ECE 445: Senior Design

Continuous Arteriovenous Fistula (AVF) Monitoring Device

Team 45

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Date: 7 February, 2024

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.

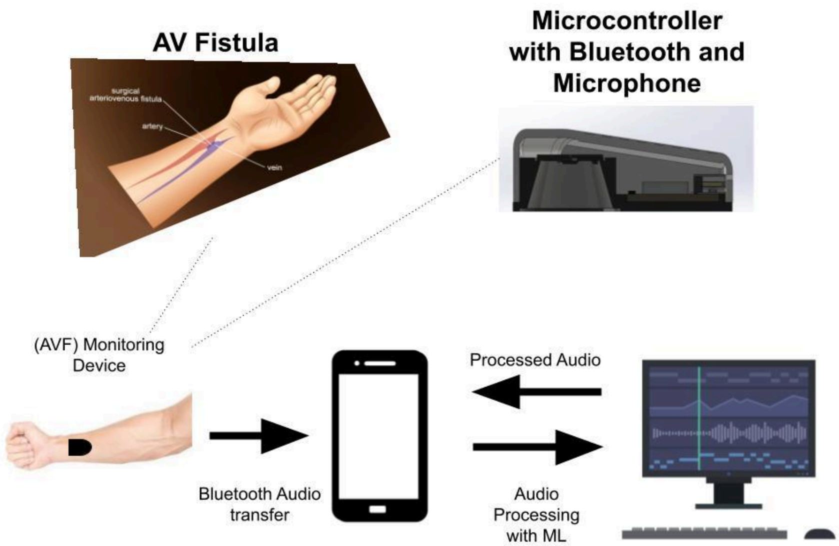


Figure 1: Arteriovenous Fistula Monitoring Device General Design

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 Physical Design

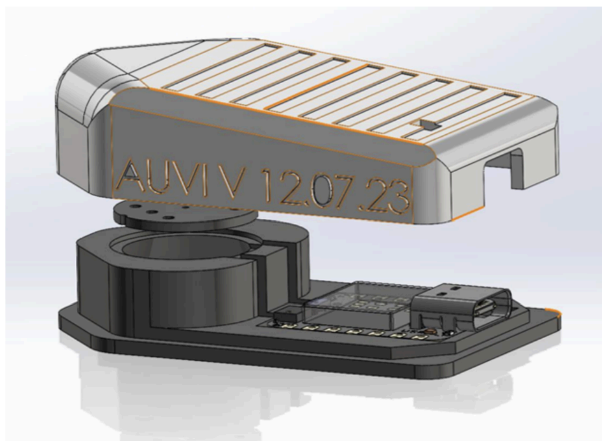


Figure 2: Exploded view of the AUVI Device

Designed as a patch, it consists of a PCB with bluetooth, microcontroller, and a charging element.

Figure 3: Posterior view of the device, highlighting the USB port and microphone module

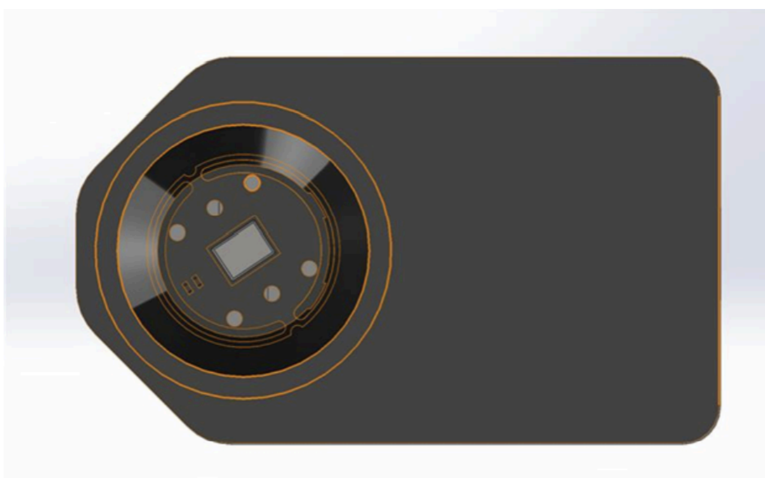


Figure 4: Bottom view of the device.

