degrees Fahrenheit. For the probe that is moved from 92.5°F to 95°F, the output reflects this change by a curve with a rise of 2.5°F over the span of 5 seconds. This represents a reaction sensitivity of 0.5°F/second for a 2.5°F temperature difference. The probe that is moved from 92.5°F to 75°F is reflected by a steep decline in the plot's corresponding curve. The curve holds an initial negative slope of -1.6°F/second for the temperature drop of 17.5°F.

5.4 Public Demonstration

The first time going public with the device was by Dr. Dowlatshahi at a conference in California. While at this conference, he walked the attendees through the device, from the probe to the mobile phone application. It was concluded with a live demonstration using one of the students as the patient and another administering the device to him. The signal was successfully sent to the conference with no distortion.

The set up the students used was simple. First, the device was plugged into the computer via USB port allowing access to the internet, and the power sources were turned on. Next, the application was opened on the mobile phone. Once this was done, one student sat with his sleeve rolled up, exposing the brachial artery. The other applied the ultrasonic transducer to the artery, allowing the signal was heard. This experiment is extremely repeatable and will give the same results every time it is undertaken.

6 Discussion

The results that were validating the design were subjected to in depth evaluation, the following is a discussion of the results we obtained, as well as the social impacts of the device.

6.1 Test Discussion

Testing is an extremely important component to any design, to validate the final design. The following describes the results that were mentioned in the previous chapter in regards to the Doppler testing, the temperature test and public demonstration.

6.1.1 Doppler Test

The signals that were extracted were good representations of that that we would witness in a typical free flap transfer. The first one that the team heard was that of a typical arterial signal, that could be seen in Figure 5.5 in the results chapter. This signal is characterized by a large initial peak, with a high order exponential decrease that never fully dies due to venous flow. This peak is the blood that is being pumped by the heart that is traveling through the arteries.

The next signal acquired was Figure 5.6, which is when the artery was occluded. This was done by fully clamping down the artery and not allowing the blood to flow. There was a minimal amount of noise detected during testing. The surgeons reported that they were able to distinguish signals from smaller blood vessels than they normal could with a traditional Doppler monitor.

The next stage of the procedure was to release some of the force that was being applied by the clamp to only partially occlude the artery. Figure 6.1 visualizes a signal with reduced amplitude and with an initial peak that then a tapers off almost linearly.

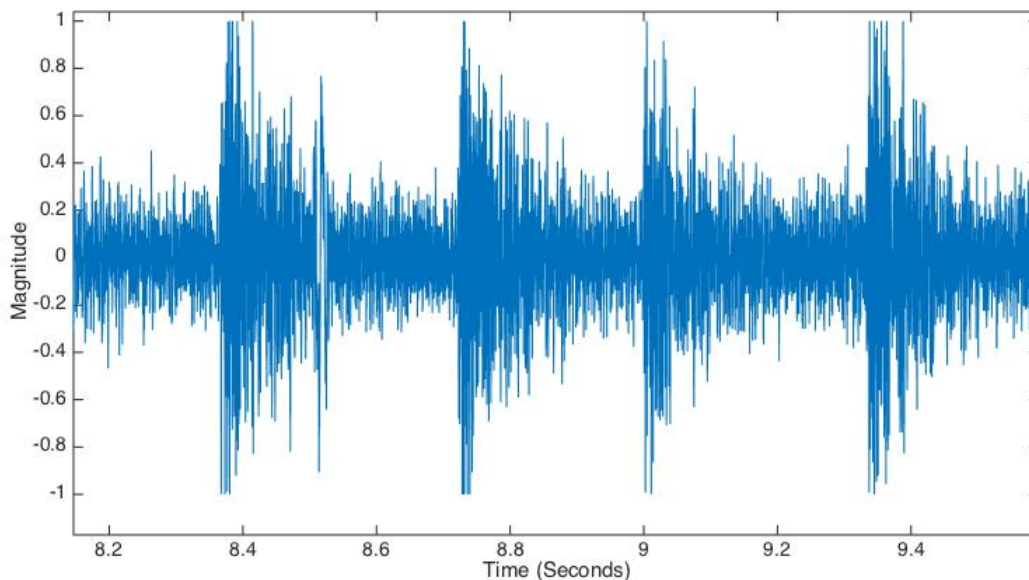


Figure 6.1 - Partially occluded artery. The increased noise following the peaks in blood flow are indicative of a partial arterial blockage.

This is most likely caused by the echo of venous flow that is backed by Figure 5.9, the spectrogram of venous flow. Figure 5.9 visualizes the venous frequencies at different parts of a particular recording. The spectrogram demonstrates that the venous flow is difficult to separate from background noise. Figure 5.8, is a spectrogram of arterial flow. In contrast to venous flow, the spectrogram of arterial flow shows clear changes in frequency that correspond to each heartbeat. The final graph that was seen was the restored arterial flow after the severing of an artery, Figure 5.7. This graph shows a rush of blood flow once reconnection occurs, which is to be expected after releasing an arterial clamp. Eventually the signal tapers off to a signal similar to that of a normal arterial flow.

Various issues arose during the procedure. The first problem that arose from this was that the casing was designed for humans. This meant that the size of the casing didn't fit the flap, it was too large. To overcome this problem Dr. Dowlatshahi sutured the ultrasonic transducer directly to the flap. The team also realized in this procedure that having four openings might not be the best and it would be better if the surgeon practicing the procedure had more options to suture the probe on. Also, the two sensing devices lied too deep within the casing, so this issue was in need of improvements as well, which lead to the final design of the probe.

There was also very few venous flow graphs. This is due to another problem that the group came across was the speaker on the Doppler system started to act as an audio input convoluting the signal that the team was acquiring. This turned out to be a setting on the computer that was being used for the signal processing.

6.1.2 Temperature Test

The use of two beakers with heated water is for the purpose of approximating two slightly different body temperatures. The 92.5°F water is representative of a potential flap temperature while the 95°F water is representative of the body temperature. This is a 2.5°F temperature difference between the two beakers. The circuit responds well to this difference by exhibiting an increase in voltage from 2.6V to 2.9V over about 5 seconds. The same reactive behavior of sensitivity is exhibited when the temperature probe is moved vice versa, from 95°F down to 92.5°F. In order for the surgeons to conclude that a flap is experiencing an occlusion or is approaching failure, the monitored temperature difference needs to be approaching 4°F. Using this testing configuration, the circuitry has shown its capability to detect a lesser temperature difference of only 2.5°F. For even subtler temperature differences, this circuitry would respond accordingly albeit over an increased length of time.

