Feb 18, 2021

Dr. Craig Scratchley
School of Engineering Science
Simon Fraser University
Burnaby, BC
V5A 1S6

RE: ENSC 405W Requirement Specifications for the The Kompression Shirt

Dear Dr. Scratchley,

Please find attached a document containing the requirement 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 requirements to make the Kompression Shirt come to life. In more detail, it will break down the requirements into the following components: general, hardware, software, safety, sustainability, and standards. Furthermore it will also provide a comprehensive background, scope and complete system overview of the product. The system overview will describe in detail the analysis of our problem and the functionality of our four lead EKG system embedded into the shirt.

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

Sincerely,

Diego Martin
Chief Executive Officer
Kardiographic Medical Solutions

Kardiographic Medical Solutions

Requirement Specifications:
The Kompression Shirt

Company 12 Project Team:

Stefan Ungurean

Jamyl Johnson

Diego Martin

Matthew Gould

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 [1]. It is an epidemic of vast proportions that has no signs of slowing. Kardiographic Medical Solutions 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 during rest and active states for early detection of heart abnormalities and arrhythmias. This document will present the requirements necessary for building a new bodywear wellness device, Kompression; a form fitting compression shirt with an embedded EKG system. Furthermore, this paper will provide an introduction to Kompression along with an overall system overview for a better understanding of the company and the product.

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Glossary

Term	Definition
Tachycardia	Tachycardia means that your heart is beating too fast. For example, a normal heart beats 60 to 100 times per minute in adults. Tachycardia is any resting heart rate over 100 beats per minute (BPM).
Atrial fibrillation	AFib causes the heart rate to increase and become erratic. It can elevate your heart rate to 100 to 200 BPM, which is a lot faster than the normal 60 to 100 BPM.
Atrial flutter	The condition is caused by a single electrical impulse that travels rapidly in the affected atrium. This often results in a fast heart rate, but it's a more regular rhythm.
Bradycardia	If you're bradycardic, it means you have a slow heart rate (less than 60 BPM), Some athletes have slower heart rates because they are in excellent physical condition, and this isn't usually the result of a heart problem.
Ventricular fibrillation	Can stop the heart from beating and cause cardiac arrest
Active diagnostic device	An active device that, whether used alone or in combination with another medical device, is intended to supply information for the purpose of detecting, monitoring or treating a physiological condition, state of health, illness or congenital deformity.
Invasive device	A medical device that is intended to come into contact with the surface of the eye or penetrate the body, either through a body orifice or through the body surface.

Table 1.1:List of Important Terms

1. Introduction

1.1 Background

Ischaemic heart disease is not only the leading cause of death in the United States, but accounts for more than 16% of all deaths worldwide [2]. The world is dealing with a heart health epidemic that is growing rapidly without signs of stopping. There are many tools available in a clinical setting to assess a patient's heart health but there are a lack of solutions developed for at-home patient care and cardiac monitoring. Without a system for early detection of abnormal heart rhythms, underlying health issues could go unnoticed for years until it is too late. Clinics often issue cardiographic tests that could take weeks to schedule appointments and even longer to receive proper results. Timing is everything, and Kardiographic Medical Solutions (KMS) plans on streamlining the entire process. KMS prides itself on wanting to develop a 4 lead electrocardiogram (EKG) system with clinical grade holter monitor accuracy for at-home cardiac recordings.

KMS plans on targeting the body wear industry and people of all ages. Having an article of clothing available that monitors heart rhythms and patterns throughout the course of the day or night is extremely beneficial to many individuals. The market for bodywear is new and growing, with a value of 37 billion dollars in 2020 and projected to scale to 104 billion by 2027 [3]. Kompression will be a leader in the wellness bodywear sector being in the forefront for computer aided diagnosis (CAD) of cardiac issues.

1.2 Scope

The Kompression product will consist of a 6 electrode and 4 lead EKG system. This EKG system will be integrated into a form fitting compression shirt allowing the user to take measurements whilst performing any physical activity. The EKG electrodes will be mounted into the shirt whilst the holter monitor device recording the signals will be removable from its attachment to the back of the shirt. In later development, the Kompression product will also have an application that allows the user to view their heart activity that the EKG will provide via bluetooth.