The bottom of the device is designed to stick to an adhesive, and the highlighted area is designed to channel signal off of the skin to the omnidirectional microphone module.

2.2 Block Diagram Overview

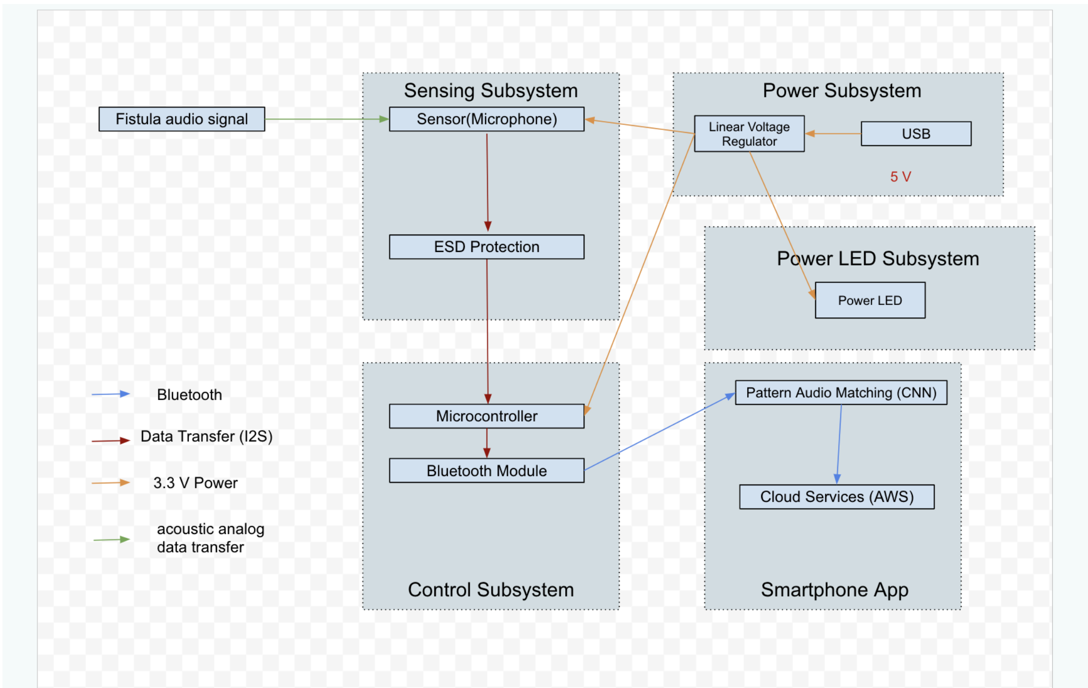
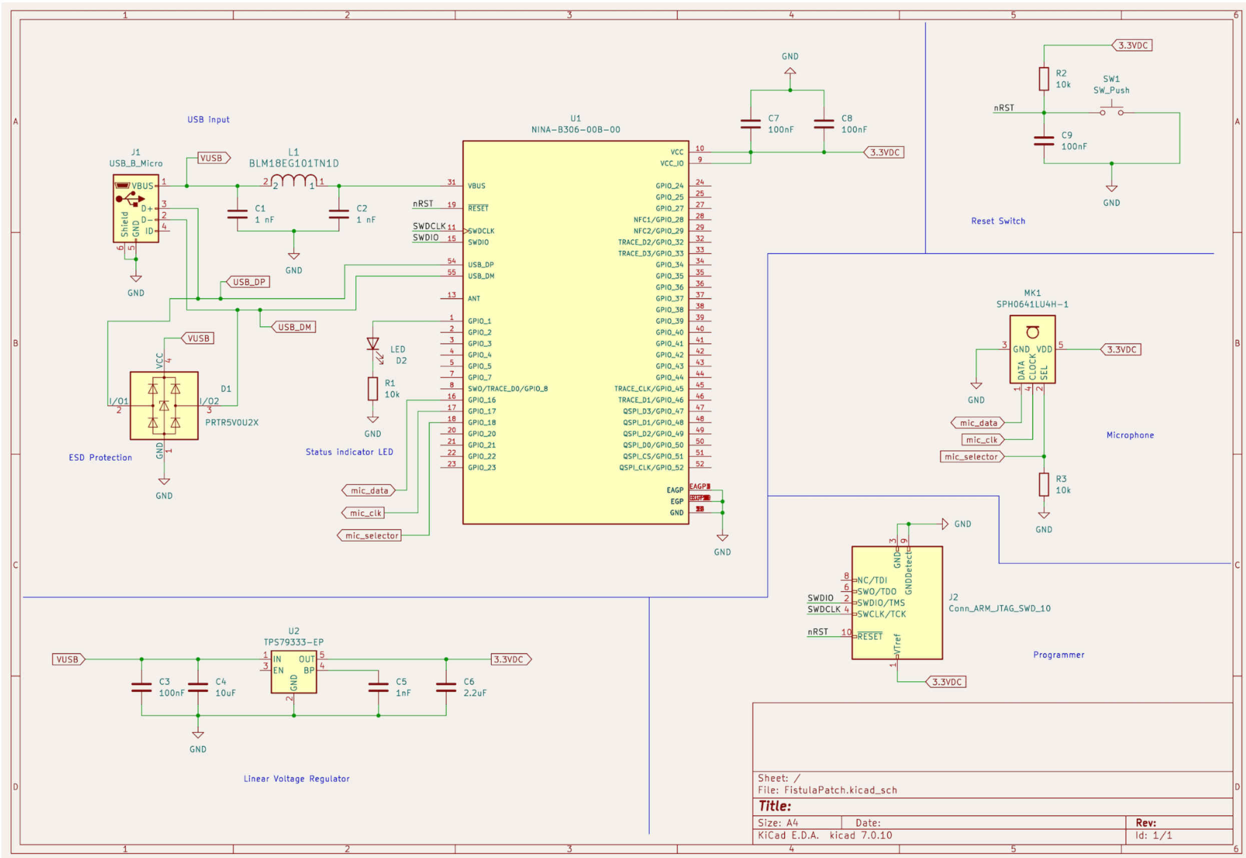