The probe that is moved from the representative flap temperature (92.5°F) to the room temperature (75°F) is used as a means to exhibit the circuit's functionality in response to a greater temperature difference. For instance, if a probe were to slide off of the patient or if temperature were to decrease rapidly, the circuit shows capability to respond accordingly. Testing this circuit on actual tissue flap transfers would require permission and clearance from a number of sources, but may show room for improvement for this temperature probing technique.

6.1.3 Public Demonstration

The week after the rat lab experiment, Dr. Dowlatshahi presented the project in a public demonstration that occurred on March 6th. Dr. Dowlatshahi presented the project to a group of reconstructive surgeons in Southern California. The presentation was the major reason for the time constraints that pushed the team to finish design at the end of C term. This is the point when the project went public.

6.2 Social Impacts

The device can impact some individuals and corporations economically, environmentally, socially, politically, ethically, and also in terms of their health as well as sustainability.

6.2.1 Economics

The potential economic gain for this is can be moderate. This is because our design incorporates patents that are not owned by Worcester Polytechnic Institute or the University of Massachusetts Medical School. For the budget that was allocated, the largest share of it was in the purchasing of the Doppler ultrasound system and probes from the Parks Medical Corporation. All the other expenses, including the casing for the probe, thermistor and circuitry could be minimized to under \$50 if ordered in bulk and mass produced. However, in order to execute the design, there is software that would need to be purchased, such as Labview. For this reason, the real economic gain would lie in the companies that we used to complete the design of the device with, such as Parks Medical and/or National Instruments, who owns Labview.

Table 6.1 - Initial Budget

Part	Allowance	Money Remaining
Sensor/Transducer	\$300	\$950
Signal Processing Hardware	\$100	\$850
Biomaterials	\$100	\$750
Remote Monitoring Software	\$50	\$700
Aesthetics	\$50	\$650

Table 6.2 - Expenses

Part Description	Quantity	Price
Probe Casing	2	\$20
Doppler Probe	2	\$150
Doppler Box	1	\$600
Temperature Sensor	5	\$18
Ultrasound Gel*	1	\$0
Arduino Uno*	1	\$0
Circuitry Components*	1	\$0
Software	1	\$99

*Not purchased using budget due to personal ownership of part

This table shows the expenses that arose during the construction of the device. The most expensive component was the purchasing of Parks Medical Electronics model 811B ultrasound detector, which was essential due to the level of sophistication in the construction of this high range of oscillating frequencies.

6.2.2 Environmental Impacts

The environmental impact of the device would be minimal. Since the means of detection is ultrasound and temperature, there would be no interferences with surrounding ecosystems.

6.2.3 Societal Influence

This product would have a huge societal influence due to its improvement over the gold standard of Doppler pencil probe monitoring. This means that the efficiency of the procedure would increase and lead to more physicians to utilize the Doppler/temperature technique for monitoring tissue flaps post-microvascular surgery. The team highly expects huge decreases in flap failure due to late detections or device complications.

6.2.4 Political Ramifications

In the political realm there is very little influence that this can have. This is a device that is an improvement on a previous technology. It may be able to be influenced by politics if there is an excess of funding in the medical field or if free health care becomes fully enacted but for now it primarily would lie in corporations.

6.2.5 Ethical Considerations

The device that was created does not infringe on any ethical viewpoint. This is a device that is meant to help others. The only potential ethical concerns lie in someone obtaining private medical data without patient permission. However, the group took many different precautions that follows FDA regulations and HIPAA compliance to avoid this from happening.

6.2.6 Health and Safety

The device is as safe as possible. It uses two proven safe means of detection, ultrasound and temperature, which do not impair any physiological process or damage tissue. The wires are also cover-protected, and the device is grounded to prevent any current from going into the patient while it is attached. The material comprising the probe is biocompatible, therefore doctors should not be expecting any biological complications.

6.2.7 Sustainability

This device has components that are ran off of a rechargeable battery and an AC power outlet. For this reason, the device is not very sustainable, but it is out of necessity. Until power technology progresses further, it must maintain at this low level of sustainability.

7 Final Design and Validation

The flow chart of the complete system that was implemented can be seen in Figure 7.1. The signal is gathered by the Doppler probes and the thermistors that are processed by their respective circuits and systems, to be filtered and uploaded to a host server the internet via the LabVIEW software, to be sent to a web page, which is then accessed by the smartphone.

