Project Proposal

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ECE 198: Project Studio

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September 20, 2023

1. Customer Problem

Within the realm of public health, there exist several conditions and diseases that present themselves as significant risks to wider populations. One such group of diseases that perhaps reflect this best are cardiovascular diseases — those affecting the heart and blood vessels [1]. In Canada, cardiovascular diseases have historically been the leading cause of death, today being 2nd in the nation [2].

We define our customer population by approximately 50,000 persons in British Columbia recorded by the Canadian Chronic Disease Surveillance System (CCDSS) as having hypertension (high blood pressure) [3]. Hypertension is one of the six diseases included by the CCDSS in their record of cardiovascular disease [4]. It defines our customer population due to its generality and is central to the problem our customer population faces.

High blood pressure is often considered a 'gateway' to other cardiovascular diseases. That is, those with the condition are at an elevated risk of their hypertension worsening into further complications [5]. The vague nature of hypertension presents a problem, in that our customers do not readily know if their conditions are intensifying. We present a solution to this issue with a device that can detect and document arrhythmias: irregularities in a person's heartbeat. Arrhythmias are regarded as a symptom of cardiovascular disease, and additionally worsen as blood pressure increases within a person [6]. Methods of recording heart rate are much more conventional for day-to-day applications than similar methods for blood pressure. Thus, such a device as we have proposed would remove the clinical barrier between our customers and their medical statuses.

Primary stakeholders in this project include our assigned TA, customer population and regulatory bodies. The concerns of our TA primarily lie in the success of our product and the achievement of our project goals. Our customer population requires a cost-effective and non-intrusive way of detecting and documenting their heart rate. Finally, regulatory bodies, which define the standards we incorporate into our product, require an ethically viable solution that abides by their principles and one that can be standardized for easy replication.

2. Initial Requirements

As our project entails creating a medical device — distinctly one that involves the heart — there are understandably clear functional, technical and safety requirements that the project must abide by and specify.

Safety Requirements

1. No more than 10 micro-amperes of current should flow through the user and the product, based on recommendations set out by the American Heart Association's Committee on Electrocardiography [7].
2. Under the project requirements, no more than 500 millijoules of energy should be present within the design at any time.
3. No more than 30 watts of power can be consumed at any point.

Functional Requirements

As stated previously, our device would involve detecting irregularities in a person's heartbeat. The device will perform an electrocardiogram (ECG) of a person's heart, and in real-time, feed the data through a neural network (that has been trained on ECG data) and determine whether there is an irregularity or not. The neural network will be running on a separate STM32 board and will communicate with the 'primary' sensor board via Bluetooth.

1. The device must inform the user about irregularities in real-time and must make it clear when a heart arrhythmia has persisted for 2-4 minutes. After arrhythmia occurs for this period, it is recommended to call 911 or visit the emergency room [8], thus, the device must act within that time frame.
2. Based on studies performed, the median accuracy for a physician's interpretation of an ECG scan was 54% [9]. Thus, the device should ideally provide correct analysis of ECG data at an accuracy higher than or equal to 54%.
3. The device verifies heart rate irregularities using a neural network. This neural network must be contained in and minimize its use of an STM32's 92 kilobytes of static random-access memory (SRAM) [10].

4. The device must be easily transportable and wearable. This is because the device's main purpose stems from being able to report heart irregularities quickly and in real-time. Arrhythmia can come and go and may last for just a few seconds/minutes [11], however, it is critical that this is monitored to track the progression of a user's condition.

