ECE 445: Senior Design

Continuous Arteriovenous Fistula (AVF) Monitoring Device

Team 45
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1. Introduction

1.1 Problem

Arteriovenous Fistulas/Grafts (AVFs/AVGs) are crucial to patients with end-stage kidney disease. They allow for hemodialysis, which has significant mortality and quality of life benefits in younger patients. Between 2000 and 2020, the prevalent count of individuals receiving HD nearly doubled to $480,516. In older patients, it's often considered a lifeline. However, AVFs are known to "go down". They are susceptible to stenosis, and thrombosis, and enlargement over time, leading to high-output cardiac failure. Currently there is no format for continuous monitoring of these grafts, and when they thrombose in the acute setting, often go undetected for days, if not weeks. The cost range to create an AV fistula is also between $3,401-$5,189. Several studies have pointed out that early graft intervention can improve the salvage of these fistulas, prolonging their use and minimizing the number of additional surgeries required. Finally, studies have found that if grafts are not intervened within 7 days, there are significant long term mortality risks and poor patient outcomes [1].

The basic tenet for vascular access monitoring and surveillance is that stenosis develop over variable intervals in the great majority of vascular accesses and, if detected and corrected, under dialysis can be minimized or avoided (dialysis dose protection) and the rate of thrombosis can be reduced [2].

Problem Statement: Graft stenosis and thrombosis are the leading causes of loss of vascular access patency, with delay in treatment leading to loss of vascular access and increased mortality rates and decreased quality of life in patients with end-stage renal disease.

