Heart Rhythm

Atrial Fibrillation Screener

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Introduction

Atrial fibrillation (afib) is the most common type of atrial arrhythmia, affecting 2.3 to 5.1 million Americans with 150,000 new cases diagnosed each year [1]. Approximately 20% of people with afib are undiagnosed and due to its paroxysmal nature, it can only be diagnosed by an ECG or by telemetry [2]. Afib can be a deadly arrhythmia, doubling the probability of heart related death and causing a 4 to 5 fold increased risk of stroke [1]. Patients are often prescribed blood-thinning medication to treat afib, while some undergo surgery as well. Once treated, the risks of stroke and heart-related death are dramatically reduced; thus, early detection is essential to reducing the risks caused by afib. By screening for afib with a simple device during normal checkups, the number people living with undiagnosed afib can be reduced, resulting in many lives saved.

During atrial fibrillation, electrical signals are not propagated from the SA node, but from the pulmonary veins [2]. Incorrectly propagated signals cause the atria to fibrillate, or contract quickly and irregularly. The irregularity of the contractions causes the AV node to receive faulty signals, which induces an irregular rhythm of the ventricles as well [3]. On an ECG strip, this manifests as a diminished p-wave and an irregular R-R interval, respectively.

When the atria fibrillate, they cannot efficiently pump blood to the ventricles. This causes many problems [2]. The biggest problem is that blood can stagnate and clot in the atrial appendage. These small clots can be released into the body where they block areas of the brain, inducing an ischemic stroke [4]. Afib also decreases oxygen distribution through the body. When the right ventricle doesn't receive a consistent amount of blood, the heart cannot deliver re-oxygenated blood back into rest of the body, causing fainting.

To diagnose afib, an electrocardiogram (ECG) is used to measure the passage of the electrical signals in the heart. A 12-lead ECG is the gold standard used to diagnose afib. The ECG of a normal heart will show QRS complex with a clearly defined P-wave as well as constant distance between each complex. In afib, however, the P-wave is not easily recognizable and QRS complex is not repeated at a constant rate, creating unequal R-R timing intervals. Using these features, we designed an algorithm to detect the presence of afib. To implement the algorithm in a clinical setting, a small handheld ECG was built to be easily integrated into a normal vitals routine.

Methods

Algorithm

To perform an afib screen, a one-lead ECG is taken for 30 *s*. The ECG signal is smoothed and filtered for further processing by the detection algorithm. Finally, the afib detection algorithm identifies each R-R interval and calculates the percentage of irregular beats in the 30 *s* screen.

The 30 *s* ECG signal is read in completely and converted from an analog to an analog digital converter (ADC) value using a 5.00 V Arduino Pro Mini microcontroller. This digital signal is sent to a Raspberry Pi computer and converted back to a voltage value using Equation 1 below.

$$\frac{ADC\ Resolution}{System\ Voltage} = \frac{ADC\ Reading}{Analog\ Voltage\ Input\ (V)} \tag{1}$$

The ADC resolution is the number of values between 0.00 V and the system voltage. The ADC resolution is represented by Equation 2.

$$ADC\ Resolution = 2^{Number\ of\ ADC\ Bits} - 1 \tag{2}$$

The Arduino Pro Mini dedicates 10 bits to its native ADC. The system voltage of the Arduino Pro Mini used is 5.00 V. Equation 3 describes the analog voltage input is the value of the ECG signal.

$$Analog\ Voltage\ Input\ (V) = s(t)\ V, t = nT \tag{3}$$

n is the current sample number and *T* is the sampling interval. The Arduino will sample the voltage at its maximum sampling interval of 0.0001 *s* [5].

Combining Equations 1, 2 and 3, Equation 4 is the current ADC value.

$$ADC\ Reading = \frac{1023 * s(nT)\ V}{5.00\ V} \tag{4}$$

The Raspberry Pi samples the ADC reading of the Arduino Pro Mini at a sampling interval of 0.004 s, equivalent to the gold standard 12-lead ECG sampling interval. The total number of samples taken is equivalent to the total screening time divided by the sampling interval. For the screener, 7500 samples are taken. The Raspberry Pi saves these 7500 ADC values in an array for further processing.

This sampled signal is processed after collection of the entire signal to make it more compatible with the algorithm. The sampled signal is smoothed out and motion artifact is eliminated from the signal.

