Artificial Intelligence Enabled Pocket Doppler Ultrasound

Josh Hanson, Ethan Hurt, Anvitha Doddipalli, Jess Miron - S.B.H.S.E.

Clinical Mentor: Robert McBane II, MD - Mayo Clinic
Faculty Mentor: Jitendran Muthuswamy, PhD - S.B.H.S.E.
Technical Mentor: Michael D'Saachs - S.B.H.S.E.

Mission Statement

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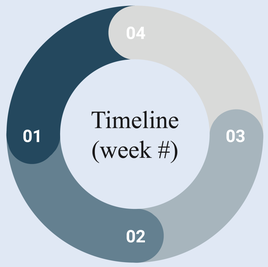
Background

Peripheral artery disease (PAD) is defined as the narrowing or blockage of arteries, both of which are often caused by athersoschlerosis. Over **100m americans are at risk of developing PAD** due largely to an increase in obesity prevalence, and there are no outstanding treatment methods for treating PAD. Because it's symptoms are often masked by other comorbidities, many patients are not diagnosed until the disease is highly progressed. Thus, the **early detection and prevention of PAD is critical** to avoiding adverse outcomes such as major adverse cardiac events (MACE), major adverse limb events (MALE), or death. Furthermore, the process of diagnosing and managing PAD is lengthy and expensive. The time between symptom onset and treatment plan is oftentimes upwards of four weeks.

Patient Symptoms
Patient complains about symptoms or physician notices risk. A vascular lab test is then requested

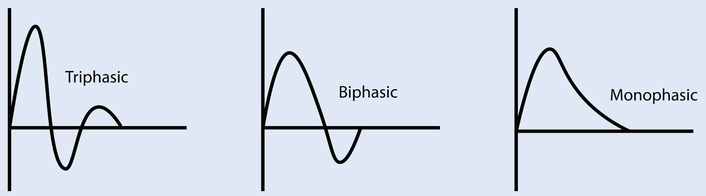
Vascular Lab Test
Ankle-brachial pressure index (ABPI) is measured by Doppler probe in non-standardised fashion



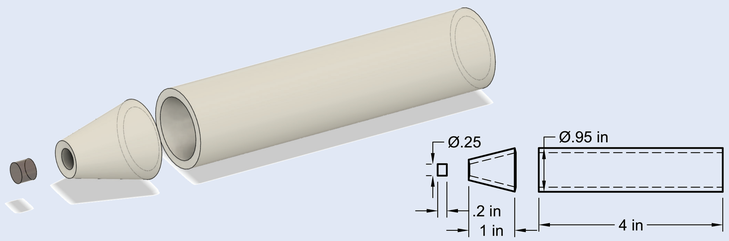
Treatment Plan
Severity and location of the disease can be measured by follow up tests and deeper waveform analysis

Vascular Consult
Patient is diagnosed by a vascular specialist who can interpret both the ABPI and waveform morphology

PAD can be diagnosed by classifying doppler waveforms as monophasic, biphasic, or triphasic (see below). Triphasic waveforms indicate healthy arteries with elasticity, whereas monophasic waveforms indicate heavily calcified arteries. Monophasic waveforms are usually indicative of severe PAD onset and can sometimes point towards MACE, MALE, or death.



Product Design



Modeling

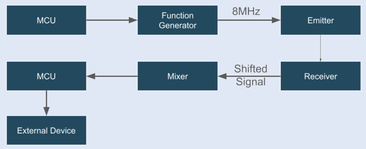


Figure 1 (above): This block diagram outlines the flow of signals through the Doppler system. A micro-controller unit controls a function generator, which generates an 8 MHz signal through an emitting PZT plate. This signal is received by another PZT plate, processed by a mixer to differentiate the shifted signal from the original one, and sent back to the MCU for export to an external device.

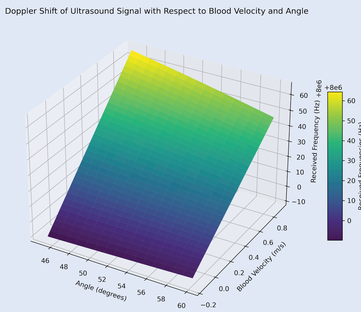
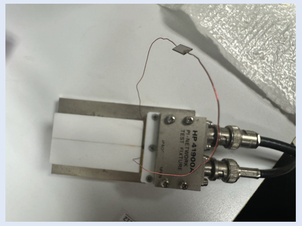


Figure 2 (above): Doppler shift is directly proportional to blood velocity but inversely proportional to angle. More importantly, values of doppler shift tend to be very small compared to those of the emitted signal, requiring precise measurement techniques to produce accurate insights.