Figure 2: Block Diagram

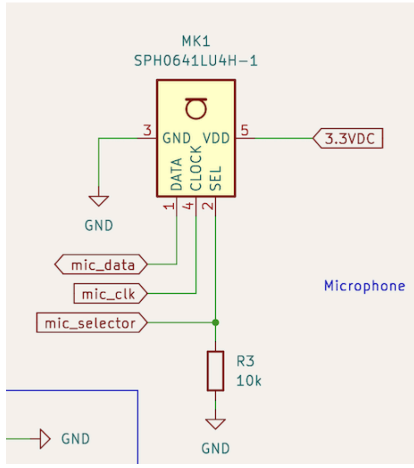
Our Project has five critical subsystems: Sensing, Power, Control, Power LED, and Smartphone Application.The Sensing subsystem includes the MEMS microphone to record audio and an Electromagnetic interference filter to protect against electrostatic discharge introduced from the analog signals from the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



2.3 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	1. Measure all sides of the enclosure

that is at most 3x2.x2 in dimension.	using a tape measure
Test whether the microphone is detecting abnormalities in fistula sounds.	Test the microphone's output by feeding it into the machine learning algorithm. Use known good and bad fistula sound samples to ensure the system accurately identifies each.
Test whether the signal of the microphone is working correctly.	Connect the microphone to an oscilloscope and generate a known sound at the frequency range of interest (below 1 kHz). Verify that the waveform captured by the oscilloscope matches the expected signal without significant distortion.

2.4 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.

2.5 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%.

We have chosen a 5V Lithium Polymer (LiPo) battery as our primary power source. This decision was guided by several factors including the battery's rechargeability and form factor which is ideal since our device is supposed to be compact and portable.