1.3 About the Product

Kompression is a new product on the market capable of measuring, analyzing and storing a four lead electrocardiogram on any cellular device. The leads are embedded within a tight compression shirt that can be used to monitor heart rhythms during periods of physical activity at any time during the day or night. The recording device is attached to the base of the shirt via a series of pins and has the option to not be removable at all. EKG's allow for in depth analysis on cardiac health by being able to measure and identify many common heart problems. Kompression will be able to give the user and furthermore their respective physicians a lateral, inferior and transverse view of the heart. Pairing these measurements with our software will allow the user to quickly identify what, where and when the problem occurred.

Current EKG systems allow only for 1 lead EKG systems that measure lateral heart health. Some allow the patients to be active while others require for them to be at rest. Kompression solves all of those issues in one product. It provides a 4 lead measurement from 3 different angles, where the user chooses when and how to perform the recording.

2. System Overview

2.1 Analysis of Problem

At KMS, the problem we are trying to tackle is in the reduction of time spent to get a clean and reliable reading from one's heart. We believe that early detection of any possible heart rhythm problem is key to a solid recovery and being able to track your progress in real time at the comfort of your own home is key to building a safe and healthy habit of checking your heart's health. Currently, in order to get a proper EKG reading, one that looks at many different angles of your heart, people rely on doctor's appointments, other portable EKG devices available in the market (mainly smartwatches within the wearable technology industry) or a visit to the ER in the worst case scenario. Wearable technology has greatly impacted the way society can take preventive measures regarding their overall health, and we at KMS, believe that this sector is worth innovating to create something unique, affordable and efficient for people to monitor their heart health in real time.

Our proposed solution to this problem focuses on the development of a special shirt that is integrated with a 4 lead EKG system and maximizes comfortability and reusability. This 4 lead EKG system is obtained through the use of 6 electrodes placed strategically in the chest area of the user which will allow us to get readings from Lead I, Lead II, and 2 precordial views of the heart, which are all useful in detecting abnormal heart rhythms. Similar to other products in the market, such as holter monitors or smartwatches, we want our software to detect, store, and present the electrical signals from the heart of the user in a clear and easy-to-understand way that will be helpful for monitoring their heart during any activity. From the results, we will create a report that the user can interpret and will be shareable with their family doctor if a follow up is needed based on the analyzer algorithm.

We envision our final software solution to be able to detect the most common types of abnormal heart rhythms [4]:

- Tachycardia
- Atrial Fibrillation
- Atrial Flutter
- Bradycardia
- Ventricular Fibrillation

In order to arrive at this proposed solution to our problem, we wanted to consider a product that is both comfortable and accurate. We went with the idea of having a shirt rather than a chest strap or a smartwatch since those types of medical devices only provide a single view of the heart which in most cases can lead to unknown readings and are prone to errors. At the same time, those devices do not have a high level of comfort as they rely on lanyards or adhesives. By having a shirt, we can fit more electrodes and thus increase our number of angles from which we can observe the heart's electrical signals.

2.2 Four lead EKG system

The EKG app on Apple Smart watches provide the same result to a single lead (or Lead I) EKG. As mentioned by Apple, they have tests comparing their single lead measurement to the usual 12 lead EKG at a doctor's office and they found that from approximately 600 subjects, 99.6% were correctly labeled for sinus rhythm classification and 98.3% for AFib classification [5]. Of course, a single lead will not be able to analyze the heart from different angles so it will give a greater number of strips that are deemed inconclusive and not classifiable.

From this article [6] the main advantages of using a 12 lead EKG are summarized in the following points:

- Accurately reproduces QRS, ST and T waveforms
- Establishes early diagnosis of any heart problem
- Detects and localizes where the arrhythmia originates
- Able to track long term effects of sustained hypertension

