February 17th, 2008

Mr. Patrick Leung
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
V5A 1S6

Re: ENSC 305/440 Functional Specification for Heart Rate and Motion Monitoring System

Dear Mr. Leung:

The attached document below presents the functional specification for the heart rate and motion monitoring system, implemented through ENSC 440, The Capstone Project course. The objective for this device is to monitor and analyze the healthiness of the heart through the use of heart rate and body position. The target consumer can be of all ages.

The functional specification, mainly intended for Corazon team members will act as a functional checklist for both our prototype device and future commercial product. Along with the general device functionalities, specific component requirements including the heart rate sensor, motion sensor, microcontroller unit, Symbian application, and documentation requirements will also be provided in the document.

Corazon Engineering Inc. is composed of four dedicated 5th year engineering students: Michael Mao, Benny Hung, Phillip Lin, and Thomas Cho. If there are any questions or comments about our proposal, feel free to contact Michael Mao by phone at (604) 782-5636 or by e-mail at mmao@sfu.ca.

Sincerely,

Michael Mao

CFO of Corazon Engineering Inc.

Corazon Engineering Inc.

Functional Specification

Heart Rate and Motion Monitoring System

Project Team Members:	Benny Hung Michael Mao Thomas Cho Philip Lin
Project Leader:	Benny Hung, CEO bennyh@sfu.ca
Submitted To:	Patrick Leung – ENSC 440 Steve Whitmore – ENSC 305
Date Issued:	February 12, 2008
Revision	2.2

Executive Summary

Modern day technology for medical and health monitoring devices are nowhere near the state of technology in consumer products. Due to an increasing number of retirees (Baby boomers) and the high cost of medical related products and services, a huge market demand for low-cost medical/health monitoring devices exists in today's society. Heart related disease; the number one killer in developed nations possesses a great threat to the health of our society both directly and indirectly from economical, environmental, political, and other aspects. Our proposed Heart Rate and Motion Monitoring System (HRMMS) can help the general public with the awareness and prevention of heart related diseases in its early phase by analyzing heart rate with respect to the physical activity of users. Irregular heart conditions can be sent to medical practitioners remotely through a custom application on the user's cell phone.

The development of the HRMMS can be divided into two phases. The first phase will be completed by the end of March. The functionalities of the HRMMS in the first phase are defined below:

- Ability to detect various static physical positions such as standing, sitting, lying up to four sides, etc.
- Ability to distinguish between passive (static position) and active (moving) activity during monitoring in real time.
- Ability to detect and calculate heart rate during static and dynamic positions.
- Ability to transmit heart information through a mobile device to user's cell phone using Bluetooth

All of the functionalities defined above will be assembled together into one mobile device that can be carried by the subject during daily activities.

The second phase of our product development will be completed by the end of 2008. The main differences between the first and second phase are:

- Ability to send critical information from user's cell phone to specified locations such as hospital and medical clinic offices.
- Extended recognition of physical activities, such as identifying different levels of physical activities such as passive, mild, medium, and extreme.
- More sophisticated custom software for user's cell phone, such as automatic reporting, emergency detection mechanisms, and customized settings for individual users.

Table of Contents

List of Figures

Glossary

AAMI	Association for the advancement of Medical Instrumentation
AC	Alternating Current
ADC	Analog to Digital Converter
ANSI	American national Standards Institute
BPM	Beat Per Minutes
CSA	Canadian Standards Association
DC	Direct Current
ECG	Electrocardiogram
FAQ	Frequently Ask Questions
FCC	Federal Communications Commission
GPS	Global Position System
GUI	Graphical User Interface
HRMMS	Heart Rate Motion Monitoring System
ICS	Image Cytometry Standard
IEEEE	Institute of Electrical and Electronics Engineers
ISM	Industrial, Scientific and Medical
ISO	International Organization for Standardization
LED	Light-Emitting Diode
MCU	Microcontroller Unit
OS	Operation System
PCB	Printed Circuit Board
UART	Universal Asynchronous Receiver/Transmitter
UL	Underwriters Laboratories Inc.

1 Introduction

The ability to detect heart rate with respect to test subjects' physical position can provide important information regarding to the subject heart's state of health. Corazon's solution is to develop a stand-alone device which will allow test subjects to attach two sensors to their body, one on the torso and another on the leg. These sensors will monitor the heart rate and position of the user and send data back to a processing unit carried by the user. The processing unit can then send monitored heart information via Bluetooth to a cellular phone. A customized software application running under Symbian OS on the phone will send data to specific locations such as the hospital or family physician office according to user's preference. Corazon Heart Rate and Motion Monitoring System's functional specification, from the general device to each individual module's specific requirements are listed in this document.

