February 16th, 2010

Dr. Andrew Rawicz
School of Engineering Science
Simon Fraser University
8888 University Drive, Burnaby, BC
VSA 1S6

RE: ENSC 440 Capstone Project Functional Specification for the HeartMon™, a cardiovascular diagnostic device

Dear Dr. Rawicz:

Please find attached the Capstone Project Functional Specification for the product HeartMon™, presented by Biomedical Engineering Solutions. We are designing and implementing a heart monitoring system that will be an improvement over the Holter monitor by including diagnostic capabilities and being more portable and accessible. The HeartMon™ is a preventative device, which will keep patients aware of their own health, save doctors time in making diagnoses, and save money in the healthcare industry.

Our functional specification provides a set of high-level requirements for the system's functionality for both the proof-of-concept and production unit. All sections will be used as a guide for our engineers in the development of the system and provide support to the viability of this product.

Our team is versatile and consists of five innovative and motivated individuals: Amir Kamyabnejad, Bobby Luk, Cheng Zhang, Eric Boyer, and Yash Trivedi. If there are any questions or concerns regarding our proposal, feel free to contact me by phone at 604-617-1478 or by e-mail at aka39@sfu.ca.

Sincerely,

Amir Kamyabnejad
Chief Executive Officer
Biomedical Engineering Solutions

Enclosure: *Functional Specification for the HeartMon™*

Functional Specification for the

HeartMon™

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Executive Summary

Every seven minutes someone in Canada dies from heart disease or stroke. In fact cardiovascular diseases account for 30% of all deaths, and heart disease and stroke are two of the three leading causes of death. It is no surprise then that every year heart disease and stroke costs the Canadian economy more than $22.2 billion in physician services, hospital costs, lost wages, and decreased productivity [1].

Unfortunately, 54% of these cardiovascular deaths are caused by ischemic heart disease (ISHD), which has no noticeable symptoms and can happen to seemingly perfectly healthy individuals [1]. This silent ischemia can lead to anything from sudden death to a massive heart attack or fatal arrhythmias, all with no prior warning [2].

Thus, there is clearly a need in the healthcare industry for creating better monitoring, diagnosing, and prevention systems for heart disease and stroke. Biomedical Engineering Solutions (BES) is determined to improve the existing technology for diagnosing ISHD by utilizing better prevention methods and more treatment options. This will then reduce the associated healthcare cost as well as the fatality rate.

The goals of the HeartMon system are:

1. Sense the patient's heart rate and movement
2. Transfer data to a processing unit for filtering and digitizing
3. Transfer processed data to a cell phone via Bluetooth
4. Analyze data on an Android platform
5. Transfer analyzed data to medical professionals

In this functional specification document various requirements of the HeartMon system will be illustrated. These requirements are divided into the following three categories:

- [I] Requirements of the prototype presented on demo date
- [II] Bonus requirements of prototype if time permits
- [III] Long-term development requirements of the system beyond academia

These requirements are discussed in detail for both the wearable unit and the cell phone application. The wearable unit consists of ECG and accelerometer sensors, the ECG circuit, and the microcontroller unit. The cell phone application contains all data processing functions.

Moreover, the functional specification illustrates the system test plan at various stages. The aim is to break down the testing process in as many isolated, individual tests as possible. These tests include the functionality of the ECG circuit, proper digitizing and filtering of data in the microcontroller, accurate sensing of accelerometer and ECG data, bi-directional communication between the microcontroller and the cell phone application, and correct analysis of the cell phone application. Finally, requirements for the user documentation of the final product are illustrated.

Table of Contents

Glossary

ADC	Analog to Digital Converter
AHA	American Heart Association
BES	Biomedical Engineering Solutions
BPM	Beat Per Minute
ECG/EKG	Electrocardiogram
FCC	Federal Communications Commission
GUI	Graphical User Interface
MCU	Microcontroller Unit

1 Introduction

Monitoring a patient's heart activity is very important in the healthcare industry. Heart monitoring is often performed after a patient has a heart attack or stroke, after having heart surgery, and after being prescribed medications that could affect the heart. However, most heart monitors currently available, such as the Holter monitor, do not offer adequate functionality for many applications. To solve this problem, Biomedical Engineering Solutions is developing the HeartMon. This will be a pocket-size device that will measure the patient's heartbeat by means of three electrocardiogram (ECG) electrodes. The ECG signal will be digitized by means of a microcontroller unit (MCU), which will then send the signal to the user's cell phone by means of Bluetooth. The MCU will also contain an accelerometer to track the user's activity, and this data will be sent to the cell phone as well. The cell phone will contain an application that processes the ECG and accelerometer data to determine if the user's current heart activity is acceptable for their current level of activity. If it isn't then the user's health professional will be notified immediately, at which point emergency personnel will come if necessary. This document outlines the functional specifications of this device.

