"Atrial Fibrillation Screener" - Tong BME Design Award Executive Summary

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Atrial fibrillation (**AF** or **A-fib**) is an abnormal heart rhythm characterized by rapid and irregular beating. A-fib in the atria can lead to clot formation, which increases a person's risk of ischemic stroke five-fold, and premature death two-fold. There are an estimated 2.3 to 5.1 million people living with afib, with up to 20% of these people undiagnosed (Harvard, 2011). The risk of afib can be reduced by half through the use of blood thinning medications such as Warfarin and Xarelto. Because afib is paroxysmal, it is very challenging to detect, and many people don't know they have it until it's too late. By creating a portable, inexpensive, and accurate device, clinicians could screen the population for afib, greatly reducing the harmful effects before they become deadly.

The screener could be an essential tool for assessing a patient's cardiac health, easily incorporated into routine visits to the doctor. The current method of detecting afib is with an electrocardiogram (ECG). Due to their limited availability, an appointment must be scheduled at an earlier time. During this appointment, a clinician must place electrodes, run the ECG, and have a doctor interpret the results. Each test can cost a patient anywhere from $30 to $550 depending on the patient's insurance (New Choice Health, 2015). The afib screener's 30 s test can be done while the medical assistant is taking vitals, saving time and unnecessary ECGs. Most importantly, the afib screener would provide point of care diagnosis to people unknowingly living with afib without the need for specialized knowledge possessed by doctors.

There are two main competitors to the afib screener, AliveCor and AfibAlert. AliveCor is a one lead ECG that doubles as a smartphone case and costs $100. When combined with an app, it displays a subject's ECG waveform in real time, and uses its own algorithm to detect afib. AfibAlert is a handheld ECG device that uses an algorithm to detect afib, display the result to a user, and send the data to a database monitored by doctors. AfibAlert is expensive, costing $300, with a $75 yearly subscription. The largest drawback to these devices, besides the cost, is their market, consumers. Since the deadly effects of afib can only be reduced by the use of prescription medication, it is not important for someone to know when they are in afib, only that they have it, making a consumer device unnecessary. Our device fills a void in the cardiac monitoring market, being made for use in hospitals and clinics, where a patient could be immediately diagnosed and treated.

The screener, which is approximately the size of a tablet, is held in the relaxed hands of the patient and is ergonomically designed so that the patient's' fingers are placed over electrodes to record the lead I ECG. Throughout initial testing, normal and afib positive ECG waveforms were taken from an MIT database, were analyzed with the algorithm, resulting in a sensitivity of 0.909 and a specificity of 0.913.

In the future, widespread use of the afib screener during normal checkups could eliminate undiagnosed afib, potentially saving thousands from strokes. The device also has the potential to screen for more than just afib. Future iterations of the screener could include screens for other arrhythmias making it a flexible and accurate way for anyone to easily and quickly determine the state of a patient's cardiac health during a routine vitals check, making a screen for afib the 5th vital sign.