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, 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 develops 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 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. The pitch should correspond with an increase in the percentage of stenosis and be interpreted as more frequent oscillations in a pressure waveform over time.

Attachment Method: The device can be attached securely to the patient's skin using medical-grade adhesive, ensuring stability and comfort during wear.

Proximity to the AV Fistula: The device should be positioned in close proximity to the AV fistula to capture the venous trill accurately. It will be placed directly over the area where the fistula is created because this is the best spot for detecting the blood flow patterns.

1.3 Visual Aid

The image below shows a very general description of how the Arteriovenous Fistula monitoring device is placed and used. The device is placed on top of the connection of the artery and vein. The microphone records the blood pumping through the fistula and transmits and audio sample to a connected mobile device. The device is processed on the cloud and the user is able to see any changes to the condition of their fistula.

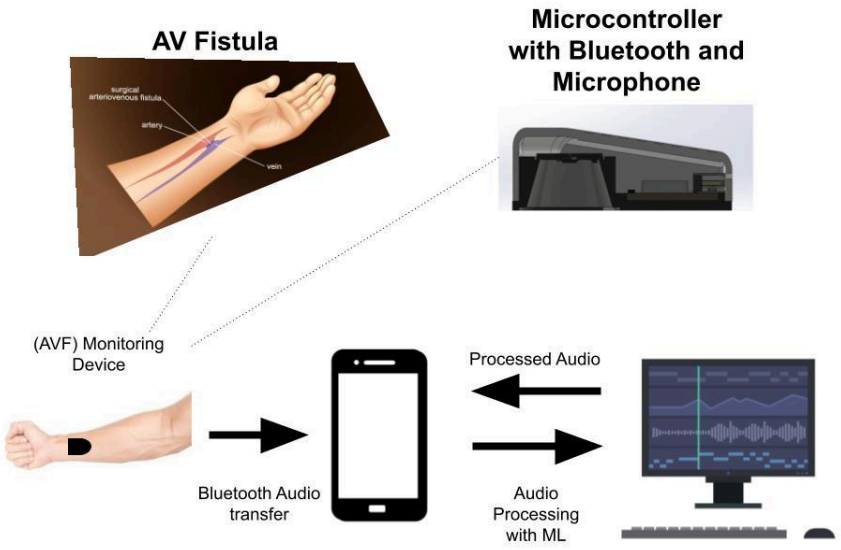


Figure 1: Arteriovenous Fistula Monitoring Device General Design

1.4 High-Level Requirements

1. The device should transmit audio signals with a minimum sampling rate of 44.1 kHz to the accompanying mobile application.
2. The device can distinguish changes in fistula stenosis (pulsatile vs continuous) correctly 75% of the time. These changes should be detected within a day, allowing for prompt intervention by healthcare providers

