

March 26th, 2021

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
Burnaby, BC
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RE: ENSC 405W Design Specifications for The Kompression Shirt

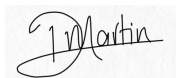
Dear Dr. Scratchley,

Please find attached a document containing the design specifications for Kardiographic Medical Solutions product, The Kompression Shirt. Our goal is to change the way we can view and keep track of our own cardiovascular health by making a product that is both convenient and easily monitorable during exercise and activity free of the inconvenience of scheduling doctor appointments. This will be accomplished in the form of a wearable EKG shirt that will record and produce cardiovascular signals to one's smartphone.

This document will outline the necessary design specifications to make the Kompression Shirt come to life. In more detail, it will break down the design process into the following components: general, hardware and software. Furthermore, this document will provide a complete guide to the design of the individually integrated components of Kompression, with supporting appendices for design options and test planning.

On behalf of Kardiographic Medical Solutions, our team would like to thank you for your time in reviewing and assessing our design documentation. Should you have any questions, comments or concerns, please do not hesitate to contact our chief communications officer Stefan Ungurean via email at sungurea@sfu.ca.

Sincerely,



Diego Martin
Chief Executive Officer
Kardiographic Medical Solutions



Kardiographic Medical Solutions

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Abstract

Heart disease is one of the world's most common illnesses, with 9 out of 10 Canadians suffering from at least 1 risk factor. It is an epidemic of vast proportions that has no signs of slowing. Kardiographic Medical Solutions (KMS) is a brand new company created by four engineers from Simon Fraser University committed to finding solutions for early diagnosis and treatment of cardiac conditions. KMS plans on developing a new product capable of recording a 4-lead electrocardiogram (EKG) during rest and active states for early detection of heart arrhythmias. This document will present the design specifications necessary for building a new bodywear wellness device, Kompression; a form fitting compression shirt with an embedded EKG system. Furthermore, this document will provide a complete guide to the design of the individually integrated components of Kompression.

Glossary

Term/Acronym	Definition
Baseline wander	Baseline wander is a commonly seen noise in EKG recordings and can be caused by respiration, changes in electrode impedance, and motion. Therefore, it is vital to effectively eliminate baseline wander before any further processing of EKG such as feature extraction. [1]
Electromyography (EMG)	Electromyography (EMG) is a biomedical signal that measures electrical currents generated in muscles during its contraction representing neuromuscular activities.
Internet of Things (IoT)	Interconnection between computing devices via the internet which enables them to send and receive data.
Analog to Digital Converter (ADC)	A system that converts an analog signal into a digital signal
Gaussian Frequency-Shift Keying (GFSK)	A type of FSK modulation that uses gaussian filters to shape pulses before they are modulated. Reduces the spectral bandwidth and out-of-band spectrum
Binary Phase-Shift Keying (BPSK)	A digital modulation technique that conveys data by changing the phase of a constant frequency signal. Widely used in Bluetooth communication, LANs and RFID
Quadrature Phase-Shift Keying (QPSK)	A form of Phase Shift Keying in which two bits are modulated at once. This allows the signal to carry twice as much information using the same bandwidth
Deep Neural Network (DNN)	A type of neural network consisting of many layers.

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1. Introduction

Over 50,000 Canadians are diagnosed with heart failure every year with well over 1 million Canadians having existing cardiovascular conditions [2]. It is now more important than ever to be able to monitor your heart health so that you do not become just another statistic. Most heart health monitoring systems such as EKG's are currently limited to a trip to the doctors office which most people will only travel to after symptoms worsen and it is too late. Kardiographic Medical Solutions (KMS) aims to find a solution of tracking one's heart health in a convenient manner with the introduction of the Kompression shirt product.

The Kompression shirt is a wearable technology product that has a 4-lead EKG built into a compression shirt. This EKG wiring is embedded into the shirt attached to reusable electrodes that create the leads that measure your heart's analog signals. The reading of the signals will be accomplished by an arduino type micro controller. These analog signals will then be transmitted wirelessly via bluetooth to an application on the users phone where they can view their heart activity demonstrated by *Figure 1.1*.

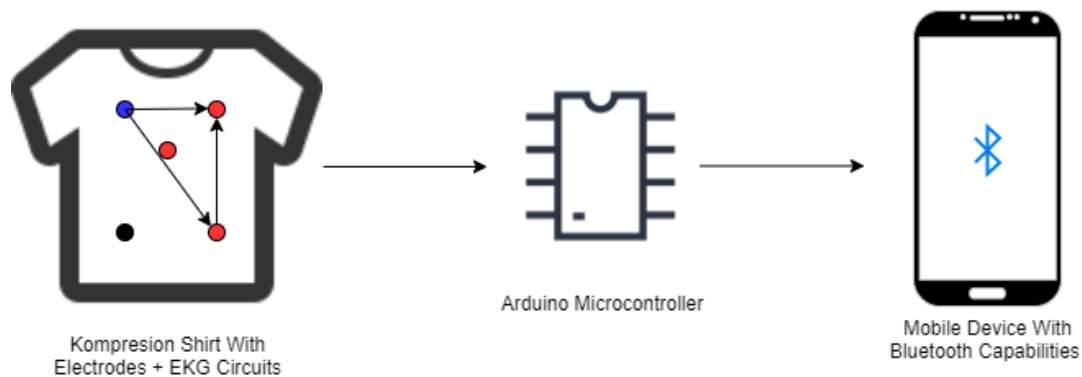


Figure 1.1 *Kompression Overview Block Diagram*

This document will provide descriptions and justifications on how the requirements of the product will be accomplished, breaking it down into sections looking at our general design, hardware design and software design. This document will also contain an appendix of supporting test plans and design options, completed with a full user interface and appearance design section. Block diagrams and illustrations will be used for further assistance in demonstrating how the Kompression shirt product will come to life.

2. General Design

The general design of the Kompression shirt will encompass its basic design principles without diving into the functionality of the hardware and software aspects. This section will mainly cover product sizing, device positioning, comfortability, and a few other regulatory designs.

2.1 KMS Device Size and Positioning

When implementing the re-attachable KMS device into the shirt, it is very apparent that it needs to be small enough in order to accomplish maximum comfortability without limiting its capabilities. The KMS device will be composed of two parts: a printed circuit board (PCB) containing the circuitry required to read the EKG signal and a recording device that can read and transmit the raw data obtained. These two components will be explained separately later in this document.

To satisfy [REQ 1.1 H-B], [REQ 1.3 H-B], [REQ 1.4 M-B], and [REQ 1.5 M-F], the KMS device attachment will be located in the lower left torso area with its dimensions being no larger than 30 mm in depth, 50 mm in width, and 100 mm in height as shown in both *Figure 2.1* and *Figure 2.2*. With these dimensions, the KMS device will not inhibit any movement or comfortability and will be large enough to contain both the PCB and the recording device.

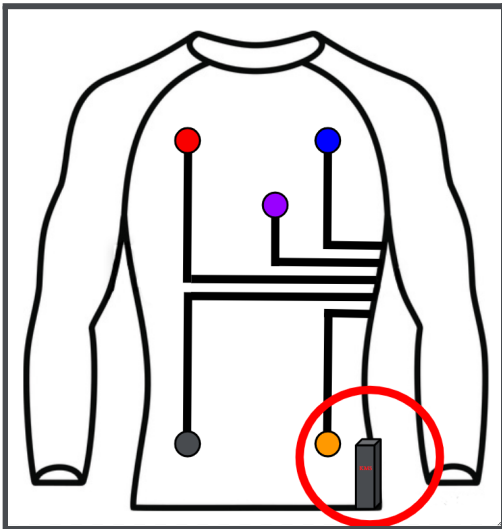


Figure 2.1 *Kompression Layout*

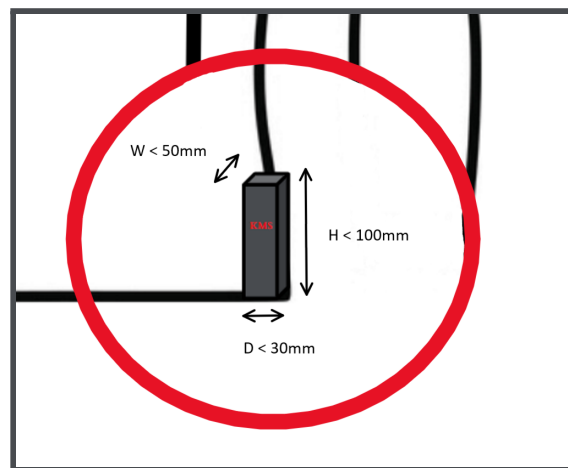


Figure 2.2 *KMS Device Sizing*

For [REQ 1.6 M-B] the device will be well under 200 grams as PCB's tend to be at most 91miligrams per millimeter squared, where the device's maximum area would be 5000 millimeters squared meaning at most the PCB component would weigh only 5 grams. As for the recording device, that will have a maximum weight of 7 grams with the arduino nano being the choice for the prototype design. The plastic casing will also not add much weight to the total being around a maximum of 5 -10 grams given the density of most plastics.

For the proof-of-concept stage these designs will not be incorporated as the showcase will be done using a battery and a breadboard. However these designs intend to be completed for the phase B prototyping stage.

2.2 Kompression Device Attachment + Washability

To satisfy the requirement [REQ 1.8 M-F], the Kompression must be machine washable. In order to make this a possibility, the KMS device with the electronic components must be removable which is defined in [REQ 1.2 M-B]. To accomplish this, the device will slide into a slot on the lower left of the shirt complete with a pin system to connect the device into the wiring in the shirt. There will be a push button release on the side of the device in order to lock it in place while using which will also allow for easy removal shown in *Figure 2.3*.

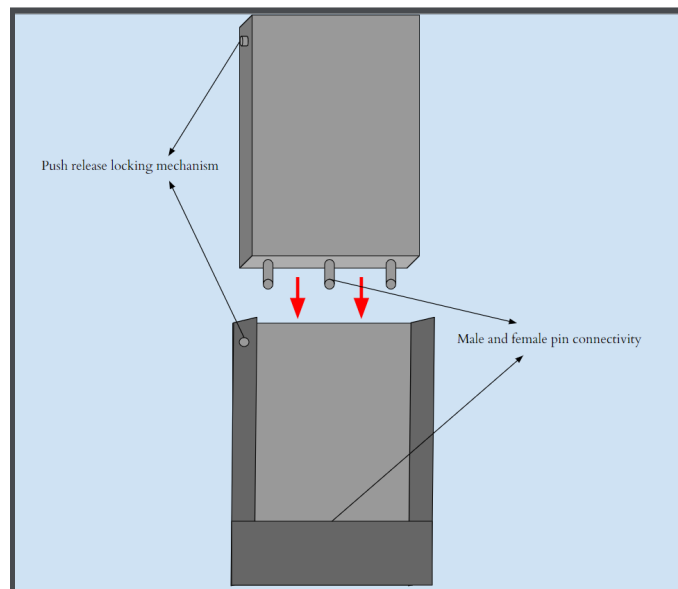


Figure 2.3 KMS Device Attachment

The wiring running through the shirt will be 22 gauge insulated alligator clips which will be safe to wash. For the proof-of-concept stage we will be using sticky electrodes that are for single use, meaning that the electrodes will be replaceable and thus will not be washed. For the prototype stage we plan on moving on to reusable silver chloride electrodes which may deteriorate in use after washing, however our plans for the working prototype do not need to be completely machine washable as this is more of an intention for the final product.

3. Hardware Design

The hardware design for Kompression is split into 3 categories. First electrode and wire design. This section goes over the justification for what kinds of electrodes we use and the types of wires used for connections. Second, is the EKG circuit design. This section includes details on what electronic components are needed to successfully record the EKG. The circuit design also includes justification on the microcontroller choice. The final section is a discussion on the battery design.

3.1 Electrodes and Wire Design

Electrodes are key to Kompression's design. For the purpose of the design, Kompression plans to use two different types of electrodes for different phases of product development. The electrode design satisfies the following requirements, [REQ 2.1 H-A], [REQ 2.1.5 H-B], [REQ 2.1.6 M-B], [REQ 2.1.3 H-F] which require the electrodes to stay on the user undisturbed for long periods of time.