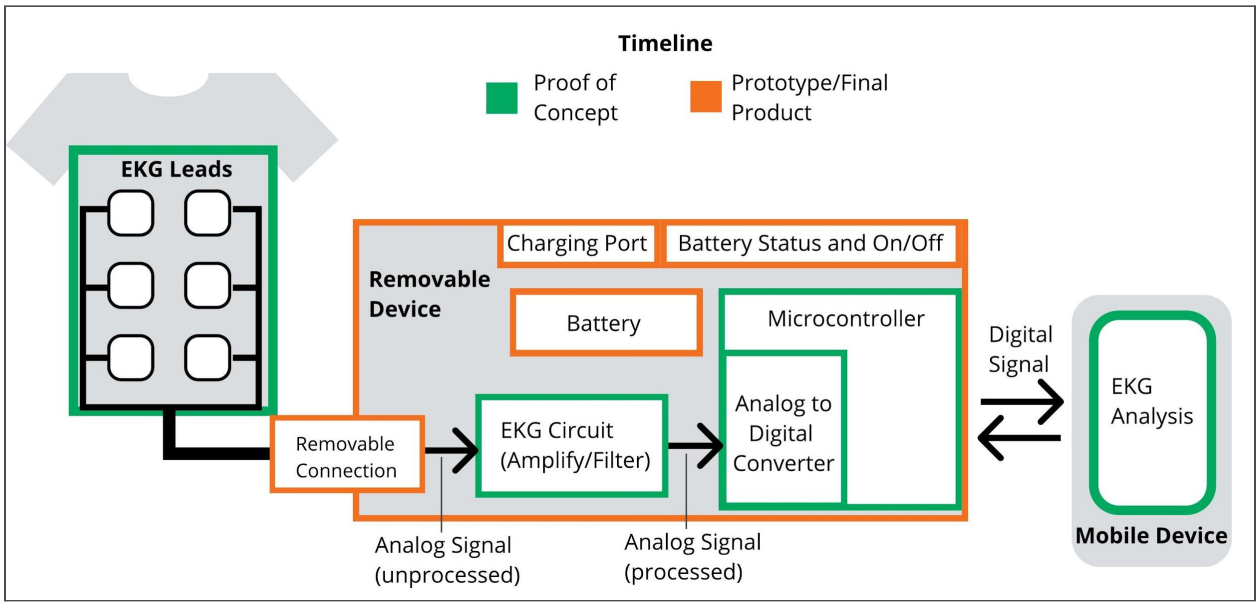

Figure 2.1 Kompression System Overview

One of the things we want to avoid is having something too bulky or uncomfortable to wear as seen at a doctor's office where it needs to establish 12 leads which require a lot of electrodes placed on the patient's body. With this in mind, we decided to go for an in between approach where we can guarantee that we check more angles of the heart as opposed to a unilateral direction but remove the bulkiness of the process by carefully creating a shirt that can be comfortable to wear. With our design, we expect to get a 4 lead EKG strip which will cover a lateral view, an inferior view, and a traversal view around the chest and limbs of the user.

After reading about other medical tests available to diagnose heart conditions, we came across the following ones: blood tests, echocardiograms, MRIs, as well as other more invasive procedures. From this article [7], we found out that blood tests are commonly ordered by a doctor after a patient has had their heart muscle damaged by an event such as a heart attack. The blood test allows the doctor to know how much of the heart has been damaged. So this type of test is not preventative but instead it is reactive as it is done after the heart has been under stress for a long time.
Echocardiograms are used to get a picture of your heart using ultrasound. This kind of test requires patients to be at a hospital setting as they need specialized equipment and personnel. Similarly, MRIs are also a way to get a 3D view of the heart and require heavy equipment.

