February 16, 2009

Patrick Leung
School of Engineering Science
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Burnaby, British Columbia
V5A 1S6

Re: ENSC 440 – Functional Specification for the Home Heart Monitor

Dear Mr. Leung,

The attached document, *Functional Specification for the Home Heart Monitor*, outlines the features that will be available on completion of our project. We at VHeart are building a portable home heart monitor that estimates a person's 10-year risk for developing CVD and educates them on how to reduce their risk.

Our device will have two major components: a hardware data collection system, and a software analysis program, which users will install on their personal computer (PC). The attached document contains the high-level functional requirements of both our prototype and final product. The document shall be used to as a guide when developing our product.

VHeart consists of four innovative and ambitious engineering students: Michelle Cua, Xiao Han, Louise Linggadaja, and Lilly Pan. If you have any questions or concerns regarding our project, please do not hesitate to contact me by phone at (604) 619-0862 or by email at emc2@sfu.ca. Our team can also be contacted at ensc440.vheart@gmail.com.

Sincerely,

Michelle Cua
CEO, VHeart

Enclosure: *Functional Specification for the Home Heart Monitor*

Functional Specification for the Home Heart Monitor

ENSC 440 – Capstone Engineering Science Project

Issued Date: February 12, 2009

Revision 3.0

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Executive Summary

~An ounce of prevention is better than a pound of cure~

Cardiovascular disease (CVD) is a growing concern for Canadians. Recent statistics from Health Canada state that 1/3 of all death are due to CVD and 8/10 Canadians are at risk for developing CVD [1,2]. Fortunately, most of CVD deaths are preventable. At VHeart, we are trying to help individuals and society to reduce CVD preventable deaths, through empowering individuals to take a more active stance in improving their health by assessing their 10-year risk for developing CVD and educating them on how to prevent the development of CVD through taking care of their bodies properly.

The development of the home heart monitor will occur in two phases: a prototype phase, and a production phase. The prototype phase shall have the following capabilities:

- ECG acquisition and analysis
- Blood pressure acquisition and analysis
- Personal Information Input and database
- Risk assessment
- Basic education results

The first phase is scheduled to be completed by April 17, 2009.

The second phase of product development shall also be capable of acquiring and analyzing body fat. It shall also have a fully functional nutritional and physical activity input and assessment. At completion of the second phase, the product will also adhere to all standards and regulations set forth by FDA and the Standards Council of Canada.

Table of Contents

List of Tables

List of Figures

Glossary

Term	Definition
BP	Blood Pressure Blood pressure is the pressure blood exerts against the arteries, and falls under systolic and diastolic. Systolic blood pressure is the blood pressure when the heart is pumping, and diastolic blood pressure is the pressure at rest.
BPM	Beats Per minute The number of times the heart beats per minute.
CVD	Cardiovascular Disease Diseases that involve the heart and blood vessels (1) which includes heart attack, stroke, high blood pressure, etc.
ECG	Electrocardiogram The electrocardiogram is a non-invasive measurement of the electrical activity of the heart.
FDA	Food and Drug Administration US Food and Drug Administration, and agency in the Department of Health and Human Services responsible for regulating safety of medical devices in US, among other things .
ISO	International Organization for Standardization ISO is an international standard setting organization composed of various national standards organizations.
MI	Myocardial Ischemia Myocardial ischemia is the term given when there is reduced blood flow to the heart due to partially blocked arteries.

1. Introduction

The home heart monitor is a device that estimates the user's relative risk for developing CVD within the next 10 years through various user inputs and gives practical suggestions on how to decrease their risk. The functional requirements of this device are outlined in this document.

Home Heart Monitor's development is divided into prototype stage and production stage. The prototype stage will span over a four months period which will end in on April 17, 2009. After careful testing and validation, production stage will soon follow in the coming year.

1.1. Scope

This document outlines the functional specifications of the Home Heart Monitor which will be followed in implementing our prototype and our final product. It also describes the testing procedure to ensure that our product is safe and reliable. Since the functional specifications of the final product only show our current vision of it, it may be modified depending on tests results and studies.