For the proof-of-concept, sticky 3M Red Dot electrodes will be used. These electrodes shown in *Figure 3.1* below are 1.6 by 1.36 inches and are primarily made of foam except for the silver chloride electrode in the middle. These electrodes are very sticky and provide a good connection with the user. Good connectivity is essential to receive a proper measurement and sticky electrodes are preferred for our prototype since they provide a clean connection without any additional gel and can stay in place and record activity for up to 3 days. However, once removed, the 3M electrodes cannot be reused as they do not provide stable connections any longer. Our team chose to use 3M sticky electrodes at first as opposed to no-name brands because 3M is a trusted Canadian product that is even used in clinical settings. Silver chloride electrodes are necessary since they are the chemical standard for EKG recordings. In our next product iterations, we hope to use reusable silver chloride electrodes so the user does not have to constantly replace the electrodes on the shirt.



Figure 3.1 3-M EKG Electrodes

[REQ 2.1.2 M-B] and [REQ 2.1.3 H-F] require the Kompression wiring to be comfortable and embedded within the shirt fabric. To establish the connection between the electrodes and the circuit board, Kompression plans to split up the wire design into two phases similar to that of the electrodes. For the proof-of-concept, Kompression will use 22 gauge alligator clips (*Figure 3.2*). These clips are decently insulated and provide a good connection between the 3-M electrodes and the circuit. There were many options for the prototype but alligator clips seemed to be the best due to their ability to be attached and removed easily. For the final design 25 gauge wire embedded in the shirt material will be used. 25 AWG is very small and the user would not be able to feel the wires. To satisfy [REQ 2.1.4 M-B], we will implement circles of coloured fabric on the shirt labeling the electrode placements as shown in *Figure 2.1*, in the previous section. This will be showcased in the proof of concept phase.



Figure 3.2 22 AWG Alligator Clips

3.2 EKG Circuit Design

Following [REQ 2.2 H-A], [REQ 2.3 H-A] and [REQ 2.4 H-A], which require the system to acquire an EKG measurement from the user, the following section will describe design choices for the analog circuit. The EKG circuit required to receive the signal from the user consists of an instrumentation amp followed by a bandpass filter. An instrumentation amp is used since it avoids the problems of low input impedance created by difference amplifiers. This is useful for low-voltage bio-signals such as EKG since the gain is easily adjustable and it has high CMRR essentially rejecting all common mode signals. The instrumentation amp also provides us with the ability of including a right leg drive which can be used to filter 60hz power line interference. An example of a potential circuit design is shown in *Figure 3.1* below. This circuit is only for recording one lead, bipolar lead 1 where we are expecting anywhere between 50 microVolts and 5 mV (*Figure 3.4*). This output will then be scaled to reach between 0 - 5V for input to the Arduino analog pins via a voltage shifter/amplifier. Each output received from a similar circuit is fed to the analog to digital converter(ADC) of a microcontroller from where it will be transmitted via bluetooth. The circuit for the first bipolar lead is shown below in *Figure 3.3*.

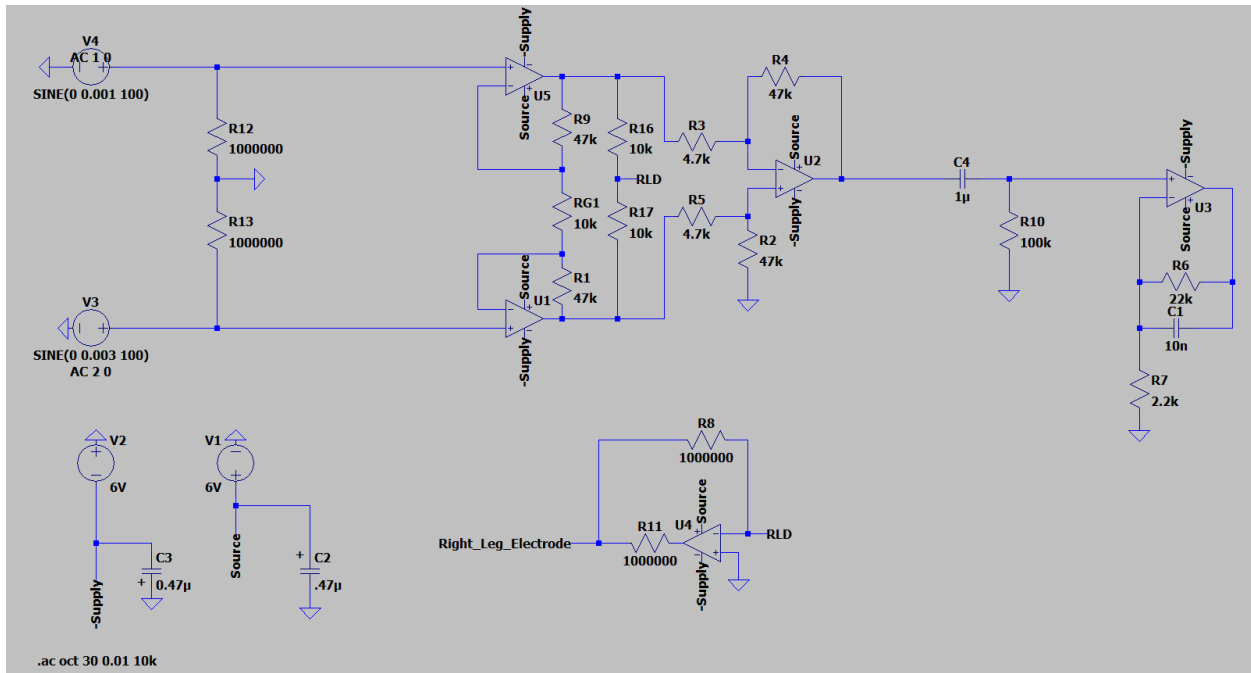


Figure 3.3 Proof of Concept EKG Circuit Design

The circuit above includes an instrumentation amp with a right leg drive, followed by a bandpass filter. Biopotential signals are extremely small and covered with noise. To aid in detection of the signal we built a bandpass filter ranging from 0.5 HZ to 500 HZ as suggested in *Figure 3.4* provided by Dr Gray. *Figure 3.4* shows the frequency and voltage ranges of differing biopotential signals. Kompression is only interested in EKG.

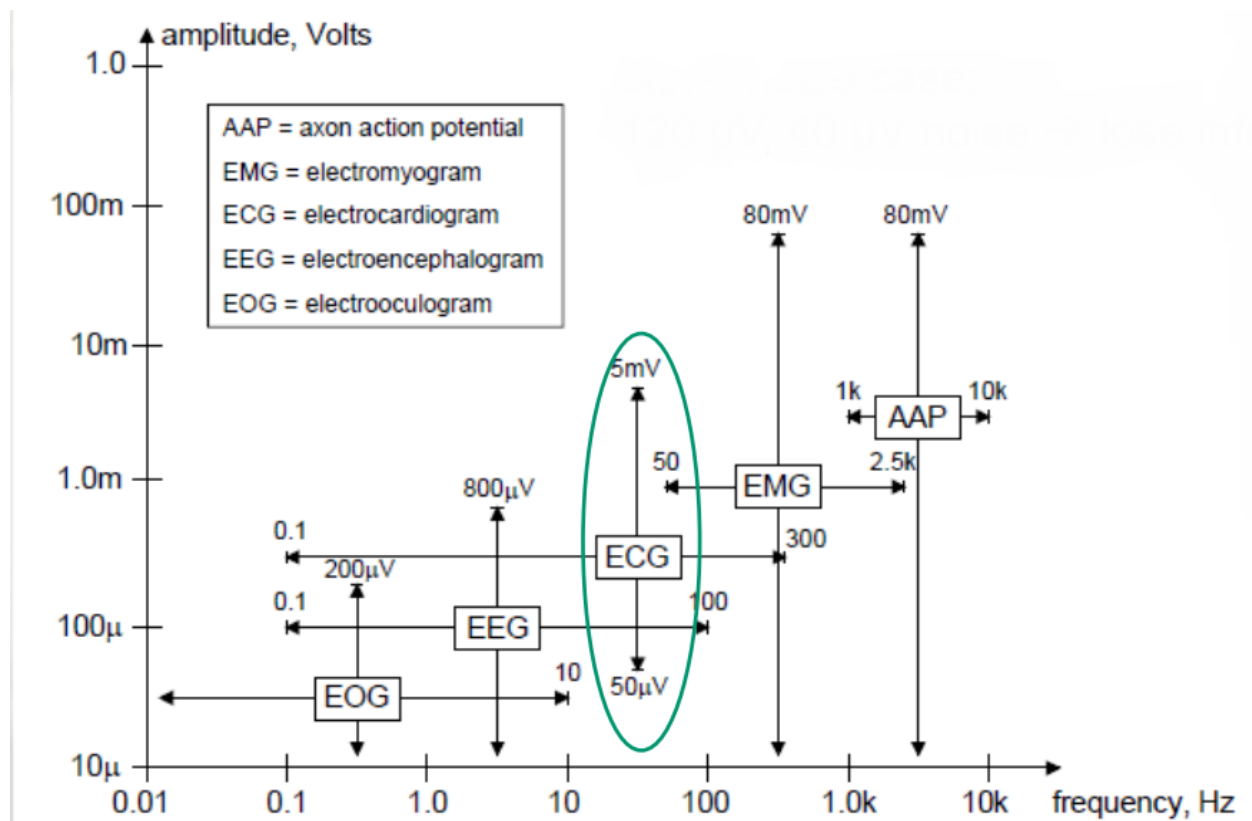


Figure 3.4 Voltage vs Frequency Range of Different Bio-Signals [3]

For our instrumentation amplifier, our team decided to use the AD623 ANZ chip. This chip is low power working on 2.7-12V supply and can work both in single and dual supply. A functional block diagram is shown below in *Figure 3.5*. It can provide gains of up to 1000 by simply replacing the RG resistor with any desired value. The AD623 is a well documented chip for biopotential signals and has a high CMRR which is what the design team was looking for. There are many other options for instrumentation amps such as the AD8223 but the AD623 is more documented and provides more references for biopotential signal use.

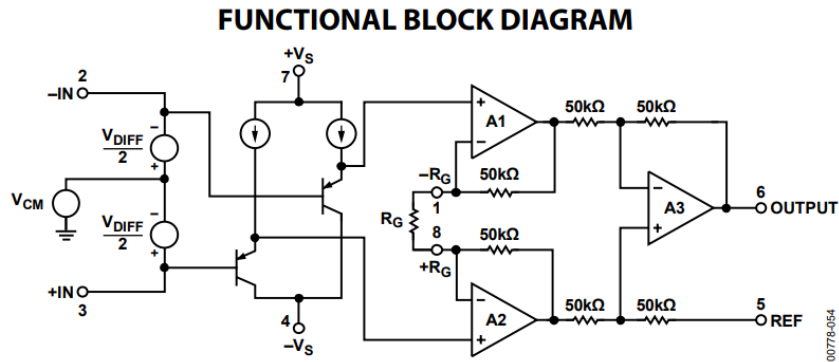


Figure 3.5 AD 623 ANZ Circuit [4]

For our bandpass filter, blown up in *Figure 3.6* below, we built it using a MCP6002 chip operational amplifier. This amplifier is also low power working with a 2.7–6V single or dual supply. It has a 1MHZ bandwidth product and contains two op-amps within the chip. It is very cheap, priced at 50 cents per unit and is a reliable op-amp. We chose the MCP 6002 over other options such as the LT1097CN mostly because of its low power ability and low price. The bandwidth of the filter in *Figure 3.4* ranges from 0.5 to 477 HZ exactly. A bode plot is shown in *Figure 3.7*. The corresponding resistors and capacitors for the corner frequencies were found using the following formula.