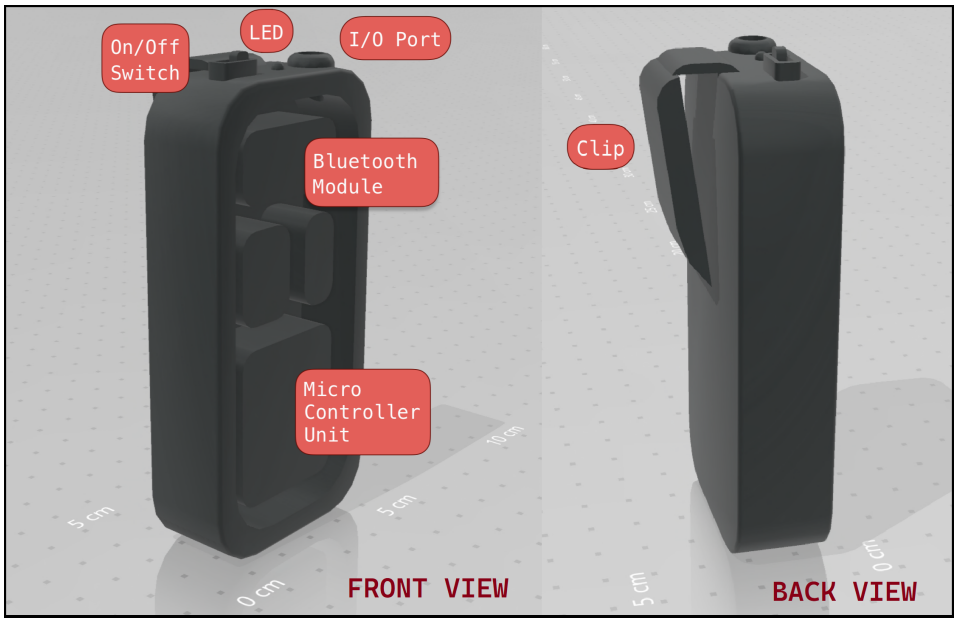

Figure 2.2 Kompression Bluetooth Module Mock Design

Based on these available methods, we believe that an EKG reading is both a faster and non-invasive option that allows for accurate readings that will be able to detect heart failures at an early stage. At KMS we believe that early detection is key in preventing bigger heart issues throughout a user's life and we want to be part of the journey, monitoring their health, and giving them valuable feedback along the way.

As seen in Figure 2.2 above, this is what we envision our device holding all of our electronic components to look like. We will have a case housing the main components such as the Bluetooth module, microcontroller, battery pack, and many more. For the final product, along the top of the device, we would like to have an On/Off switch, an LED showing battery or device status and a I/O port where we can connect all the electrodes from the shirt to the microcontroller for signal processing. For the back of the device, we have a clip on feature that allows it to be carried in a belt or any pants. It is still early in the design process, so anything could be subject to change as we continue this project.

3.Requirements

The Kompression product has various types of requirements that are needed in different stages of the products design. These requirements will be split up into four different sections: General, Hardware, Software and Safety and Sustainability. These base requirements will then be further broken down in terms of their priority level and stage of development. The requirement scheme will be shown as follows:

Requirement Classification Scheme: [REQ {**RT**}. {**RN**}.{*__SRN__} {**PL**}-{**DS**}], where
RT = Requirement Type
RN = Requirement Number
__SRN =__ Sub-requirement Number
PL = Priority Level
DP = Development Phase
*will only apply if a sub requirement exists

The tables on the following page will describe the encoding for each requirement classification. Table 3.1 displays the encodings for the types of requirements, table 3.2 displays the encodings for the different priority levels associated with the requirement being high, medium, or low, and table 3.3 displays the target development phase that the requirement aims to achieve. The requirement numbers sub-requirement numbers differentiate each requirement.

Requirement Classification Encodings

Requirement Type	Encoding
General Requirement	1
Hardware Requirement	2
Software Requirement	3
Safety and Sustainability Requirement	4

Table 3.1 Requirement Type Encoding

Priority Level	Encoding
High	H
Medium	M
Low	L

Table 3.2 Priority Level Encoding

Development Phase	Encoding
Alpha (Proof of Concept)	A
Beta (Engineering Prototype)	B
Final Production	F

Table 3.3 Development Stage Encoding

An example requirement classification structure can be described as follows:

Ex. [REQ 2.1.1 H-A]

The first sub-requirement of the first hardware requirement which is of high priority and has a target completion of the alpha phase (proof of concept).

3.1 General Requirements

The general requirements will describe all requirements that don't fit under a specific niche but are important to the system as a whole to function. This can umbrella decisions relating to things such as the product's weight, functionality under certain temperatures, size of system and other over arching items to the product as a whole.

Requirement Class	Description
[REQ 1.1 H-B]	Recording device must be small enough to wear
[REQ 1.2 M-B]	Must be simple to remove the device from the shirt
[REQ 1.3 H-B]	Device must not impede physical activity
[REQ 1.4 M-B]	Device must be located in a non-intrusive place
[REQ 1.5 M-F]	Device should be compact enough to be comfortable to wear
[REQ 1.6 M-B]	Device should weigh under 200 grams
[REQ 1.7 L-B]	Device should be usable between -20 and +40 degrees
[REQ 1.8 M-F]	Shirt must be machine washable

Table 3.4 General Requirements

3.2 Hardware Requirements

The hardware requirements in the Kompression products system will cater to that of the physical EKG electrodes and leads, transmission of data, and battery power. Here we will describe the number of electrodes in the system, their connectivity and usability. This section will also outline the signals that will be measured by the system and what will be used in the transmission of these signals to devices.