The signal is first smoothed out to account for different artifacts that are common in ECGs. The algorithm performs a weighted smoothing described in Equation 5 [6].

$$s(nT) = \frac{s((n-2)T) + 2s((n-1)T) + 3s(nT) + 2s((n+1)T) + s((n+2)T)}{9} \quad (5)$$

$s(nT)$ is the signal at a specified time nT.

$s((n -^*)T)$ is a signal at a shifted time.

The smoothing effect is evident when comparing the ECG waveform before and after the smoothing algorithm. The difference is shown in Figure 1.

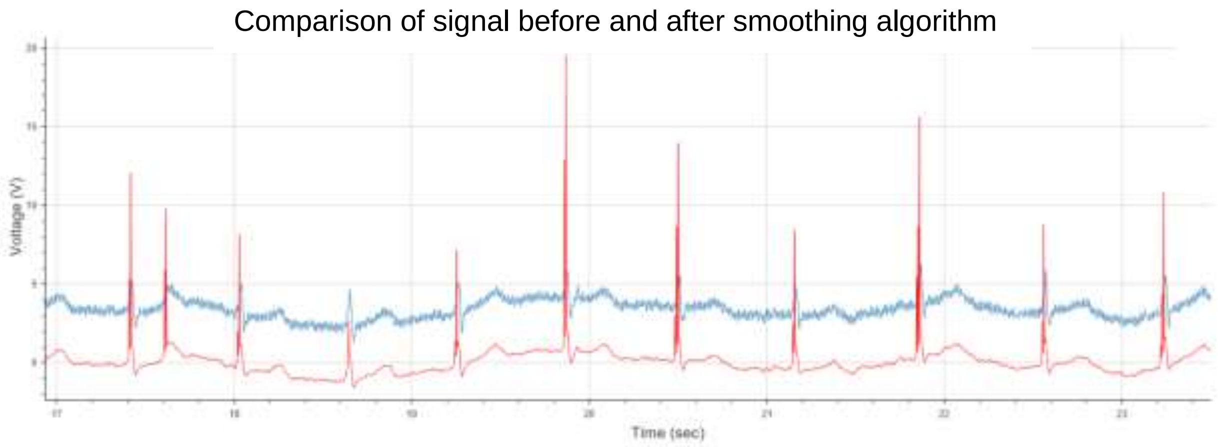


Figure 1: Comparison of a signal before and after a weighted smoothing algorithm is applied. The blue signal represents the original signal. The red signal is the original signal after the smoothing algorithm has been applied.

After smoothing, the signal is split into many contiguous and equivalent length sections to account for and eliminate the baseline shift artifact caused by patient motion like breathing.

Each section's average value is found and is subtracted from each value in the section. This will shift the signal average to 0.0 V. Smoothing and shifting the center of the signal to 0.0 V eliminates the sharp instantaneous slopes between points. Figure 1 shows this effect with the red signal centered at 0.0 V. The last part of the algorithm uses these instantaneous slopes and actual voltage values to identify the R-waves in the signal.

After the preprocessing, the algorithm runs the signal and returns the binary result, afib positive or afib negative. The algorithm is realized using three separate thresholds. The first threshold helps to identify R-waves, called the R-wave identifier threshold. The second threshold is a confidence interval range value used to determine the number of irregular beats in a signal. The third threshold is a percentage threshold for the number of irregular beats over the total number of beats.

The algorithm finds the maximum voltage value of the signal and multiplies that value by the R-wave identifier threshold to calculate the R-wave threshold. The signal is scanned for all voltage values that are above the R-wave threshold and have a slope above $0.15\ \frac{\mathrm{mV}}{\mathrm{msec}}$, a clinically accepted slope for the Q-R curve of an ECG [7]. The times of the identified R-waves are saved in the R-wave array with a length equal to half the heart rate of the patient.