$$f = \frac{1}{2\pi RC}$$

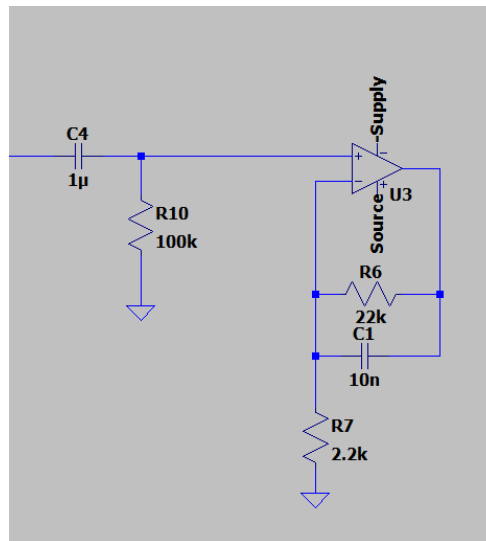


Figure 3.6 Bandpass Filter

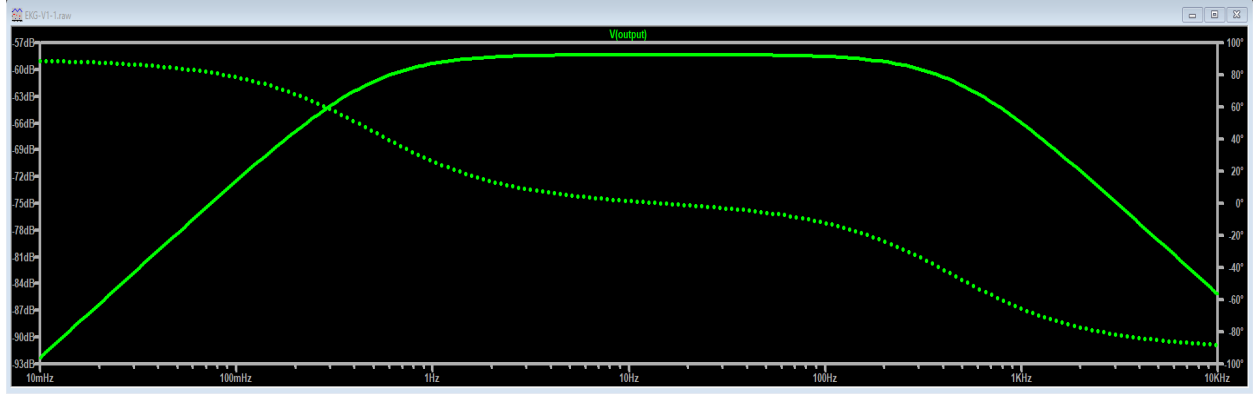


Figure 3.7 Bandpass Filter Bode Plot

The right leg drive shown in Figure 3.8 is also built using an MCP6002 operational amplifier. The advantages of this chip have been discussed above. The right leg drive helps filter 60HZ power line interference. It is better than building a traditional notch filter since the notch filter could potentially remove other important EKG frequencies around 60HZ. The right leg driven circuit however “extracts the average input signal, inverts it, and feeds it back through the right leg electrode which results in noise reduction” [3].

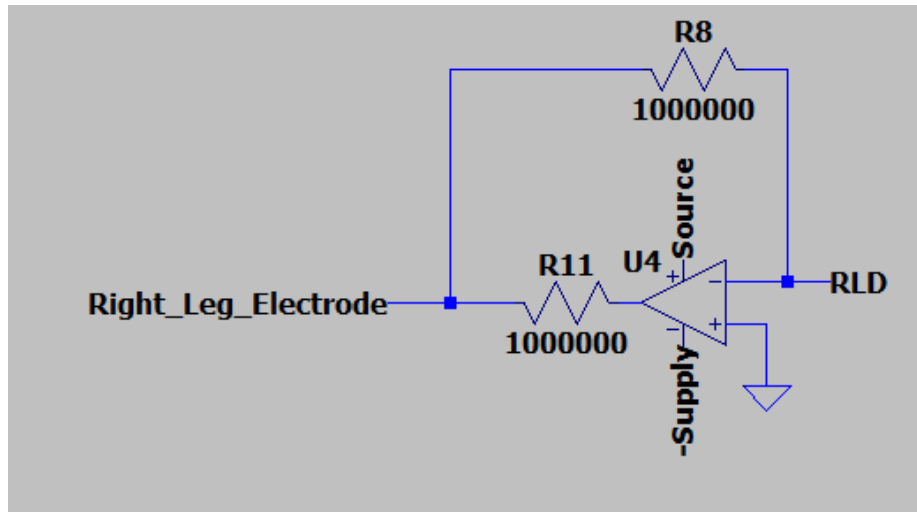


Figure 3.8 Right Leg Drive Circuit

3.3 Microcontroller Design

Requirement [REQ 2.5 H-A] states that the device must be able to connect wirelessly to other cellular devices. To accomplish this a microcontroller is needed to interface between the analog circuit and a digital system. For the microcontroller, our design team decided to go with the Arduino Nano for our prototype with a potential switch to a different chip like the Arduino Due for the final design. The Arduino Nano shown in *Figure 3.9* is very small, measuring 18mm x 45mm. This is very advantageous since we would like our device to be wearable. It can also operate on a 5V supply and has 8 analog inputs with an 10-bit ADC. This means we can feed it our 4 analog EKG signals (leads 1 through 4) and send them via bluetooth simultaneously. The biggest issue with this microcontroller is its rather small ADC. 10-bit might not be enough to sample the measurements from the circuit. Nevertheless it is a cheap and quite effective tool for the purposes of our prototype and possibly our final design. Out of all the microcontrollers, the Arduino Nano's size makes it an attractive choice not to mention the large amounts of documentation surrounding Arduino which will help our design team. The only reason a switch to the Arduino Due might occur, is if the 10-bit ADC turns out to not be enough. The Due has a 12-bit ADC which provides better accuracy at the cost of being a larger microcontroller.

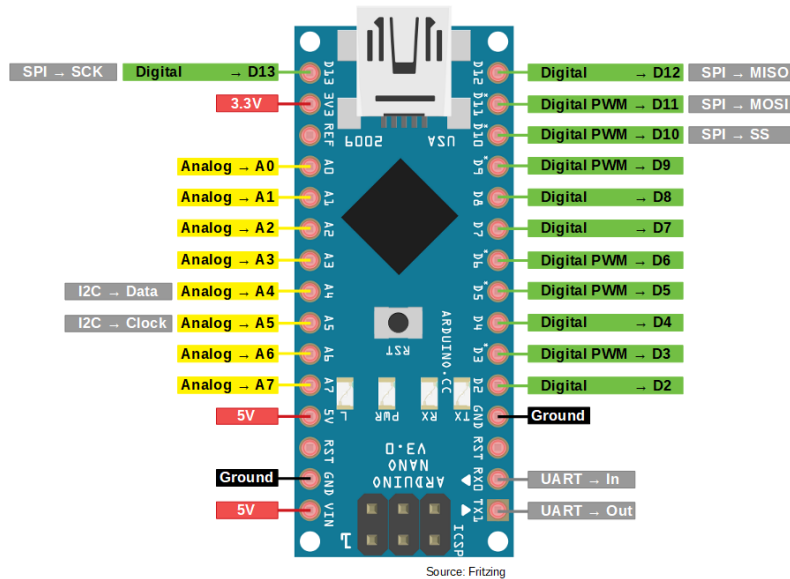


Figure 3.9 Arduino Nano Pin Layout [5]

3.4 Battery Design

Looking at requirement [REQ 2.6 M-F], which requires the device to have a long battery life, there are a lot of battery options available. But for the purpose of this circuit and device we need a battery with a long charge life that would be able to supply power to the circuit and microcontroller for significant periods of time. Lithium batteries tend to perform better than their Alkaline counterparts hence we narrowed our design options to the former.

For our prototype we will most likely be using Energizer L522BP Energizer Ultimate, this is a rather cheap lithium battery with a 9V supply. Ideally we will be using two batteries for dual supply to the operational amplifiers and to power the microcontroller. This battery is long lasting providing power for up to 10 hours. In terms of lithium batteries, there are plenty of options, but the Energizer L522BP seems to be the best in terms of performance and reviews for the price. In later designs we may switch to the EBL High Volume 9V Lithium-ion rechargeable battery to add a recharging feature to the device.

3.5 Pulse Oximeter

The pulse oximeter will be a feature included in the design that will help with verification of EKG heart rhythms. This design option will also satisfy requirements [REQ 2.2 H-A] and [REQ 2.4 H-A]. It will be able to verify if the QRS rhythms and match the pulse rhythms to ensure everything is working properly. The MAX30100 pulse oximeter is a ready-to-go Arduino compatible chip that doesn't require a back side unlike other pulse oximeters. The fact that the measurement is taken on the same plane rather than on opposite sides of a finger or earlobe allows it to be incorporated within a shirt. It is also very small and rather inconspicuous. This is perfect for our design and more efficient than having us build the pulse oximeter from scratch. This feature will aim to be included in the final design. The chip is shown in *Figure 3.10* below.

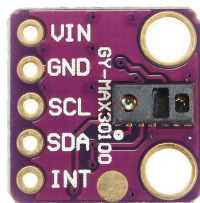


Figure 3.10 MAX30100 Pulse Oximeter Chip [6]

3.6 Hardware Design Summary

To summarize, the following design choices have been made to construct the proof-of-concept EKG measurement system. The interface between the user and the circuit will be using 3M sticky electrodes connected via 22 AWG alligator clips. The biopotential signals will be fed to an instrumentation amplifier built from 3 MCP-6002 operational amplifiers. This amplifier has a differential gain of 100. A right leg drive system is attached using another MCP6002 op-amp to reduce 60Hz power line interference. The output of the instrumentation amp is fed to a bandpass filter ranging from 0.5 Hz to 477 Hz as specified in *Figure 3.4*. The overall output will have a gain of 1000 and will then be fed to the ADC of the Arduino Nano. The entire circuit will be powered using a dual battery supply operating at $\pm 6V$ provided by the Energizer L522BP Energizer Ultimate.

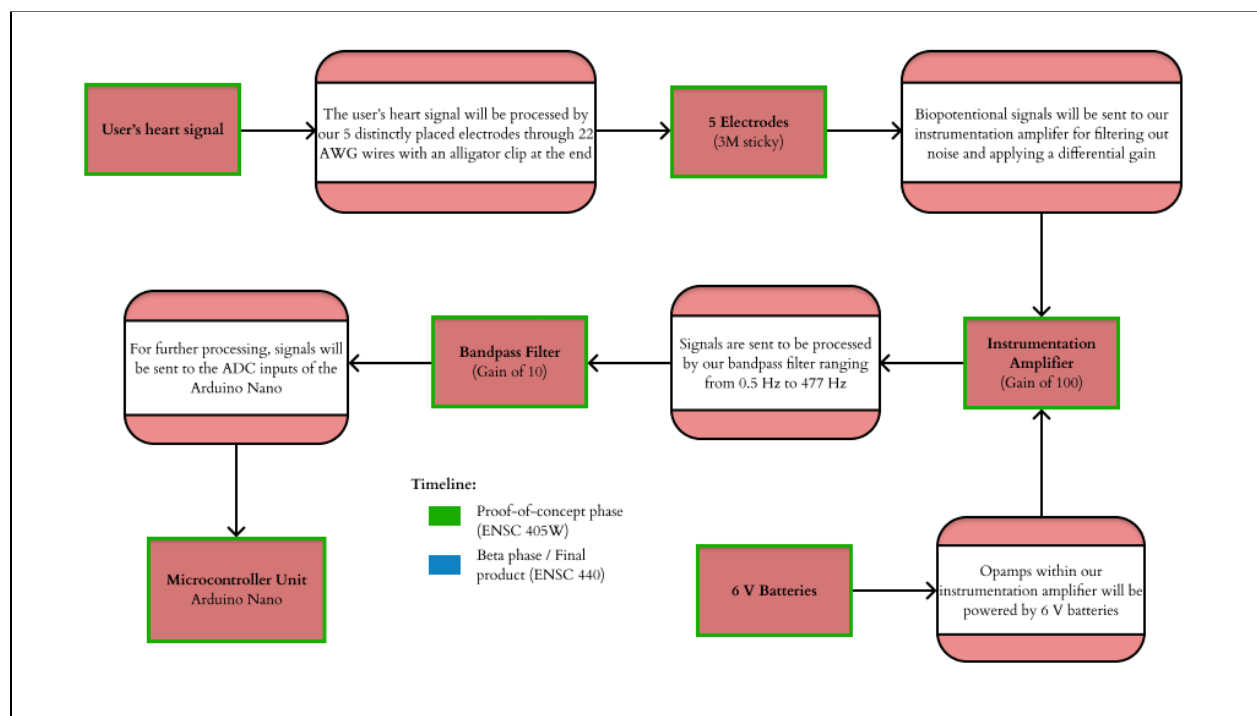


Figure 3.11 Complete Hardware Block Diagram (For full view version visit [here¹](#))

¹ **Hardware Block Diagram:**

<https://www.figma.com/proto/bngeWXA/Z73OTnn7q0zxTD/diagrams?node-id=17%3A4&scaling=min-zoom&page-id=17%3A2>

4. Software Design

Our software design will cover how our data from the hardware will integrate into our application and how the user will be able to store, track and interpret the results based on our EKG analyzer algorithm of choice. We will explore different options for each of our subsystems and provide our final decision with proper justification as to why it best fits our product, Kompression. Finally, details on when each design choice is expected to be implemented will be presented in our software summary.