Battery Specifications

Type: Rechargeable Lithium Polymer (LiPo) Battery

Voltage: 5V

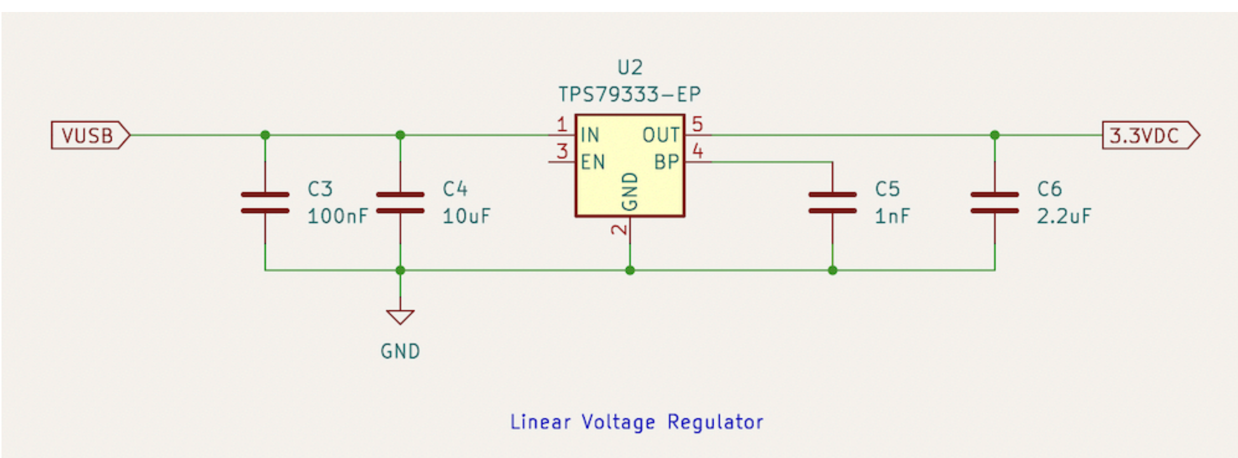
Capacity: 2000mAh, this provides us with a good balance between longevity and the actual physical size.

The integration of the battery into our power subsystem is really important in our design. The battery connects directly to a power management module that includes safe charging and discharging. This module ensures protection against overcharging, deep discharging, and short circuits, thereby extending the battery's lifespan and maintaining user safety.

To accommodate the microcontroller and other components requiring regulated 3.3V power, a voltage regulator (model TPS79333-EP) steps down the 5V from the battery to a stable 3.3V output. This regulator was selected for its low dropout voltage and overall efficiency.

The regulated 3.3V output from the TPS79333-EP is distributed to the NINA-B306-00B-00 microcontroller and other critical subsystems, such as the sensing and control units.

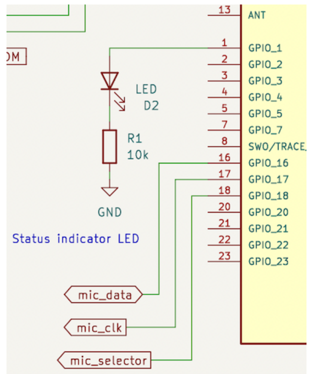
Power Management: This system minimizes energy waste and maximizes battery life by providing each component with the precise voltage it requires for optimal operation. Through this method, we ensure that the device remains energy-efficient, extending the operational duration between charges while maintaining high performance and reliability.



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

2.6 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.

2.7 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.

Data Collection, Cleaning, and Simulation

A significant portion of our advancements in the software component is attributed to data collection, cleaning, and simulation efforts. We used a specialized fistula pump to mimic a broad spectrum of AVF flow patterns to create a dataset mirroring real-world conditions. After the design review, we made sure that this dataset has a lot of different heartbeats and we also introduced white noise so we can account for white noise that people will have in real life as well as to expand the samples.

After the design review, we also recognized the limitations of just physically collected data, so we are also going to include additional simulated data to our datasets. This simulation will replicate a wide range of venous hum patterns, encompassing both continuous and pulsatile flows. This larger dataset bolsters the training of our machine learning models, significantly enhancing their predictive accuracy and reliability. Through rigorous data cleaning, we ensure the integrity and utility of this information for our model training processes.

Machine Learning Model Development

Our technical contributions include the development and refinement of advanced machine learning models, particularly leveraging convolutional neural networks (CNNs) and recurrent neural networks (RNNs). These models undergo training on both collected and simulated data to classify the status of AVFs accurately, focusing on distinguishing between continuous vs. pulsatile flow patterns.