The R-wave array is then used to find the R-wave interval array. The R-wave interval is the length of time between the current R-wave and the next R-wave. Equation 6 describes how the R-wave interval array was calculated.

$$m[n] = r[n+1] - r[n] \tag{6}$$

r[*n*] is the R-wave array

m[*n*] is the R-wave interval array

n is from 0 to length(*r*) – 1

The average R-wave interval is calculated using all the R-wave intervals. Then the average interval with a confidence interval is used to determine if each R-wave is at steady positioning. The range of the R-wave position confidence interval is set by Equation 7 below.

$$\begin{aligned} &R - wave\ position\ confidence\ interval\ range \\ &\qquad = average\ interval\ \pm (average\ interval * confidence\ interval\ threshold) \end{aligned} \tag{7}$$

Each R-wave interval is compared to the R-wave position confidence interval. If the interval is inside of the R-wave position confidence interval range, the interval and therefore R-wave is considered a regular beat. If the interval is outside of the range, the R-wave is considered irregular.

The final threshold compares the number of irregular R-waves to the total number of R-waves. This is used to give the binary result of afib positive or negative. If the percentage of irregular R-waves is greater than the final percentage threshold, the result of the screen is afib positive.

To find the best set of threshold values, data from PhysioBank, a database of patient ECG samples exhibiting normal sinus rhythm and afib, was used [8]. The ECG samples were run through the screening algorithm and compared the result of the screen to the samples expected value. The sensitivity and specificity were found for each threshold value set by using 25 randomly selected samples from the PhysioBank database. The sensitivity and specificity of each set was mapped a Receiver Operating Curve (ROC) (Figure 7).

Figures 2, 3, and 4 shows each step of the algorithm using a sample taken by the screener of an individual without afib. The signal represented is only an 8 *s* strip of the full 30 *s* screen.

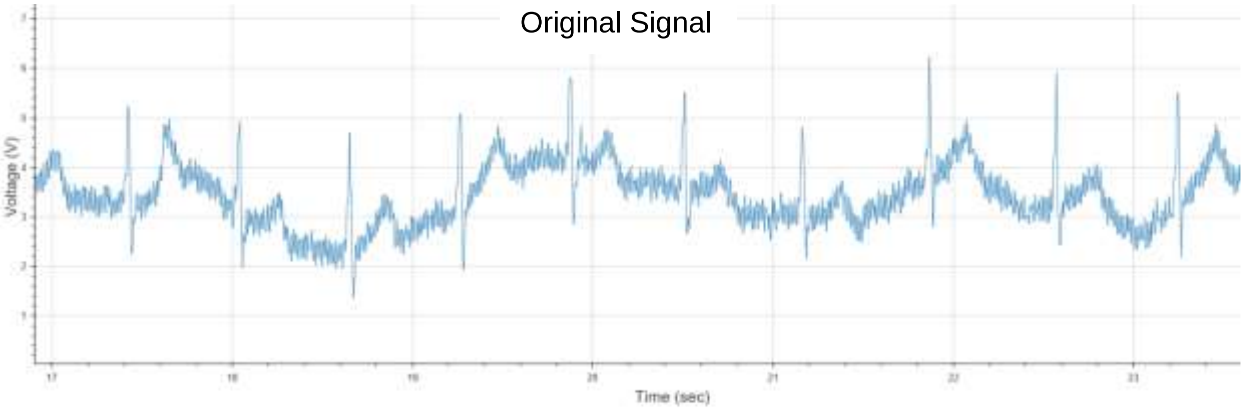


Figure 2: The original signal. The blue line is the signal read in by the screener itself.