4.1 Application Design

To cover [REQ 3.4 M-F] and [REQ 3.9 M-F], which requires that our EKG analysis be readily and easily accessible to the user and have a clean and easy UI, we will be developing a mobile application to go along with our device, Kompression. This design choice allows for portability, ease to use, and its simplicity. We want our software to be in the hands of people and be ready to use at a moment's notice. This is where mobile apps shine and become a better investment of time and effort. We have outlined our design choices in Appendix B Table B.6 where we compare the advantages and disadvantages between developing a Web versus Mobile application.

Our application will look to implement a hub for the user to track, store and maintain their heart health with features such as, real-time EKG signal monitoring, a timeline with all their past data recordings, and an analyzer that will try to find abnormal cardiac rhythms and create a detailed report that users can take to their doctors for further diagnosis. The app will be user-friendly and will be suitable for anyone, without requiring prior medical knowledge. This choice of developing a mobile app best fits with our vision as a company of having something that will work offline, run fast and efficient, and is secure for our users [7].

4.2 Framework Design

To cover [REQ 3.1 H-A], we will be making a cross-platform mobile application using Flutter as our framework along with Dart as our programming language of choice. Cross-platform development is great because it will allow us to deploy for both Android and iOS devices with a single codebase. With Dart, we are able to utilize the core mechanics of object oriented

programming, c-style syntax, and be backed up by well-written documentation provided by Google. With Flutter, we get a wide range of libraries that will be used for calling native C methods that will be used to develop our EKG analyzer software and is intuitive to learn. Dart also has key features that make it the more attractive option as opposed to our other design choices outlined in Appendix B Table B.7. These key features include a programming language that yields solutions that are concise, easy to debug, easy to extend, easy to document and easy to fix.

As mentioned above, Flutter allows us to have one codebase for two applications, and this will allow us to write roughly 50% fewer automated tests, and our app UI will stay consistent even with older devices. A pure Dart written application can run smoothly in most of the major mobile operating systems and that is something we value, as we want to target as many people as possible.

4.3 Wireless IoT Network Protocols

In this section, we will discuss how the hardware and the mobile application will communicate with each other by exploring our network protocol design of choice.

4.3.1 IoT Protocol Design

As part of our communication protocol and to cover [REQ 2.5 H-A] and [REQ 2.5.1 H-A] we will be using Bluetooth to stream data from the microcontroller's ADC to the mobile application. Our ADC will have a resolution of 10 bits which will give us 1,024 discrete digital levels that will be received by the application and interpreted by our software. Our choice of Bluetooth comes from its maturity and well-written documentation as well as being ideal for device-to-device data transfers. As opposed to other options, outlined in Appendix B Table B.8, we do not require a high range device since it will be kept at a very close proximity from the device. With our design, we will try to keep a minimum sampling frequency of 1 KHz. Finally, in our design choice we also look for a high data transfer rate and that it is compatible with the latest Android and iOS versions, where Bluetooth fits perfectly.

4.3.2 Bluetooth Module Design

To complement our design choice mentioned above and to comply with requirements [REQ 1.1 H-B], [REQ 1.6 M-B] and [REQ 2.6 M-F] we will be using a specific Bluetooth module known as BLE (Bluetooth Low Energy). The HM-18 BLE module supports Bluetooth 5.0, which is

compatible with the latest mobile OS versions and allows for faster data transfer speeds of up to 2 Mbps. With this BLE module, our goal is to utilize the GATT (Generic Attribute Profile) where we send data back and forth using services and characteristics defined by each module [8]. First, for our proof-of-concept, we want to isolate the custom characteristics that allow for streaming a single EKG lead data to the app, and then in our later stage of development we will attempt to create multiple custom characteristics with read, write, and notify attributes that will allow us to send multiple data packages for each EKG lead in our hardware subsystem.

As mentioned in our Appendix B Table B.9, we are also taking into consideration that we need to keep all our subsystems as small as possible which means that dimensions and weight play an important role in our design choice as well as power consumption. Using a BLE module is our best option for this category as it will allow the device to last for a longer time and conserve power when not in use. Based on all these requirements. Our HM-18 module complies with our requirements and is affordable so it will not drive our device price up by much and will not take a lot of space in our design as it comes at $3.81 \times 1.65 \times 0.25$ cm and only weighs 1.7 grams, allowing us to keep one of our subsystems compact.

4.4 QRS Detection Algorithm Design

4.4.1 QRS complex introduction

As the name suggests, the QRS complex is composed of a downward deflection (Q wave), a high upward deflection (R wave) and a final downward deflection (S wave). It represents the electrical impulse as it spreads through the ventricles and indicates ventricular depolarization. Under normal circumstances, the duration of the QRS complex in an adult patient will be between 0.06 and 0.10 seconds. The QRS complex is usually positive in leads I, aVL, V5, V6 and II, III, and aVF. The QRS complex is usually negative in leads aVR, V1, and V2 [9]. Other important points in the data are the P and T wave, where the P wave represents the depolarization of the left and right atrium, usually a very small wave before the QRS complex. The T wave follows the QRS complex and indicates ventricular repolarization. This set of points in the EKG strip are what doctors use to diagnose patients and need to be identified correctly using software tools to avoid inconclusive results.

To cover [REQ 3.7 M-F] and [REQ 3.5 H-F], which give the users a summary on their overall heart health and performs real-time EKG analysis, we will be using the Pan-Tompkins algorithm. This

will allow us to compute the QRS complex and once found, we can determine if any irregular heart rhythms are present in the signal. The benefit of using this algorithm is that it can be done in real-time, it can filter out unwanted noise, and it will highlight the frequency content of the heart's electrical signal. We discussed our other design options for this feature in Appendix B Table B.10 where we have outlined three different algorithm options that have proven to be successful at determining the QRS complex. In our following section, we touch on the high level details on how the Pan-Tompkins algorithm works.

4.4.2 Pan-Tompkins Algorithm

The Pan-Tompkins Algorithm applies a series of filters to the received EKG data and it highlights the frequency contents of the heart's electrical signal [10]. It also removes some background noise. Pre-processing steps involve getting an input as the raw EKG data from the electrodes and that feeds into a low pass filter, followed by a high pass filter in cascade to reduce the computational cost and allow real-time detection. In the decision stage, the signal goes through a derivative filter and a squaring and integration step where the goal is to enhance the peaks and reduce the possibility of incorrectly recognizing a T wave as an R peak.

Stages [10]

- Band Pass filter
 - This stage is used to reduce the influence of noise. It involves the cascade of a LPF (to remove the high-frequency noise such as EMG) and a HPF (to remove the low-frequency noise such as the Baseline Wander)
- Derivative
 - After the filtering process, the EKG signal is differentiated (meaning that the slope information was determined). This allows for the low frequency P and T waves to be suppressed in the derivative process and to gain high frequency signals existing in the higher slopes of the QRS complex.
- Squaring function
 - After the differentiation process, the signal gets squared so that all components of the signal display a positive value. The higher amplitudes observed correspond to the QRS complex. The squaring also helps reduce the usual higher amplitudes from T waves that can cause false detection.

- Moving Window Integration (MWI)
 - This stage is to acquire information from the waveform feature with the addition of the R wave slope. The widest integrated window must be used to match with a possible QRS complex.
- Decision step
 - After the signal has been pre-processed, the next step is to decide whether or not the result of the MWI is a QRS complex by using thresholds.

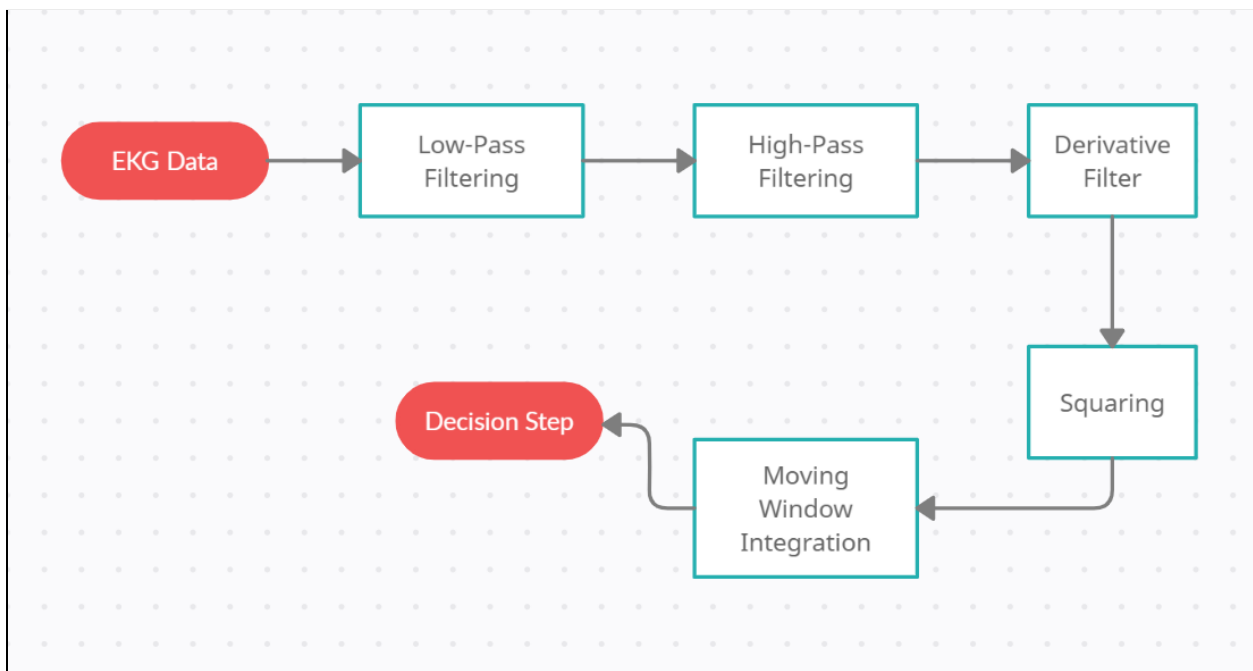


Figure 4.1 Pan-Tompkins algorithm filter steps

Metrics to consider [11]

Visualized in *Figure 4.2* below,

(1 mm corresponds to 0.1 mV on standard EKG grid)

- QRS duration
 - Normal QRS duration is 0.04 – 0.10 seconds
 - A prolonged QRS segment might indicate a bundle branch block which could be relatively benign or a sign of an underlying heart disease
- PR duration
 - Normal PR interval is 0.12 – 0.22 sec
 - A prolonged PR interval (> 0.22 sec) is consistent with first-degree (AtrioVentricular) AV-block
 - A shortened PR interval (< 0.12 sec) indicates pre-excitation
- R-wave amplitude
 - R-wave amplitude in leads I, II, III should all be ≤ 20 mm
 - If R-wave in V1 is larger than S-wave in V1, the R-wave should be < 5 mm
- QT duration and corrected QT (QTc) duration
 - Measured from the beginning of the QRS complex to the end of the T-wave and it represents the total time for de- and repolarization
 - Prolonged QT duration predisposes to life-threatening ventricular arrhythmias
 - QT duration is inversely related to heart rate
 - Bazetts' formula:
 - $QTc = QT\ duration \div \sqrt{RR\ interval}$
 - Normal values for QTc interval
 - Men: ≤ 0.450 seconds
 - Women: ≤ 0.470 seconds
- Heart Rate
 - When the cardiac rhythm is regular, the heart rate can be determined by the interval between two successive QRS complexes
 - Heart rate in beats per minute (bpm) is the number of R-R intervals in 60 seconds and can be calculated from the R-R interval (ms) by:
 - $HR = 60,000\ (ms) \div R-R\ interval\ (ms)$