Convolutional Neural Networks (CNN): The development of our machine learning capabilities begins with the application of CNNs, which help identify differences between pulsatile and continuous flow patterns. The CNN's is good at analyzing visual representations of these flow patterns in the spectral data, which makes it effective at classifying the type of flow based on its characteristics.

Recurrent Neural Networks (RNN): Building upon the foundational analysis provided by the CNN, our use of RNNs takes a dynamic approach. The RNN focuses on tracking the temporal changes between pulsatile and continuous flows, analyzing the sequence of data over time to identify trends or shifts in the flow patterns. This capability is particularly valuable for predicting transitions in the fistula's condition, which will really help signal the onset of complications. By recognizing these changes early, the RNN will help our objective of preempting adverse events, offering insight that could inform timely medical intervention before the AVF fails.

Dataset Preparation: I am currently combining the synthetic signals with real-world data collected from the fistula pump simulations, ensuring a balanced and diverse dataset for training and testing.

Model Training: I am currently training the CNN model to differentiate between pulsatile and continuous flow patterns based on the spectral features of the signals. Simultaneously, training the RNN to identify temporal changes in the flow patterns that might indicate an evolving fistula condition.

Performance Evaluation: I am using a validation dataset to evaluate the models' accuracy, sensitivity, and specificity. Run simulations to test the models' response to unseen data, adjusting the architecture and parameters as necessary to improve performance.

Requirement	Verification
Model Training and Validation	1. Utilize a split of training and validation datasets to train the CNN and RNN models, ensuring they

	accurately classify pulsatile and continuous flow patterns. The validation dataset, unseen by the model during training, will test the model's ability to generalize to new data.
Cross-Validation	1. Employ k-fold cross-validation to assess the model's performance across different subsets of the dataset, ensuring reliability and reducing the likelihood of overfitting.
Get additional samples of data for continuous and pulsatile flow to improve the accuracy of the machine learning algorithms	1. Change the heartbeat rate to receive additional samples 2. Add white noise and get more samples 3. Take 1 minute samples and use samples between different intervals such as 1-3 seconds, 4-7 seconds.
The development of our machine learning capabilities begins with the application of	1. Use precision to evaluate the model's ability to correctly identify instances

CNNs, which help identify differences between pulsatile and continuous flow patterns.	of AVF condition changes (e.g., onset of stenosis or thrombosis) from the audio signals, minimizing false alarms. 2. Recall measures the proportion of actual positives correctly identified by the model. It assesses the model's ability to capture all relevant cases of condition changes 3. F1 Score is the harmonic mean of precision and recall. It balances the two metrics, providing a single measure to assess the model's overall accuracy. 4. Application: The F1 Score will be used to evaluate the model's balanced performance in correctly identifying AVF condition changes while avoiding false positives and negatives.
The RNN focuses on tracking the temporal changes between pulsatile and continuous flows, analyzing the sequence of data over	1. sequence accuracy will help assess model performance over time. sequence accuracy could be used to

time to identify trends or shifts in the flow patterns. This capability is particularly valuable for predicting transitions in the fistula's condition, which will really help signal the onset of complications.	evaluate how accurately the RNN model predicts the temporal pattern of flow changes in an AVF. For example, assessing whether the model can accurately predict the sequence of transitions from normal flow to a stenosis condition over consecutive time intervals. 2. edit distance can be useful in evaluating the performance of the RNN model when predictions are not exactly accurate but are close to the true sequence. It can help quantify how far off a prediction is, providing a nuanced understanding of model performance. For instance, if the model predicts a sequence of flow changes that are slightly out of order or includes minor inaccuracies, the edit distance can quantify how much the prediction deviates from the true sequence.