Signal after Identifying R-waves

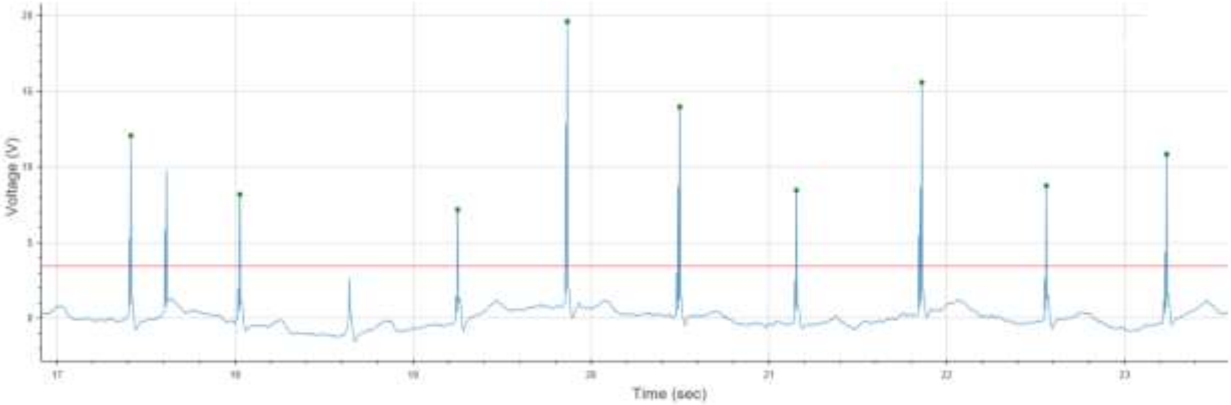


Figure 3: The signal after identifying the R-waves. The blue line is the signal after smoothing and zero-ing the average. The red line is the R-wave identifying threshold. At the top of all the identified R-waves, there is a green dot. Note: the algorithm missed one R-wave between 18 and 19 *s*.

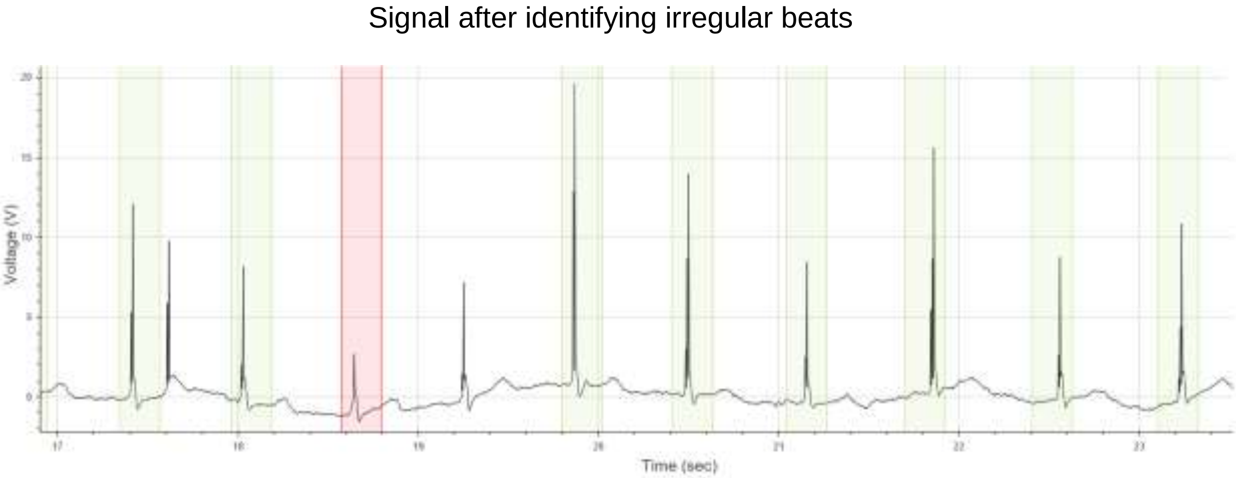

Signal after identifying irregular beats

Figure 4: Each identified R-wave is either categorized as irregular or regular. The R-waves within green boxes are regular beats while red boxes signify irregular beats. The red box is a result of the missed R-wave from Figure 3.

Electrical Hardware

The screener uses a one lead, three electrode ECG design where all three electrodes are placed on the fingertips. The electrical signals are synthesized into a single voltage value by the Single Lead Heart Rate Monitor from Sparkfun Electronics [9]. The single voltage output from the monitor is read by a 5.00 V Arduino Pro Mini where the voltage is converted to an ADC value using Equation 4.

The true sampling interval, *T* in Equation 3, used to sample the electrical signals of the heart is set by the afib screening algorithm. The algorithm is written in the Python Programming Language and is run on a Raspberry Pi 2 Model B computer [10]. The Raspberry Pi only transfers an ADC value from the Arduino Pro Mini to the Raspberry Pi every 0.004 *s*, the standard sampling interval for a 12 lead ECG. The ADC value is transferred from the Arduino Pro Mini to the Raspberry Pi using an USB to TTL serial communication chip, which allows for the easy transfer of the ADC values.

The result of the algorithm will be displayed on a 12.7 cm display with touchscreen capabilities. Both the display and Raspberry Pi have HDMI and USB ports for easy communication between the two devices.

A Wi-Fi dongle is also used by the computer to allow a wireless connection to the internet. The Raspberry Pi has the capability of running as a web-server once connected to the internet. Each screening sample can then be saved in a database system called MySQL and can be used for further analysis. Keeping ECG samples will allow the algorithm to be revised and improved over time.