- Heart Rate Variability (HRV)
 - Heart rate variability (HRV) is the temporal variation between sequences of consecutive heartbeats
 - Time Domain
 - SDNN: Standard deviation of the N-N (R-R) intervals over a given time period of interest
 - RMSSD: Root mean square of the successive differences
 - For RR_i denotes the time from the i th to the $i+1$ R peak and N intervals in total
 - $$RMSSD = \sqrt{\frac{1}{N-1} \sum_{i=1}^{N-1} (RR_{i+1} - RR_i)^2}$$

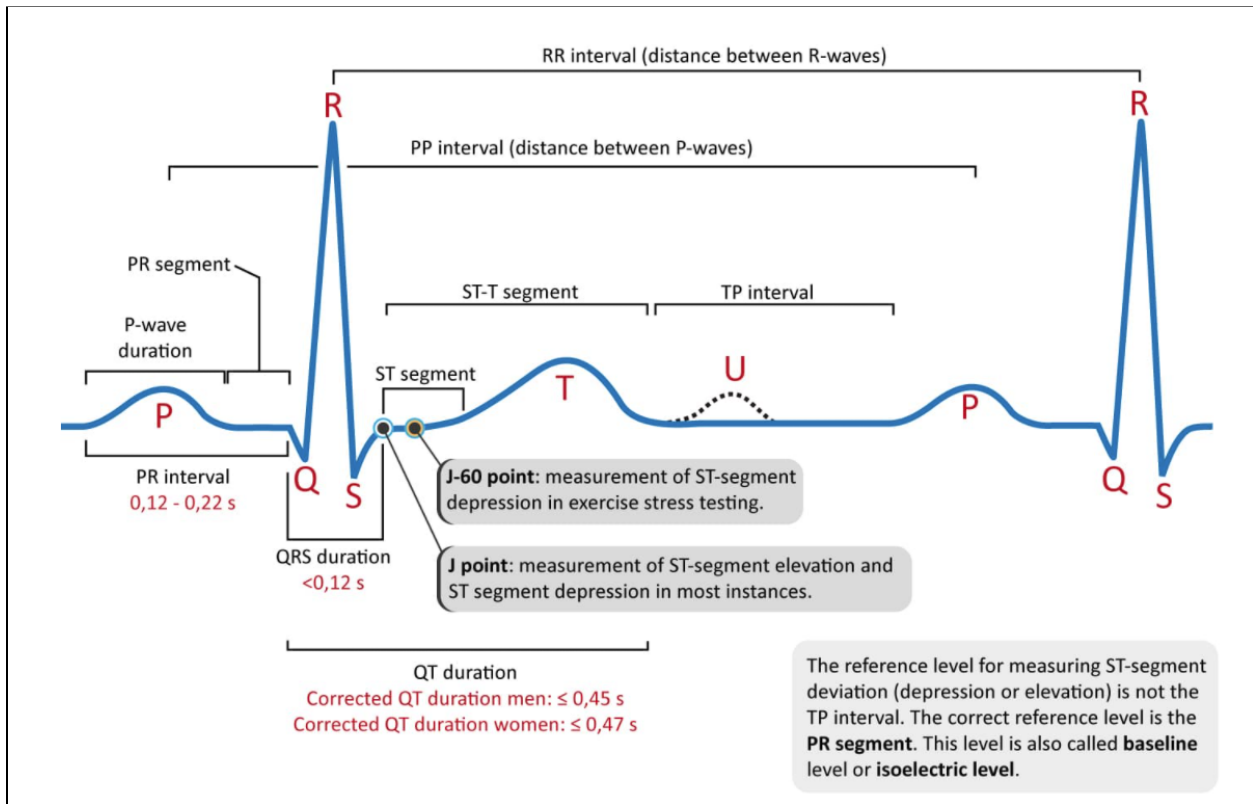


Figure 4.2 Important interval in a classical EKG curve with its most common waveforms [11]

4.5 Arrhythmia Detection Design

In our requirements [REQ 3.2 M-A], [REQ 3.2.1 M-B] and [REQ 3.2.2 M-B] we specified the requirements for Kompression to be able to classify and detect heart arrhythmia. Modern efforts to perform this task automatically with computers have used machine learning methods. One of these methods that has been applied successfully recently is different architectures of deep neural networks (DNN)[12]. The Kompression shirt will similarly use a DNN to detect arrhythmia events. A benefit of this choice over some other machine learning methods is that the DNN can perform inference directly on the raw EKG signal without needing feature extraction first [12]. Rather than implement our own DNN to perform the analysis we will utilize an already trained network from source [13]. The authors of this paper made their code and trained neural network weights available on GitHub [14]. This network utilized 2,322,513 EKG records from 1,676,384 different patients, to successfully classify 6 types of arrhythmia (*Figure 4.3*). Using this network will allow us to save valuable company time and avoid the challenges of finding enough training data as well as data imbalance which is a problem for training EKG arrhythmia classifiers [12]. Since we will only have 4 leads from our device we will feed the missing neural network inputs with zero. We will run tests to determine how this affects the classification properties of the model. Feeding in zero can be motivated by the fact that some of the training samples were smaller than the sample size and thus had to be zero-padded in [13]. Once the EKG recording is completed in our application it will be broken up into 10s sections, downsampled to 400Hz to match the training data and fed into the neural network for classification. Output classification labels will be attached to the recording and saved for viewing on the rhythm analysis page and for generating reports.



Figure 4.3 Types of arrhythmia classified by the neural network.

Source [<https://www.nature.com/articles/s41467-020-15432-4#rightslink/>]

The trained model will be deployed into the application using tensorflow light. The tflite_flutter package will allow us to integrate the trained network into our flutter application after we have converted it to the TensorFlow lite format. Having the network deployed locally will allow the application to perform arrhythmia detection even when not connected to a server.

4.6 File Format Design

To cover [REQ 3.3.1 M-B], our software must be able to save the results of the analysis in a common and easy to share format. This exported file will be used to share the analysis results and will contain information on detected arrhythmia events. Data collected from all sensors while the event was taking place will also need to be present in the exported file. In addition this file will have a disclaimer about the intended accuracy of our system in detecting arrhythmia and that the user should seek medical advice with this report for proper interpretation.

A pdf document will be generated summarizing the arrhythmia events to satisfy [REQ 3.3.1 M-B]. This is motivated by the ability to include text and graphics in the document and commonplace use of PDF for document sharing. Since PDFs are commonplace, the user will be familiar with viewing and sharing them. Additionally supporting this decision is the availability of a flutter pdf package that can create multi page documents with graphics, images and text.

4.7 Graphing Library Design

Based on requirements [REQ 3.6 M-F] and [REQ 3.3 H-A], which specifies that our graphs must be easily interpretable without prior professional medical knowledge, we want our Flutter app to use advanced graphing libraries for plotting real-time EKG data and be able to annotate the graph with easy-to-understand terms.

To cover [REQ 3.6 M-F] and [REQ 3.3 H-A] we will be using the Flutter package: FL Chart as our main graphing library. This decision revolves around being able to annotate and plot data as well as easy customization. This package has a wide range of charts available and its documentation is well supported and will allow us to match the planned charts in the design UI appendix.

4.8 Database Design

The requirements [REQ 3.8 L-F] and [REQ 3.9.1 L-F] motivate that various persistent data will need to be stored while running the application. The format and use of this data is outlined in *Table 4.1* on the following page.

Data	Format	Use
<ul style="list-style-type: none"> ○ HR ○ Pulse Oximeter Values ○ HRV 	Maps of Time/Date String and double values	<ul style="list-style-type: none"> ○ Access daily values for plotting and statistics ○ Access values that were present during an Arrhythmia event
EKG Recording	List of ints storing each discrete analog level from the signal (0 - 1023) <ul style="list-style-type: none"> ○ 2 minute ○ 5 minute ○ 10 minute List of string tags associated with the recording	Access for running Arrhythmia analysis code
Arrhythmia Event	EKG Recording data during the event List of statistics (HR,HRV,O2%) present during time recording took place	Access for generating report and Rhythm analysis page
User Information	Strings and Integers representing user information	Profile page and generating report

Table 4.1 Summary of persistent data in the application

For storing this data we will be using the Hive key-value database package available for use with flutter. This option is a local NoSQL option that is completely native to dart, thereby ensuring cross platform compatibility. All of our data has simple relationships between it and will be successfully modelled and stored with the key-value Hive database. This choice gives users peace of mind knowing their data is stored on their device compared to an online option. Additionally the user will have PDF exports from the application, which can be backed up off the device, further supporting that on device storage is sufficient.

4.9 Software Design Summary

The software portion of the Kompression shirt will be a cross platform mobile application developed with flutter. Bluetooth Low Energy protocol version 5.0 will be used to transfer all collected data between the shirt and the application. A real time implementation of the Pan Tompkins algorithm will be used to detect and annotate QRS complexes for calculating heart rate and heart rate variability. Arrhythmia analysis of EKG recordings will be done on application using a deep neural network. Detected events will be available to share through generated PDFs summarizing information from the Kompression shirt during the event. A charting library built for flutter will be used to generate live and static charts. Similarly a flutter package for creating non-relational databases will be used to locally store all persistent data. See *Figure 4.4* on the following page to see how our data flows from our different entities and processes.

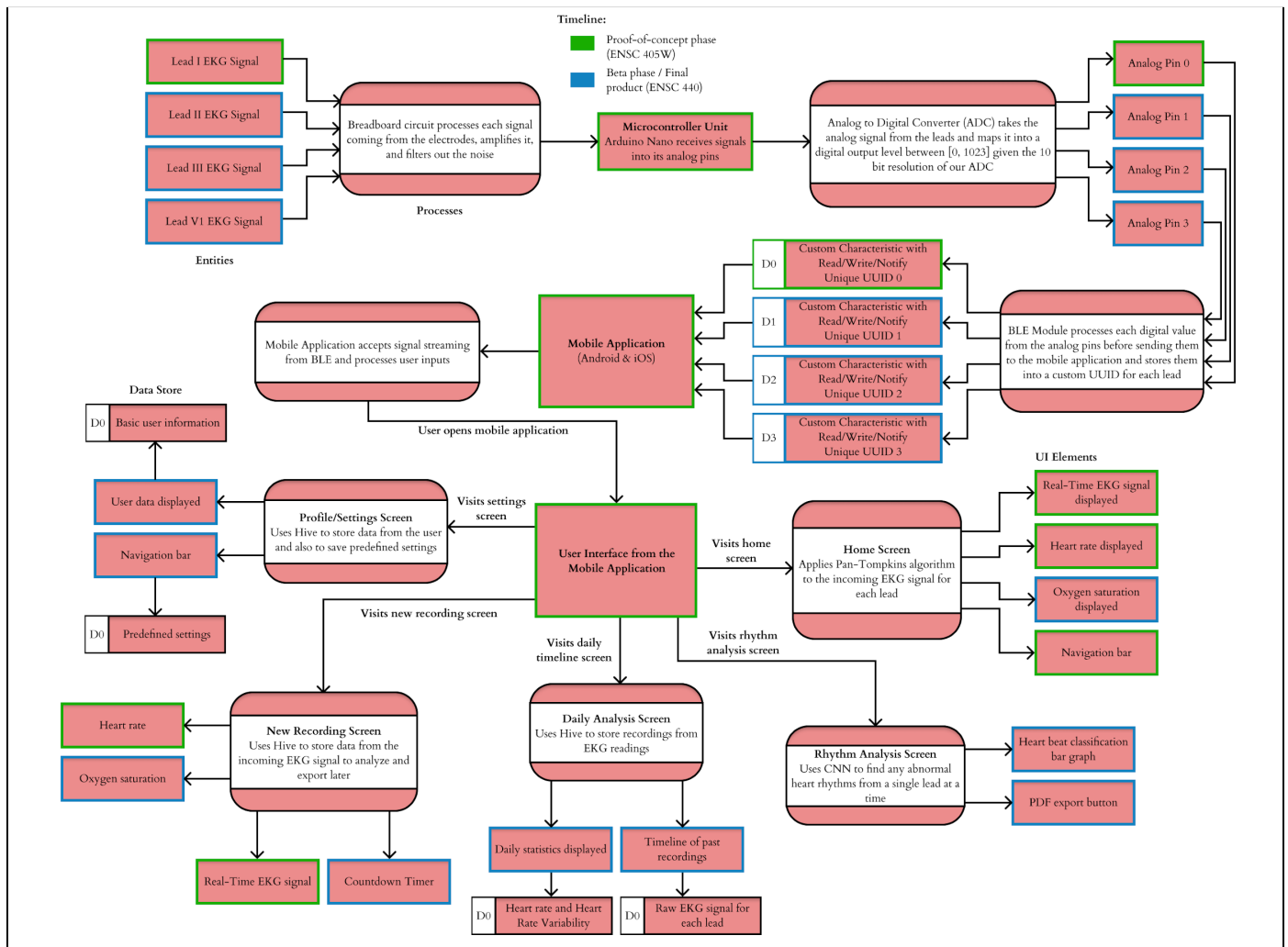


Figure 4.4 Complete Software Data Flow Diagram (For full view version visit [here](https://www.figma.com/proto/bngeWXA/Z73OTnn7q0zxTD/diagrams?node-id=7%3A0&scaling=min-zoom&page-id=0%3A1)²)