To verify the BLE connection stability between the ESP32 (peripheral) and the central device.	1. The ESP32 was programmed to advertise its presence continuously. The central device, a smartphone running a BLE scanner app, attempted to connect to the ESP32. Upon connection, a simple data packet was sent back and forth every second for a duration of 10 minutes.
To assess the fidelity of audio recordings captured by the ESP32.	1. The recordings were analyzed for clarity, noise levels, and fidelity using audio analysis software.
To determine the speed and efficiency of transferring audio files from the ESP32 to the central device over BLE	1. Audio files of varying sizes (529.2 kB (3 seconds), 882 kB (5 seconds), and 1.41 MB (8 seconds)) were transferred from the ESP32 to the central device. The time taken for each transfer was recorded.
Refine programs to ensure seamless integration with the NINA board, incorporating support for a MEMS microphone. Ensure file management and	1. Confirm that audio is successfully recorded and sent to the mobile application.

transfer capabilities via the onboard file system and Bluetooth module continue to work on the board.	
To evaluate the stability of the BLE connection over extended periods. Procedure: Establish a BLE connection between the ESP32 and the central device, maintaining the connection for 24 hours. During this period, small data packets will be exchanged every 10 minutes.	1. The test will verify if the BLE connection can remain stable without drops for an extended period, which is critical for the application of the device and the patient.
To measure the power consumption of the ESP32 during different stages: idle, recording audio, and transmitting data over BLE.	1. This test will highlight the power efficiency of the ESP32, ensuring that it meets the requirements for low-power devices. It's particularly important for battery-operated devices to ensure longevity.

2.8 Tolerance Analysis

Estimating Model Accuracy Confidence Interval with Bootstrapping

Bootstrapping is a statistical technique that can help estimate the distribution of a statistic (like model accuracy) from the data itself, without needing to assume a normal distribution. This method can be particularly useful for understanding the variability in model performance due to the dataset's size and composition. We will use this to estimate the confidence interval for the machine learning model's accuracy, giving us insight into the reliability and tolerance of the software subsystem's performance.

Model Accuracy

From the original dataset of size N, we will randomly sample N instances with replacement to create a bootstrap sample. This sample will likely contain some duplicates and miss some instances from the original dataset.

We will train our model on this bootstrap sample and then test it on the original dataset to calculate the accuracy.

We will repeat process B = 1000 times to generate a distribution of accuracy scores.

Calculate the Confidence Interval:

From the bootstrapped distribution of accuracy scores, we calculate the desired confidence interval (e.g., the 95% confidence interval) to understand the range in which the true model accuracy is likely to fall.

Mathematical Example:

To calculate the 95% confidence interval:

We sort the bootstrapped accuracy scores in ascending order.

We find the 2.5th percentile and the 97.5th percentile values in the sorted list. These values define the bounds of the 95% confidence interval.

For example, if after sorting our accuracy scores, the 2.5th percentile value is 78% and the 97.5th percentile value is 82%, our 95% confidence interval for model accuracy is [78%, 82%].

This confidence interval provides a quantitative measure of how much the model's accuracy might vary due to variability in our dataset. A narrower interval indicates more reliable model performance, while a wider interval suggests greater sensitivity to data variability.

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. Cost Analysis

The average salary for a student graduating with an electrical engineering degree and computer engineering degree at University of Illinois Urbana-Champaign is around $104,000 [4]. For 50 work weeks at 40 hours per week, this comes out to $52/hour. The project is estimated to take 8 hours of work per week and per person. We calculated using 9 weeks as designing actually starts during week 5 of class and we have spring break in between. Therefore to complete this project, it results in 72 total hours per person (8 * 9). We will not be utilizing the machine shop for our project. We will also multiply our costs by 2.5 to account for any overhead for the development of this project. $52/hour * 2.5 * 72 = $9,360 per person * 3 = $28,080 in labor costs for the project.