3. Have maximum dimensions of 3” by 2” by 2” so it is compact enough to be able to be placed on the forearm.

2. Design

2.1 Block Diagram Overview

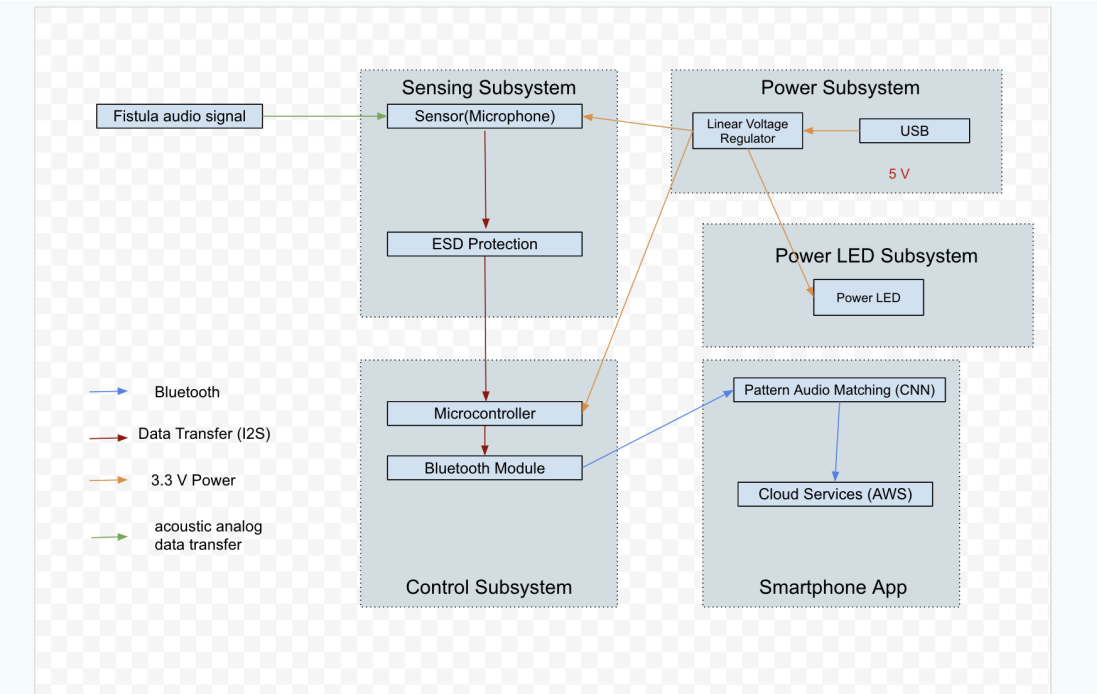
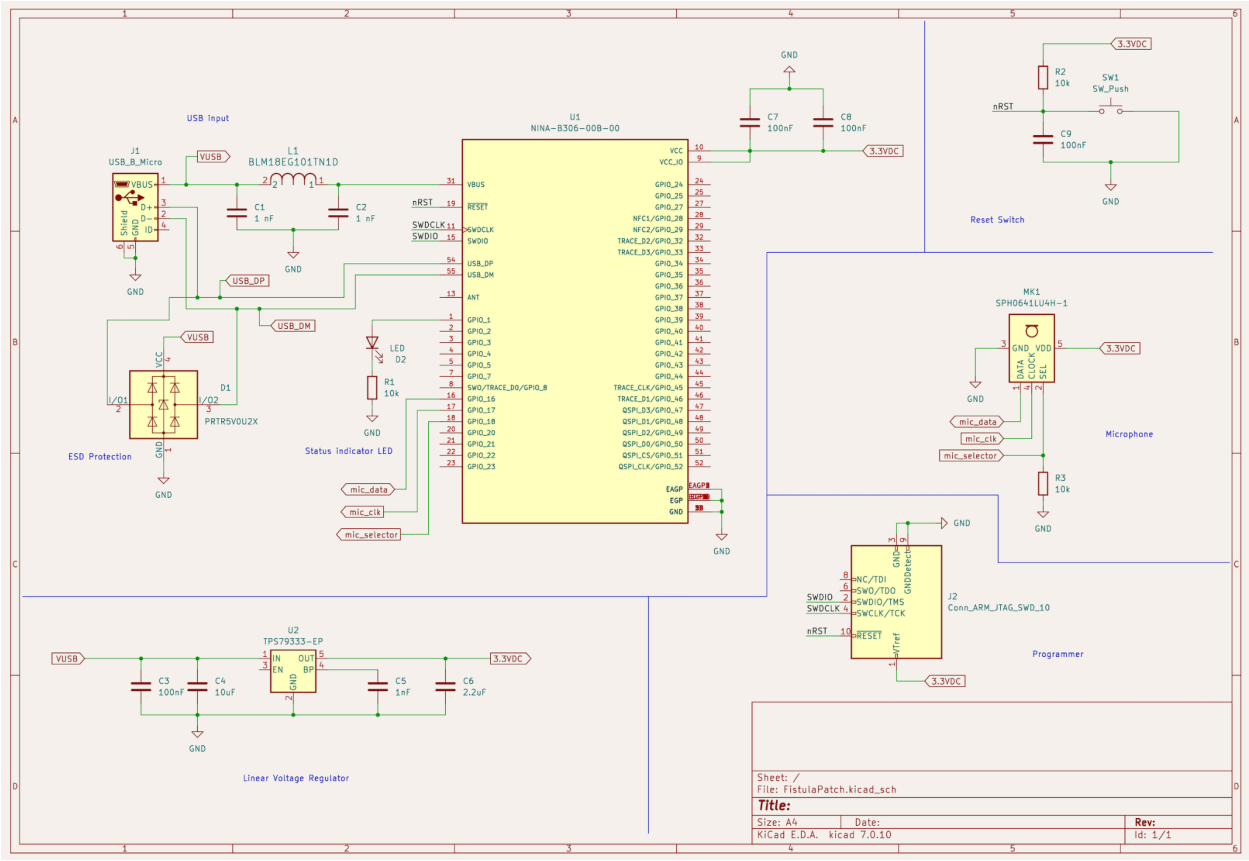


Figure 2: Block Diagram

Our Project has five critical subsystems: Sensing, Power, Control, Power LED, and Smartphone Application.The Sensing subsystem includes the MEMS microphone to record audio and an Electromagnetic interference filter to protect against electrostatic discharge introduced from the analog signals from the microphone. The power subsystem supplies power to the rest of the

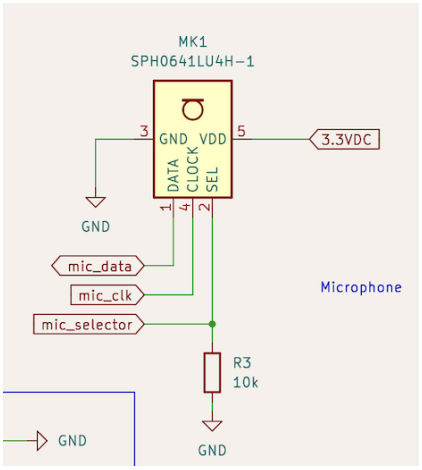
board through a linear voltage regulator. The control subsystem contains our microcontroller and uses the bluetooth module to connect and transmit recorded analog audio signals to our application. The smartphone app processes audio through a CNN hosted on the cloud and displays processed data to the user.



