October 27th, 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 Design Specification for a Personalized Medical Emergency and Distress System

Dear Dr. Rawicz and Mr. Whitmore,

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

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

The purpose of this design specification is to describe the design and testing methodology of the functional components, subsystems, and processes of the PMEDS.

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) 889-5690.

Design Specification for a

Personalized Medical Emergency and Distress System

Submitted to:

Steve Whitmore – ENSC 305
Dr. Andrew Rawicz – ENSC 340
School of Engineering Science, SFU

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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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Document Information

Revision history

Version number	Date	Summary of changes
0.1	October 16th, 2003	Incomplete first draft containing only a template for the Design Specification
0.2	October 25th, 2003	Added the Letter of Transmittal, Executive Summary, and Introduction sections; also added various section headings as an outline for the document
0.3	October 26th, 2003	Added the System Overview section and the Body Temperature Sensing Subsystem subsection
0.4	October 26th, 2003	Added the RF Transmission and Reception section; also made some minor editing changes and changed the temperature sensing circuitry design schematic
0.5	October 27th, 2003	Added the Base Station Hardware, RF Transmission and Reception, and the Software Analysis and Monitoring sections and also the ECG subsection
0.6	October 27th, 2003	Added the Shirt hardware test plan section and also the Temperature result accuracy, Ventilatory (breathing) rate sensing, and Base station hardware test plan subsections
1.0	October 27th, 2003	First complete draft; added the Conclusion and References sections; also made some editing changes to the entire document

1 Introduction

The Personalized Medical Emergency System (PMEDS or PMED System) is a wearable system that will monitor and analyze 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. This document specifies the design and testing methodology that we will employ during the development of the PMEDS.

1.1 Scope

This document is intended as a guideline and plan for the design and development of the PMEDS. The document will contain schematics, test plans, and other design details necessary for the development of the PMEDS.

1.2 Glossary

Bpm – (heart) beats per minute
Bps – bits per second
ECG – Electrocardiogram; the electrical signal measured from the heart
FM – Frequency Modulation
FSK – Frequency Shift Keyed
GUI – graphical user interface
Hyperventilation –abnormal breathing characterized by its excessive rate and depth
MHR – Maximal Heart Rate
Op-amp – Operational amplifier
PMED System – Personalized Medical and Emergency Distress System
PMEDS – Personalized Medical and Emergency Distress System
RF – Radio Frequency
Ventilatory rate – the breathing rate (a single breath is defined as an inspiration and an expiration), in terms of breaths per minute

2 PMED System Overview

Figure 1 is a diagram of the PMEDS functionality and components. This document specifies the design and testing methodology for the development of the system represented below.