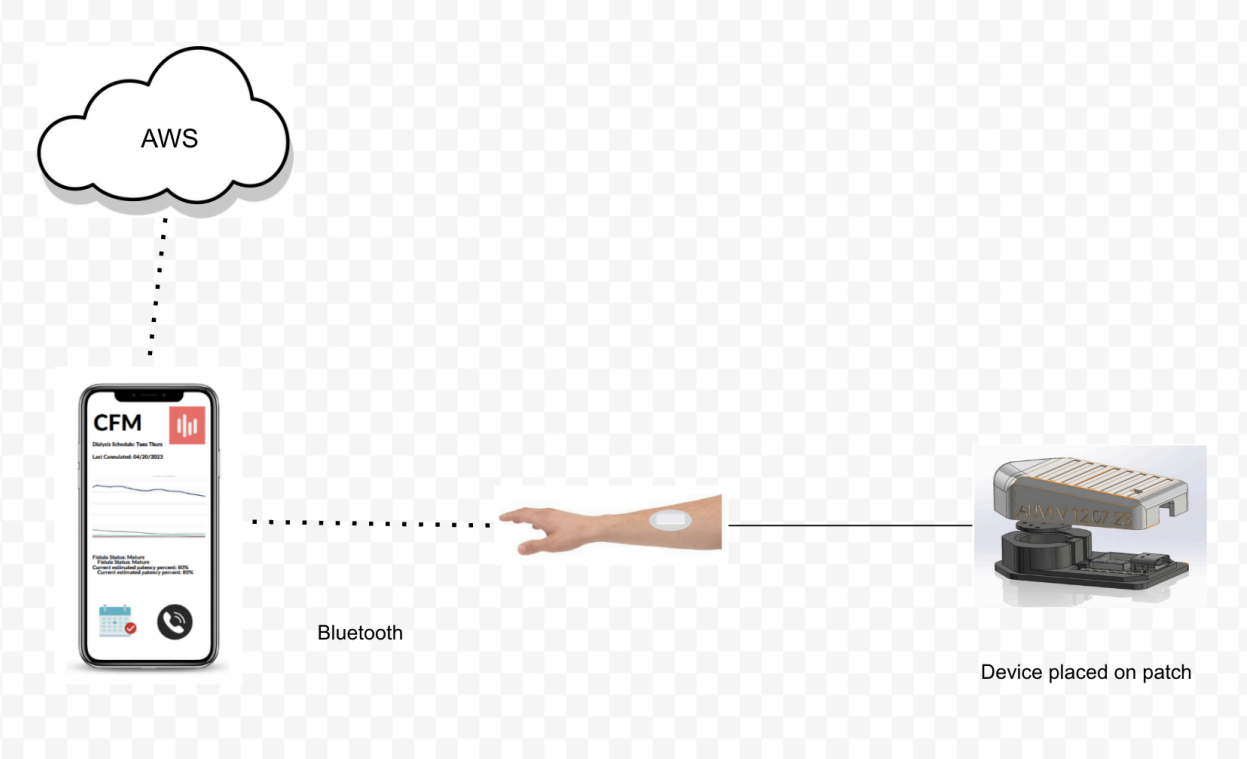
1.2 Solution

AVFs are often embedded in the arm, where the radial artery and adjacent veins are involved in their creation. What clinicians use to determine fistula viability is palpation, where the palpable trill (or vibration) of the graft can be felt. In the context of vascular access for hemodialysis, a trill is often associated with the feeling of blood flow or the movement of blood through the graft. A strong, palpable trill suggests good blood flow through the access site, indicating that the fistula is functioning well.

The idea is to develop a device that can be attached as a patch adjacent to the fistula to sample this venous trill using auditory input and machine learning to gauge deviations from an initial

baseline. The device would be placed initially and cross-referenced with the current gold standard of duplex ultrasound to establish a baseline. As the device lives with the patient, it will learn progressive changes in venous hum pattern (stenosis) that can provide information to clinicians on optimal follow-up. Otherwise, if it detects the absence of a hum (thrombosis) it will immediately alert the patient and provider for attention. Pitch should correspond with an increase in percentage of stenosis and be interpreted as more frequent oscillations in a pressure waveform over time.