2.2 Sensing Subsystem

The sensing subsystem incorporates the SPH0641LU4H-1 microphone positioned adjacent to the AV fistula for capturing acoustic signals related to venous hum patterns. The microphone output is passed through the PRTR5V0U2X ESD protection component that helps safeguard against electrostatic discharge. Analog signal transmission makes data transfer possible to the control subsystem for frequency spectrum analysis.

The microphone chosen also has a built in amplifier that helps ensure optimal signal strength so there is no need for a separate amplifier.



Requirement	Verification
The sensitivity of the SPH0641LU4H-1 microphone is -26dB ±1dB at a sound pressure level (SPL) of 94dB to accurately capture acoustic signals.	1. Environment: a. Use a quiet, reflection-minimized setting 2. Equipment Needed: a. Sound level calibrator for 94dB SPL at 1kHz. b. Audio interface or preamplifier to capture the microphone's output. c. Computer with analysis software 3. Calibration:

	a. Secure the microphone facing the calibrator. Emit a 94dB tone at 1kHz from the calibrator, positioned in front of the microphone. 4. Measurement: a. Record the microphone's output while the calibrator is active. b. Analyze the recording to measure the dB level of the microphone's output. 5. Calculation & Verification: a. Determine sensitivity by comparing the microphone's output level with the 94dB SPL input. b. Adjust for any signal chain gain to reflect the microphone's true output. c. Verify the measured sensitivity matches the -26dB ±1dB specification.

The device must be situated in an enclosure that is at most 3x2.x2 in dimension.	1. Measure all sides of the enclosure using a tape measure

2.3 Control Subsystem

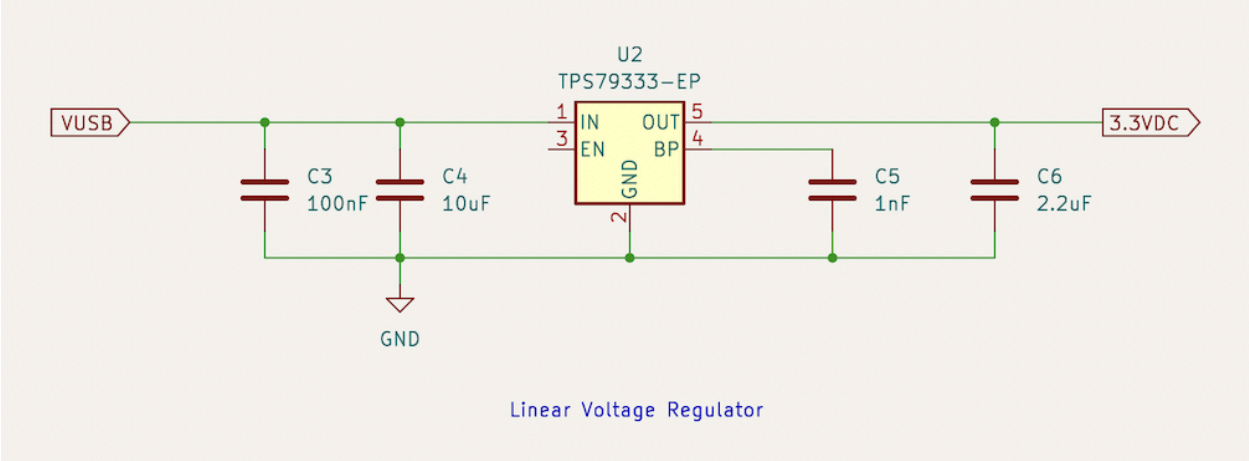
The control subsystem revolves around the NINA-B306-00B-00 microprocessor, responsible for signal analysis and processing. It interacts with the sensing subsystem through analog signal input, incorporating the USB_B_Micro for communication. The microprocessor communicates with the power subsystem, managing stable voltage supply through the TPS79333-EP voltage regulator, utilizing protocol I2S. Bluetooth capabilities enable good data transmission to the mobile application, ensuring remote monitoring.