1.1 Scope

This document will be used as a reference throughout the device's Proof-of-concept model implementation process. Upon the completion of each sub-module, this document will be check-listed to ensure all of the functional requirements are completed. The final device will also meet all of the requirements listed in the general device requirement section of this document.

1.2 Intended Audience

This functional specification is intended for all members of the Corazon Engineering team. Each member of the team will develop the modules that they are responsible for according to the requirements listed.

1.3 Classification

The convention used throughout this document is defined below:

[R# - x] A functional requirement
\# The Requirement number
x Priority of the functional requirement:
- I Proof of Concept Prototype only
- II Proof of Concept Prototype and Retail Product
- III Retail Product only

2 System Overview

The following diagram presents our entire system layout:

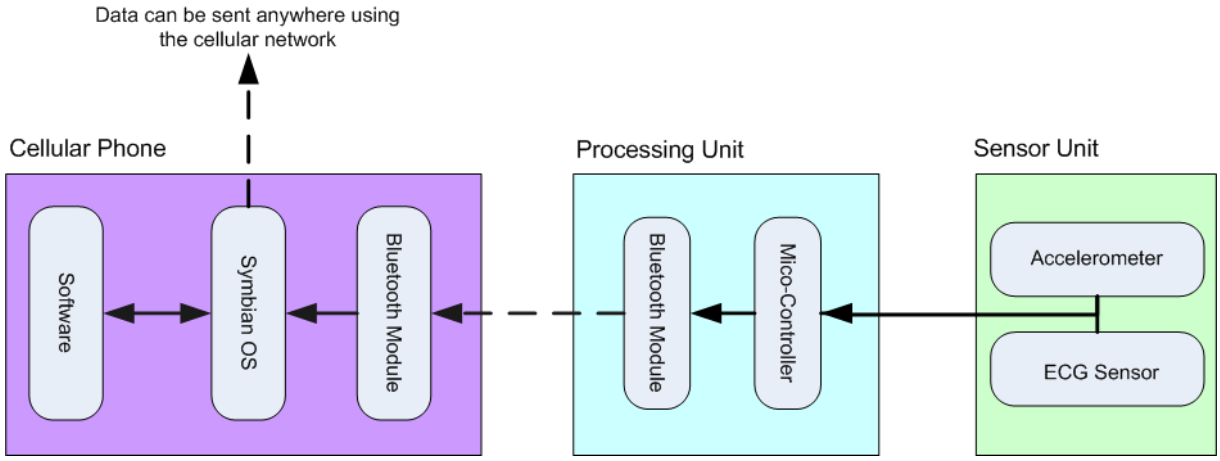

Figure 1 System Block Diagram

Starting from the right side of figure 1 above, three electrodes and two accelerometer sensors are attached to user's chest and thigh. The sensor unit then transmits analog output signals to the processing unit carried by the user. The microcontroller calculates the heart rate and determines the physical state of the user. The processed information is then transmitted through Bluetooth to a mobile cellular phone. Customized software written on Symbian OS can be process the transmitted information through a user interface display on the phone or send the digitized signals to a remote location, such as the hospital for further analysis.

HRMMS device is designed to be worn or to be strapped to the user's body for long periods of time. Therefore comfortable, light weight, compact, and easy to carry are all important factors that needs to be considered. The functional requirement for the overall system, standards and regulation, ECG heart rate sensor, motion sensor, microcontroller, Symbian application, documentation, and test plans are listed in detail in the following sections respectively.

3 Overall System Requirement

The functional requirements for our overall heart rate and motion monitoring system are categorized into subsections: General, physical, electronic, communication, mechanical, environmental, performance, reliability and durability, safety, and luxury sections. The first prototype and finalized commercial product are separated using the classification listed in section 1.3 above.