1.1. Scope

This document will be used as a guide by BES during the development of the prototype of the HeartMon. This document contains a complete description of the functionality of the device, and BES will use it to determine which features have been implemented and which still need to be worked on during the development of the HeartMon prototype. Although implementation details may change over the course of the project, it is expected that the overall functionality of the final device will adhere to the specifications of this document.

1.2. Audience

The intended audience of this document is the engineers of BES. They will use it as a reference as they progress in their work on the prototype. This document should also be readable for technically-knowledgeable investors interested in the HeartMon.

1.3. Classification

The formatting convention for the requirements in this document is as follows:

[R#-L] <requirement text>

The requirement number

L The priority level of the requirement:

- I Requirements for both the prototype and the final HeartMon
- II Additional requirements for the prototype, if time permits
- III Requirements for only the final HeartMon

2 System Overview

The system can be divided into 3 modules:

a) Sensors and ECG Circuit
b) Microcontroller
c) Software

2.1 Sensors and ECG Circuit

There are three ECG sensors attached to the patient's body and an accelerometer attached to the microcontroller unit (MCU). The ECG sensors monitor the patient's heart rate and the accelerometer monitors any physical activity being performed. The ECG signals enter the ECG circuit where common-mode rejection and amplification is performed, and then enter the MCU for signal conditioning and processing.

2.2 Microcontroller

The microcontroller receives the signals from the sensors and digitizes them. Thereafter, digital filtering is performed to strip away noise and artifacts. Filtered signals are then sent to the Bluetooth transmission port of the MCU. The Bluetooth port then starts transmitting these digitized signals to the Android device.

2.3 Software

The Android device establishes a secure connection over Bluetooth with the MCU and receives the signals. These signals are then put through an algorithm which distinguishes the data coming from different sensors. The separated data is then put through a corresponding algorithm depending on which sensor reading it was obtained from. This algorithm analyzes the data and determines whether all of the readings combined display healthy functioning of the patient's heart. If that is not the case appropriate actions are taken, such as automated alerts to the hospital.

3 System Requirements

3.1 Overall

[R1-II] System shall be easy to use and easy to connect to the user's cell phone.

[R2-III] System shall be comfortable enough to wear for several days.

[R3-III] System shall be waterproof so the patient does not have to remove it while showering or bathing.

[R4-III] System will have a retail price of less than $200.

3.2 Physical

[R5-I] The prototype will weigh a maximum of 400 g.

[R6-II] The prototype will have maximum dimensions of $4" \times 3" \times 2"$ $(W \times L \times H)$.

[R7-II] The system will have the MCU, accelerometer, ECG circuit, and battery built into one package.

[R8-III] HeartMon will weigh a maximum of 200 g.

[R9-III] HeartMon will have maximum dimensions of $3" \times 2" \times 1"$ $(W \times L \times H)$.

3.3 Electrical

[R10-I] All electrical components on the prototype must be powered by a single power source in the range of 2 – 5V: small, easily replaceable batteries such as 2 AAs. Voltage converters and inverters will be used as needed for each individual component.

[R11-II] The patient's heartbeat and movement shall be measured accurately enough to determine if there is any abnormal heart activity.

[R12-II] The system will not interfere with other devices.

[R13-II] The system will operate normally when there is interference from other devices.

[R14-III] All electrical components on the final product must be powered by a single power source in the range of 2 – 5V: a small, built-in rechargeable battery that can be charged with a built-in charger that is powered by a provided 120V power adapter. Voltage converters and inverters will be used as needed for each individual component.

[R15-III] The device will have a battery life of at least 4 days (96 hours).

3.4 Environmental

[R16-II] The system will work in temperatures ranging from -20° C to 50° C.

