October 6, 2003

Dr. Andrew Rawicz and Mr. Steve Whitmore
School of Engineering Science
Simon Fraser University
Burnaby, British Columbia
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Re: ENSC 305/340 Functional Specification for a Personalized Medical Emergency and Distress System

Dear Dr. Rawicz and Mr. Whitmore,

The attached document, *Functional Specification for a Personalized Medical Emergency and Distress System*, lists and describes the functional requirements for our ENSC 305/340 project.

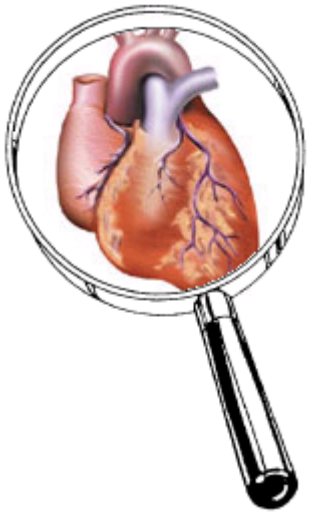
We are currently in development of a personalized medical system that will monitor and analyse a person's vital signals and contact certain medical parties if a life-threatening situation is detected.

The purpose of this functional specification is to provide a detailed listing of the functionality that will be provided by the completed version of the Personalized Medical Emergency and Distress System. This document also specifies the functionality that will be implemented in our mockup by the project deadline of December 2003, and also the functionality that will be implemented at a future date in our final product.

If you have any questions or concerns about our project, functional specification, or company, please feel free to e-mail or phone us at en-Focus@sfu.ca or (604) 738-8133.

Functional Specification for a

Personalized Medical Emergency and Distress System



Submitted to:

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Executive Summary

Our Personalized Medical Emergency and Distress System (PMEDS) is designed to provide real-time monitoring and analysis of a person's vital signals, along with the capability to immediately contact various medical authorities should a life-threatening situation be detected. The PMEDS will consist of a shirt module, a base station module, and a wireless RF connection between the two. The shirt module will transmit the gathered vital data to the base station module, which will perform the required analysis of the data and decide on what appropriate action to take. For the mock-up of the PMEDS, we will perform all data analysis on a PC, and we will only detect when a life-threatening situation is occurring, without taking action. For the final product, we plan to incorporate all data analysis and emergency action onto a base station, without a PC.

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1 Introduction

The Personalized Medical Emergency System (PMEDS) is a wearable system that will monitor and analyse a person's vital signals and detect and take action upon any life-threatening situations. The project will start with the development of a mockup system by December 2003 that will show proof of concept, while a final product that will contain the full desired functionality will be developed at a later date.

1.1 Scope

This document is a functional specification for the PMEDS development project that clearly describes and outlines the functional requirements that will be fulfilled in the mock-up and the final product.

1.2 Glossary

BER – bit error rate
DTMF – Dual Tone Multi-Frequency; the telephone standard for touch-tone signals
ECG – Electrocardiogram; the electrical signal measured from the heart
GUI – graphical user interface
PSTN – Public Switched Telephone Network - the international telephone system based on copper wires carrying analog voice data
RF – Radio Frequency

1.3 Conventions

The following numbers will indicate whether the functional requirement relates to the mock-up and/or the final product:
M – Mock-up functional requirement
F – Final product functional requirement

The following suffix will indicate if a particular functional requirement is desired but not necessarily feasible for the mock-up and/or final product:
d – Desired, but not necessarily feasible

For example, the label, "– Md, F", means that the functional requirement is desired, but not necessarily feasible for the mock-up, and is a functional requirement for the final product.

2 Functional Requirements

The block diagram shown below in Figure 1 gives an outline of the PMEDS functionality.