² Software Data Flow Diagram:

<https://www.figma.com/proto/bngeWXA/Z73OTnn7q0zxTD/diagrams?node-id=7%3A0&scaling=min-zoom&page-id=0%3A1>

5. Conclusion

The Kompression shirt has the potential to help Canadians make heart health a top priority in their daily activity and can eliminate a fear of not knowing their own state of heart health. This design specification document has outlined general, hardware, and software design specifications to achieve a successful product creation. The proof-of-concept development stage will provide a basic shell of what needs to be accomplished in proving a functional product. The main design aspect that will be finished for the proof-of-concept stage will be a raw assembly of the electrode filled shirt attached to a breadboard and arduino device complemented with a mobile application. The data collected from the EKG circuit will be read and transmitted through the arduino device to the mobile application. The mobile application will then use a real time implementation of the Pan Tompkins algorithm to analyse the hearts signal and produce heart rate and heart variability for the user. We truly believe that this product and it's capabilities will find a niche within the wearable technology market and add an additional grounding for future innovations in the heart health industry.

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Appendix A: Supporting Test Plans

A.1 Hardware Test Plans

Test Procedure	Desired Result
Ensure instrumentation amplifier is working correctly by feeding each input 1V	Output should be 0V since the instrumentation amplifies the difference in input voltages
Ensure operational amplifiers are working by building a buffer with 1V input	Output voltage should also be 1V
Ensure the bandpass filter has proper bandwidth following health canada guidelines[15]. Modelling filters in LT spice provide a good sense of filter design.	Bode Plot has cutoff frequencies at 0.5Hz and 477Hz
Simulate entire circuit on LTSpice using simulated EKG signals created by ECGSYN open source software	Simulated circuit output should display proper PQRST waveform
Test circuit with user hooked up to electrodes. Circuit powered by DC power supply	Oscilloscope displays PQRST waveform
Test circuit with user hooked up to electrodes. Circuit powered by Energizer batteries	Oscilloscope displays PQRST waveform
Testing Arduino Nano by feeding a 2V amplitude 1kHz sine wave to the ADC	Check if the Arduino reads the discretized analog signal
Testing Pulse Oximeter by placing finger on sensor and then sensor on chest	Pulse and oxygen saturation levels should be almost identical
Testing EKG QRS complex accuracy by counting number of QRS complexes occur in one minute and compare with pulse from pulse oximeter sensor	QRS complexes/min should be equal to pulse from pulse oximeter

Table A.1 Hardware Test Plans

A.2 Software Test Plans

Test Procedure	Desired Result
Power and program the arduino. Utilize a 3rd party application that can view services and characteristics of bluetooth devices.	Check bluetooth services and characteristics with a 3rd party application and ensure that all necessary services and characteristics can be viewed after connection
Transmit a predefined EKG signal through bluetooth and receive and plot it on the application while comparing values.	The transmitted signal should match the received signal
Check that we are able to detect the QRS complex from a single EKG lead using Pan-Tompkins algorithm	Application should show proper QRS detection. It will be verified by checking the heart rate value and comparing it with a third party device
Test our arrhythmia detection algorithm. If possible, use a third party device that can generate custom heart signals and pass in different types of arrhythmias to verify if our system is able to correctly categorize each one	In the app, arrhythmias should be correctly categorized based on our accepted criteria
Midway recording, remove one of the electrodes to verify app notification system	App should still be able to show the noisy signal in the real-time view but should detect that one of the electrodes is not connected properly and notify the user
Try to enter the following special characters on any text field within the app: !"#\$%&'()*+,-./:;<=>?@[\\]^_`{ }~	App should accept any special character and not throw any exception errors or crash
User Interface testing: Check usability issues. Compatibility testing with other devices. Run application on both Android and iOS devices	To verify, make sure the experience is smooth and the same features are available on both operating systems

Table A.2 Software Test Plans

Test Procedure	Desired Result
User Interface testing: Check navigation between the different screens using the navigation bar buttons	App should allow the user to navigate to such screens without crashing and should take them to the correct screen based on the button. Screen transition animation should be smooth.
User Interface testing: Check all UI elements in Home Screen is present	App should have the following UI elements: <ul style="list-style-type: none"> ○ App name at the top ○ Real-Time EKG graph ○ Heart rate widget ○ Oxygen saturation widget ○ Navigation bar at the bottom
User Interface testing: Check all UI elements in Daily Analysis Screen is present	App should have the following UI elements: <ul style="list-style-type: none"> ○ Scrollable timeline at the top where user can select the day the wish to see ○ Graphs showing trends for both the user's heart rate and their heart rate variability ○ Daily statistics ○ A list view of recording items for that given day ○ Navigation bar at the bottom
User Interface testing: Check all UI elements in Arrhythmia Analysis Screen is present	App should have the following UI elements: <ul style="list-style-type: none"> ○ Bar graph at the top showing the user's heart beat classification ○ A list view with all their recording events saved on their phone ○ Navigation bar at the bottom

Table A.2 Software Test Plans (Cont'd)

Test Procedure	Desired Result
User Interface testing: Check all UI elements in Profile Screen is present	App should have the following UI elements: <ul style="list-style-type: none"> ○ User details should be visible and editable ○ Notification settings preferences ○ Navigation bar at the bottom
External factors: Turn off Wi-fi from phone	App should continue to work normally and not crash
External factors: Turn off bluetooth from phone	App should show a notification to the user to let them know to turn on Bluetooth on their phone. It should not crash
Regression testing	Whole app system should be tested again whenever a new feature is added to check that no new bugs are discovered

Table A.2 *Software Test Plans (Cont'd)*

Appendix B: Design Options

B.1 General Design Options

Design Options	Requirements	Description
Attach recording device to lower right torso	[REQ 1.3 H-B] [REQ 1.4 M-B] [REQ 1.5 M-F]	Attaching the recording device to the lower right torso area will allow for the most minimal movement of the device. As when a person runs unless shifting in directions, their torso will stay centered. This may however have to sacrifice comfortability compared to other options. The device will also have the closest connectivity to the electrodes and thus use the shortest amount of wiring. Will be easy to attach and take off.
Attach recording device to shoulder		Attaching the device to the shoulder could be a more comfortable option when comparing it to the torso area. This positioning however is at greater risk of unintentional removal as the shoulder area tends to move quite a lot during physical activity. The wires within the shirt will also need to be longer using more surface area and production time of the shirt. Will be moderately easy to attach and take off.

Table B.1 General Design Options

B.2 Electrode and Wire Design Options

Design Options	Requirements	Description
Sticky Electrodes Single Use (3M Red Dot Monitoring Electrode)	[REQ 2.1 H-A] [REQ 2.1.5 H-B] [REQ 2.1.6 M-B] [REQ 2.1.3 H-F]	These electrodes will most likely be used for our prototype. They provide good contact with the skin and have conductive gels on the electrode itself. Can be worn for up to 3 days. They provide good contact and are small enough to include in a shirt design. Their biggest problem is that they are single use. Once you remove them it's hard to get a good signal again.
Reusable Electrodes		There are some options available that seem to be reusable and could be integrated within the shirt fabrics. These reusable electrodes have the same benefits as the single use sticky electrodes, but at a higher per unit price.
Fabric Woven Electrodes		Fabric woven electrodes seem to be a promising tool for bio-wear and monitoring. They provide comfortability but cannot be removable and their ability to stay in contact with the skin is dubious. Additionally these kinds of electrodes are difficult to come by commercially. But extra research into this needs to be done.
SE TL10 10-Piece Test Leads with Alligator Clips	[REQ 2.1.2 M-B] [REQ 2.1.3 H-F]	These alligator clips will most likely be used for our prototype demo at the end of 405W. They provide a reliable connection between the electrodes and the user. The 22 gauge wire could easily be included within the shirt itself. It's easy to come by and cheap.
25 Gauge Insulated Wire		A smaller gauge wire that when insulated provides a clean connection. Small enough to be included in a shirt and washer/dryer friendly if insulated correctly.

Table B.2 Electrode and Wire Design Options

B.3 EKG Circuit Design Options

Design Options	Requirements	Description
Instrumentation Amplifier (AD 623 ANZ)	[REQ 2.2 H-A] [REQ 2.3 H-A] [REQ 2.4 H-A]	This instrumentation amplifier is a low cost and low power amp that can function on 2.7 - 12 V single supply. This is useful since it could potentially run on a 9V battery. The circuit model for this amplifier is shown in <i>Figure 3.4</i> . The gain is easily adjustable by replacing the R_G resistor with any value up to an overall gain of 1000. The downside to this amplifier is that we cannot build a right leg drive since the whole amp is in a chip and cannot be opened up.
Instrumentation Amplifier (AD8223)		A cheaper and less documented version of the AD623 ANZ. Low power, and another good choice for biomedical instrumentation
Instrumentation Amplifier (MCP6002 Chip)		This operational amplifier is low voltage operating on 1.8-6 volt single supply. A figure of a circuit using these amplifiers is shown in <i>Figure 3.3</i> . Using these amplifiers allows the instrumentation amp to be built from scratch hence allowing the addition of the right leg drive. The gain of this circuit will also have a gain of up to 1000.
Bandpass Filter/Right Leg Drive (MCP6002 Op Amp)		After receiving the signal from the instrumentation amp, the signal needs to be filtered to range between 0.1 and 300 HZ (<i>Figure 3.4</i>). The circuit for the bandpass filter itself is shown in <i>Figure 3.5</i> . The capacitor values have not been chosen yet since the overall gain for the filter has not been decided. The filter at 0.1 HZ is needed to remove any DC bias that may be created.
BandPass Filter / Right Leg Drive (LT1097CN)		A more expensive low power alternative to the MCP 6002. Works on a 2.7-15V supply range.

Table B.3 EKG Circuit Design Options

Design Options	Requirements	Description
Notch Filter	[REQ 2.2 H-A] [REQ 2.3 H-A] [REQ 2.4 H-A]	A notch filter could be used to remove 60 HZ power line interference. This filter would be appended to the end of the circuit shown in <i>Figure 3.1</i> . The problem with a notch filter is that it can remove other important frequencies close to 60HZ which is undesirable.
Electrolytic Capacitors		Electrolytic Capacitors is a great option for designing bio potential circuits since they function well in low frequency environments
Microcontroller (Arduino Nano)	[REQ 2.5 H-A]	The Arduino Nano shown in <i>Figure 3.6</i> is a small and compact microcontroller that suits the project needs. This microcontroller (<i>Figure 3.6</i>) has an on board 10-bit ADC with 8 analog inputs which means it would be able to record the 4 analog signals from the leads simultaneously. A 10-bit ADC might not provide the level of accuracy needed but it is a good start for a cheap price. It can operate on a 5V supply and is quite small measuring in at 18mm x 45mm.
Microcontoller (Arduino Due)		The Arduino Due is a larger microcontroller, at 53.3mm x 101.52 mm. However, it has 12 analog pins available and a 12-bit on board ADC. Although larger, it may provide a larger level of accuracy when the analog signal is scaled.

Table B.3 EKG Circuit Design Options (Cont'd)

B.4 Battery Design Options

Design Options	Requirements	Description
Energizer L522BP Energizer Ultimate Lithium 9V Battery	[REQ 2.6 M-F] [REQ 2.6.1 M-F] [REQ 2.7 H-B]	This battery is long lasting and provides the EKG circuit with enough power to operate the op-amps and the microcontroller.
EBL High Volume 9V Lithium-ion Low Self-Discharge Rechargeable Battery (600 mA)		These batteries are extremely useful since they have a long charge life. They can also be recharged which makes changing the battery in the device a rare occurrence.