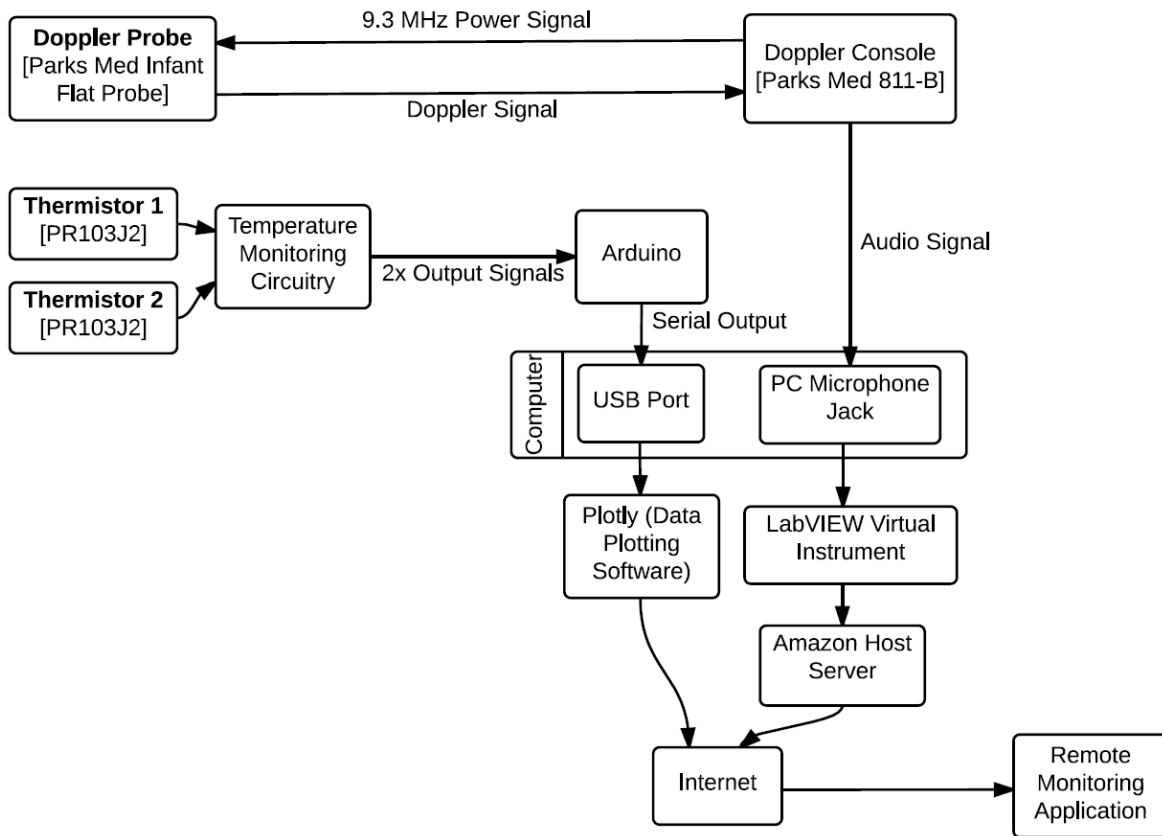


Figure 7.1 - System Flow Chart

7.1.1 Probe

As discussed before the probe has two main components, the transducers/sensors that detect the physiological signals and the casing that secures them to the patient. Silicone was not used in the final design due to the better availability of clinically used ultrasound gel (propylene glycol).

7.1.2 Thermistor and Ultrasound Transducer

The Doppler probe that was chosen was based off of the acoustical and electrical impedances of the body, and the practicality of matching the probe with the body. For this reason, we used the current Doppler ultrasound monitoring device to obtain a signal. The signal processing device and ultrasonic transducer are shown in Figure 7.2 and Figure 7.3, respectively.



Figure 7.2 - The signal processing device for Doppler ultrasound



Figure 7.3 - The ultrasonic transducer

Ultrasound was incorporated in this project due to the comfort and familiarity that doctors have with the modality. Doctors are currently trained to use the device and rather than introducing a new monitoring modality, ultrasound was incorporated into the project. The transducer itself is designed for maximum feedback of the ultrasound signal. The crystal's specific diameters are classified within the company, Parks Medical, however the crystal is angled to 15 degrees. This allows for resolution of the transducer as well as increased magnitude of the signal that is being reflected. The transducer is marketed for infants, however the electrical and acoustic properties are not different than that of the adult models; only the dimensions differ. The superiority of this unit can easily be seen in the difference in the clarity of the signal with the pencil probes that are currently used. We also found that temperature was a viable means of detection of flap failure, so we added this component as well.

The choice in thermistor is one of the most important component to insure the reliability of the temperature monitoring. We would need a thermistor that could quickly detect change in temperatures that has a high enough resolution to detect the change in the flap temperature.

Biocompatibility is also a factor, to avoid potential reactions from the patient's body and thermistor. The thermistor chosen for this is seen in Figure 7.4.



Figure 7.4 - Chosen Thermistor

7.1.3 Casing

The probe housing is one of the most essential components of the design of the device. It is sutured to the patient and contains the ultrasound transducer and thermistor. The final design of the probe is displayed in Figure 7.5.

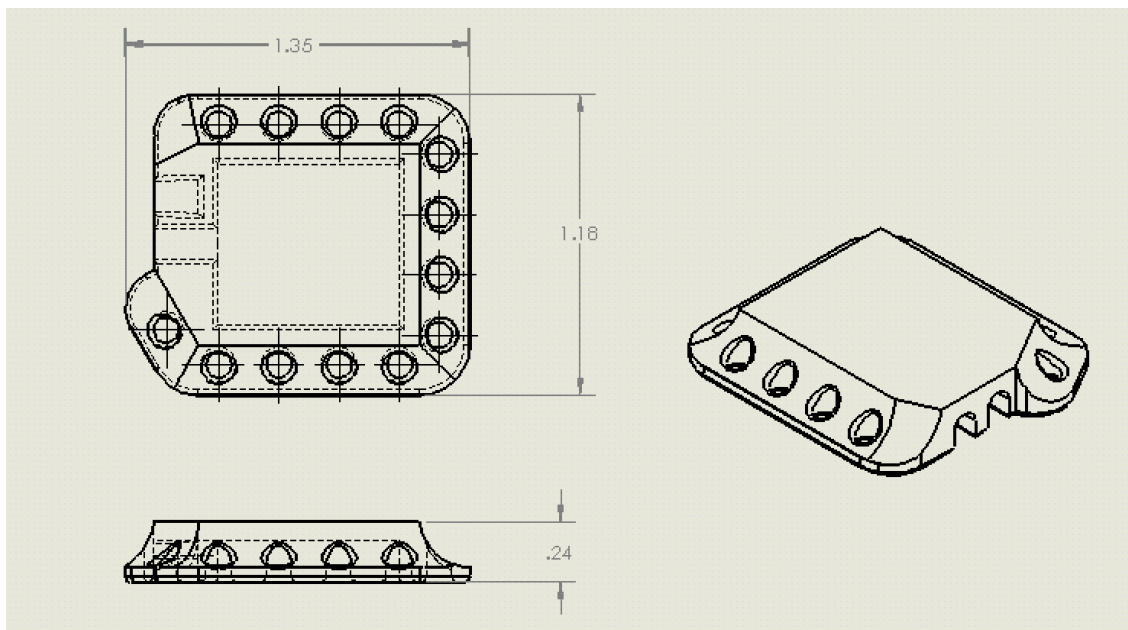


Figure 7.5 - The final design of the casing

The design has many improvements from our final concept design that was used in our live animal testing. The previous design had four large suture holes, whereas this design has 13 holes located on three sides of the device. Also all the edges that come in contact with the patient have been rounded to prevent any sharp edges. The size of the probe housing was reduced. The previous design had a volume of 0.38 cubic inches whereas this model has a volume of 0.27 cubic inches. Finally the probes do not nest as deep in the housing as before, allowing better contact with the

skin when it is sutured in place on the flap. This device is intended to be produced in a flexible material so it can contour to the surface of the skin.

7.2 Circuitry

7.2.1 Temperature Monitoring Circuitry

The evaluation of the preliminary circuit concepts and designs lead towards the simplification of the temperature monitoring circuitry. In the latest concept design it was found that the instrumentation amplifier was not necessary for this application. Instead a single stage amplifier could be used to scale a voltage divider output to the desired range. This single amplifier could have a varied offset in order to generate the proper output such that a full 0-5V range was acquired instead of being capped by the rail voltage and showing ~1.3V to 5V. The most updated circuit is shown in Figure 7.6.