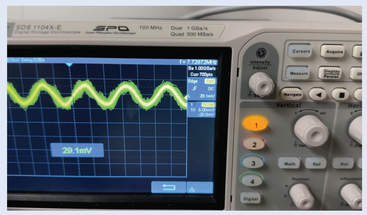
Prototyping

Prototyping required that we split circuit development into two parallel tracks: transducer integration and main circuitry (emitter and receiver). While the fragile transducers required careful wiring and power testing, the emitter (function generator/amplifier) and receiver (demodulation/signal processing) circuits were more straightforward. This parallel approach allowed for nonlinear verification and accelerated prototyping progress.



Testing Mechanism

The testing mechanism was designed as a flow phantom to emulate blood flow through an artery. Using special tubing with similar flow properties to a human tibial artery, we constructed a device which was capable of creating liquid flow at a controlled speed through a vessel. This system was then analyzed with the doppler ultrasound probe to test its accuracy.



Validation

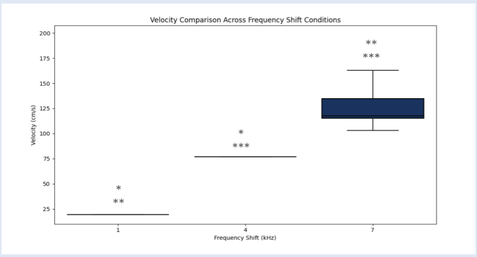
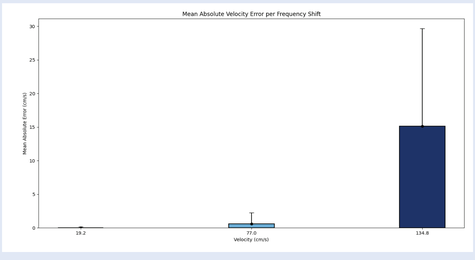


Figure 3 (left): Box plot with ANOVA comparison of recorded Doppler velocities across frequency shift conditions, showing that all velocities can be distinguised at a statistically significant degree from one another. Notably, velocity measurements at a higher frequency shift experience a larger range of values and error, but maintain statistical significance from all other frequency shift values as seen below:

1 kHz vs 4 kHz: $p \approx 4.43 \times 10^{-307}$ (***)
1 kHz vs 7 kHz: $p \approx 1.88 \times 10^{-158}$ (***)
4 kHz vs 7 kHz: $p \approx 7.68 \times 10^{-94}$ (***)

**denotes statistical significance between data groups where $p < 0.01$*

Figure 4 (right): Bar plot of mean absolute error between recorded and actual Doppler velocities measured across three parameters. These metrics offer valuable insight in that the current system lacks accuracy in its measurements at high veocities (frequency shifts). Thus, further testing is needed to determine whether the velocity of human blood flow falls in a frequency shift range with minimal error.



We performed two statistical analyses on Doppler velocity data collected across three frequency shift conditions (1, 4, and 7 kHz). First, we ran a one-way ANOVA to determine whether the recorded velocities significantly differed across these conditions, followed by pairwise t-tests with significance levels annotated directly above the boxplots to clearly visualize group differences. Second, we assessed the accuracy of the recorded velocities by recalculating the expected frequency shift from each velocity using the known equation and comparing them to the theoretical velocities derived from the exact input frequencies. We then quantified the absolute error between actual and recorded values and visualized the mean absolute error per group using a bar plot.

Moving Forward

This project is nearing the point of being considered an early-stage MVP. Regulatory steps include research into the 510(k) FDA approval pathway, along with adherance to various ultrasound standards such as the ISPTA regulations, which specifies that power output must be less than 720 mW/cm^2. We anticipate that the 510(k) pathway will be appropriate due to the widespread use of ultrasound technology in today's healthcare ecosystem.

Acknowledgements

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