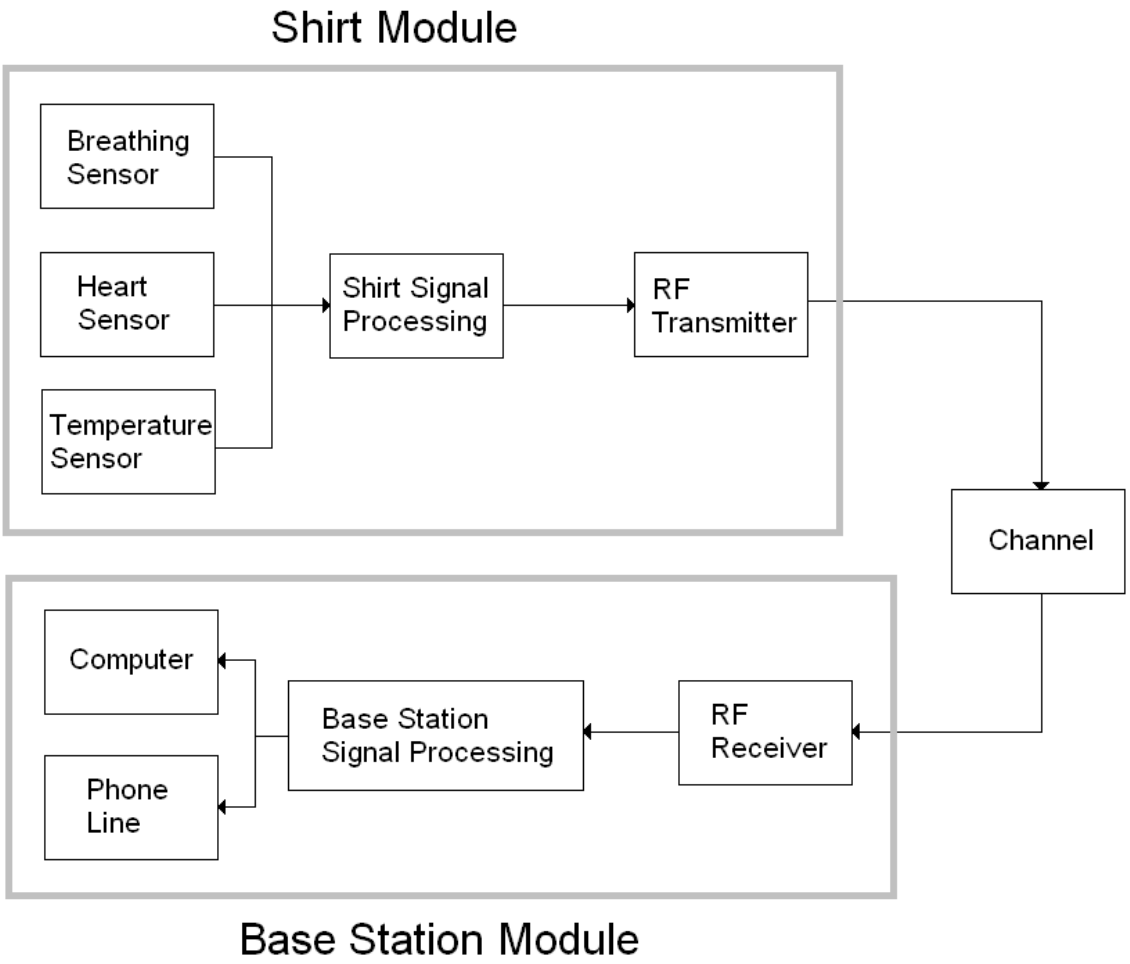

Figure 1 Block diagram overview of the PMEDS functionality.

2.1 Shirt requirements

2.1.1 Physical specifications

- The shirt shall be tight on the consumer in order to read the sensor data reliably – M,F
- The shirt shall not affect the vital signs that are being observed, i.e. the shirt shall not cause excessive sweating and/or breathing difficulties due to the tightness of the shirt. – M,F
- The shirt shall be light and comfortable to the consumer, i.e it shall be unobtrusive removing the constant reminder that the shirt is a medical sensing device. – F

- The shirt shall be electrically isolated in order to remove the possibility of consumer electric shock. – M,F
- The shirt electronics shall produce a minimal amount of radiation. – M,F
- Electronics within the shirt shall be invisible to the consumer. – F
- Consumers shall have a choice of styles and colors to fit their preferences. – F
- The shirt system and its electronics shall be waterproof in order to allow machine washing – F
- The shirt electronics shall be able to withstand temperature ranges from -10°C to 100°C – F
- The shirt electronics shall be able to withstand forces exerted on it by routine procedures, such as machine washing/drying and ironing as well as movement – F
- The shirt system shall be able to operate under normal atmospheric pressure. – M,F

2.1.2 Sensor / data gathering requirements

- The sensors shall be reliable, robust and with a low zero drift, i.e operate with minimal degradation in performance due to movements, temperature and skin secretions of the wearer. – Md,F
- The system shall not be significantly affected by external (electro-magnetic, thermal, or acoustic) noise that may result sensor data error. – Md,F
- The sensors shall have a high sensitivity to the measured variable but low cross-sensitivity to the variable orthogonal to the intended measured variable, i.e. sensors shall be able to have a high sensitivity to the body temperature but low sensitivity to the outside temperature. – M,F
- The sensors shall be accurate with a maximum error of 0.5% in order to ensure trustworthy diagnosis – Md,F
- The sensor shall be accurate:
    - The temperature sensor shall have a maximum error of 2%, to ensure accurate readings – M,F
    - The ECG sensor shall have a maximum error of 10% – M
    - The ECG sensor shall have a maximum error of 2% – F
    - The breathing sensor subsystem shall be able to detect a minimum of 95% of all breaths taken – Md,F