[R17-II] The system will work in humidity levels ranging from 0% to 90%.

[R18-III] The system will be waterproof to allow the patient to shower or bathe with it.

3.5 Safety

[R19-III] The system will comply with all FCC requirements for wireless communications.

[R20-III] The system will comply with all CSA and UL safety requirements for medical devices.

[R21-III] The system will comply with all CSA and UL environmental requirements for medical devices.

4 ECG Circuit Requirements

4.1 Overall

[R22-I] Amplify the ECG signal to a level near the MCU's maximum input voltage (without clipping) to ensure the maximum dynamic range possible.

[R23-I] Output the ECG signal as an analog waveform to be digitized by the microcontroller.

[R24-II] The ECG circuit will filter out as much noise as possible from muscle movement and other electrical devices.

[R25-I] Three electrodes will be used: one on each arm and one on a leg. These electrodes will use a standard electrode gel to make good electrical contact with the patient's body.

4.2 Physical

[R26-II] The electrodes should be comfortable to wear.

[R27-II] The electrode leads should be flexible and comfortable on the body, and should be long enough to reach the appropriate spots on the body.

[R28-II] The electrodes should stick to the patient's body even when the patient sweats or moves excessively.

4.3 Electrical

[R29-I] The circuit will use the same battery power source as all the other electrical components (refer to requirements **[R10-I]** and **[R14-III]**).

[R30-I] The circuit will use minimal power: less than 10mA.

[R31-I] The circuit will have a bandwidth of 0 – 100Hz.

[R32-I] The electrodes will make good electrical contact with the body.

[R33-I] The output of the ECG circuit will be within the input voltage range of the microcontroller analog inputs.

4.4 Safety

[R34-I] Any current flowing through the body due to no-fault or single-fault conditions will be less than 10μA in order to comply with AHA specifications [3].

[R35-II] The circuit will not have exposed live wires.

[R36-II] The circuit will not have sharp objects accessible.

4.5 Reliability and Durability

[R37-III] The circuit will be compatible with X-rays, so patients can wear the device during

imaging.

[R38-III] The circuit will be waterproof, so patients can wear the device while in the shower.

[R39-III] The circuit shall be able to sustain continuous and heavy work load.

4.6 Performance

[R40-I] The circuit will monitor heart rate.

[R41-I] The circuit will take analog data from ECG electrodes.

[R42-I] The circuit will reject common-mode noise.

[R43-I] The circuit will amplify the ECG signal.

[R44-III] ECG electrodes will be wireless.

4.7 Usability

[R45-I] Electrodes can be easily and accurately attached by nurses.

[R46-III] Device will be comfortable to wear throughout the day.

[R47-III] Electrodes can be easily and accurately attached by all customers.

[R48-III] Electrodes can be easily and painlessly removed from all customers.

[R49-III] Connection of electrodes to ECG circuit board will be simple and intuitive.

[R50-III] Unit will be protected against damage caused by dropping.

[R51-III] Circuit board will be accessible only via tools for technicians.

5 Accelerometer

5.1 Overall

[R52-I] The accelerometer will measure acceleration in 3 axes to enable measurements of all types of movements.

[R53-I] The raw accelerometer data will be sent to the microcontroller in analog form, where it will be digitized and sent to Android phone.

5.2 Physical

[R54-I] The accelerometer will be small enough to mount onto the microcontroller board.

[R55-I] The accelerometer will be durable enough and mounted solidly enough to withstand regular user activity

5.3 Electrical

[R56-I] The accelerometer will use the same battery power source as all the other electrical components (refer to requirements **[R10-I]** and **[R14-III]**).

[R57-I] The accelerometer will use minimal power: less than 1 mA.

[R58-I] The output of the accelerometer shall be within the input voltage range of the microcontroller analog inputs.

5.4 Safety

[R59-III] The accelerometer will not have exposed live wires.
[R60-III] The accelerometer will not have sharp objects accessible.

5.5 Reliability and Durability

[R61-III] The circuit will be compatible with X-rays, so patients can wear the device during imaging.
[R62-III] The accelerometer will be waterproof, so the patient can wear the device while showering.
[R63-III] The accelerometer will be capable of sustaining a continuous and heavy work load.