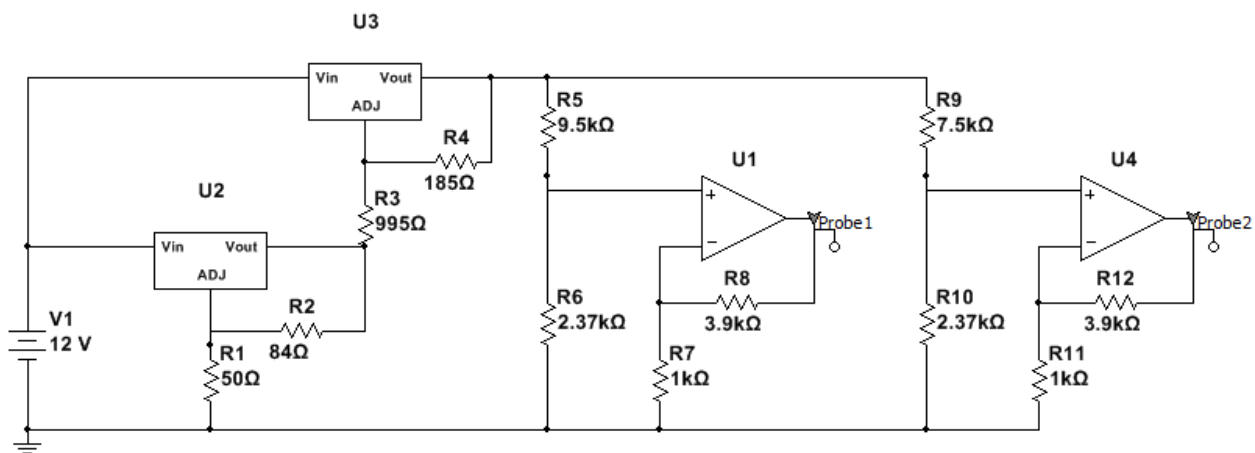


Figure 7.6 - Single amplifier circuit model with voltage regulators

In the above circuit diagram, voltage regulators U_1 and U_2 were used to generate fixed voltage lines of 2V and 10V respectively. The 2V line would serve as a reference for the op-amp output and as an offset for the amplifier. In order to achieve a 5V range for the output, the amplifier would need to therefore output 2V to 7V. The 10V line would power the voltage divider containing the thermistor. The series resistor R_6 was adjusted to 2.37kOhm such that the voltage divider's output would measure 2V (matching the 2V line reference) when the thermistor measured 9.5kOhm (low temperature point). This 2V output would be referenced to the 2V line, where there is a 0V difference to be scaled and the amplifier outputs 2V as shown in the circuit simulation. When the thermistor experiences the high temperature, the voltage divider circuit outputs a higher voltage of almost 3.3V. In reference to the 2V line, there is a 1.3V difference which undergoes amplification to demonstrate the 5V range of the amplifier output. The resistors R_8 and R_7 are used to offer the necessary gain of 3.9. This circuit simulated properly and was replicated in the lab for testing. The thermistor voltage divider and amplifier portions of the circuit were duplicated for the second thermistor so that both thermistors could be monitored. This was a last minute choice after

ensuring the Arduino would in fact be used instead of a different DAC or microcontroller. Both amplifier outputs were connected to the Arduino analog input pins and the Arduino ground was connected to the 2V line of the circuit. The digital plotting of the Arduino confirmed the circuit worked as desired. This is tentatively the final iteration of the temperature monitoring circuit. Further research into resistor values may be necessary as well as ensuring low tolerance levels. The circuit requires testing under various temperature conditions also to show there's little to no fluctuation of line voltages.

7.2.2 Doppler Monitoring Circuitry

Additional RF switches were introduced in order to isolate any issues that were apparent with the previous design iteration. Figure 7.7 shows the updated circuit using one RF switch per signal line of each probe.