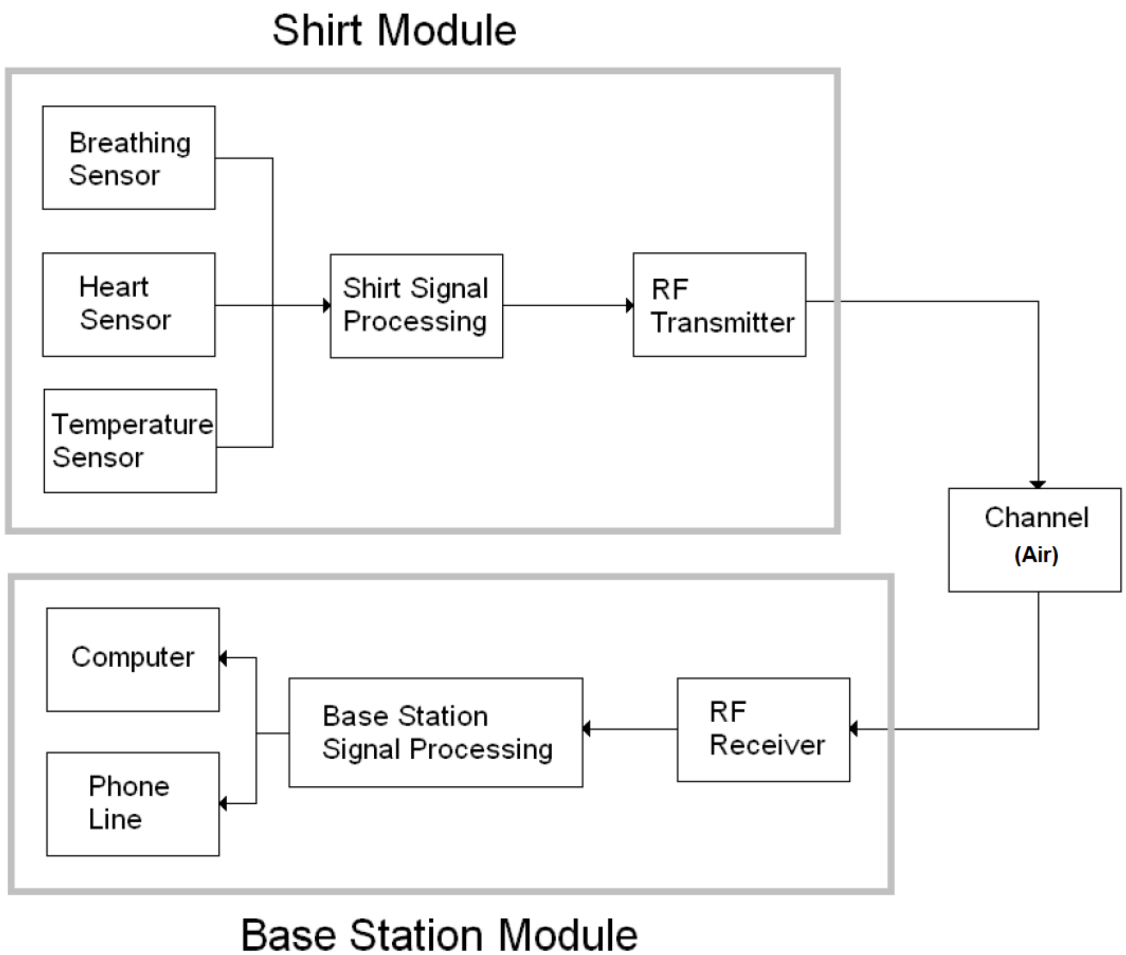

Figure 1 System overview diagram for the PMEDS.

3 Shirt Hardware

3.1 Body Temperature Sensing

3.1.1 Physical specifications

A temperature sensor will be embedded or attached to the shirt such that it is in contact with the body, possibly through the shirt fabric, near the armpit such that the axillary temperature of the body, which is a good measure of core body temperature, can be measured. In order to minimize the cooling effects that the outside environment may have on the measured axillary temperature value, the distal side of the temperature sensor will be covered by thermal insulation.

3.1.2 Integrated Circuit (IC) temperature transducer characteristics

We will use the Analog Devices AD592CN IC temperature transducer as our temperature sensor. The AD592CN is a two-terminal temperature dependent current source that has a 1μA/°K transfer function, as shown below in Figure 2.