5.6 Performance

[R64-I] The accelerometer will monitor acceleration.
[R65-II] The accelerometer will monitor orientation.
[R66-II] The accelerometer will monitor the incline/decline of movement.

5.7 Usability

[R67-I] The accelerometer will be easy to attach to the microcontroller.
[R68-I] The accelerometer will be powered by the microcontroller.
[R69-III] The accelerometer will be comfortable to wear all day.
[R70-III] The accelerometer will be protected against damage by dropping the unit.
[R71-III] The circuit board will be accessible only via tools for technicians.

6 Microcontroller

6.1 Overall

[R72-I] The microcontroller will have at least 4 analog inputs with digital-to-analog converters for each (3 for the 3 axes of the accelerometer and 1 for the ECG circuit).
[R73-I] The microcontroller will have at least 1 digital output for testing purposes (for example, to turn on an LED)
[R74-I] The microcontroller must have a Bluetooth transmitter that can communicate with Android phone application to send digital versions of the ECG and accelerometer data.

6.2 Physical

[R75-I] The microcontroller shall be small enough to fit in the space requirements defined by requirement **[R6-I]**.

6.3 Electrical

[R76-I] The ADC on the inputs will have a resolution of at least 10 bits for sufficient accuracy.

[R77-I] The microcontroller will use the same battery power source as all the other electrical components (refer to requirements **[R10-I]** and **[R14-III]**).

[R78-II] The microcontroller will use minimal power: less than 50 mA.

6.4 Software

[R79-I] The microcontroller shall be capable of applying digital filtering to the digital ECG signal.

[R80-I] The microcontroller shall have at least 2 kilobytes of memory for the software.

6.5 Safety

[R81-III] The microcontroller will have no exposed live wires.

[R82-III] The microcontroller will have no accessible sharp objects.

6.6 Reliability and Durability

[R83-III] The microcontroller shall be compatible with X-rays, so the patient can wear the device during imaging.

[R84-III] The microcontroller shall be waterproof, so the patient can wear the device while showering.

6.7 Performance

[R85-I] The microcontroller will receive analog data from the ECG and accelerometer.

[R86-I] The microcontroller will perform analog to digital conversion.

[R87-I] The microcontroller will perform digital filtering.

[R88-I] The microcontroller will transmit digital data to the Android phone.

[R89-III] The microcontroller will monitor the location of patients via GPS.

[R90-III] The microcontroller will monitor oxygen level.

[R91-III] The microcontroller will monitor temperature.

6.8 Usability

[R92-I] The microcontroller shall be provided a simple power connection via batteries.

[R93-I] The microcontroller shall be scalable for extra features.

[R94-III] The microcontroller shall be easily programmable.

[R95-III] The microcontroller will have an available external reset button.

[R96-III] The microcontroller shall be comfortable to wear throughout the day.

[R97-III] The microcontroller shall be protected against damage caused by dropping the unit.

[R98-III] The circuit board shall be accessible only via tools for technicians.

7 Cell Phone Application Requirements

The cell phone application is used to receive the heartbeat and activity information from the microcontroller via Bluetooth. Then, it will interpret the information and determine if the results are within a safe range. The application will provide warning if any irregular signal is detected.

7.1 Overall

[R99-I] The application must be able to establish two-way communication between itself and the wearable device via Bluetooth.

[R100-III] The application shall adhere to the four principles of good design: visibility, good conceptual model, good mappings, and adequate feedback.

7.2 Platform

[R101-I] The application requires a cell phone running the Android 2.1 operating system or higher.

[R102-III] The application will work on all Android, iPhone, and Blackberry platforms provided the selected models have Bluetooth capability.

7.3 Performance

[R103-I] The application shall be able to receive ECG and accelerometer information from the microcontroller via Bluetooth.

[R104-II] The application will have the ability to detect when the patient's heart rate is too fast, too slow, or has an irregular rhythm.

[R105-II] The application will have the ability to detect ST segments (a segment between the S wave and T wave) in the patient's ECG data.

[R106-II] The application will display a warning message with sound alarm and phone vibration when it detects an irregularity in the patient's heart rate.

[R107-II] The application will have two warning levels: one for minor heart irregularities and one for emergencies.