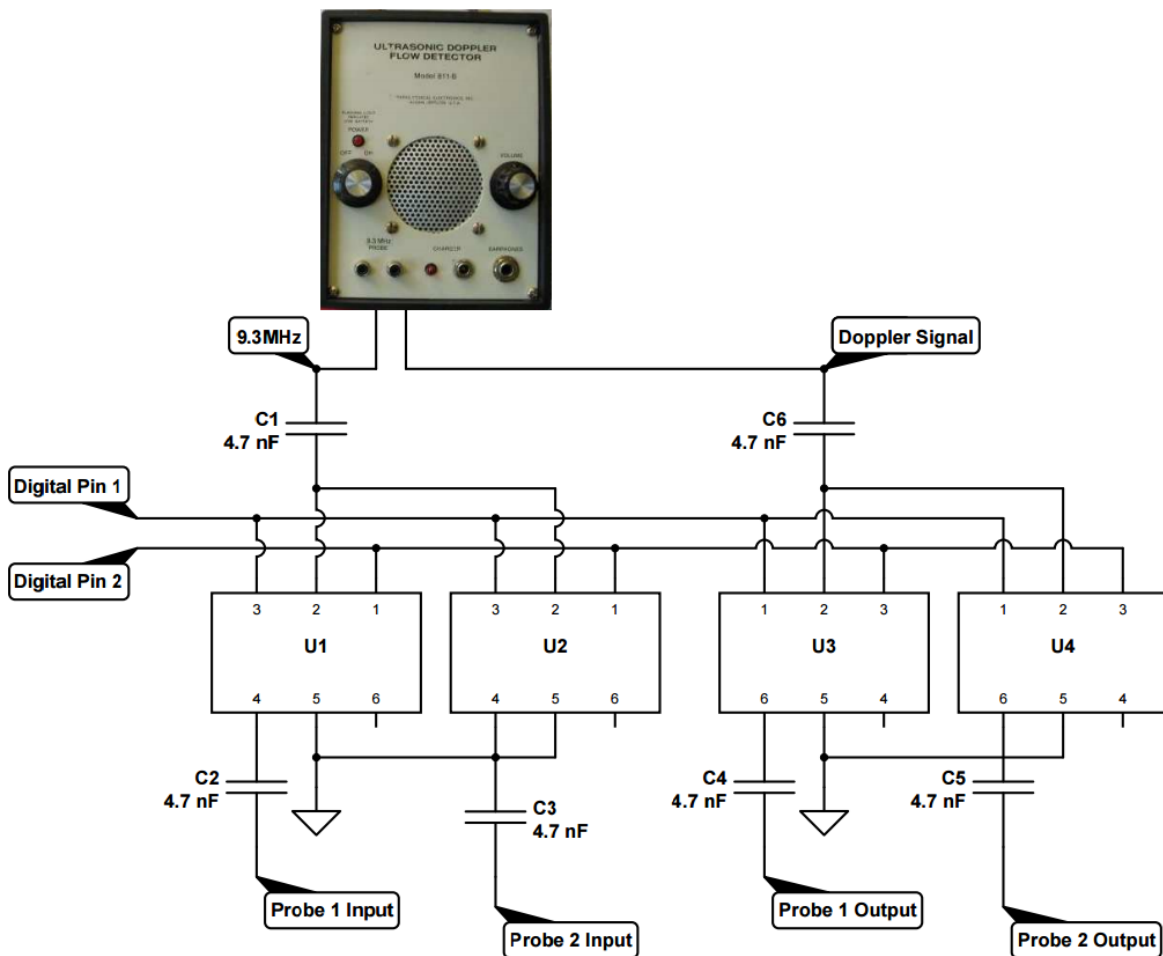


Figure 7.7 - Updated Doppler Multiplexing Circuit Concept

The function of the circuitry remains the same, however, the 9.3 MHz power signal is passed to two RF switches instead of just one. This allows each switch to act as an on/off switch instead of being an ON switch to one probe or an ON switch to another probe. This was duplicated for the receiving end of the signal, where the Probe 1 Output would be sent to one RF switch and the Probe 2 Output

would be sent to a different RF switch. This would theoretically isolate any potential issue that could have been apparent in the previous design. This circuit remains to be tested with the Doppler console and probes.

7.3 Signal Processing

7.3.1 Acquisition Hardware

As discussed in Chapter 4, the hardware necessary for data acquisition went through many different revisions and set ups. The final set up involves splitting the acquisition of the Doppler and temperature signals into two separate devices running in parallel. The Doppler was successfully sampled using a desktop computer's sound card. An independent line-in port is required to sample the Doppler. The output of the Doppler was connected to a mono-channel audio jack in order to interface with the computer. The computer sound card can sample at frequencies up to 44.1 kHz, well above the necessary frequency for this project. The temperature signal, of both probes, is sampled by an Arduino microcontroller continuously. The Arduino was ultimately chosen because it was more easily integrated with Plotly in order to integrate the temperature data with the cell phone app.

7.3.2 Signal Acquisition Software

Figure 7.8 displays the final implementation of the Labview program is detailed. The processes for acquiring and then writing the Doppler signal to file are located within the inner loop. The Labview VI saves the Doppler signal as a Wave file that can be played on a phone. The length of the sample is controlled by the 'Acquire Sound' VI that is located in blue in the lower left hand corner of the loop. User input has dictated that a 30 second sample is most efficient for the Doctors. The VI functions that interface the Doppler signal with the Amazon S3 cloud server are seen on the right half of the inner loop. As the Doppler signal is saved to file, it is then passed to the cloud server for access through the cell phone app. The time dated file names are controlled by the VI functions located outside of the inner loop, but still within the larger while loop.