Requirement Class	Description
[REQ 2.1 H-A]	Shirt must have 6 built-in EKG electrodes
[REQ 2.1.1 H-A]	All electrodes must connect to a single/common device
[REQ 2.1.2 M-B]	Cables coming out of each electrode must be incorporated into the shirt's fabric
[REQ 2.1.3 H-F]	Cables and EKG contact points must be flexible and washer/dryer safe
[REQ 2.1.4 M-B]	Each electrode's placement must be clearly labeled in the shirt
[REQ 2.1.5 H-B]	Each electrode must be in contact with the user's skin for the majority of time for accurate readings
[REQ 2.1.6 M-B]	Each electrode must be removable or replaceable
[REQ 2.2 H-A]	Device must measure two bipolar leads (I, II) and two precordial leads (V1, V2)
[REQ 2.3 H-A]	EKG must produce a measurable signal that is clean and well defined
[REQ 2.4 H-A]	EKG must measure lateral view, an inferior (bottom of heart to top) view (coronal/frontal plane) and a transverse (horizontal) view
[REQ 2.5 H-A]	Device must be able to connect to cellular devices via bluetooth
[REQ 2.5.1 H-A]	Device must be able to transmit EKG measurements via bluetooth
[REQ 2.6 M-F]	Battery life must be long enough to last through physical activities and part of the night
[REQ 2.6.1 M-F]	Device must notify user of charge level
[REQ 2.7 H-B]	Device must be able to turn device on or off

Table 3.5 Hardware Requirements

Figure 3.1 [REQ 2.1 H-A] Kompression Proof of Concept

Above is a proof of concept design for Kompression. The red circles indicate positive electrodes placed at distinct locations around the chest whereas the blue circles indicate negative electrodes. The device, marked as a capital D in on the bottom right indicates the placement of the EKG module on the shirt. This arrangement of electrodes will yield 4 leads. Further discussion on the lead system found in figure 3.2 below.