1.2. Intended Audience

This functional specification is intended for the use of VHeart members in implementing and testing project's prototype. Furthermore, it will align engineers' goal as they work on different aspect of the project.

During production cycle, this document will be referred to by engineers and project managers to ensure product standard is met and to manage the production timeline.

1.3. Classification

Throughout this document, functional requirement will be listed using the following convention:

FR**n**-**x** A functional requirement

Where **n** is the functional requirement number and **x** represents the priority of the requirement, which can take on one of two values:

i Requirement needs to be satisfied for prototype model

ii Requirement needs to be satisfied for production model

2. System Overview

Our system can be categorized into four different components:

1. Electrocardiogram (ECG) Acquisition and Analysis
2. Blood Pressure (BP) Acquisition and Analysis
3. Body Fat Content Acquisition and Analysis
4. Software Program

This system is shown in the system overview and system block diagram in figures 1 and 2 below.

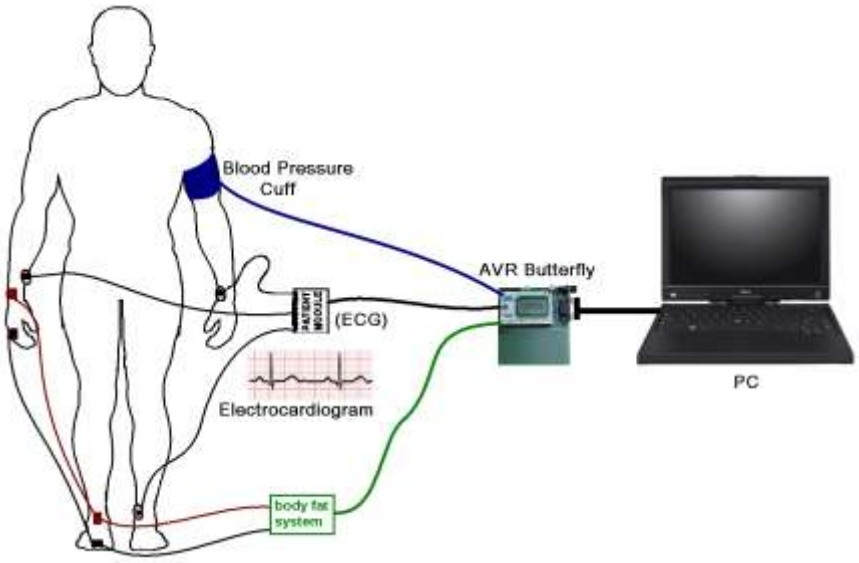

Figure 1 System Overview

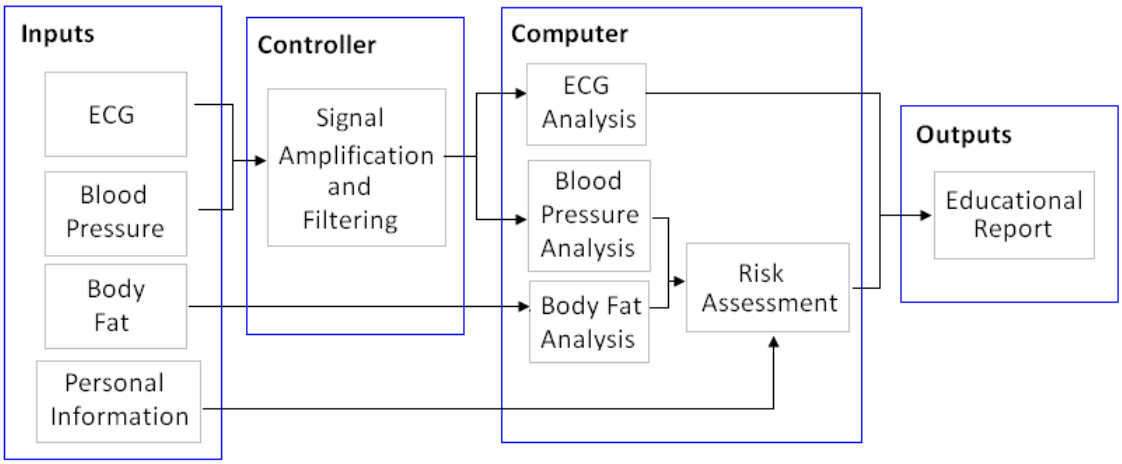

Figure 2 Home Heart Monitor Block Diagram

The ECG, body fat, and blood pressure module will collect data from individuals. Based on the personal information supplied by the user, the body fat, and blood pressure results, the user's risk of developing CVD is estimated using published risk score assessments. The ECG data is also analyzed to see whether or not the person has any other heart problems that might require some medical attention.

Using the ECG, body fat, blood pressure, and personal information collected from the individual, the software program shall estimated the user's risk of developing CVD and give an educational report on actions the user can take to prevent CVD from occurring. The device shall also be able to track the progress of the individual over time by storing previous data collected and/or inputted by the user.