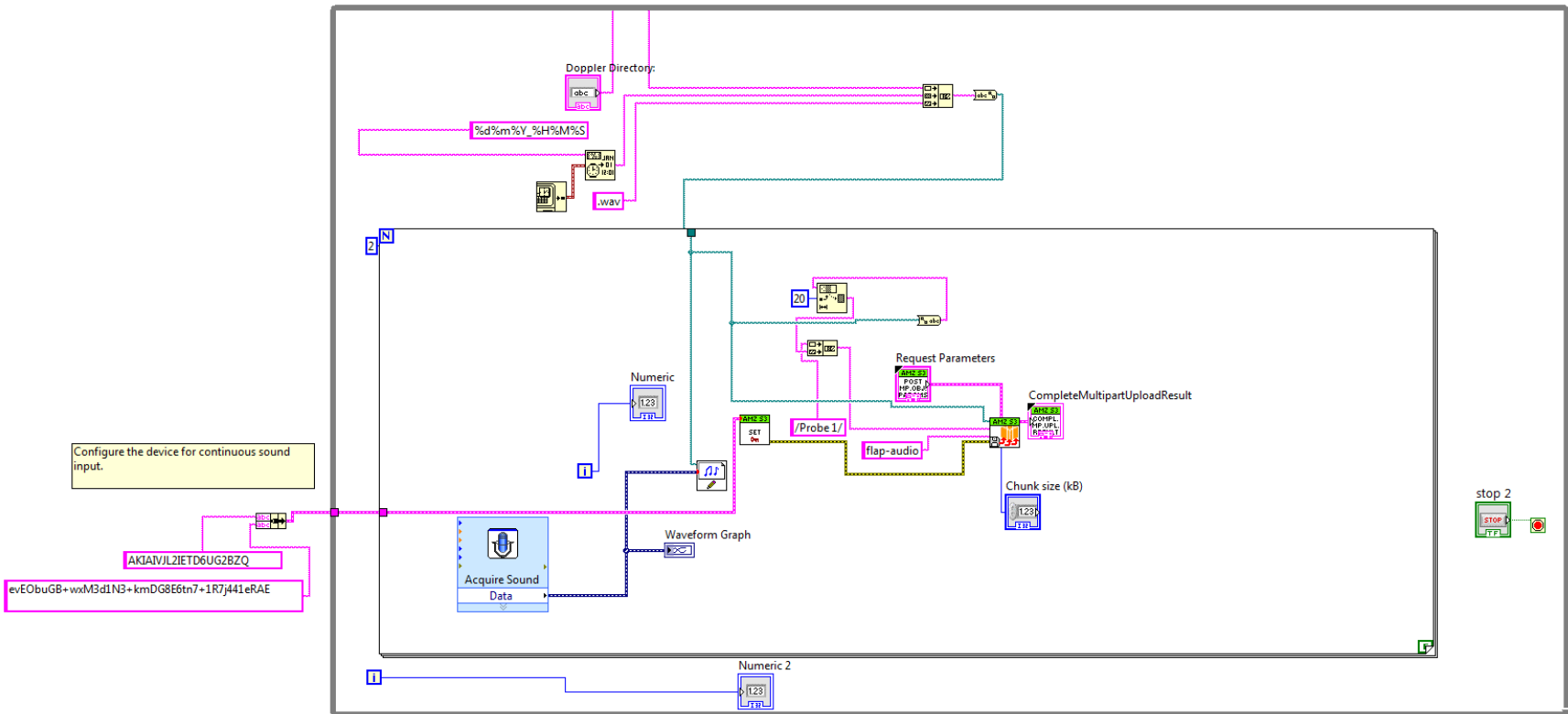


Figure 7.8 - Final Design of Labview Program

The temperature signal is acquired by using two analog ports on the Arduino. The Arduino is capable of reading each port simultaneously. The data is then streamed to Plotly at a rate of 50 ms/sample. The Arduino software utilizes API's produced by Plotly in order to communicate efficiently with their servers. The configuration of the Plotly graph can be controlled to change how much temperature data is sent to the app and how it is manipulated by the user of the app. Details of the Plotly implementation on the cell phone app are detailed in further detail in later chapters.

7.4 Remote Application

The application has three main components that it needs to execute: to function properly, to be secure and apply to HIPAA's regulations, and possess the ability to be distributed to users.

7.4.1 Functionality

The structure of the app was modified as seen in Figure 7.9:

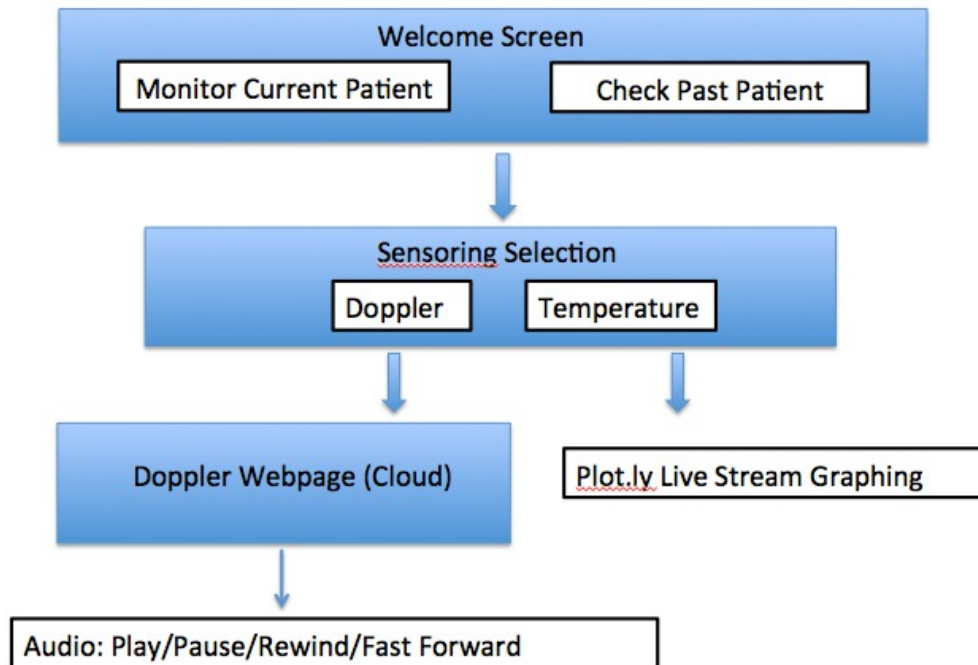


Figure 7.9 - Revised App Structure

The functionality of the application has the same sequence for both modalities: the welcome page, to the choice of modality. It then diverges depending on your choice: if you select the Doppler option, the app navigates to a static website host supplied by Amazon S3. This bucket/webpage can be restricted to certain users by the owner of the Amazon account. The user can now select whether he/she would like to monitor Probe 1 or 2, bringing them to the signal of the probe chosen.

The welcome screen is presented below in Figure 7.10. This page possesses the logos of our two sponsors, WPI and the University of Massachusetts Medical School. It displays a button that if pressed, allows one to progress to the next page

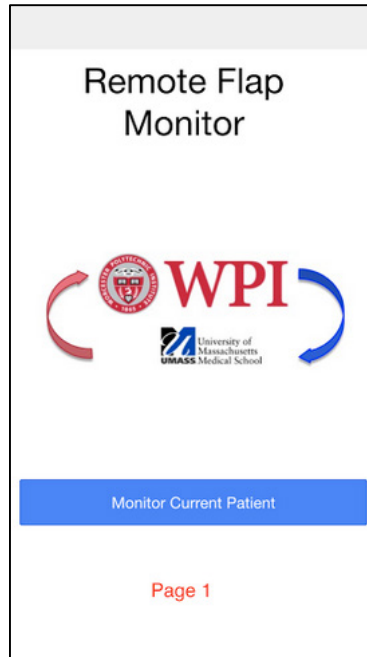


Figure 7.10 - The Welcome Screen

This page in Figure 7.11 is extremely simple, allowing one to look into what monitoring modality you want to see at the present time.

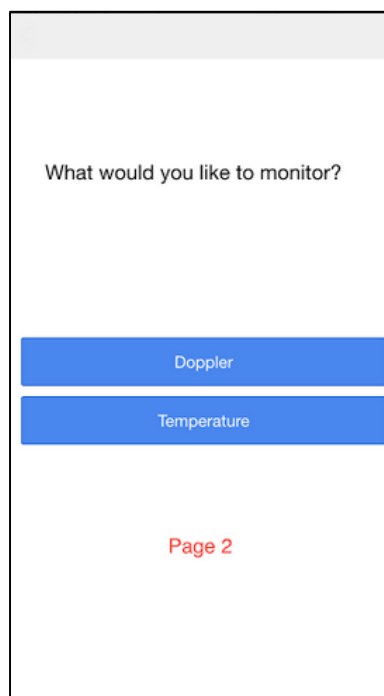
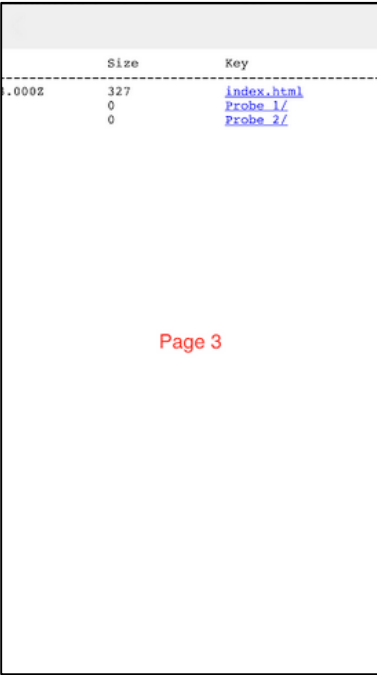


Figure 7.11 - Select the Modality

Figure 7.12 displays the page showing the static website where the files are uploaded to. The website is static due to the slightly limited capabilities of Amazon S3. Further development on Amazon Web Services is still being conducted (Amazon Lambda) to allow for a dynamic website host. One in which files are immediately updated to the app's page while the user is viewing the page. However, currently the user must simply navigate backward to refresh the page. Files are uploaded to these things called buckets, which allow one to upload data to them for broadcasting purposes when called upon. Then the user can select the probe he/she would like to monitor simply by clicking one of the file directories highlighted in blue.