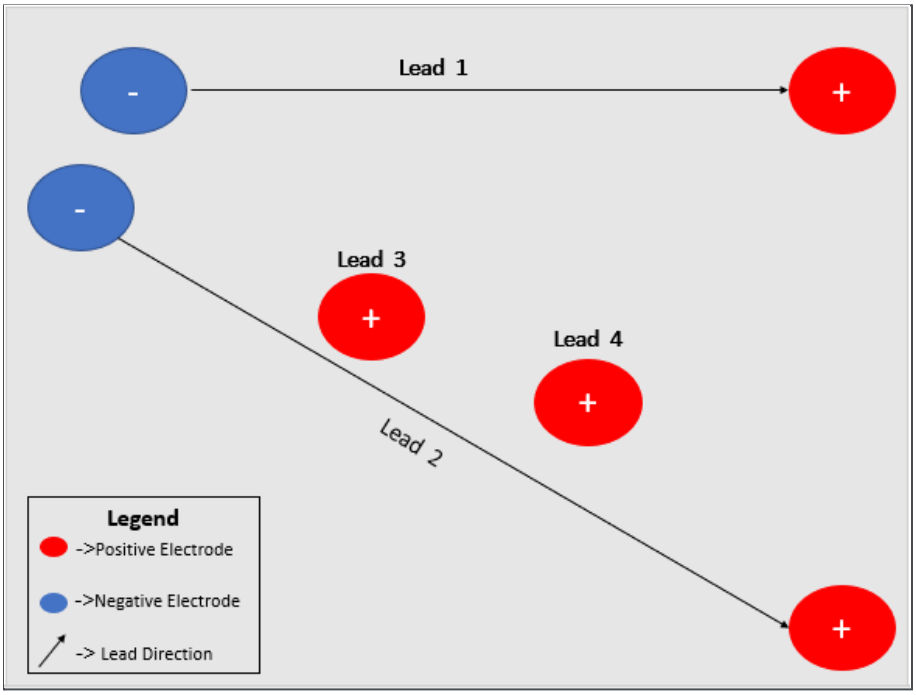

Figure 3.2 [REQ 2.2 H-A] Kompression Lead System

Figure 3.2 is an explanation of the lead system built within the Kompression. Lead 1 measures heart activity laterally and is labelled above. It corresponds to electrodes 1+ and 1- in figure 3.1. Electrodes 2+ and 2- give an inferior view of the heart shown as lead 2 [8]. Finally, leads 3 and 4 give transverse views of the heart (signals coming out of the page) [8]. This arrangement of electrodes allows the device to receive measurements from three different directions. This will provide a more encompassing view of cardiac functionality.

3.3 Software Requirements

The software requirements will mostly cater towards the prototype/final version of the Kompression product. As for the alpha phase it is important that the EKG system will provide enough data that the software can analyse via the bluetooth transmission and reception. The software requirements will outline all the measurements and storage that the product will produce and hold onto for the consumers usage.

Requirement Class	Description
[REQ 3.1 H-A]	Must be able to connect and receive measurements via bluetooth from the device
[REQ 3.2 M-A]	Must detect at least 1 type of abnormal cardiac rhythms
[REQ 3.2.1 M-B]	Should detect at least 4 types of abnormal cardiac rhythms
[REQ 3.2.2 M-B]	Must be able to track multiple abnormal rhythms in a given period of time
[REQ 3.3 H-A]	Must be able to display measurements
[REQ 3.3.1 M-B]	Must be able to save resulting graphs in a common and easy to share format
[REQ 3.4 M-F]	Must have a clean and easy to use UI
[REQ 3.5 H-F]	Must be able to perform real time analysis of EKG reading
[REQ 3.6 M-F]	Measurement graphs must be easily interpretable by user without a medical professional
[REQ 3.7 M-F]	Must provide a summary on user's overall heart health (pulse, heart rhythm, HRV value)
[REQ 3.8 L-F]	Could have the ability to store the user's info (name, age, weight, height)
[REQ 3.9 M-F]	Resulting EKG must be easily accessible
[REQ 3.9.1 L-F]	Resulting EKG graphs should be stored chronologically

Table 3.6 Software Requirements

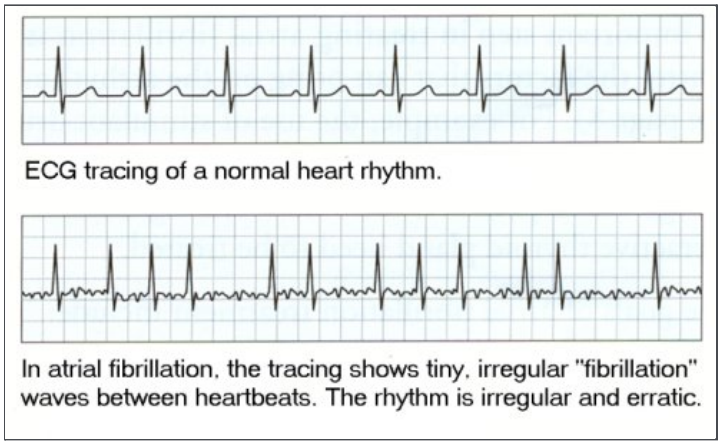

Figure 3.3 [REQ 3.2 H-A] Example of Normal vs Abnormal Rhythm

Figure 3.3 above provides a brief comparison between a normal and abnormal heart rhythm. Our software will look for patterns such as those in atrial fibrillation and notify the user when arrhythmias occur.

3.4 Safety, Standards and Sustainability Requirements

Safety and sustainability are a top priority at KMS. These requirements will outline that the Kompression product will abide by the medical standards set by Health Canada. It will also cover any novelties that will be inplace in order to fully protect the consumer and make sure that the Kompression is fully risk free to use.