Table B.4 EKG Circuit Design Options

B.5 Pulse Oximeter Design Option

Design Options	Requirements	Description
MAX30100 pulse Oximeter Chip	[REQ 2.2 H-A] [REQ 2.3 H-A] [REQ 2.4 H-A]	Small chip that doesn't require the measurement to be taken around the finger or earlobe. Measurement is done in the same plane so it can be incorporated into wearables. Perfect for our design and compatible with Arduino.
MSP 430 Double Chip Pulse Oximeter		This chip is good but requires the user to place it around one's finger or earlobe. This would be difficult to include within a wearable device such as Kompression.

Table B.5 Pulse Oximeter Design Options

B.6 Application Design Options

Design Options	Requirements	Description
Mobile Application	[REQ 3.9 M-F] [REQ 3.4 M-F]	The advantages of going with a mobile application is that it can run faster than web apps, have greater functionality, can work offline and they are safe and secure for the user.
Web Application		Web applications are good due to their common code base so they are easier to maintain and quicker to build. However, they do not work offline, do not have as many advanced features, and can sometimes be at risk of security breaches.

Table B.6 Application Design Options

B.7 Framework Design Options

Design Options	Requirements	Description
Flutter + Dart	[REQ 3.1 H-A]	In terms of coding style and syntax, it has Java-like syntax, so OOPS (Object Oriented Programming) developers can master it once they learn the basics. Dart can be compiled both AOT (ahead-of-time, which produces machine optimized code) and JIT (just-in-time, meaning that it executes code that involves compilation during run time, rather than before execution) which helps building apps faster. [16]
React Native + JavaScript		JavaScript has been around longer in the industry and is a mature and stable language. React Native uses bridge and native elements, so it may require separate optimization for each platform. It is an interpreted language, and it is faster than other compiled languages like Java. [16]

Table B.7 Framework Design Options

B.8 IoT Protocol Design Options

Design Options	Requirements	Description
Bluetooth	[REQ 3.1 H-A] [REQ 2.5 H-A] [REQ 2.5.1 H-A]	Frequency range varies from 2.4 GHz to 2.483 GHz Uses GFSK modulation technique Requires low bandwidth Radio signal range is 10 meters Transmit power around 10 mW which is ideal of low power devices Ideal for connecting devices around a user.
ZigBee		Frequency range mostly 2.4 GHz worldwide Uses BPSK and QPSK modulation techniques Requires low bandwidth but greater than Bluetooth's bandwidth Radio signal is 10 to 100 meters Transmit power around 100 mW Main purpose is to connect devices that require a much wider range, making it ideal for home automation and smart lighting.

Table B.8 IoT Protocol Design Options

B.9 Bluetooth Module Design Options

Design Options	Requirements	Description
HC-05 Module	[REQ 3.1 H-A] [REQ 2.5 H-A] [REQ 2.5.1 H-A] [REQ 1.6 M-B] [REQ 1.1 H-B] [REQ 2.6 M-F]	<p>This module comes at 9.07 grams with dimensions of: 2.79 x 1.52 x 0.25 cm.</p> <p>It supports 2.0 SPP (Single Packet Protocol). SPP allows for low data rate wired bus networks.</p> <p>Has a voltage input range of 3.6V to 6V and a default data rate of 9600.</p> <p>Does not support iOS devices.</p>
HM-10 Module		<p>This module comes at 5.1 grams with dimensions of 3.05 x 1.52 x 0.25 cm.</p> <p>It supports 4.0 BLE (Bluetooth Low Energy). BLE allows for low power consumption, meaning that applications can run a smaller battery for a longer period.</p> <p>Has a voltage input range of 3.6V to 6V and a default data rate of 9600.</p> <p>Supports Android, iOS and PC.</p>
HM-18 Module		<p>This module comes at 1.7 grams with dimensions of 3.81 x 1.65 x 0.25 cm.</p> <p>It supports 5.0 BLE which has a faster transfer rate and a larger MTU (Maximum Transmission Unit). A larger MTU brings greater efficiency in transmitting because each packet carries more data.</p> <p>Has a voltage input range of 3.6V to 6V and a default data rate of 9600.</p> <p>Supports Android, iOS and PC.</p>

Table B.9 Bluetooth Module Design Options

B.10 QRS Detection Algorithm Design Options

Design Options	Requirements	Description
Pan-Tompkins	[REQ 3.7 M-F] [REQ 3.5 H-F]	<p>Pan-Tompkins algorithm uses a series of filters to highlight the frequency content of the heart's depolarization and also removes the background noise.</p> <p>It is the most widely used QRS complex detector for the monitoring of many cardiac diseases including in arrhythmia detection. This method could provide good detection performance with high-quality clinical EKG signal data.</p>
Neural Network		<p>This option involves the use of 1-D convolutional neural network (CNN), which then extracts the EKG morphological features which are then passed through a multi-layer perceptron (MLP) which detects the QRS complex.</p> <p>It does involve some preprocessing on the EKG signal before it is ready to be analyzed.</p>
Hilbert Transform		<p>This is a less frequently used method that involves doing a Hilbert Transform along with Adaptive thresholding which has the ability to distinguish between dominant peaks in the signal among other peaks.</p> <p>Would require our team to put more time and effort into research since it is not a well known source for detecting QRS complexes.</p>

Table B.10 QRS Detection Algorithm Design Options

B.11 Arrhythmia Detection Design

Design Options	Requirements	Description
Pre-trained Neural Network from [13]	[REQ 3.3.1 M-B]	This option would use the pre-trained network with some of the neural network input leads set to 0. Using this approach would require that we correctly match our data to the training data when feeding it to the neural network. This option would require the least company time and additionally make use of a larger more generalisable model then we could train ourselves.
Company designed and trained Neural Network		For this option we would design our own convolutional neural network architecture. We would use the PhysioNet MIT-BIH Arrhythmia database [17] for training, validation and testing. We will only utilize the Lead II recordings from our device for heart arrhythmia detection as this will simplify the design and training of the DNN. This dataset has a large imbalance of labels so we would have to take this into account when designing the architecture. This option would take a lot of company time to ensure that the network is being correctly trained and would generalize correctly.

Table B.11 Arrhythmia Detection Design

B.12 File Format Design

Design Options	Requirements	Description
PDF document	[REQ 3.3.1 M-B]	This option would allow the user to download a pdf document that summarizes the information from the application analysis. It would show the plotted portion of the EKG that was determined to be abnormal.
CSV file		There would be an option available to export the analysis results in a csv file along with the raw data. This option would involve less work on the programming for our company. This option would make it more work for the user to interpret the exported data.
Separate image files		Individual graphics and tables from analysis in the application would have a download option. This method would allow the user to download only graphics of interest rather than all at the same time.

Table B.12 File Format Design Options

B.13 Graphing Library Options

Design Options	Requirements	Description [18]
Fl_animated_linechart	[REQ 3.6 M-F] [REQ 3.3 H-A]	Support for DateTime axis Multiple y-axes, supporting different units Highlight selection animation of the chart
FL Chart		Multiple chart types available: Line chart, bar chart, pie chart, scatter charts Well defined animations Plenty of documentation online
syncfusion_flutter_charts		Create beautiful animated and high-performance charts 30+ chart types available Update the chart dynamically with live data (Real-time) Commercial license needed
Bezier Chart		Multi bezier lines Allow numbers and datetimes Gestures support like touch, pinch/zoom, scrolling Highly customizable both Android and iOS.

Table B.13 Graphing Library Design Options

B.14 Database Design Options

Design Options	Requirements	Description
Firebase	[REQ 3.8 L-F] [REQ 3.9.1 L-F]	Online NoSQL storage option More involved setup could take more company time
Hive		Fast local NoSQL storage option Completely native to Dart and consequently doesn't require device-specific implementation

Table B.14 Database Design Options

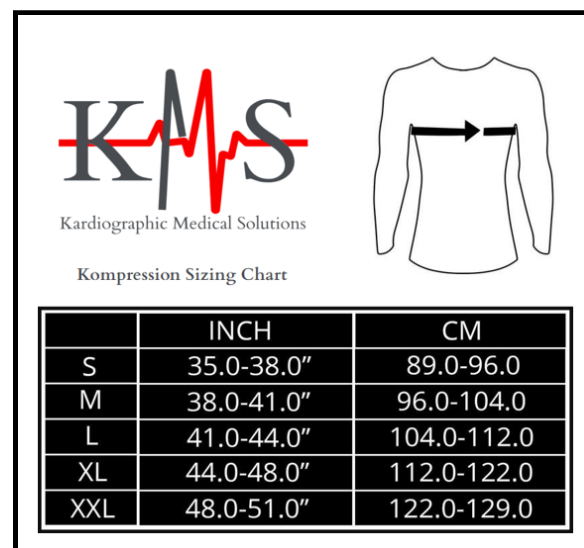
Appendix C: User Interface and Appearance Design

C.1 Introduction and Background

This documentation will capture the usability and appearance details of both hardware and software features of the Kompression Shirt. The sections included will outline user analysis, technical analysis, engineering standards, analytical usability testing, and empirical usability testing. The user analysis will provide a brief run down of what the user is required to know in order to obtain the best experience with the Kompression Shirt product. The technical analysis section will provide a detailed look into how the product satisfies the seven elements of UI interaction. The engineering standard section will state any standards associated within the scope of the products needs. Lastly the analytical and empirical usability testing sections will provide multiple scenarios in which KMS will test the design and how results will be achieved.

C.2 User Analysis

A user of the Kompression shirt will be a physically active and healthy individual, who is familiar with technology and has a strong interest in understanding and analyzing their heart health. The user will not need to have professional medical knowledge or experience interpreting ekg readings. The user should be familiar with installing and using applications on their phone. Users should also have the manual dexterity to connect the device to the shirt socket. The users body measurements will be restricted to fitting into one of five sizes of Kompression shirt defined in the design document above: small, medium, large, extra large, double extra large. A sizing chart can be seen in *Figure C.2.1*.



	INCH	CM
S	35.0-38.0"	89.0-96.0
M	38.0-41.0"	96.0-104.0
L	41.0-44.0"	104.0-112.0
XL	44.0-48.0"	112.0-122.0
XXL	48.0-51.0"	122.0-129.0

Figure C.2.1 *Kompression Sizing Chart*

C.3 Technical Analysis

In this section we outline the important aspect of having the “Seven Elements of UI Interaction” where we strive to achieve an intuitive and easy-to-use design for described users. For a full blown up version of our software UI with interactions please visit [here](#)³.

C.3.1 Discoverability

Hardware: For the discoverability of our product, we want users to feel right at home while using Kompression by making it clear how to navigate around the system and how to locate certain features. The user will be required to attach the combined PCB and Arduino recording device to the shirt for use or whilst idle and will be able to remove the device and the electrodes from the shirt for cleaning . The connection location will be outlined clearly to avoid any confusion of where it attaches as shown in *Figure C.3.1*. The latching mechanism for release will also be visible to the eye. *Figure C.3.2* shows that there will be a clearly indicated on and off button attached to the device signaled by an LED for easy discovery.

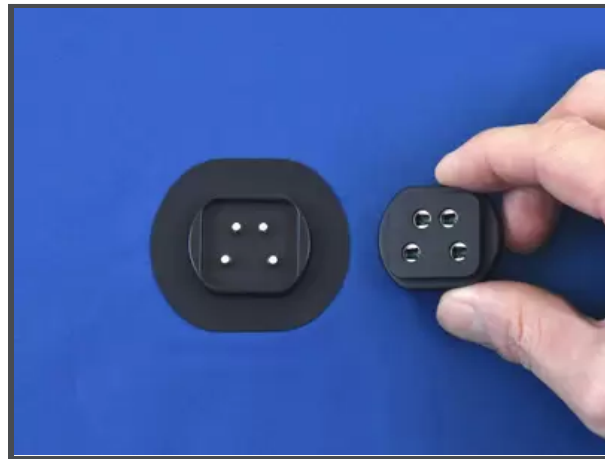


Figure C.3.1 Connector between Shirt and Device

³ Figma Prototype:

<https://www.figma.com/proto/MAX1YAUdZrt7046hanMjRf/Kompression?node-id=35%3A8025&scaling=scale-down>

Click the mouse on the screen to see which parts can be interacted with.