To power the full screener, a 3.7 V, 1200 mAh Lithium-Polymer (LiPo) rechargeable battery is included in the screener device [11]. The Raspberry Pi, Arduino Pro Mini, and display all run on 5.0 V however, so a 3.7 V to 5.0 V DC/DC converter is used to boost the voltage and to recharge the battery [12]. The battery will last approximately 2 *h* before a recharge is necessary according to Equations 8, 9 and 10.

$$Battery\ Length\ of\ Life = \frac{mAh\ rating\ of\ battery}{Total\ current\ draw\ (mA)} \tag{8}$$

$$\begin{gathered} Total\ Current\ Draw = Current\ Draw\ from\ all\ components\ of\ circuit \\ Total\ Current\ Draw\ of\ Screener = 300\ mA\ (avg) Raspberry\ Pi \\ +\ 300\ mA\ (avg) Display\ +\ 10\ mA\ Arduino\ Pro\ Mini \\ +\ 0.2\ mA\ ECG\ Monitor\ Circuit\ [5][9][10][13] \end{gathered} \tag{9}$$

$$Total\ Current\ Draw\ of\ Screener = 610.2\ mA$$

$$Battery\ Life = \frac{1200\ mAh}{610.2\ mA} = 1\ hour\ 58\ minute \tag{10}$$

Since each screen last just over 30 *s*, about 240 individual screens can be performed without needing to recharge the battery. The DC/DC converter is also able to recharge the LiPo battery and power the device.

Electrode Manufacturing

The electrodes will be fabricated using a method similar to the method described in Meziane et al. [14]. A 0.1 mm thick titanium foil, which will serve as the surface of the dry electrode, will be epoxied to a 0.635 mm thick sheet of stainless steel using MG Chemicals 8331S two-part, pure-silver electrically conductive epoxy. A snap fastener (male end) will be epoxied to the stainless steel using the same MG Chemicals epoxy. A female snap connector and cord traditional to ECG readings will be attached to the male snap fastener, and serve as the connection between the three electrodes and the ECG circuit. A diagram depicting the layers of the electrode is seen in Figure 5.

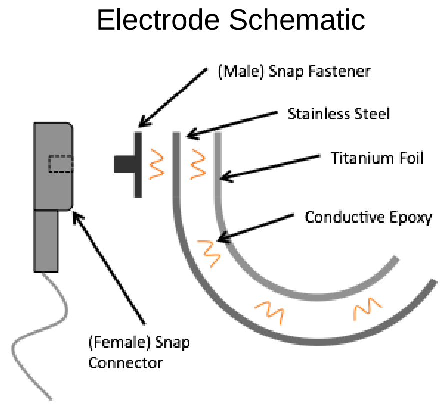
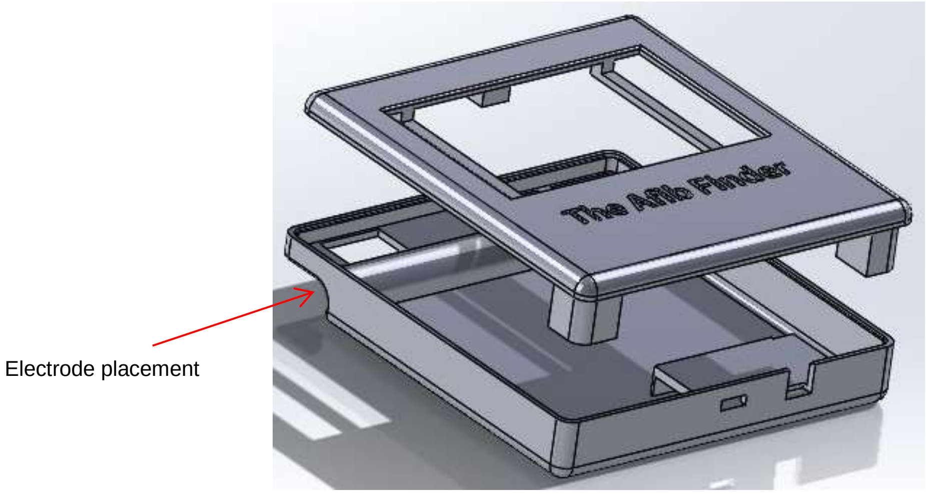


Figure 5: Electrode Schematic. A male snap fastener will be attached to a dual layer of Stainless Steel and Titanium foil with conductive epoxy. The male snap fastener will connect to a female snap connector to propagate the electrical signals to the ECG monitor.