Technical Requirements

1. To achieve regular results, the device will process ECGs in 5 second intervals. The standard RR interval (time between heartbeats) of an ECG scan is between 0.6-1.2s [12]. Thus, a sample of 5 seconds will allow for roughly 6 cycles to be processed. This is corroborated by the dataset used to train the model [13] and is enough data in one scan to allow for accurate results.
2. To achieve a high degree of accuracy, a neural network will be used for its ability to efficaciously interpret time-series data. More specifically, a recurrent neural network will be used as it allows for the consideration of sequentially dependent data, including time-series [14]. Neural networks have notable applications in clinical spaces, specifically cardiovascular medicine [15].
3. The neural network must be based on a resource-friendly framework as defined in [17] to minimize resource consumption on an STM32.
4. The device must incorporate a non-invasive and fully capable ECG sensor, such as the AD8232 [18], to regularly document a user's status regarding arrhythmias, as well as be portable.

3. Principles

Our design involves many different systems that each employ different principles and standards. Some notable ones include: the implementation of Bluetooth protocols, the structure of the feed-forward neural network, and the analysis of ECG waveforms.

Engineering Standard: Bluetooth

The use of two STM32 boards implies the need for communication between them. To accomplish this, we will use Bluetooth to communicate data between the 'primary' and 'secondary' boards, where the primary board contains the main hardware, and the secondary board houses the neural network. Bluetooth's extensive standardization allows for easy implementation in the two microcontrollers; STM32 officially supports Bluetooth in conjunction with an equivalent IEEE standard [19]. Additionally, Bluetooth's long-noted effectiveness in short-range applications cements it as an invaluable aide to the success of our device. As such, our device will incorporate communication via Bluetooth as defined in core specification 5.3 [20].

Scientific & Mathematical Principle: Feed-Forward Neural Network

For our device to accurately determine irregularities within the heart, we have decided to create a neural network to analyze the heart data. More specifically, we have decided to design and create a multi-layer perceptron (MLP) feed-forward artificial neural network (ANN), as it can process nonlinear and confusing data well. The model itself is straightforward to construct and there is a large, accessible, amount of research online [21]. By designing our own neural network, we can customize the model to fit our data needs, including testing various nonlinear activation functions and selecting the one that minimizes loss. Some common functions of this characteristic include: $Sigmoid(z) = \frac{1}{1+e^{-z}}$ and $ReLU(z) = \max(0, z)$.

Engineering Standard: Analysis of ECG Waveforms

As our device deals with the prediction of heart irregularities, it is imperative that we consider and understand the type of data we will receive. As is widespread practice, an analysis of ECG data is the most common test for diagnosing arrhythmias [22], which is consequently the test that we will perform. Thus, our device will capture heart data as ECG waveforms and will perform an analysis following the algorithmic requirements set out by the under-development and drafted standard: IEC/CD 80601-2-86 [23].

References

[1] "Cardiovascular Disease," NHS, https://www.nhs.uk/conditions/cardiovascular-disease/ (accessed Sep. 19, 2023).

[2] C. Nair, H. Colburn, D. McLean, and A. Petrasovits, "Cardiovascular disease in Canada," National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/2491348/ (accessed Sep. 19, 2023).

[3] "Canadian Chronic Disease Surveillance System (CCDSS)," Canada.ca, https://health-infobase.canada.ca/ccdss/ (accessed Sep. 19, 2023).

[4] "Canadian Chronic Disease Surveillance System (CCDSS)," Canada.ca, https://health-infobase.canada.ca/ccdss/ (accessed Sep. 19, 2023).

[5] G. Tackling and M. B. Borhade, "Hypertensive Heart Disease," National Library of Medicine, https://www.ncbi.nlm.nih.gov/books/NBK539800/ (accessed Sep. 19, 2023).

[6] M. R. Afzal, S. Savona, S. J. Kalbfleisch, A. Mohamed-Osman, and O. Mohamed, "Hypertension and Arrhythmias," National Library of Medicine, https://pubmed.ncbi.nlm.nih.gov/31472889/ (accessed Sep. 19, 2023).