3.1 General Requirements

[R1 - III] *HRMMS should be mobile, easy to use, and comfortable to wear during exercises.*

[R2 - II] *HRMMS should accurately detect the user's heart rate and physical position.*

[R3 - III] *The retail price for HRMMS device should be lower than $200 dollars.*

3.2 Physical Requirements

[R4 - I] *The prototype design should have a maximum dimension of 10cmx 8cm x 5cm (L x W x H).*

[R5 - III] *HRMMS device should not weight more than 200 g.*

[R6 - III] *HRMMS should be pocket size and easy to carry.*

[R7 - III] *The electrodes and the accelerometers should be integrated into one package.*

[R8 - III] *The circuit board for ECG and the microcontroller unit should be integrated into one package.*

[R9 - I] *Cables connecting the sensors to the microcontroller should be soft and flexible.*

3.3 Electronic Requirements

[R10 - III] *HRMMS should work with rechargeable battery. A charger can be provided that will work with 120/240V AC.*

[R11 - III] *HRMMS should have a battery life-time of at least 72 hours on a fully charged battery.*

3.4 Communication Requirement

[R12 - II] *Bluetooth 2.0 Class I communication module is required [2].*

[R13 - II] *Bluetooth is required to be in slave mode with a baud rate of 115,200.*

3.5 Mechanical Requirements

[R14 - II] *The entire system will be encased in a waterproof plastic box.*

[R15 - I] *The motion sensor will be connected to the MCU via an eight-pin ribbon cable.*

[R16 - I] *The heart rate sensor will be connected to the MCU via a four-pin ribbon cable.*

3.6 Environmental Requirements

[R17 - III] *The final commercial product should be weatherproof.*

[R18 - II] *The operational temperature should be between -40 degree and +50 degree Celsius.*

[R19 - II] *HRMMS should not interfere with other electronic devices [3].*

[R20 - II] *HRMMS should accept interference by other electronic devices and operate normally at the same time [3].*

3.7 Performance Requirements

[R21 - I] *The prototype heart rate sensor should have an accuracy of ± 10% for all conditions.*

[R22 - III] *The retail product heart rate sensor should have an accuracy of ± 2% for all conditions.*

[R23 - II] *The temperature sensitivity of the motion sensor device output voltage should be ± 0.01% per degree Celsius.*

[R24 - II] *Motion detection should be at least 90% accurate under normal operating conditions*

[R25 - II] *The process time for the data to the display should be under 100ms.*

[R26 - II] *The Bluetooth module should be able to transmit up to 100 meters.*

3.8 Reliability and Durability

[R27 - II] *The device should be able to withstand day-to-day physical treatment.*

[R28 - III] *The mean time to failure of the HRMMS should be at least 2 years.*

[R29 - III] *The device will be serviceable by company trained technician.*

[R30 - II] *The custom Symbian application must not interfere with normal phone operation.*

3.9 Safety Requirements

[R31 - II] *HRMMS should not explode or leak any hazardous material [4].*

[R32 - II] *The operation current of HRMMS should not be more than 50mA [1].*

3.10 Luxury Requirements

[R33 - III] *Integrate GPS module for emergency services*

[R34 - III] *Exercise training program for the user.*

[R35 -III] *HRMMS device should look sexy and attractive*

4 Standards and Regulation Requirements

This section listed out all the necessary standard and regulation requirements needed for our device. This section is categorized into: electronic, medical device, PCB, and software standards respectively.

4.1 Electronic Standards

[R36 - III] *Title 47, chapter 1 FCC, section 18 of the Code of Federal Regulations regarding ISM device requirements [5].*

[R37 - III] *Title 47, chapter 1 FCC, section 15 of the Code of Federal Regulations regarding Radio Frequency devices [6].*

4.2 Medical Device Standards

[R38 - III] *The regulations set forth for medical devices in the Canadian Food and Drugs Act [2].*

[R39 - III] *ANSI/IEEE Std 602-1986 Standard for Electric Systems in Health Care Facilities.*

[R40 - III] *CSA and UL requirements for medical devices.*

[R41 - III] *CSA 601-1M90(R2005): Medical Electrical Equipment Part 1.*

[R42 - III] *CSA 60601-1-2: Medical Electrical Equipment Part 1-2. General Requirements for Safety*

[R43 - III] *CSA 60601-2-27: Medical Electrical Equipment Part 2-27. Particular Requirements for the Safety of Electrocardiographic Monitoring Equipment.*

[R44 - III] *CSA 60601-2-49: Medical Electrical Equipment Part 2-49. Particular Requirements for the Safety of Multifunction Patient Monitoring Equipment.*

4.3 PCB Standards

[R45 - III] *ICS 31.180: printed circuit board standards*

4.4 Software Standards

[R46 -III] *ISO 9241-3 AMD 1: Visual Display Requirements*

5 ECG Heart rate Sensor

The ECG heart rate sensor is used to detect and process heart rate information. This section is categorized as below: general, physical, and electrical requirements