- The sensors shall be precise with a maximum standard deviation of 2% from the mean value, in order to receive consistent data reading. – Md, F

- The sensor resolution shall be high:
  - The temperature sensors shall be able to detect a change in 0.5 degrees in order to distinguish abnormal temperatures deviating from 37°C. – M,F

  - The breathing sensors subsystems shall have a resolution of 1 breath/min, in order to achieve meaningful breathing rate values. – M,F

  - The ECG sensor shall have a resolution of 1 ms hence it shall be able to detect a 1000 Hz signal.
    - ECG shall also be able to detect amplitudes in the millivolt range, in order to be able to detect normal ECG characteristics and abnormalities. – M,F
    - ECG shall also be able to detect amplitudes in the microvolt range, in order to be able to detect myocardial ischemia – Fd.

2.1.3 Data processing requirements

- The A/D shall be able to perform over 2000 conversions per second (resolution and accuracy depends upon the sensors) – M,F

2.1.4 Power requirements

- The shirt shall be able to remain active for 48 hours without the need for replacement batteries. – Md

- The shirt shall be able to remain active for 120 hours without the need for replacement batteries. – F

- The shirt shall consume less then 50mA. – M

- The shirt shall consume less then 20mA. – F

- The base shall contain a charger circuit for the batteries that will be used for the shirt. – F

- The base station shall be powered by a standard 5V transformer/wall-adapter. – M,F

- The base shall consume less then 100mA. – Md,F

- The shirt's components shall be powered by a 2.4V battery source. – M,F

2.2 RF requirements

2.2.1 Frequency spectrum requirements

- The transmitter and receiver shall transmit and receive data in the 916.48 Mhz frequency band. – M
- The signal will have a bandwidth of 28Khz – M

2.2.2 Data bandwidth requirements

- The transmitter and receiver shall exchange data at 52,000 bits per second – M,F
- The transmitter will send digital sensor data to the base station – M
- The base station will send back and acknowledgement when data has been received – F
- The base station will message the shirt when it senses the user is at risk – F

2.2.3 Data integrity/reliability

- The RF system shall have an average BER of 10^{-6} – M,F
- The RF communications subsystem shall have a maximum of 1% packet loss – Md,F
- Accurate data analysis shall not be affected by the maximum RF data loss – M,F

2.2.4 Range

- The roaming range of the shirt from the base station will be 30m, with line of sight – M
- The roaming range of the shirt from the base station will be 100m, with line of sight – F

2.3 Base station requirements

2.3.1 I/O requirements

- The base station shall communicate with a PC using RS232 standard serial communications. – M
- The base station shall be able to communicate with a PC at a bit rate of 115,200 bits per second. – M
- The base station shall be able to communicate via RF with the shirt. – M,F

- The base station shall be able to connect to a PSTN telephone line. – F
- The base station shall be able to transmit DTMF signals onto the telephone in order to dial a telephone number. – F
- The base station shall be able to recognize when the telephone line has been picked up. – F
- The base station shall be able to recognize a dial tone. – F
- The base station shall be able to hang up the line, if it is already in use, and take control of the line for the duration of the emergency call. – F
- The base station shall be able to transmit a prerecorded message onto the telephone line. – F

2.3.2 Data analysis requirements

- 99.9% of all 16-bit data words to be processed, after verification, shall be correct; that is, they will match exactly to what was measured and transmitted by the shirt – M,F
- The software shall present the data using a GUI – M
- The software shall run on a Windows platform – M
- The software shall process and display the data no later than 0.5 seconds after it has received it – M
- The base station shall immediately contact the medical authority number should a critical situation be detected – F

2.4 Certification

- The PMEDS system shall be approved by the CSA – F
- The PMEDS system shall be approved by the FDA – F
- The PMEDS system shall follow FCC regulations regarding electromagnetic interference – F

Conclusion

The functional requirements set out in this specification will allow us to develop a proof of concept mock-up that will be both effective in its purpose and completed on-time. The functional requirements specified for the final product clearly state our future goals and capabilities of the PMEDS that we intend to implement. We believe that with these functional specifications, we will be able to complete our project within the project deadlines, while providing an effective proof of concept mock-up that will clearly demonstrate the capabilities of the PMEDS.