Part Expenses			
Part Name	Quantity	Cost	Link
Capacitors 1nF	3	$1.62	https://www.digikey.com/en/products/detail/kemet/C0805C102K5GECAUTO/16680427?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Supplier_Focus%20Supplier&utm_term=&utm_content=&utm_id=go_cmp-20243063242_adg-_ad-__dev-m_ext-_prd-16680427_sig-EAIaIQobChMIxPbNmsqQhQMVY9zjBx34qA55EA0YAiABEgImNvD_BwE&gad_source=1&gbraid=0AAAAADrbLIi7upNbGjgIEExpne-VkHIRB&gclid=EAIaIQobChMIxPbNmsqQhQMVY9zjBx34qA55EA0YAiABEgImNvD_BwE
Capacitors 2.2uF	1	$0.40	https://www.digikey.com/en/products/detail/kemet/C0603C225K8PAC7867/1090906?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Supplier_Focus%20Supplier&utm_term=&utm_content=&utm_id=go_cmp-2024306

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Capacitors 10uF	1	$0.60	https://www.digikey.com/en/products/detail/murata-electronics/GRM188C80G106KE47D/5026386?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Supplier_Focus%20Supplier&utm_term=&utm_content=&utm_id=go_cmp-20243063242_adg-_ad-__dev-m_ext-_prd-5026386_sig-EAIaIQobChMImbyn2MqQhQMVd2dHAR3_7QhYEAQYAyABEgJ2pvD_BwE&gad_source=1&gbraid=0AAAAADrbLli7upNbGjglEExpne-VkHIRB&gclid=EAIaIQobChMImbyn2MqQhQMVd2dHAR3_7QhYEAQYAyABEgJ2pvD_BwE
Capacitors 100nF	4	$2.42	https://www.digikey.com/en/products/detail/kemet/C0603C104K3RAC7081/12701599?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Supplier_Focus%20Supplier&utm_term=&utm_content=&utm_id=go_cmp-20243063242_adg-_ad-__dev-m_ext-_prd-12701599_sig-EAIaIQobChMI9fHZ68mQhQMV6JxaBR0K6AEWEAQYASABEgIWHvD_BwE&gad_source=1&gbraid=0AAAAADrbLli7upNbGjglEExpne-VkHIRB&gclid=EAIaIQobChMI9fHZ68mQhQMV6JxaBR0K6AEWEAQYASABEgIWHvD_BwE
Resistors 10k	3	$1.00	https://www.digikey.com/en/products/detail/yageo/RC0603FR-1310KL/12756437?utm_adgroup=Yageo&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Shopping_Supplier_Yageo&utm_term=&utm_content=Yageo&utm_id=go_cmp-17816160916_adg-_ad-__dev-m_ext-_prd-12756437_sig-EAIaIQobChMIwsCwstCQhQMVcWBHAR3ZNwdtEAQYASABEgJGm_D_BwE&gad_source=1&gbraid=0AAAAADrbLliV4j6oUcADCNqe6ov8iQorl&gclid=EAIaIQobChMIwsCwstCQhQMVcWBHAR3ZNwdtEAQYASABEgJGm_D_BwE

NINA-B306-00B-00	1	$14.35	https://www.digikey.com/en/products/detail/u-blox/NINA-B306-00B/10257713?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Shopping_Product_Medium%20ROAS%20Categories&utm_term=&utm_content=&utm_id=go_cmp-20223376311_adg-_ad-__dev-c_ext-_prd-10257713_sig-Cj0KCQjw8J6wBhDXARIsAPo7QA_HfXsuiNnml8WKj-3ORaxi-v_tj0cBJ_R5Pqy8YFllmMmVTicJHyAaAhlXEALw_wcB&gad_source=1&gclid=Cj0KCQjw8J6wBhDXARIsAPo7QA_HfXsuiNnml8WKj-3ORaxi-v_tj0cBJ_R5Pqy8YFllmMmVTicJHyAaAhlXEALw_wcB
USB_B_Micro	1	$1.95	https://www.mouser.com/ProductDetail/Amphenol-FCI/10103594-0001LF?qs=EnLMdcWnKABYZwdMsmC%2Fag%3D%3D&mgh=1&utm_id=17222215321&gad_source=1&gclid=EAIaIQobChMI3KrkgMyQhQMVh3BHAR2R-AVgEAQYAyABEgIvCvD_BwE
PRTR5V0U2X ESD	1	$0.420	https://www.mouser.com/ProductDetail/Nexperia/PRTR5V0U2X215?qs=LOCUfHb8d9sDkgY4cRj8Lw%3D%3D
SPH0641LU4H-1	1	$2.14	https://www.digikey.com/en/products/detail/knowles/SPH0641LU4H-1/5332438
BLM18EG101TN1D Inductor	1	$0.21	https://www.mouser.com/ProductDetail/Murata-Electronics/BLM18EG101TN1D?qs=rjbY5pkpCp4yQ17nVbKqBw%3D%3D
LED	1	$0.15	https://www.digikey.com/en/products/detail/würth-elektronik/150060AS75000/10468330?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Supplier_Focus%20Supplier&utm_term=&utm_content=&utm_id=go_cmp-20243063242_adg-_ad-__dev-m_ext-_prd-10468330_sig-EAIaIQobChMIkMOw2suQhQMVBtXjBx2gsAo_EAQYASABEgLibPD_BwE