5.1 General Requirements

[R47 - II] *Filters noise accompanied the heart beat signal, caused by AC power noise, muscle movement, and skin surface artifacts*

[R48 - II] *Amplifies filtered heartbeat signals*

[R49 - II] *Digitalizes the heart rate signal for further processing by the microcontroller*

5.2 Physical Requirements

[R50 - II] *Electrodes used with the HRMMS should be Silver Chloride wet-gel based*

[R51 - III] *Cables connecting from the electrodes to the heart rate sensor for the prototype should be soft, flexible, and sufficiently long.*

5.3 Electrical Requirements

[R52 - II] *The ECG heart rate sensor should work with supply voltage of 5 V.*

[R53 - II] *The operational bandwidth for the heart rate sensor is from 0 to 100Hz.*

[R54 - II] *Notch filter to cut off the 60 Hz power supply noise*

[R55 - II] *Specialized filter to isolate noise artifacts in various bandwidths needs to be implemented*

[R56 - I] *Instrumentation amplifier with adjustable gain for the prototype version*

6 Motion Sensor

The motion sensor is used to determine the physical position of the body through the use of accelerometers. This section is categorized as follows: general, physical, electrical, and accuracy and performance requirements.

6.1 General Requirements

[R57 - II] *The accelerometer captures dynamic (movement) and static (gravity) acceleration through the body and thigh of the user.*

[R58 - II] *Four distinct outputs, three from on the upper body and one on the lower body position will be used to capture information simultaneously.*

6.2 Physical Requirements

[R59 - III] *The size and weight of the sensor unit is small enough so that normal physical activities can be done without interference.*

6.3 Electrical Requirements

[R59 - II] *The accelerometer outputs voltage levels should be in the range of 0 to 3.3V.*

[R60 - II] *Maximum supply current to accelerometer should be 1.5mA.*

[R61 - II] *The maximum supply voltage to the accelerometer should not exceed 3.6V.*

6.4 Accuracy and Performance Requirements

[R62 - II] *The range of acceleration values that can be accurately detected with the motion sensor is from -2.0g to +2.0 g.*

[R63 - II] *Output signals will correspond to the current test subject's position with minimal delay.*

7 Microcontroller Unit

The microcontroller unit acts as a signal processor unit for the Heart Rate sensor and the motion sensor, and it is also a communication client that prepares data for the host cellular phone. This section is dedicated to the specific requirements regarding the microcontroller unit, it is categorized as follows: general, electrical, software, and usability and reliability requirements.

7.1 General Requirements

[R64 - II] *Measure Heart Rate in Beat per Minute (BPM) accurately (± 10% for the prototype and ± 2% for the retail version).*

[R65 - II] *Detect Motion of the user and translates motion sensor output voltage readings into user's activity.*

[R66 - II] *Able to prepare data and send them to a cellular phone that contains our Symbian application via Bluetooth.*

7.2 Electrical Requirements

[R67 - II] *A 16 bits microcontroller is required.*

[R68 - II] *A Minimum 4 ADC input channels will be required*

[R69 - II] *A Minimum 1 Digital input channels with timer input capture peripheral function will be required*

[R70 - II] *At least one UART port is necessary for communication with the Bluetooth*

[R71 - II] *At least 5 digital output pins should be required.*

[R72 - II] *The supply voltage to the microcontroller should be 5 V.*

7.3 Software Requirements

[R73 - II] *The microcontroller should support C complier and debugger.*

[R74 - II] *At least 4 Kilobyte of flash memory programming available*

7.4 Usability and Reliability Requirements

[R75 - I] *One LED indication for Bluetooth connectivity status and another LED for heartbeat detection.*

8 Symbian Application

The Symbian application is used to interface the user with the final GUI display on the cell phone. This section is categorized is follows: general, platform, functional, and user interface requirements.

8.1 General Requirements

[R76 - II] *The Symbian application should be a GUI application.*

[R77 - II] *The application must be able to use the phone's onboard Bluetooth device for communication.*

[R78 - II] *The user interface must be user friendly.*

8.2 Platform Requirements

[R79 - I] *The application requires a cellular phone with S60 Symbian OS 9.2 (Nokia) and up.*

[R80 - III] *The final retail product should be able to work with any cell phone that is Bluetooth compatible*

8.3 Functional Requirements

[R81 - III] *The application should be able to keep a log of the data collected for a pre-defined period.*

[R82 - III] *The application should warn the user about any possible heart problems*

[R83 - III] *The user should be able to choose the type of warning and where the data can be sent.*

8.4 User Interface Requirements

[R84 - II] *The heart rate and user activity level should be displayed in the GUI*

[R85 - III] *There should be a menu that allows the user to set the dangerous heart rate levels and types of warning given for our final commercial product.*

[R86 - III] *There should be a simple user help section to guide the user to use the setup and use the final commercial product*

9 Documentation Requirements

This section lists out the required documents attached to both our prototype and commercial device.