	Size	Key
.0002	327	index.html
	0	Probe 1/
	0	Probe 2/

Page 3

Figure 7.12 - Probe Selection

Figure 7.13 shows the page that allows the user to choose the audio file he/she would like to listen to based on specific time intervals of 30 seconds.

	Size	Key
:43.000Z	673324	..
:27.000Z	327	index.html
:47.000Z	129534	test1.xlsx
:44.000Z	5916204	venous .wav

Page 4

Figure 7.13 - Select the Doppler Audio File

Once the probe and the time is chosen, doctors can then listen to the signal, which was recorded at that time, as shown in Figure 7.14. Since it is not in real time, one can choose the signal and hear which part of the signal that is of interest including the possibilities of pausing, rewinding, fast-forwarding, and skipping.

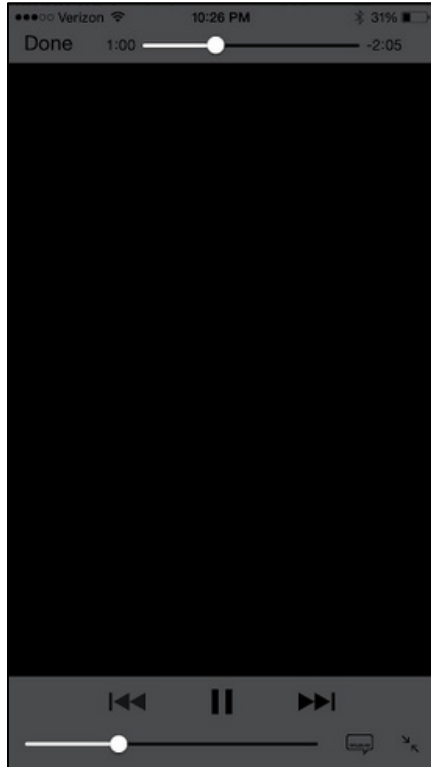


Figure 7.14 - Listening to the Doppler Signal

Unlike Doppler, temperature is monitored continuously through Plot.ly and streamed to the app via HTML coding provided by Plot.ly. As long as the Arduino is connected to the monitoring computer, a temperature graph is streamed to the app and rendered as shown in Figure 7.15, displaying readings for both probes (temperature still required calibration at this stage in the project).

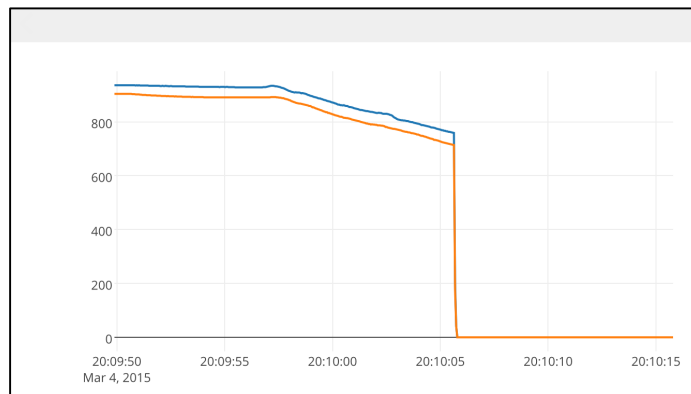


Figure 7.15 - Watching Live Temperature Readings

7.4.2 Security

As mentioned before, the patient confidentiality is a major concern and our application must meet HIPAA compliance. This is a critical reason why Amazon S3 software was chosen; it fulfills this requirement. Still in development, but in the future, the user will be required to sign in to the bucket, having the proper credentials that were given to them by the creator. This ensures that the

information does not fall into the wrong hands and only medical practitioners will be able to monitor their patient.

7.4.3 Distribution

Currently, the app is distributed to users via a shareable link displaying the QR code as well as a built-in simulator of the app directly on the webpage, as shown in Figure 7.16.

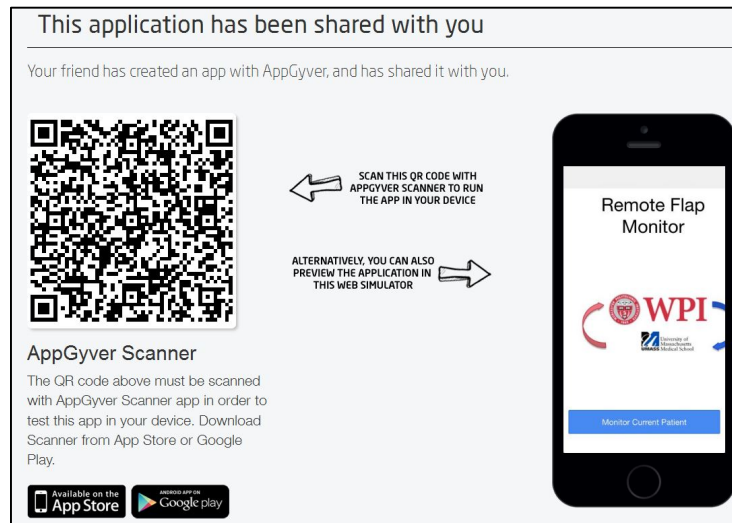


Figure 7.16 - Sharable Webpage

The app will be available for download in the App Store as well as Google play in the future. However, for now, it is still under development and only shareable using the link.

One of the major functions of the product design was the ability to provide early detection of flap failure through some sort of signal processing. This was accomplished through the implementation of a notification service controlled through two free online programs called Temboo and Twilio. Temboo is a service that enables the user to configure an Arduino microcontroller directly to an account and communicate with the program over a WiFi or Ethernet connection. Another feature offered by Temboo was direct compatibility with Twilio, which is a service that allows the user to configure his/her cellular phone directly to their free Temboo/Twilio account. Through these two services, the team was able to configure a smartphone to receive text notifications for whenever there was a significant change in temperature between both temperature sensors based on literature. These notifications were sent immediately from the Arduino through the network to the smartphone, enabling the doctor to see the complication and quickly address it.