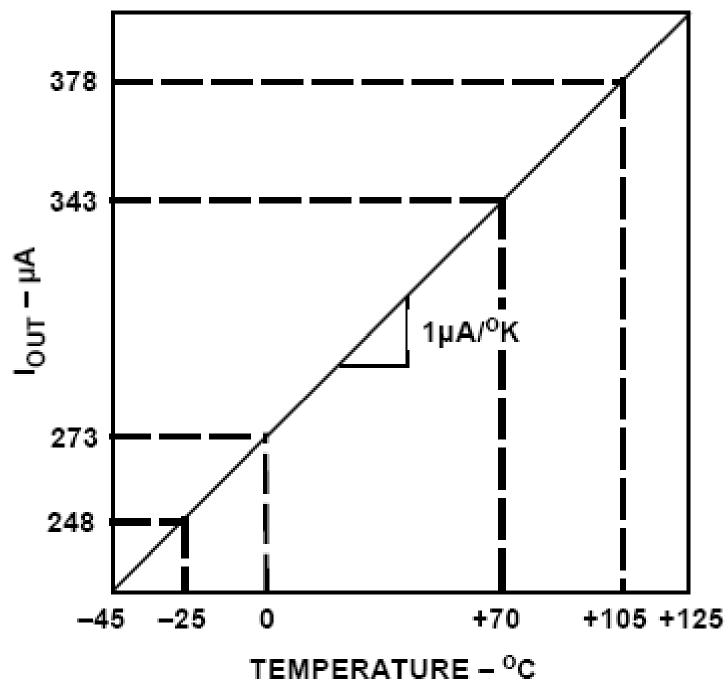

Figure 2 IC temperature transducer connection diagram.

After calibration at a particular temperature and for a temperature range of 0 to 70 °C, the AD592CN has a typical output error of 0.4°C, and a maximum output error of 0.8°C.

3.1.3 *Temperature sensing circuitry*

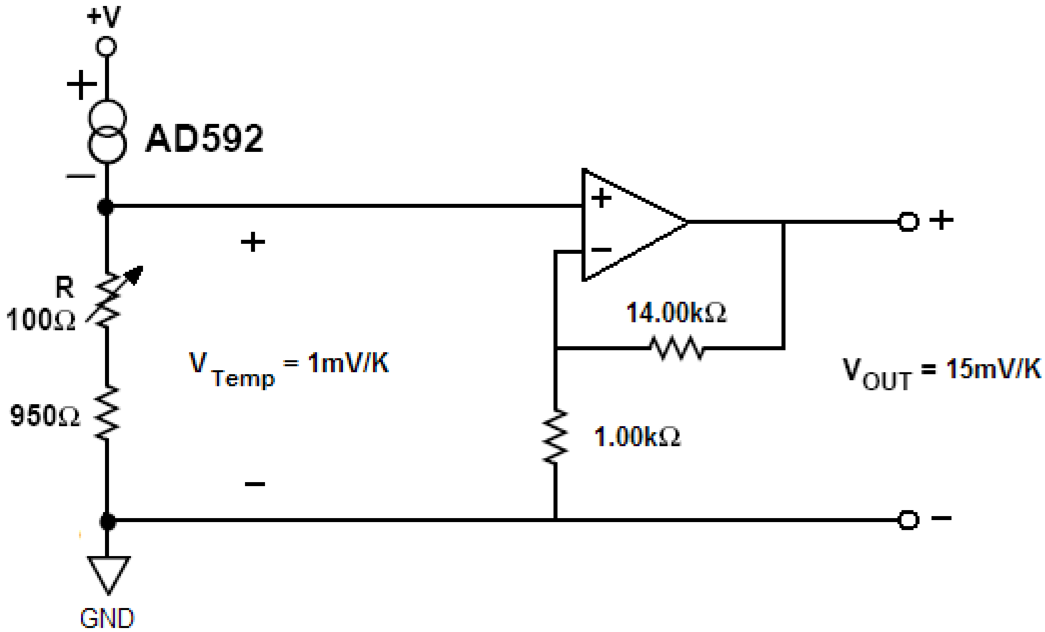

Figure 3 Circuit schematic of the temperature sensing circuitry.

Figure 3 shows the schematic of a circuit that yields a voltage output corresponding ideally to 15mV/°K. Therefore, at a temperature of 37°C (310.2 °K), the circuit should give V_{OUT} = 4.653V.