			&gad_source=1&gbraid=0AAAAADrbLli7upNbGjglEExpne-VkHIRB&gclid=EAIaIQobChMIkMOw2suQhQMVBtXjBx2gsAo_EAQYASABEgLibPD_BwE
Conn_ARM_JTAG_SWD_10		$1.50	https://www.digikey.com/en/products/detail/molex/0702461004/2405283?utm_adgroup=&utm_source=google&utm_medium=cpc&utm_campaign=PMax%20Supplier_Focus%20Supplier&utm_term=&utm_content=&utm_id=go_cmp-20243063242_adg-_ad-__dev-c_ext-_prd-2405283_sig-CjwKCAjw5ImwBhBtEiwAFHDZx5tBPYqGu7J2V6av4Yie5m29PvtMirxkHB8RksBNLRFeBSb29_wzTxoCIUEQAvD_BwE&gad_source=1&gclid=CjwKCAjw5ImwBhBtEiwAFHDZx5tBPYqGu7J2V6av4Yie5m29PvtMirxkHB8RksBNLRFeBSb29_wzTxoCIUEQAvD_BwE
		$0.24	https://www.digikey.com/en/products/detail/c-k/PTS636-SM25F-SMTR-LFS/10071742?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-m_ext-_prd-_sig-EAIaIQobChMI1vLInNKQhQMVRp1aBR0ZcQfVEAAYASAAEgL45PD_BwE&gad_source=1&gbraid=0AAAAADrbLljfFypjK0DiU4xGkOd5SLDJ3&gclid=EAIaIQobChMI1vLInNKQhQMVRp1aBR0ZcQfVEAAYASAAEgL45PD_BwE

$26.19 + $28,080 = $28,106.19

The total cost for the project is the Labor Cost for all three members and the parts total is $28,106.19

4. Schedule

Week	Task	Person Assigned
February 26 - March 1	Finish working on PCB design	Rishab
	Start basic outline of the app	Satyansh Aryan
March 4 - March 8	Review PCB design	Rishab
	PCB Design Feedback and Assemble PCB Board	All
March 18 - March 22	Start getting audio samples	All
	Continue working on app	Satyansh Aryan
March 25 - March 29	Teamwork Evaluation 1	All
	PCB Design Feedback	Rishab

	and Assemble PCB Board	Aryan
	Continue working on app	Satyansh
April 1 - April 5	Assemble PCB Board	All
	Final additions to application	All
April 8 - April 13	Test PCB Design and functionality	Rishab
	Work on increasing accuracy of Machine Learning algorithm	Satyansh Aryan
	Finish creating app	All
April 15 - April 19	Mock demo + fix issues	All
April 22 - April 26	Final Demo Work on Presentation	All

April 29 - May 3	Final presentation	All

5. 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.

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].

6. References

[1] Grainger Engineering Office of Marketing and Communications. (n.d.). *Salary averages*. Electrical & Computer Engineering | UIUC. https://ece.illinois.edu/admissions/why-ece/salary-averages

[2] Home Page: American Journal of Kidney Diseases. (n.d.). https://www.ajkd.org/article/S0272-6386(11)00070-9/fulltext

[3] U.S. Department of Health and Human Services. (n.d.). *Annual data report*. National Institute of Diabetes and Digestive and Kidney Diseases. https://usrds-adr.niddk.nih.gov/2022/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities

[4] IEEE code of Ethics. IEEE. (n.d.). https://www.ieee.org/about/corporate/governance/p7-8.html