Conclusion and Recommendations

In conclusion, the device was a success. The following are some closing remarks and future improvements.

7.5 Conclusion

The device has met every function, objective, and constraint in terms of the probe, circuit, signal processing software, and smartphone application. It was proven to sample Doppler and temperature signals from both human and animal models continuously and make this information available for remote access. The device also assists the doctor with detecting complications early through temperature signal processing and a notification service linked to the doctor's smartphone. These features represent a major improvement to the gold standard of the Doppler pencil probe. However, there are some minor improvements that could be made to certain aspects of the project in order to make the device more efficient and useful for the doctor.

7.6 Future Improvements

The following are recommendations for each component of the design that should be investigated and added in order to make sure the product is ready for distribution.

7.6.1 Probe

The final design iteration of the probe housing resulted in many improvements from the final concept design, however a few recommendations can be made. The size of the probe can be continued to be reduced depending on manufacturing ability. It is also recommended to use a translucent flexible material. This would allow better inspection of the tissue covered by the probe housing.

Contrary to this, there are changes that could be made to the transducers. The main one is matching the frequency that is emitted and received by the piezoelectric element. The lower the frequency, the farther it can go into the body. The lowest frequency that can penetrate the surface of skin is 1 MHz. This means the lowest ultrasound frequency that can be utilized is 1MHz. For free tissue transplants, the frequency to penetrate the implanted flap is between 9MHz and 10MHz. The team used a 9.3MHz transducer because this is the one that is used by the University of Massachusetts Medical School for the procedure. This allows very good results for vessels close to the skin, but depending on the depth, the choice between transducers that have different emitting frequencies would be beneficial.

The best way that the probe can be improved is by changing the dimensions of the piezoelectric element. This is due to the basic characteristic of the crystal and/or ceramic's vibration capability. The larger the dimensions, the more limited the element can vibrate since it would require more energy to do so. This is why we are unable to create an adjustable ultrasonic transducer.

7.6.2 Circuitry

The final circuitry for temperature monitoring exhibited subtle sensitivity problems. Upon one of the probes experiencing a temperature increase, the circuit output would increase accordingly, however the output for the second probe would decrease even though it was not actually

experiencing a temperature decrease. This was only a subtle problem regarding the circuitry and is caused by a variable current through the thermistor voltage dividers. When a thermistor decreases its resistance, that voltage divider experiences greater current which tends to draw current from the other voltage divider. For future improvement to this circuit, it is recommended that voltage regulators are used to independently drive the voltage dividers whilst also supporting the necessary current. In addition to this fix, potentiometers may be added to amplification circuitry. This will allow precision control over the gain of the amplifiers. Preliminary testing of the thermistors showed that they were not built to operate equally. This may be due to the epoxy coating around the bead, the glue around the bead, or the heat shrink tubing that is used around the probe. There would need to be significant control over the probe's material handling in order for each probe to operate similarly. To avoid this control, however, the potentiometers allow the gains to be adjusted and thus calibrate the functional outputs of the circuit such that they are representative of each thermistor's physical functionality.

The multiplexing circuitry simply requires finished development. After hearing from Dr. Dunn's argument that monitoring Doppler ultrasound with two probes is not practical, the development was put on hold. The final circuit is designed but needs construction and thorough testing. The use of additional RF switches in the design are used to fix the noise problem that is experienced with fewer RF switches, as mentioned in Chapter 8, Section 2.

7.6.3 Signal Processing

Future steps could be taken to further improve and test the signal processing system. In general, the robustness of the system should be evaluated and the complexity could be reduced. During the project thus far, not many steps have been taken to evaluate the robustness of the device in a clinical setting. Prolonged testing in a clinical setting could provide invaluable information to future teams. User input will help determine what future designs of the device will look like.

Currently the device employs a parallel system to sample the Doppler and temperature signals. This does help reduce cost and made the project more approachable for a student team. If there are concerns, based on user feedback, about the complexity of the system, a single DAQ board could be used to acquire both signals. A single DAQ board for Doppler and temperature would be more expensive, but could simplify the project. It would provide increased sampling abilities, which could allow for further expansion of future project beyond simply Doppler and temperature monitoring. The sponsors have expressed interest in expanding the monitoring modalities utilized by this project to include pH monitoring.

7.6.4 Mobile Phone Application

In terms of the smartphone application, some future improvements include better HIPAA compliance, authentication, Doppler notifications, and push notifications.

The app currently complies with HIPAA due to its usage of Amazon S3 Simple Storage. Amazon S3 offers many features for ensuring HIPAA compliance, however, the team was only able to provide compliance utilizing the server side encryption feature (AES-256 encryption) as Doppler data was saved to the server. Some better features could have included a restriction to the server using some

sort of authentication such as IAM (another feature of Amazon Web Services or AWS), ensuring that the owner of the AWS account can limit how and who can access the file bucket.

With that being said, another improvement to the security of the application would be the addition of an authentication page as soon as the user opens the app. Currently, anyone that is given the shareable link to the test version of the app can access data located on the server. The app needs better security protocol to ensure that the user is actually the doctor of the patient that is being monitored. This login information can be established utilizing AWS or some other backend.

Due to the fact that the Arduino Uno was used to monitor temperature, it made the process of configuring a notification service for the probe much easier. This was due to the discovery of Temboo, an online program that communicated directly with the Arduino over a wireless network. Temboo enabled the team to watch for certain changes in only temperature since Doppler was monitored via Labview. Labview did not seem to have any functions for communicating with Appgyver's software and plugins, therefore the team was unable to pursue a notification service for Doppler monitoring. However, in the future, it would be more beneficial for the doctor to get notifications not only for serious temperature changes but Doppler changes as well.

An additional feature to the app would be a feature that most apps on the market currently have: push notifications. Currently, the notification service for the product is configured through online programs called Twilio and Temboo. Temboo communicates with Twilio to ensure that certain signal changes are monitored and sent to the doctor's phone via their cellular network. However, these notifications are configured for only the doctor's cellular number. It would be more beneficial for the app to have some sort of configuration page in which the doctor can simply set the app to deliver push notifications directly to his phone regardless of his/her phone number without the need of an external service.

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