3.1.3.1 Temperature result accuracy

The output error of the AD592CN IC temperature transducer after calibration is typically 0.4μA/°K (maximum error is 0.8μA/°K). The A/D conversion using the microcontroller also introduces a small error. The maximum error from the microcontroller is ½ the LSB of the 10-bit conversion, which results in a maximum 3mV error when using a 3V reference voltage. There will also be error introduced from the op-amp's offset voltage which is approximately 0.2mV (we will be using a OPA344 op-amp). The error from input impedance of the op-amp is negligible due to its extremely high input impedance of 10^{13} ohms. The error from any resistor mismatches and/or tolerances, plus the offset voltage error will be further minimized by calibrating the temperature sensor using the 100Ω trimpot.

3.1.3.2 Temperature result transmittal

The voltage output, V_{OUT}, from this circuit will be fed to the analog-to-digital converter that is onboard a PIC microcontroller, and converted into a binary number, which will then be transmitted to the base station and then analyzed.

3.1.3.3 Temperature result analysis

The base station will receive the temperature results representing the measured axillary body temperature. If the temperature is deemed to be high enough to be life-threatening for the user (e.g. 40°C, which is a high fever), or if the temperature is deemed to be too low (e.g. 35°C and below, which is a key sign of hypothermia), then the appropriate medical and/or emergency parties will be contacted.

References:
Health Library – Rectal, ear, oral, and axillary temperature comparison
http://health_info.nmh.org/Library/HealthGuide/IllnessConditions/topic.asp?hwid=tw9223
AD592: Low Cost, Precision IC Temperature Transducer Data Sheet (Rev.A, 7/93)
http://www.analog.com/UploadedFiles/Data_Sheets/136700329AD592_a.pdf

Hypothermia (Mayo Foundation for Medical Education and Research)
http://www.mayoclinic.com/invoke.cfm?id=DS00333

3.2 ECG

3.2.1 Physical specifications

The ECG detects and outputs small voltages that the heart generates. Hence, the ECG must amplify the heart's electrical signals, remove all other noise and display the result. The output is in the shape of the QRS wave, whereas the rate of the QRS wave is the heart rate.

Figure 4 shows a normal QRS wave.

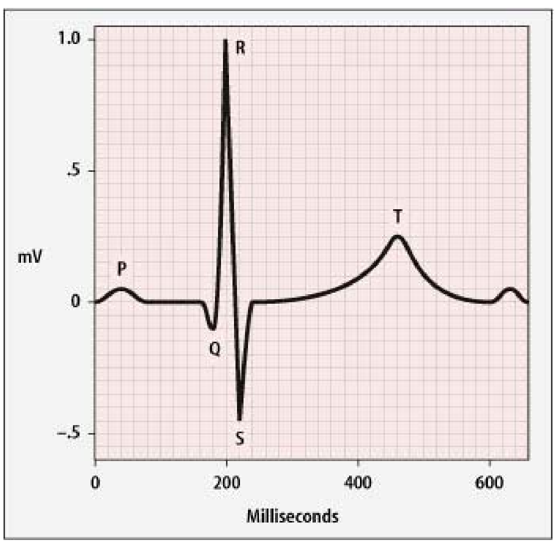

Figure 4 Graph of a normal QRS wave.

We will use a homemade ECG circuit[1] as our heart rate detection sensor.
The ECG will be measuring heart's electrical impulses via three electrodes. Two of these electrodes are placed on the chest near the heart and the third, acting as the reference point, on the lower left arm. Copper pennies will be used as electrodes.

3.2.2 Design concerns

As shown in Figure 4, the voltages from the heart are in the mV range; hence the detection is highly prone to noise.

In order to reliably and safely detect the voltages we must be able to:

1. Minimize noise from the electrodes and wires and minimize the detection of other body signals, i.e. muscles
   We will remove unwanted noise at the output of the ECG using a low pass filter.

2. We must use high quality components with low tolerances, hence decreasing the amount of fluctuations and improving the precision.
   The operational amplifiers used in building the ECG have low noise sensitivity high input impedance and low input, bias, and offset currents.

3. Lower the resistance between the electrodes and the skin to improve conductivity
   We will use lotion/shampoo between the electrodes and skin to increase the conductivity, and hence improve the detection.