Figure C.3.2 Device Mock-Up

Software: The app will contain familiar and universal icons for navigating the different screens and all the features available will be clearly labeled. We will avoid cluttering our UI with redundant information to keep the user focused on the main purpose of the app, to track their heart health. Regarding the cardiac rhythm analysis, we will be prioritizing them in a consistent order, based on severity levels. For example, a more severe arrhythmia event detected will always be on the top of the list among other less severe events. In the main page of our app, as seen in our UI mockup design below, we will provide the more important aspects of our product, the real-time EKG signal and their heart rate, as well as a navigation bar for moving around different screens. A screen snippet of the apps homepage can be seen in *Figure C.3.3*.

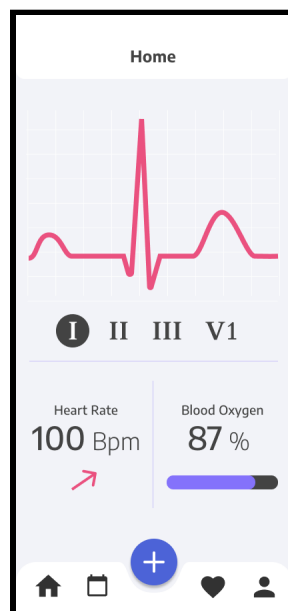


Figure C.3.3 Homepage Mock-Up

C.3.2 Feedback

Hardware: When attaching the device to the shirt, there will be a clicking sound indicating that the device has been properly slotted in. The user will also be able to feel that it is okay to remove the device after using the releasing mechanism to avoid any damage to the device. There will be an indicating LED light to let the user know the shirt is active and recording data after pressing the on/off button. Also, while charging the device, we will show a LED status that it is in fact charging properly.

Software: On the app side, we will provide progress indicators while performing any analysis or events that may result in a waiting state from the user. Also, if at any point while wearing the shirt one or more electrodes fall off, we will be providing a notification on the app to alert the user immediately. From the data collected, we will be putting the analysis in a single screen where we will provide feedback to the user on what the result was via waveforms and statistics. *Figure C.3.4* shows a picture from our UI mockup design as to what this page would look like.

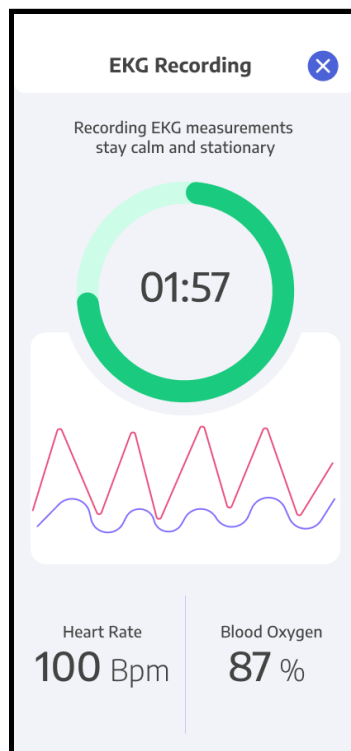


Figure C.3.4 EKG Countdown Timer

C.3.3 Conceptual Models

Hardware: The shirt and device holding the electronics will only be responsible for sending data via bluetooth to the app, so conceptually, the user will be made aware that the main functionality of our product lies in our application.

Software: EKG data collected through the application will be stored in a timeline following the common conceptual model of calendars, where the user will be able to browse past recording events in the same way they would if they were using a calendar as shown in *Figure C.3.5*. This will make it intuitive to use and avoid any confusion.

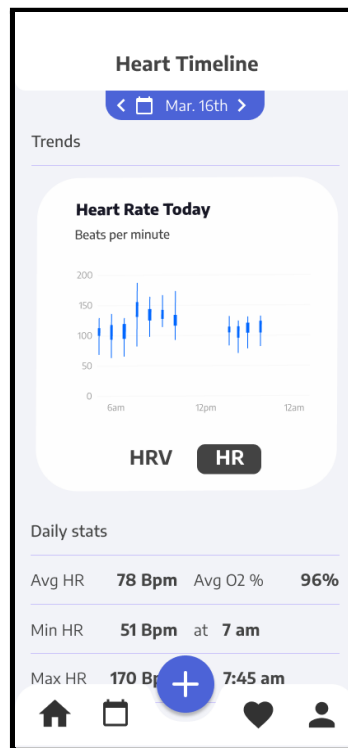


Figure C.3.5 Heart Timeline

C.3.4 Affordances

Hardware: The electrodes on the Kompression shirt will be clearly labeled with colored circles and will have a sleek circuitry design running through the shirt showing how everything is connected within. There will be a clear attachment point for input on the device showing the user it affords attachment to the shirt.

Software: For the app, we want to follow a minimal design with a clear color scheme where everything is accessible to the user for them to explore. Button size and clear labeling will be thoroughly examined so that it gives clues to the user on how it is supposed to be used.

C.3.5 Signifiers

Hardware: We will provide users clear indication where the electrodes will be attached on the shirt, along with other various labels on the on/off button and charging location. LEDs will also be used to indicate the state of the device as it is operating.

Software: On the app, the user will always see a large plus icon, signifying the affordance of starting an EKG recording. Similarly, to see the analysis, we will have big buttons clearly labeled so as to grab the user's attention and to ensure their actions are intentional when clicking any button.

C.3.6 Mappings

Hardware: Our device holding the electronics will only have a pin connector that will connect all the electrodes to the microcontroller. In our shirt, the mapping will be the circles that show where each electrode placement is, and will be color coded to ensure no confusion as shown in *Figure C.3.6*.

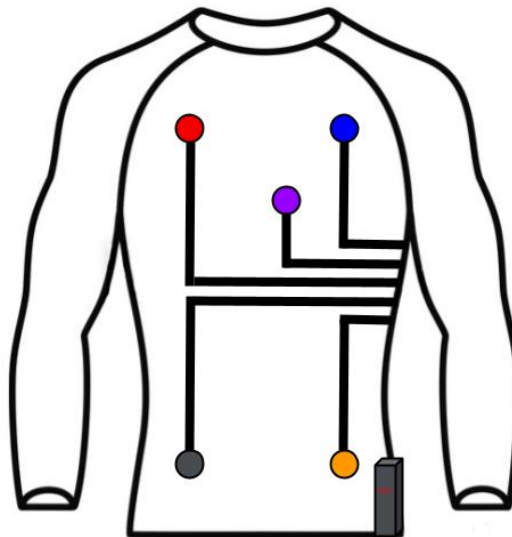


Figure C.3.6 Electrode Mapping

Software: Our navigation bar will be located at the bottom of the screen where the user can click each button and go to a clearly labeled screen. Each button will have a clear identifier, in the form of a standard icon or text, that the user will be able to interpret before clicking on it.

C.3.7 Constraints

Hardware: For our physical components, the main constraints will be the placement of each pin and electrode. This will guarantee the user does not connect the device in the wrong place and will allow for an intuitive setup even without requiring the user's manual.

Software: On the app, the user will only be able to view and export information about one arrhythmia event at a time, we will not be concatenating data from different recording events in our exported PDF document. Another constraint will be that the user will not be able to start a recording if the electrodes are not attached to the body or if the bluetooth module is not connected to the app. We will provide notifications that alerts the user if that case were to happen.

C.4 Engineering Standards

The Kompression user interface will adhere to the following engineering standards.

- Clothings size standards
 - Kompression uses an american standard for compression shirt sizes.
- P360 – Standard for Wearable Consumer Electronic Devices [19]
 - Kompression follows the security and suitability of wearables provided in the P360 project standard
- IEEE Std 2410-2017 [20]
 - Provides identity assertion, role gathering, multilevel access control, assurance, and auditing for software running on clients such as smartphones or mobile devices
- IEC 62304:2006: Medical device software — Software life cycle processes [21]
 - Automated unit testing on user interface will be conducted

C.5 Analytical Usability Testing

For Kompression's analytical usability testing, the designers created the following UI test scenarios which can be seen in *Table C.5.1* on the following page.

Test	Description	Expected Result
User at Rest	Designers record the measurements using Kompression while at rest (sitting or supine).	The EKG signal recorded from the product and sent to the device must range between 0 to 5V
Active User	Designers record the measurements using Kompression while active(walking or running).	The EKG signal recorded from the product and sent to the device must range between 0 to 5V
Low Battery	Designers use Kompression until the LED monitoring battery life turns red, indicating the battery level has dropped below 5V	The recording device shuts off when low battery power is detected
Time for Recording	Designers record an EKG, and the signal takes no longer than 10 seconds to transmit to application	Resulting signal is displayed within 10 seconds of recording on the application UI
Proper Display of EKG Measurement	Designers send an EKG recording to the application	Proper PQRST heart wave complex is displayed on the recordings tab.
Proper Analysis of Healthy EKG Measurement	Designers send an EKG recording to the application	The application correctly identifies heart rate variability, pulse (60-100 beats per minutes) and the PQRST complex.
Proper Analysis of Unhealthy EKG Measurement	Designers send an EKG recording to the application	Application indicates the location and time of a skipped heart beat, elongated complex waves and other abnormalities.
Application Boot Up	Open Application	Application boot up should not take longer than 3 seconds.

Table C.5.1 Analytical Usability Tests

C.6 Empirical Usability Testing

For Kompression’s empirical usability testing, both male and female users will be used to ensure the usability and accuracy of the product. Users testing the product will be of differing sizes to simulate the products performance in the market. The test scenarios will be as follows in *Table C.6.1*.

Test	Description	Expected Result
User at Rest Sitting	Test users will sit down and stay relaxed for 5 min; without moving while wearing Kompression. This will allow the product to record measurements at a resting state.	The EKG recordings will be displayed on the application and the user will feel comfortable.
User at Rest Lying Down	Test users will lie down and stay relaxed for 5 min while wearing Kompression. This will record measurements during a “sleep state”.	The EKG recordings will be displayed on the application and the user will feel comfortable.
User Walking	Test users will walk for 5 min while wearing Kompression. This will record measurements during a low to moderate active state.	The EKG recordings will be displayed on the application and the user will feel comfortable.
User Running	Test users will run for 5 min while wearing Kompression. This will record measurements during an intensive active state.	The EKG recordings will be displayed on the application and the user will feel comfortable.
Proper EKG Display	After the Recordings have been completed in any of the test scenarios 1 through 4 ensure the application displayed the signal and any underlying issues it detected.	The EKG recordings will be displayed on the application with the areas of interest highlighted
Comfortability	Test users must wear Kompression for 30 min	There should be no pain, itchiness or any other uncomfotability.

Table C.6.1 Empirical Analytical Tests

User Safety and Reliability

To use Kompression safely and effectively, the following safety and reliability procedures should be adhered to.

- Do not use Kompression underwater
- Ensure the transmitting device is securely connected to the pins on the shirt
- Ensure the shirt fits tightly
- Ensure the electrodes make good contact with the skin. They should not shift or fall out of place during activity or rest
- Do not plug the transmitting device directly into an outlet to charge. This will damage the device
- If the device stops recording mid session. Simply power off the device, disconnect and reconnect it to the shirt.
- If the device does not record properly, ensure electrodes are in good contact with the skin and the device battery level is still green
- Disconnect the device and electrodes from the shirt before putting the shirt in a wash cycle
- Ensure there are no cracks/rips in the shirt electrodes or recording device

C.7 Conclusion

The interface of the application and appearance of the device has been created using figma that has included every main UI function that needs to be accomplished. The device mockup has also been started to represent the location of the main electronic components. The main software user interface that needs to be completed for the proof of concept is the skeleton of the application. The priority after the skeleton layout will be plotting the live EKG signal on the Home page. Creating the appearance of the physical product will be achieved in the final stages of the proof of concept design. The proof of concept hardware appearance will consist of a breadboard circuit attached to single use electrodes via alligator clips running through the shirt with fabric sewed over indicating the electrode and wire placement.

Appendix D: Revision History

Version #	Implemented By	Revision Date	Approved by	Approval Date	Reason
1.0	DM, MG, SU, JJ	2021-03-25	DM, MG, SU, JJ	March 26th, 2020	First revision of our design specification document

Table D.1 *Revision History*