Requirement Class	Description
[REQ 4.1 H-A]	Must be safe for public use
[REQ 4.1.1 H-A]	Must adhere to rule 7 of class II medical device standards [10]
[REQ 4.1.2 H-A]	Must be safe to attach and remove from skin
[REQ 4.1.3 H-B]	Must be safe for consumer to install EKG device without risk of shock
[REQ 4.1.4 H-B]	The battery must not produce any hazards during normal product usage
[REQ 4.1.5 M-F]	The product must have instructions detailing safe usage for consumer
[REQ 4.1.6 M-F]	Product should adhere to IEEE standard 11073-10406-2011 [11]
[REQ 4.1.7 M-F]	Product should adhere to IEEE Std 1625-2008 - IEEE Standard for Rechargeable Batteries for Multi-Cell Mobile Computing Devices. [12]
[REQ 4.1.8 M-F]	Transmission of data should comply with IEEE 802.15.1-2002 for Telecommunications and Information Exchange Between Systems [13]

Table 3.7 Safety and Sustainability Requirements

3.6 Acceptance Test Plan

The acceptance test plan found below, will provide a series of testing steps and desired results for the proof of concept design. These are the requirements that will be presented as the alpha design for the 405W demo.

Requirement	Test Procedure	Desired Result
[REQ 2.1 H-A] [REQ 2.1.1 H-A]	Check shirt has 6 electrodes available and they are all connected and sending data	Shirt indeed has 6 electrodes
[REQ 2.2 H-A] [REQ 2.4 H-A]	Record the same lead EKG with a known working EKG module	Resulting graphs from both Kompression and the control device should be the same
[REQ 2.3 H-A]	Verify that signal on oscilloscope matches the theoretical lead measurement	Oscilloscope displays a proper EKG reading from every lead
[REQ 2.5 H-A] [REQ 3.1 H-A]	Connect device to another bluetooth device,	Connection must be established between two bluetooth devices
[REQ 2.5.1 H-A] [REQ 3.1 H-A]	Transmit EKG measurements between devices	Transmitted signal matches received signal
[REQ 3.2 M-A]	Input labelled open source sample EKG measurements with abnormal rhythms	Correctly detects positive and negative cases of the abnormal rhythms
[REQ 3.3 H-A]	Check on a device if signal received is displayed	Displayed signal must match signal on oscilloscope if measured directly from device electronics

Table 3.8 Acceptance Test Plan

4. Conclusion

Through the analysis of the problem, we have defined the software, hardware, safety and sustainability requirements of the Kompression shirt. The Kompression shirt requirements have been motivated by the challenges in getting a clean and reliable signal of the heart with minimal sacrifices in comfort and accuracy. The general requirements established how the device will integrate into a shirt while maintaining comfort and the ability to be washed. The hardware requirements look further into what level of EKG signal must be captured and other requirements for functionality and comfortability. The Kompression device must also include a software portion to show the signals in a presentable and interpretable way. Motivated by the potential need to share the EKG signals, the software visualizations and analysis must be easily accessible and shareable over various periods of time. The Kompression shirt will be safe to use and approved as a class II medical device in Canada. We at KMS will meet these requirements through the alpha, beta and final product design iterations to create a shirt that comfortably and reliably tracks heart health.

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Appendix

A-1 Revision History

Revision Number	Date	Description	Performed by
1.0	2021-02-03	Initial Creation	MG
1.1	2021-02-03	Added in many requirement specifications	DM, MG, SU, JJ
1.2	2021-02-08	Updated and Altered requirements	DM, MG, SU, JJ
1.3	2021-02-12	Added requirement classifications and formatted accordingly	JJ
1.4	2021-02-12	Added introduction paragraphs	SU
1.5	2021-02-13	Added discussion in the analysis of the problem and labelled development stages	DM, MG, JJ
1.6	2021-02-15	Discussed organization of requirements, what figures to include, and started adding/researching safety standards for our device	DM, MG, SU, JJ
1.7	2021-02-16	Updated System Overview section and added a glossary table	DM
1.8	2021-02-16	Added conclusion paragraph	MG
1.9	2021-02-16	Finished Intro & Abstract & Figures	SU
2.0	2021-02-17	Added system overview image	MG
2.1	2021-02-17	Added requirements paragraphs and reformatted	JJ
2.2	2021-02-18	Added device mockup image	DM

2.3	2021-02-18	Finalized sections and added acceptance test plan	DM, MG, SU, JJ
2.4	2021-02-19	Finalized document formatting and added letter of transmittal	JJ