4. Decrease the risk of shock
   In order to decrease the risk of shock, diodes were placed at each input.

5. Another important design criterion is the cost of an ECG
   The store-bought ECG produces far more accurate and precise results, which would allow us to measure the sub peaks of the QRS wave and hence detect a wider range of abnormalities. Unfortunately, the cost of such an ECG is in the range of $2000; far beyond our financial ability.
   The homemade ECG is certainly less accurate and more prone to noise, but it would still enable us to detect the QRS wave at an acceptable amount of accuracy for this project, and would cost just below $5.

6. Low power consumption
   The op-amps chosen have low power consumption and can be powered with 5V.

3.2.3 ECG schematic

The resulting ECG schematic circuit is shown in Figure 5.

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[1] The homemade ECG schematic is available from - http://www.eng.utah.edu/~jnguyen/ecg/ecg_index.html

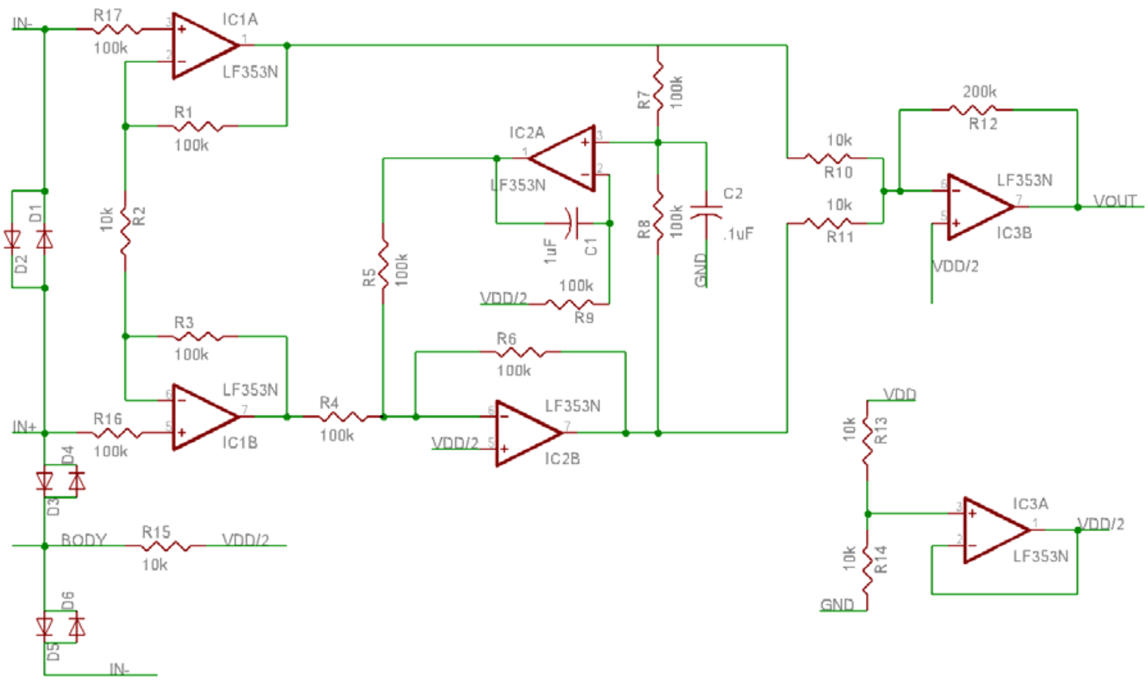

Figure 5 Schematic diagram of the ECG circuitry.

The following are important inputs and outputs of the ECG as shown in the above schematic.

Table 1 Listing of the ECG inputs and outputs.

IN-	Chest input #1
IN+	Chest input #2
BODY	Lower Left Arm
V_{DD}	5V
V_{CC+}	5V
V_{CC-}/GND	0
V_{out}	Output to the A/D in the microcontroller

In order to decrease the amount of noise from the electrodes and wires, a low pass filter will be placed at the output (V_{out}). The cutoff frequency of this filter is approximately 200 Hz. The resulting schematic is shown in Figure 6.