The three electrodes will be contoured to match the patient’s fingers and positioned at the rear of the device as seen in Figure 6. The device requires the use of three total electrodes: two active electrodes and one reference electrode. One active electrode will have dimensions of 50 × 25 mm, while the other active electrode and reference electrode will have dimensions of 25 × 25 mm. Each electrode will be placed flush with the surface of the curve, forming a comfortable groove for the user. The one active electrode that is 50 × 25 mm will be placed on the left, while the other two electrodes will be placed on the right. In order to prevent grounding of the second active electrode with the reference electrode, the two will be separated by a 1 mm buffer.

Case Design



Electrode placement

Figure 6: The proposed case design in prototype form. This physical prototype was fabricated using foam board to aid in the process of determining the internal layout. The electrodes will be placed along the curved edge at the rear of the device.

The use of snap fasteners in this design allows for the electrodes to be swapped out in case of failure. However, according to testing completed in the report detailing the method for fabrication of these electrodes, the titanium will provide a very durable and high quality signal to the ECG, likely removing the need for replacement of the electrodes.

Human Testing

The afib screener was recently approved by the Institutional Review Board of the Dean Clinic and St. Mary's Hospital for human testing which will begin soon. Our protocol was approved by the IRB and is outlined below.

When a patient comes in for their scheduled appointment, they will be asked to sign a consent form, allowing the patient to participate in the device testing. To test the validity of the screener two screen will be run, one sitting up and during vitals, and the second simultaneous to a 12-lead ECG laying down. The patient will be instructed on how to use the device while a medical professional performs their vitals sign routine. The medical professional will prompt the patient to follow the instructions on the screen while staying relaxed and still for the best possible during the reading. The test will be administered again simultaneously with a 12-lead

ECG test. The results of the screener test will be transferred to a computer to allow the results to be reviewed. A participating physician will review and determine whether the patient was in afib or not, by looking at the feedback from the screener as well as the generated ECG strips from both the screener and the 12-lead ECG.

The study will comprise at least of 50 participants. Running the test simultaneously with the ECG means that the afib screener can be compared to the results provided by ECG so no discrepancies between the two analyses are allowed.

Results

Using the PhysioBank ECG recordings, the maximum accuracy set of thresholds were found. The best set was found using an optimization script that runs through a large number of parameter sets and tests each parameter set on 34 different ECG samples. This optimization allows the algorithm to use the set the thresholds that were statistically proven to provide the best results. Table 1 below shows the statistics gleaned about a single threshold set in the optimization script. The accuracy of this set is 91.2%. The parameter set in Table 1 is the threshold set found to have the highest accuracy and will be used during IRB testing. The set of thresholds used in the algorithm will change and improve after receiving new samples to use in future executions of the optimization script.

Parameterization Statistics			
Results		**ROC Statistics**	
Accuracy	91.2%	Distance from (0,1)	0.126
		Sensitivity	0.909
Parameter Set		1 – Specificity	0.087
R-Wave Threshold	0.27		
Confidence Interval	0.19	**Set Statistics**	
Percentage	0.23	# True Positives	10
		# True Negatives	21
Statistics		# False Positives	2

Accuracy	91.2%	# False Negatives	1
%True Positive	29.4%	# Heart Rate Errors	0
%True Negative	61.7%		
%False Positive	5.9%	**Test Statistic**	
%False Negative	2.9%	# of Runs	34

Table 1: Example output from an optimization script execution. The threshold set used is displayed first along with the accuracy of the set. The statistical counts of the set are displayed on the lower half of the table.

Figure 7 displays a standard ROC Curve for all the parameter sets in a single optimization run. A ROC curve plots the sensitivity versus 1 – specificity of a binary classification algorithm. Sensitivity, in this application, is the proportion of patients with afib that are tested positive by the algorithm [15]. Specificity is the proportion of patients without afib that test negative [15]. The higher the sensitivity and specificity, the better the algorithm is at the set of thresholds. This is represented in Figure 7 by the point closest to (0,1).