Due to time and budget constraints, our prototype device will not contain the body fat measurement, nor will it contain a full nutritional and physical activity input data and assessment.

3. System Requirements

The following section outlines the functional requirements of the device. The system requirements are divided into general device requirements, user manual requirements, and the different components of the system as described in the system overview section above.

3.1 General Device Requirements

The following section outlines the general device requirements.

3.1.1 Production Requirements

[FR1-II] The device shall cost less than $50, not including the cost of the PC.
[FR2-II] The device shall be capable of being mass produced.

3.1.2 Physical Requirements

[FR3-I] The hardware module should not weigh more than 1 kg.
[FR4-II] The device shall have a modern look.
[FR5-I] The device shall be user friendly.
[FR6-II] The device shall display the blood pressure, body fat, and heart rate information.
[FR7-II] The device should be made out of non-corrosive materials.
[FR8-II] The total number of functions and buttons on the device should be kept to a minimum without affecting the capabilities of the device.

3.1.3 Electrical Requirements

[FR9-I] The device should operate using no more than 9 Volts to coincide with the 9V power source.
[FR10-I] The system should have low power consumption.
[FR11-II] The device should have its own portable power source.

3.1.4 Environmental Requirements

[FR12-I] The device should operate reliably from -10 to 40 degrees Celsius.
[FR13-I] The device shall operate within minimal electrical noise.

3.1.5 Safety and Reliability Requirements

[FR14-I] The failure of any electrical or mechanical component of the hardware will not cause any danger for the user.
[FR15-I] The device should follow American FDA Class II Standards [3].
[FR16-I] The device should adhere to Canadian CAN/CSA-ISO 13485 standards for medical devices [4].

3.2 ECG Requirements

The ECG component is useful in diagnosing heart conditions such as blockages or arrhythmias through deviations from the deviations from the standard ECG waveform.