[7] M. M. Laks, R. Arzbaecher, J. J. Bailey, D. B. Geselowitz, and A. S. Berson, "Recommendations for Safe Current Limits for Electrocardiographs," Circulation, vol. 93, no. 4, pp. 837–839, 1996. doi: 10.1161/01.cir.93.4.837

[8] "Heart arrhythmia," Mayo Clinic, https://www.mayoclinic.org/diseases-conditions/heart-arrhythmia/diagnosis-treatment/drc-20350674 (accessed Sep. 19, 2023).

[9] D. A. Cook, S.-Y. Oh, and M. V. Pusic, "Accuracy of Physicians' Electrocardiogram Interpretations," JAMA Internal Medicine, vol. 180, no. 11, p. 1461, 2020. doi:10.1001/jamainternmed.2020.3989

[10] "STM32F401RE," STMicroelectronics, https://www.st.com/en/microcontrollers-microprocessors/stm32f401re.html (accessed Sep. 19, 2023).

[11] E. Klein, "Arrhythmia," Healthline, https://www.healthline.com/health/arrhythmia (accessed Sep. 28, 2023).

[12] A. Verma *et al*, "Standards for the Provision of Electrocardiography (ECG)-Based Diagnostic Testing in Ontario," Cardiac Care Network, https://www.corhealthontario.ca/resources-for-healthcare-planners-&-providers/ecg/ECG-Standards-Document-FINAL.pdf (accessed Sep. 19, 2023).

[13] G. B. Moody and R. G. Mark, "The Impact of the MIT-BIH Arrhythmia Database," IEEE Engineering in Medicine and Biology, 2001. doi:10.13026/C2F305.

[14] M. D. Pra, "Time series forecasting with deep learning and attention mechanism," Medium, https://towardsdatascience.com/time-series-forecasting-with-deep-learning-and-attention-mechanism-2d001fc871fc (accessed Sep. 29, 2023).

[15] D. Itchhaporia, P. B. Snow, R. J. Almassy, and W. J. Oetgen, “Artificial Neural Networks: Current status in Cardiovascular Medicine,” *Journal of the American College of Cardiology*, vol. 28, no. 2, pp. 515–521, 1996. doi:10.1016/0735-1097(96)00174-x.

[16] M. E. Sánchez-Gutiérrez and P. P. González-Pérez, “Multi-class classification of medical data based on neural network pruning and information-entropy measures,” *Entropy*, vol. 24, no. 2, p. 196, 2022. doi:10.3390/e24020196.

[17] F. Sakr, F. Bellotti, R. Berta, and A. De Gloria, “Machine Learning on Mainstream Microcontrollers,” *Sensors*, vol. 20, no. 9, p. 2638, 2020. doi:10.3390/s20092638.

[18] “AD8232,” Single-Lead, Heart Rate Monitor Front End, https://www.analog.com/media/en/technical-documentation/data-sheets/AD8232.pdf (accessed Sep. 28, 2023).

[19] “STM32WB Series,” STMicroelectronics, https://www.st.com/en/microcontrollers-microprocessors/stm32wb-series.html (accessed Sep. 19, 2023).

[20] D. Hollander *et al*, “New Core Specification v5.3 Feature Enhancements,” Bluetooth, https://www.bluetooth.com/blog/new-core-specification-v5-3-feature-enhancements/ (accessed Sep. 19, 2023).

[21] M. Y. Rafiq, G. Bugmann, and D. J. Easterbrook, “Neural network design for engineering applications,” *Computers & Structures*, vol. 79, no. 17, pp. 1541–1552, 2001. doi:10.1016/s0045-7949(01)00039-6.

[22] “Arrhythmia - Diagnosis,” National Heart Lung and Blood Institute, https://www.nhlbi.nih.gov/health/arrhythmias/diagnosis (accessed Sep. 19, 2023).

[23] “Medical electrical equipment,” IEC 80601-2-26, https://cdn.standards.iteh.ai/samples/23696/1b447ef4c6e54b62b85d987bbae7802f/IEC-80601-2-26-2019.pdf (accessed Sep. 19, 2023).