1.3 Visual Aid

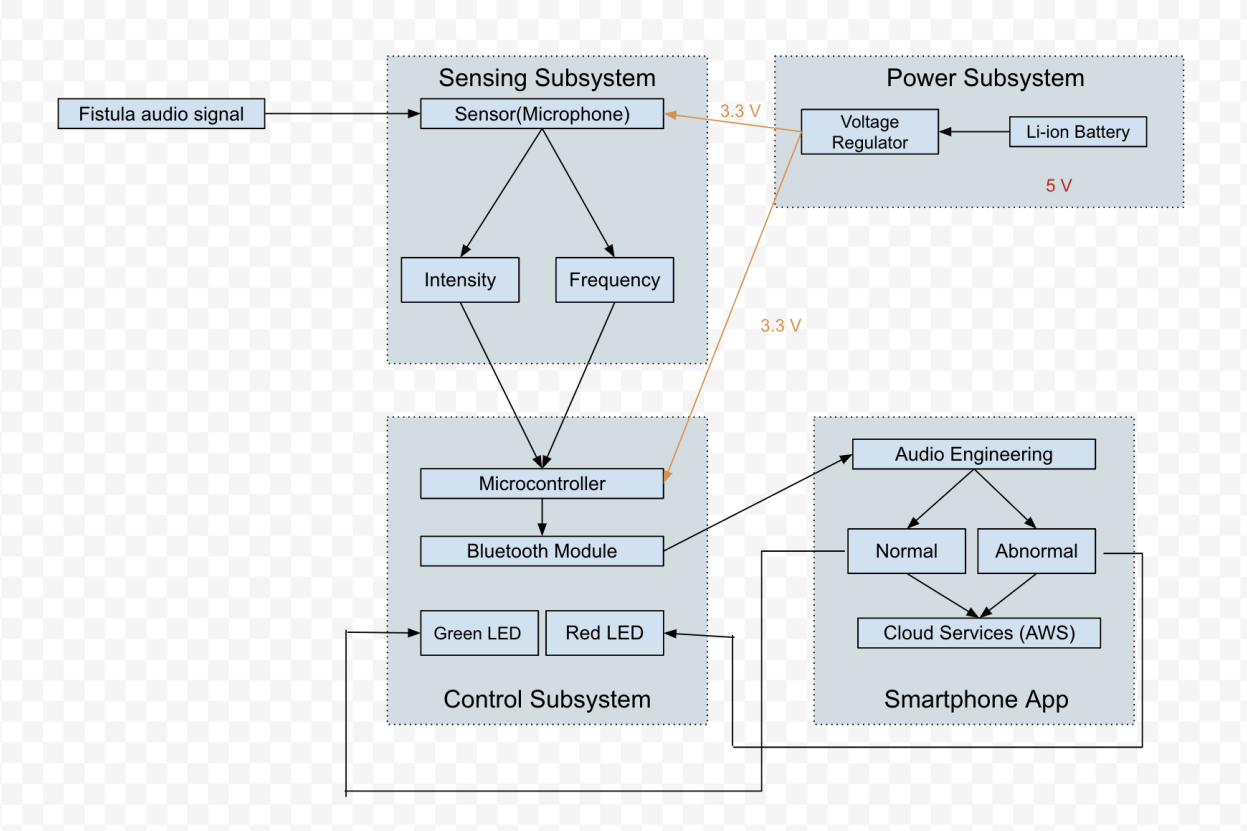


1.4 High-level requirements list:

- The device should transmit audio signals with a minimum sampling rate of 48 kHz to the accompanying mobile application.
- Device is able to distinguish changes in fistula stenosis (pulsatile vs continuous)
- The device should achieve real time data transmission facilitating immediate action in response to detected issues

2. Design

2.1 Block Diagram



2.2/2/3 Subsystem Overview and Requirements

Sensing Subsystem
This subsystem would take in sound input from a small microphone to capture a signal underneath the skin and feed into a microprocessor input [3].
Requirement 1 - MIC MEMS ANALOG OMNI -38DB
MEMS microphone requires 3.3V power consumption.

For the sensitivity, frequency response, signal-to-noise ratio (SNR), influencing the microphone's performance in capturing clear audio. This makes it the perfect microphone to record.
Requirement 2 - Amplifier
AN-1165 – Op Amps for MEMS Microphone
A single op amp can be easily used in a circuit as a preamp for a MEMS microphone output. The MEMS microphone is a single-ended output device, so a single op amp stage can be used to add gain to the microphone signal or just to buffer the output.

Control Subsystem
We will use an Attiny85 and supporting components on our PCB. We will have to add a micro usb programmer for the Attiny85 and then add bluetooth capabilities on top of that. The microcontroller will receive input from the Microphone Module which captures acoustic signals related to venous hum patterns. These signals are essentially sound waves produced by blood flow in veins. We will use an algorithm on the acquired data to help analyze the different frequency components present in the venous hum patterns. Then the microcontroller can analyze the frequency spectrum of the venous hum patterns. The microcontroller can then help us compare the identified patterns with predefined patterns associated with normal and abnormal venous conditions. Based on the comparison, the system can detect differences in the venous hum patterns. Depending on the detected differences, the microcontroller will generate an alert if needed.
Requirement 1: NINA-B306-00B
Bluetooth Modules - 802.15.1 nRF52840, PCB antenna, low power crystal, open CPU
The microcontroller chip with integrated Bluetooth module operates at 8 dBm transmit power, achieves a data rate of 1 Mb/s, operates at a frequency of 2.4 GHz (bluetooth 5), and requires a supply voltage ranging from 1.7 V to 3.6 V.
Requirement 2: DAC
Convert analog signals from the microphone for the GPIO pins on the microcontroller.
a single digital-to-analog converter (DAC) with a resolution of 12 bits, operating with a sampling rate of 3.4 million samples per second (3.4 MS/s). The DAC communicates via the I2C data interface, and it has a settling time of 6 microseconds.

Power Subsystem
It will be a 5 V lithium ion battery. We will have to step down the voltage to 3.3 V. We have no need for battery recharging. We will also have supporting components for the battery.
Requirement 1: The power system must be able to supply 3.3 V.