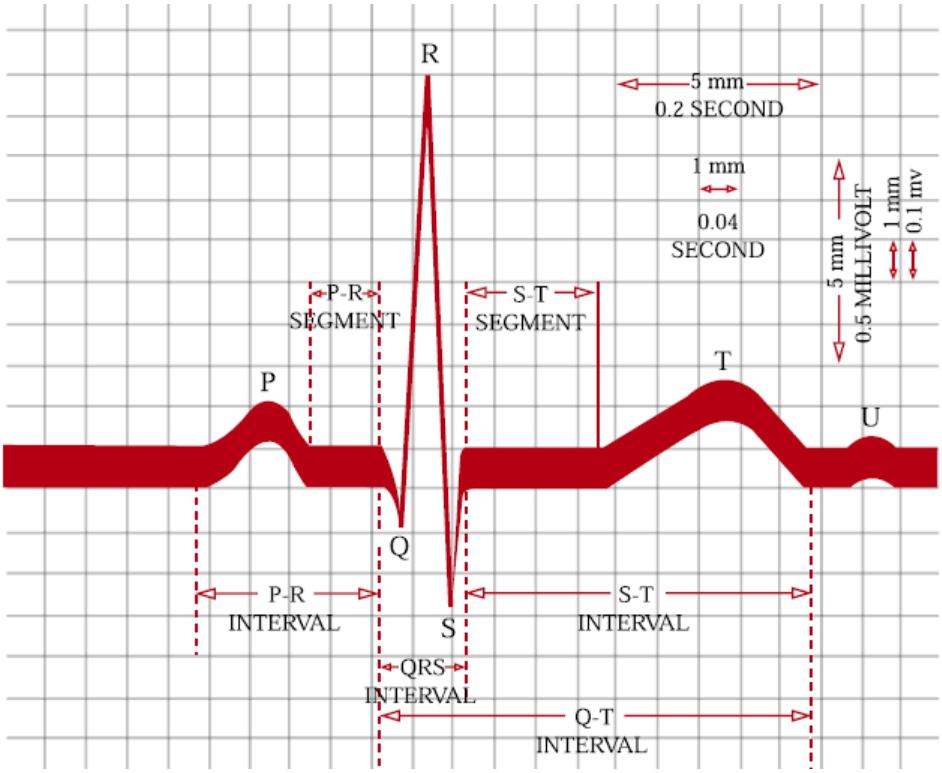

Figure 3 below shows the standard ECG waveform, with normal amplitude and time intervals given in Table 1.

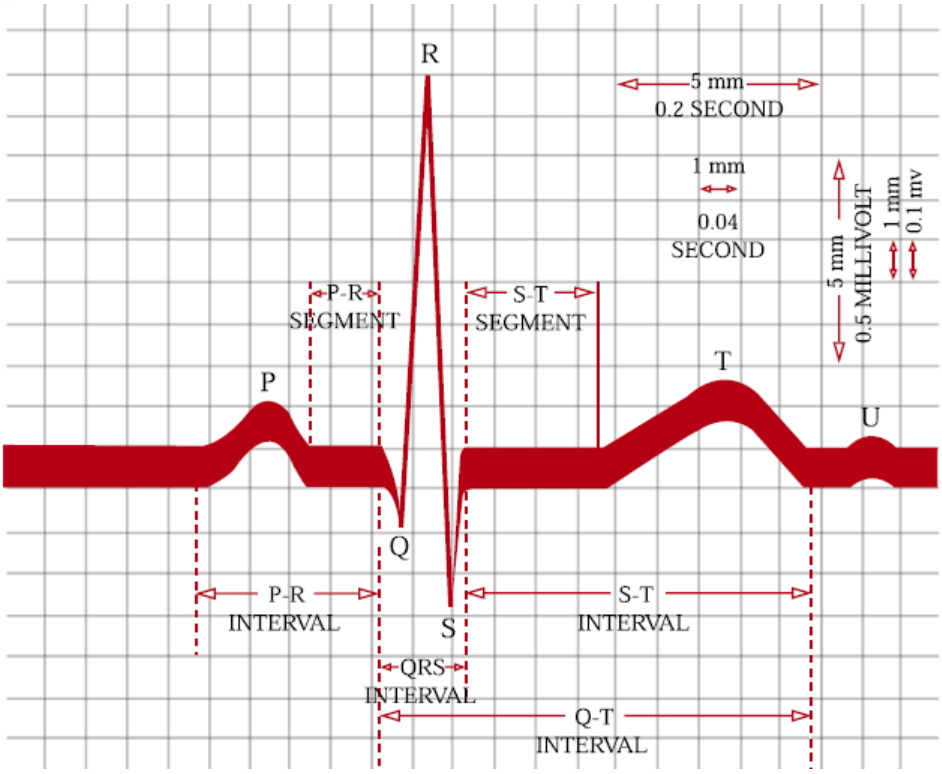

Figure 3 Standard ECG Waveform [5]