[R87 - III] *User instruction manual with multi-language support will be provided*

[R88 - III] *Maintenance and modification documents for technicians will be provided*

[R89 - III] *Online website with company information, technical support, software updates, FAQ, purchasing information, and contact information will be provided.*

10 Test Plan

Our test plan below is designed for the prototype device:

10.1 Sub Module Testing

Power Supply Test

The power supply for the heart rate sensor and the microcontroller will be tested in order to ensure that the required power supply level can be met and operation safety level is achieved.

Heart Rate Sensor Output

The ECG heart rate sensor outputs a square wave every time a heart beat is detected. We will experiment the generation of the pulse base on the ECG waveform peak from the heart rate sensor input. We will ensure that the acceptable error rate under our requirement for different activity level from the user.

Motion Sensor Output

Motion detection sensors are tested by recording the DC voltage offset values for the normal operation values of 0, -1, and +1g. All of the axes of the sensors are measured and values recorded for motion analysis. The motion detection algorithm will be developed based on the offset values. In order to achieve obtain high accuracy, each sensor is manually calibrated.

Symbian Firm work

Basic Symbian application will be developed and tested with a Nokia Cellular phone. The ability for controlling the on-board Bluetooth resources and performing data transmission will be tested. Various crash tests for the application will also be implemented in order to ensure reliability.

Bluetooth Communication for dummy data

Dummy data will be written to the on-board Bluetooth transmitter from the MCU and transmits to a Nokia phone with Bluetooth data logging application installed. One of Corazon's members will carry the Nokia phone a certain distance away from the MCU for communication range test.

10.2 System Integration

Heart Rate Measurement

One digital input pin of the MCU will connect to the output of the Heart Rate Sensor. A timer will be initialized in the MCU to measure the period of the pulse that is generated from the heart rate sensor. The heart rate will be calculated with two consecutive pulses from the input pin. The accuracy of measuring the heart rate with our required error rate will be ensured.

Motion Detection

Four analog input pins in the MCU will be connected to the motion sensor outputs. The MCU will perform analog to digital conversion and motion detection based on the digitalized data. The accurate detection of the user's physical state and motion within our pre-defined error range needs to be ensured.

Bluetooth Communication with Heart Rate and Motion information

In the second stage of Bluetooth test, the heart rate and the motion of users acquired from the MCU will be transmitted from the on-board Bluetooth module to a Bluetooth receiver on a cell phone. The same radius range test in first stage will be performed again to ensure that we can transmit the heart rate and motion information in our required range.

Symbian Application user ability test

After finishing the data transmission test over Bluetooth from the MCU to cellular phone, more development on the user interface of the Symbian application will be required to enhance the user experience.

11 Conclusion

The functional specifications above listed out all the requirements need for both our proof of concept prototype model and the final commercialized product. The prototype model will be completed by the end of March 2008 and the final commercialized product will be completed by the end of 2008. No major design changes will be implemented unless normal operational functionalities listed above cannot be met. All Corazon team members will continue the design, implementation, and test procedures according to the requirements within this document.

12 Reference

[1] ANSI/AAMI ES1-1993, "Safe current limits for electrometrical apparatus"

[2] Wikipedia, "Bluetooth," [Online document] Feb. 2008, [2008 Feb15], Available at http://en.wikipedia.org/wiki/Bluetooth

[3] Wikipedia, "Title 47 CFR Part 15," [Online Document] Feb. 2008, [2008 Feb 15], Available at http://en.wikipedia.org/wiki/Part_15_(FCC_rules)

[4] "Medical Devices Regulations," [Online Document] May 1998, [2008 Feb 15], Available at http://www.canlii.org/ca/regu/sor98-282/whole.html

[5] Wikipedia, "ISM Band," [Online Document] Jan. 2008, [2008 Feb 15], Available at http://en.wikipedia.org/wiki/ISM_band

[6] Wireless Telecommunications Bureau, "Rules and Regulations," [Online Document] Jan. 2008, [2008 Feb 15], Available at http://wireless.fcc.gov/index.htm?job=rules_and_regulations