App Subsystem
The app aims to process audio recordings from the microphone and classify them by leveraging cloud computing and machine learning. The audio is uploaded to the cloud for processing using advanced signal processing algorithms and machine learning models. Amazon Web Services

(AWS) will be utilized for storage, processing, and deployment of machine learning models. The app provides the users of the app a simple application that alerts them of their fistulas. Requirement 1- Classify audio recordings from a microphone using cloud computing and machine learning.

2.4 Tolerance Analysis

One aspect of the design that poses a risk to successful completion of the project is the sensing subsystem, particularly the MEMS microphone's performance in capturing clear audio signals underneath the skin. Since the device will be placed adjacent to the fistula, it's crucial that the microphone effectively captures venous trill sounds despite potential interferences from surrounding tissues or environmental noise.

Feasibility of this component can be demonstrated through mathematical analysis through factors such as signal-to-noise ratio (SNR), sensitivity, and frequency response of the MEMS microphone. By analyzing these parameters, we can assess whether the microphone is capable of accurately capturing and distinguishing venous trill sounds amidst potential interference.

Signal-to-Noise Ratio (SNR):
SNR is a measure of the strength of the useful signal compared to background noise. It's given by:
$SNR = P_{signal}/P_{noise}$
Power of signal and power of noise

Sensitivity:
Sensitivity indicates the microphone's ability to convert sound pressure into electrical signals. It's typically specified in terms of output voltage per unit of sound pressure level (e.g., mV/Pa).

Frequency Response:
Frequency response refers to the microphone's sensitivity to different frequencies of sound. It's crucial for capturing a wide range of frequencies accurately.

To demonstrate feasibility, we can calculate the SNR of the MEMS microphone and compare it against the required SNR for accurate detection of venous trill sounds. If the calculated SNR meets or exceeds the required threshold, it indicates that the microphone is suitable for the intended purpose.

Additionally, we can simulate the microphone's performance in various conditions, such as different levels of interference or varying distances from the fistula, to ensure reliability under real-world scenarios.

By conducting mathematical analysis or simulation, we can confidently assess the feasibility of the sensing subsystem and decrease the risk associated with its performance.

3. Ethics and Safety

During development, ensuring the reliability and safety of the project is very important to prevent complications in medical procedures such as misdiagnosis or incorrect incisions, which could jeopardize patient health and safety. To mitigate these risks, a comprehensive review of the project and technical quality will be conducted before any potential clinical usage. We will make sure that areas where the development team lacks expertise will be supplemented with consultation from appropriate specialists by those who pitched us this project.
Safety and Regulatory Standards Industry Standards: Within the medical device industry, regulations will be determined by the intended use case of the technology. For instance, if the desire is to use it as a preliminary tool for a patient diagnosis of skin cancer, it could potentially qualify as a Class II device and follow the FDA's guidelines for further development in a clinical setting. However, if there were a demand to use such a product as a small surgical tool, the product would undergo a stringent regulatory review known as Premarket Approval as it likely qualifies as a class III device.
Accidental misuse of the product due to a lack of understanding of its limitations in a clinical setting is a significant concern for patient safety. Therefore, it is very important to standardize aspects such as the device's durability and its appropriate usage in patient settings to prevent potential complications. Additionally, thorough testing of the device's diagnostic capabilities is essential to ensure accurate diagnoses and prevent patient misdiagnosis [2].

4. References

[1] https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

[2] https://www.ajkd.org/article/S0272-6386(06)00646-9/fulltext#relatedArticles

[3] https://www.digikey.com/en/products/detail/tdk-invensense/ICS-40720/6148222?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Shopping_Product_Low%20ROAS%20Categories&utm_term=&utm_content=&utm_id=go_cmp-20243063506_adg-_ad-__dev-c_ext-_prd-6148222_sig-CjwKCAiA_OetBhAtEiwAPTeQZ1sc67MtqD9bc6ZUm8EW4Alv5aP8HTyc8g7icYawqJpPbKTSzCbV7hoC4S0QAvD_BwE&gad_source=1&gclid=CjwKCAi

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