Table 1 Standard ECG Parameters [6]

Feature	Normal Value	Normal Limit
P Width	110 ms	± 20 ms
PQ/PR Interval	160 ms	± 40 ms
QRS Width	100 ms	± 20 ms
QT Interval	400 ms	± 40 ms
P Amplitude	0.15 mV	± 0.05 mV
QRS Height	1.5 mV	± 0.5 mV
ST Level	0 mV	± 0.1 mV
T Amplitude	0.3 mV	± 0.2 mV

The following section outlines the functional requirements of the ECG component.

3.2.1 ECG Acquisition Requirements

[FR17-I] ECG acquisition circuitry shall measure the ECG of individuals who have a heart rate that is less than 220 bpm.

[FR18-I] Electrode shall not have a voltage greater than 0.7V and a current greater than 1mA.

[FR19-I] Proper patient isolation will be implemented in the development of the circuitry.

[FR20-I] User will be given instructions on the proper placement of the three ECG electrodes.

[FR21-I] User will be educated on proper care of the ECG electrodes.

[FR22-I] The circuitry will have high amplification and input resistance to increase the sensitivity and accuracy.

[FR23-I] The circuitry will implement proper preprocessing and filtering.
[FR24-I] For the prototype, the measured ECG data will be transferred straight to the PC.

3.2.2 ECG Analysis Requirement

[FR25-I] The ECG analysis software shall be able to properly detect the PQRST waveforms using documented software ECG analysis techniques.
[FR26-I] The software shall be able to extract heart rate and standard clinical ECG features (PQRST widths, amplitudes, and intervals) from the measured ECG.
[FR27-II] The software shall be able to detect blockages in the conduction system of the heart, arrhythmias, or MI by analyzing the 6 lead ECG system (I,II,II,aVR, aVL, and aVF).
[FR28-I] The algorithm will implement proper filtering and processing techniques to take into account noise due to movement artifacts, power line noise, and baseline wandering.

3.3 Blood Pressure Requirements

The blood pressure system non-invasively measures the systolic and diastolic blood pressure of the user. The systolic blood pressure refers to the pressure the blood exerts on the arteries when the heart is pumping, while the diastolic pressure refers to the arterial pressure at rest. High blood pressure, especially high diastolic blood pressure, is highly associated with developing CVD. The textbook definition of normal blood pressure is 120/80 mmHg. The following section describes the requirements of the blood pressure system.

[FR29-I] The device should be able to detect the cuff pressure.
[FR30-I] Cuff pressure will not go any higher than 165 mmHg.
[FR31-I] User should be able to turn off air pump motor using a push button during the blood pressure measurement procedure.
[FR32-I] User should be able to activate a system power off/ emergency stop button which will cut off the power to the hardware module.
[FR33-I] Module should measure the individual's blood pressure accurately.
[FR34-I] The circuit should have a high amplification gain (around 100) and input resistance to increase the sensitivity
[FR35-I] The device should give an error sign if no heartbeat was detected throughout the entire testing procedure.

3.4 Body Fat Requirements

The body fat component estimates the body fat percentage of the user through measuring the user's bioelectrical impedance, since the electrical resistance of fat is different from lean tissue and bones. The following section outlines the functional requirements of the body fat system.

[FR36-II] The circuit should be able to accurately determine the bioelectrical impedance of the user.
[FR37-II] Body fat percentage of the user will be measured within 10%.
[FR38-II] Proper patient isolation will be implemented in the design of the circuit.
[FR39-II] The user manual should provide instruction on proper care of the electrodes.

3.5 Software Program Requirements

3.5.1 General Software Requirements

[FR40-I] The software should be user friendly for all ages.
[FR41-I] The software shall be programmed in C# or C++.
[FR41-I] The software shall be compatible with Microsoft Windows Vista, XP, and 2000.
[FR42-II] The software shall be delivered via CD to users for installation.
[FR43-II] The software should be able to store the data of multiple users.
[FR44-I] Each user account should be password protected.
[FR45-II] User accounts should only be deleted after user verification through password.
[FR46-I] The software should be able to store the user's historical data for comparison purpose.