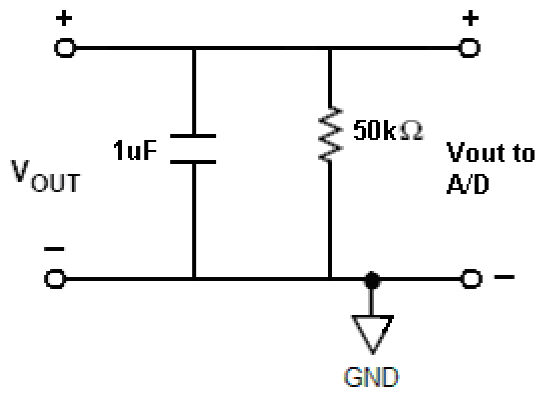

Figure 6 Low Pass Filter Schematic.

3.2.4 ECG result analysis

The voltage output, V_{out} from the low pass filter circuit will be fed to the analog-to-digital converter that is onboard a PIC microcontroller on the shirt, and converted into a binary number.

The relevant output of the ADC will be transmitted to the base station and analyzed by the computer software. Subsequently, the heart rate will be determined from the heart data every 5-10 seconds.

A normal heart rate at rest is approximately 60-100 bpm. Any heart rate outside this norm is called arrhythmia. Depending on the age, the theoretical maximum exercise heart rates can reach up to 180 bpm. This is called the Maximal Heart Rate (MHR) and is approximately given by:

$$MHR = 220 \text{ bpm} - \text{age}$$

The base station will contact the appropriate medical authorities if any of the following occurs:

- If the average calculated heart rates vary by more then 15% from each other
- If the average heart rate is higher then 75% of the maximal heart rate
- If the average heart rate is slower then 40 bpm

3.3 Ventilatory (breathing) rate sensing

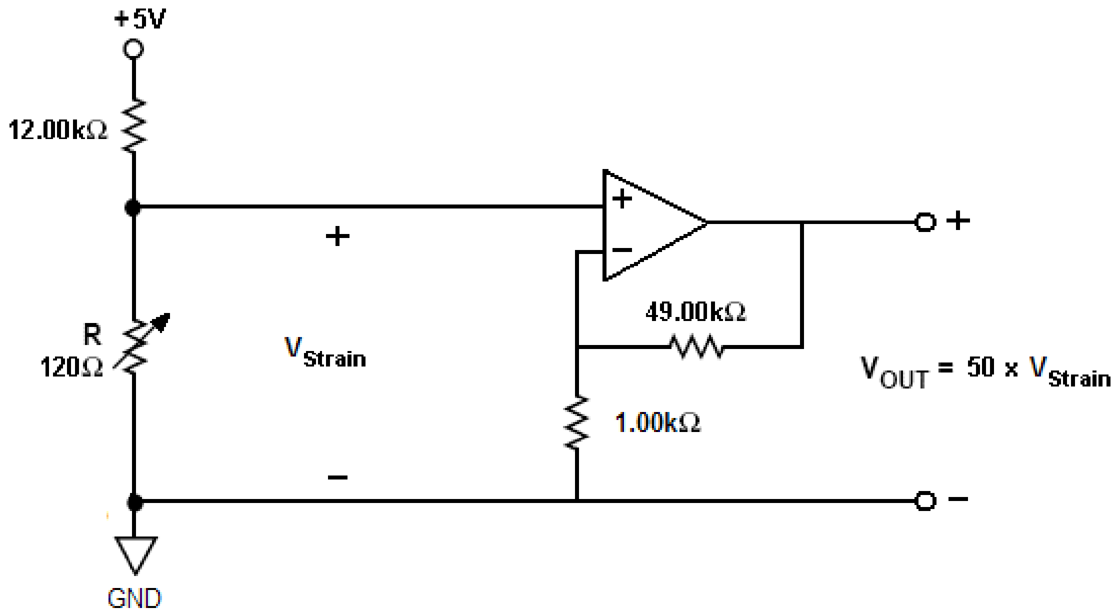

Figure 7 Circuit schematic of the breathing sensing circuitry.