[R108-II] The application shall send a message to the pager/cell phone/phone of the patient's medical professional when a warning occurs.

[R109-III] The application shall be able to detect symptoms of heart disease.

[R110-III] The application's battery usage shall be minimized so that the cell phone can be used for up to 4 days (96 hours) without charging.

[R111-III] The application will have a start-up time of less than 2 seconds.

[R112-III] The application shall be able to achieve a Bluetooth connection with the main unit within 1 second when starting up.

7.4 Reliability

[R113-III] False alarms on the application will only have 1% chance of occurrence.

[R114-III] The application shall have accurate diagnoses 99% of the time.

7.5 User Interface

[R115-I] The application GUI will have a field displaying the patient's health status as normal, irregular, or dangerous.

[R116-I] The application GUI will display graphs for heart rate and activity level.

[R117-II] The application GUI shall not display graphs of the heart rate and activity level to conserve battery life, but can display this data if the patient requests it.

[R118-II] The application GUI shall have menus to set the heart rate levels that correspond to normal, irregular, or dangerous.

[R119-III] The user interface will be user friendly.

8 User Documentation

The following documentation and user support will be provided:

[R120-III] Instruction Manual

[R121-III] Quick Guide

[R122-III] Company Website

[R123-III] Product Website

9 System Test Plan

The system test plan will incorporate modularity in the beginning. Individual modules (sensors, hardware, and software) will be tested at first, and then the integrated system will be tested at the end.

9.1 Sensors

The readings from both types of sensors, ECG electrodes and the accelerometer will be tested using an oscilloscope. The range of values displayed by the readings will be verified against the expected values from datasheets.

9.2 Hardware

The microcontroller will perform signal conditioning and filtering on input signals coming in from certain ports. This conditioning is required so as to remove any noise or interference that may result from electrode-skin contact, muscle movement, 60Hz interference from household power, and electromagnetic interference from electrical devices. Band-pass and notch filters will be used for this purpose. The output will once again be monitored using oscilloscopes to verify that the wanted signal is indeed within the desired bandwidth whereas the unwanted signal is not.

9.3 Software

At first, communication between the microcontroller and the Android phone over Bluetooth will be tested. Data will be sent back and forth to verify a bi-directional communication line. The software's ability to distinguish between different data types (i.e. accelerometer vs. ECG sensors) will be tested. The algorithms to process the data will be tested by displaying output values of the samples received and plotting them on corresponding graphs. Also, values to trigger alarms and alerts will be provided to test critical cases.

9.4 Integrated System

The overall system once integrated, will be subjected to various tests to ensure that the desired functions are being performed. Various scenarios will be incorporated to cover different situations. The ECG electrodes will be connected to a person who will display readings within the normal range. Correct measurement and basic functioning of the application will be verified from this. For another case, a person will perform jumping jacks with the accelerometer lying stationary to simulate irregular heart behavior. In such a case an alert will be displayed. For the next case, the accelerometer will be moved vigorously with the person at rest which will display a different kind of alert. Similar experiments will be conducted based on the nature of the test.

10 Conclusion

Biomedical Engineering Solutions is in the process of developing a human heart monitoring system named HeartMon to provide an easy-to-use solution for patients with heart disease to keep track of their health condition. The functional specifications above outlined the features and technology involved in the HeartMon system for both the proof of concept prototype model and the final commercialized product. The proof of concept prototype model is expected to be finished and meet the functional requirements marked with either **I** or **II** in this document by the end of March 2010. Our team will continue the design to achieve all the expected features listed in this document and eventually commercialize the product.

11 References

[1] Statistics Canada, “Mortality, Summary List of Causes”, 2006 [Online]. Available: http://www.statcan.gc.ca/bsolc/olc-cel/olc-cel?catno=84F0209X&CHROPG=1&lang=eng [Accessed: 20 Jan, 2011]

[2] American Heart Association, “Silent Ischemia and Ischemic Heart Disease”, 2009. [Online]. Available: http://www.americanheart.org/presenter.jhtml?identifier=4720 [Accessed: 20 Jan, 2011]

[3] American Heart Association, “Recommendations for Safe Current Limits for Electrocardiographs”, 1996. [Online]. Available: http://circ.ahajournals.org/cgi/content/full/93/4/837 [Accessed: 15 Feb, 2011]