3.5.2 Personal Information Input

[FR47-I] The personal information input should be arranged in an easy-to-use and logical manner.
[FR48-I] The user should be able to access and modify his/her personal information.
[FR49-I] The personal information should include age, gender, weight, and height data, as well as whether the person is diabetic or smokes.
[FR50-II] The personal information input database should allow the user the option to record nutritional intake and physical activity.

3.5.3 Risk Assessment Software Requirements

[FR51-I] The software should reliably estimate the 10-year CVD risk of user, using published risk score methods.

3.5.4 Educational Report Requirements

[FR52-I] The software should give an educational report that is meaningful and in language suitable for the user.
[FR53-II] The software should be able to convert the report into .pdf and .xml when specified by user, for easy printing and transmission.
[FR54-II] The educational report should be tailored to the person, including physical activity and nutritional information when specified.
[FR55-I] The report should clearly warn users to seek medical attention if user has a health condition that requires medical attention.

3.6 User Manual Requirements

[FR56-II] The user manual shall be available in English, Chinese, French, German, and Spanish.
[FR57-I] The user manual shall contain instructions on proper care and use of the device.
[FR58-I] The user manual shall be written for an audience that has no previous medical, scientific, or engineering background.

4 Test Plan

The system has four main parts that need to be tested:

1) Acquisition and analysis circuitry:

   The blood pressure, ECG, and body fat acquisition and analysis must be tested to ensure accuracy and reliability in both acquisition and analysis. To this end, we need to collect data from various subjects using both our device and commercial devices to see they whether the results are in agreement with each other.

   To test blood pressure module, we have to compare the data collected by our device with results obtained from either

   - Manual (auscultatory) method using a sphygmomanometer and stethoscope
   - Another approved commercial electronic blood pressure monitor

   To test the ECG acquisition, we need to measure the ECG of the person using both our device and a commercial device operated by a trained technician, and see whether they are in agreement with each other. We can test the analysis software by analyzing a library of annotated ECG's and comparing the doctor's annotation to our algorithm's results to see whether or not the software algorithm currently detects problems in the waveform.

   To test the body fat module, we have to compare the data collected by our device against the results shown by another bioelectric impedance analysis, and see whether they agree within reasonable error range.

2) Risk Assessment and Results software

   The risk assessment software shall be tested by inputting a large library of sample body fat and personal information data, and seeing whether or not the software correctly estimates the person's risk for developing CVD within the next 10 years.

   As well as analyzing the risk assessment, the results (suggestion on actions the user can take) outputted by the software will also be compared with the results derived manually to see whether the software has given the correct suggestions.

   In tracking multiple data over time, the software shall also be tested to see that it is displaying the correct values of the graphs of progress.

3) User Interface Usability

   To test the user interface, the prototype device shall be given to various volunteers ranging from 20 to 60 years old, with no instructions on its usage other than the user manual. They shall use

the device for a week, and report back on any problems they had using the device, and feedback on how it could be improved. As well, at the end of the 1 week period, they shall give a demonstration of the acquisition of ECG, body fat, and blood pressure to show whether or not they know how to use the device properly.

4) Safety

To test for safety, the currents between the ECG and body fat electrodes will be tested at different voltages to ensure that they do not exceed 1mA. The blood pressure measurement system will also be tested by ensuring that the emergency pressure release system works at any state of the blood pressure measurement.

5 Conclusion

The functional specifications listed in the document clearly define both the functionality and requirements of our device, and ensures that our system is reliable, accurate, and follows national safety standards and regulations.

The development of this device will occur in two distinct stages. The development of the first stage is already under way, and is scheduled to be completed by mid April 2009. The completed prototype shall adhere to the list of functional specification given in this document that are labeled [FRn-I].

6 Reference

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