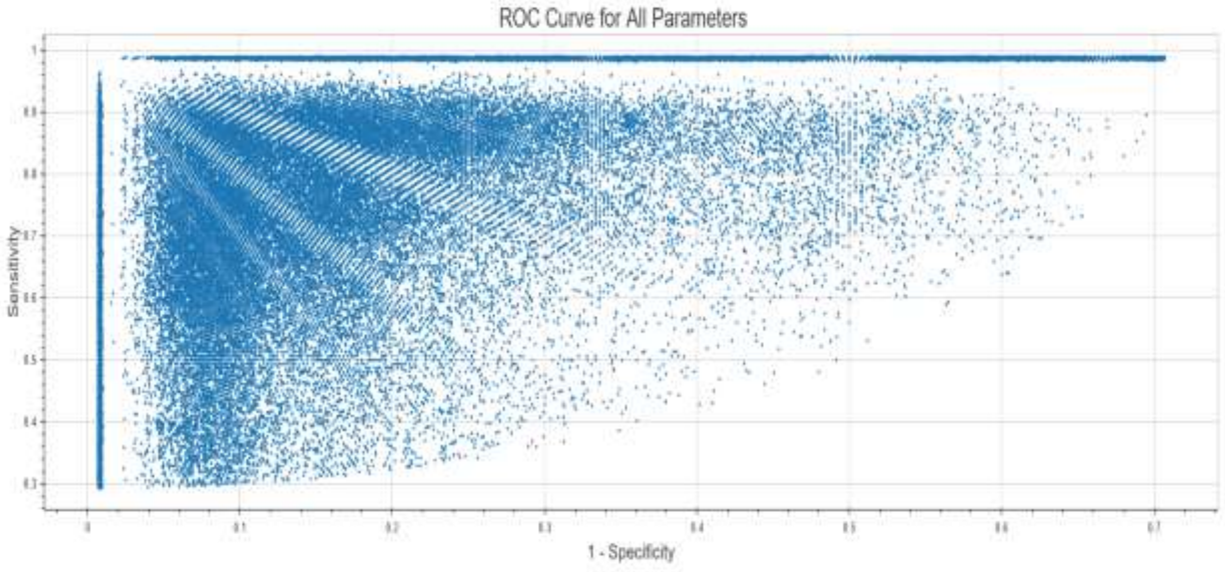


Figure 7: Receiver Operating Characteristic (ROC) constructed from the optimization execution of the afib detection algorithm. The blue point closest to the point (0,1) is regarded as the best set of thresholds.

Discussion

The goal with building this device is to quickly screen patients for afib. Ideally, every patient could get a full ECG every time they go in for a checkup, however this would be very time consuming and expensive. By screening all patients during a routine vitals check, unnecessary ECGs will be eliminated and decrease the amount of undiagnosed afib.

The nature of the device, being a prototype, is not without its flaws. The screener is not a diagnostic tool, as such, it is not meant to replace an ECG. The screener's accuracy is limited by its one-lead design and dry electrodes which are prone to motion artifacts.

The calculation of the complete cost of manufacturing the device for distribution is difficult because many of the components have come from pre-designed microprocessor boards. To effectively change this, a printed circuit board would be necessary, allowing for a reduction in size as well as reducing the need to purchase those bulky, individual microprocessors.

A hardware issue that is problematic is the current draw that is required to power the microprocessor components. As stated before, a printed circuit board could solve the issue of replacing the microprocessor components, but the LiPo battery utilized in the device could also be changed. By finding a battery that has a higher mAh rating, while still being rechargeable, would be ideal for the device.

The last hardware constraint for the device is the physical housing of the device. Currently, the housing is 3-D printed which allows for the different contours and curves. This process is quite expensive, so mass manufacturing a 3-D printed case would be unfeasible. This problem could be remedied by utilization of a cast-molding, but only on the large scale. In the end, a price estimate for the production of the prototype is skewed from the actual manufacturing costs because of the pre-made components currently utilized.

Conclusion

Afib is a vastly underdiagnosed disease, with potentially fatal implications if unmonitored. The afib screener aims to reduce the cost of diagnosing afib by allowing patients to go through an additional test to determine whether diagnostic testing is necessary or not. A detection test could not only cut down on the costs for running ECGs, but also help in the early detection of afib. The best way to diagnose afib more effectively is to make sure every person that steps into a physician's office is screened quickly and effectively, something the afib screener achieves remarkably.

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