Requirement	Verification
The microprocessor we use is a NINA-B306-00B-00 with integrated Bluetooth capabilities for good data transmission.	1. Firmware Installation: a. Install the initial firmware, ensuring it's designed to test or utilize Bluetooth capabilities. This involves using a development environment or tools specific to the NINA-B306-00B-00. 2. Bluetooth Functionality Test: a. Discovery Mode: Ensure the

	microprocessor can enter discovery mode and be visible to other Bluetooth devices. b. Pairing and Connectivity: Test pairing with various devices to verify the microprocessor can establish and maintain stable connections. c. Data Transmission: Test sending and receiving data over Bluetooth to evaluate transmission quality and range. This can include sending files, commands, or streaming data to assess throughput and reliability. 3. Software Diagnostics: a. Use software tools and diagnostics to monitor the Bluetooth module's performance, checking for any errors or interruptions in service.

2.4 Power Subsystem

The power subsystem, driven by the TPS79333-EP voltage regulator, ensures stable voltage supply of 3.3V to the system. It interfaces with the control subsystem, providing power through USB_B_Micro and managing fluctuations through communication protocol I2S. The voltage regulator maintains a stable output voltage with a maximum deviation of ±3%.

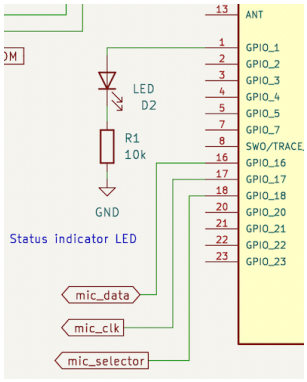


Requirement	Verification
The power subsystem will maintain a stable output voltage of 3.3V with a maximum deviation of ±3% which depends heavily on the load conditions.	1. Connect the TPS79333-EP in a circuit according to the datasheet recommendations, ensuring all capacitors and any additional recommended components are in place. 2. Apply the input voltage as per the datasheet's recommended operating conditions.

	3. Initially, with no load connected (or the minimum load the regulator can support), measure the output voltage using the DMM. 4. Record the voltage to verify it's within the 3.3V ±3% range (3.20V to 3.40V). 1. Repeat with load

2.5 Power LED Subsystem

The power LED subsystem provides visual feedback on the system's operational status, with the LED turned on when the board is operating.



Requirement	Verification
Power LED is for visual feedback. It is used just to let us know that the system is functioning.	1. The power LED turns on when the board is operational.

2.6 Software Subsystem

The software subsystem interfaces with the control subsystem through Bluetooth communication, receiving data and alerts. This subsystem processes audio recordings to classify them based on predefined patterns utilizing cloud computing and machine learning algorithms. In audio deep learning models, spectrograms serve as a compact, image-like representation of audio signals. The process typically involves converting raw audio data into spectrograms, augmenting this data, and then using CNNs to extract features from these images. The features are then used to classify the audio as a healthy fistula or one that has closed.

Requirement	Verification
The app classifies audio recordings using cloud computing based on predefined patterns.	1. The machine learning algorithm has an accuracy rate of at least 75%.

2.7 Tolerance Analysis

The TPS79333-EP voltage regulator is specified to have an output voltage of 3.3V.

The datasheet indicates that the output voltage tolerance is typically ±2%, with a maximum of ±3%.

$$Nominal\ output\ voltage\ (V\_nom)\ =\ 3.3V$$

Typical Tolerance Range:

The typical output voltage tolerance is ±2% of 3.3V:

Lower tolerance limit: V_min_usual = 3.3V - (0.02 * 3.3V) = 3.234V

Upper tolerance limit: V_max_usual = 3.3V + (0.02 * 3.3V) = 3.366V

Maximum Tolerance Range:

The maximum output voltage tolerance is ±3% of 3.3V:

Lower tolerance limit: V_min_max = 3.3V - (0.03 * 3.3V) = 3.201V

Upper tolerance limit: V_max_max = 3.3V + (0.03 * 3.3V) = 3.399V

Feasibility Assessment:

We then have to make sure to check whether the tolerance ranges provided by the TPS79333-EP voltage regulator meet the system's requirements.

Typical Tolerance Range:

The typical output voltage tolerance ranges from 3.234V to 3.366V, which is within the acceptable range of 3.3V ± 2%. This range should be able to power the system components without exceeding their voltage ratings.

Maximum Tolerance Range:

The maximum output voltage tolerance ranges from 3.201V to 3.399V, which is within the acceptable range of 3.3V ± 3%. This is slightly wider than the typical range, but it still ensures that the output voltage remains within safe limits for the system.

Conclusion:

After doing the tolerance analysis using the specifications provided for the TPS79333-EP voltage regulator, we conclude that both the typical and maximum tolerance ranges for the output voltage appear feasible for meeting the system's requirements. The output voltage remains within acceptable limits which means that the system will have a stable power supply to the system components. Therefore, the critical subsystem function of providing stable power supply by the TPS79333-EP voltage regulator is proven feasible through our mathematical analysis.

3. Ethics

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 [4].

4. References

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