The variable resistor shown in Figure 7 is a strain gage that will change resistance up to approximately 1Ω as it is stretched. We will embed this strain gage into the shirt, somewhere around the lower torso, and use it to measure the person's ventilatory rate. As the person breaths the strain gage will stretch proportionally allowing us to measure the change in voltage (V_{Strain}) corresponding to the change in resistance of the strain gage. The average frequency of the resulting sinusoidal waveform (V_{OUT}) will be the measured breathing rate, in breaths per minute.

3.3.1 Power consumption

We chose not to use a conventional Wheatstone bridge to measure the change in resistance because the matched resistor network would consume too much current and power, especially due to the strain gage's low resistance of approximately 120Ω. Instead, we chose the circuit shown in Figure 7 due to its larger resistances, especially the very large input resistance of the op-amp, which results in lower current and power consumption.

3.3.2 Mounting the strain gage

The strain gage embedded in a material that will surround the lower torso (just below the chest), wherever maximum displacement during breathing occurs.

In order to get accurate results we need to mount the strain gage appropriately. The following are the requirements for the material the strain gage will be mounted on:

- Must be comfortable around the chest, hence not too rigid.
- Must be flexible, in order to be able to stretch proportional to breathing.
- Should not be too flexible, in order to prevent the strain gage stretching beyond its yield point.
- The surface of the material must be smooth, flat and clean, such that the adhesive between the material and the gage doesn't slip and the results are accurate.

We plan to embed the strain gage in a strip of soft aluminum, which will be embedded in the shirt.

4 Base Station Hardware

In the prototype the base station simply acts as a bridge between the RF transmitter and the PC. The base will perform some basic error checking on the RF signal and then relay the signal to the PC's serial port. The signal will be sent to the PC using the RS-232 protocol, and will be connected via a 9-pin D-Sub connector to the PC's serial port as shown below in Figure 8.

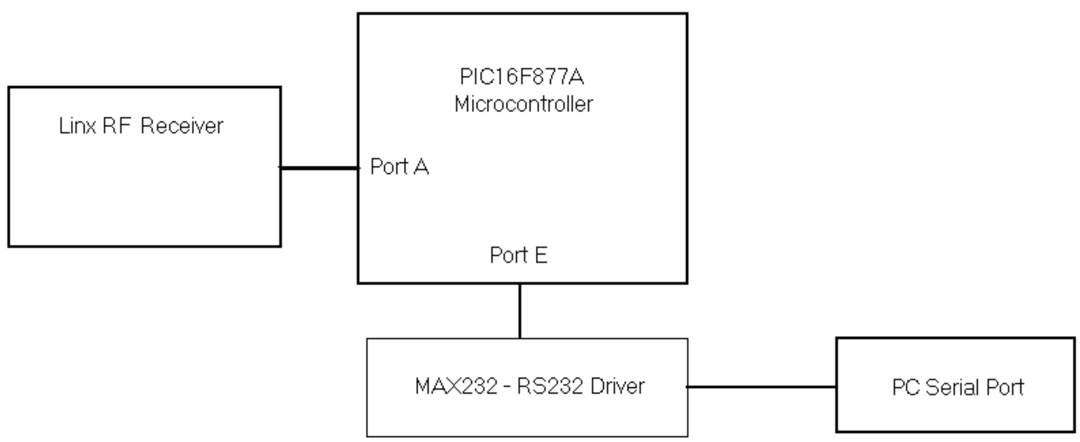

Figure 8 Block diagram of the base station.

4.1 Microcontroller

We chose a PIC16F877A as the microcontroller for the prototype since it's large amount of RAM, program memory, and I/O pins make more than suitable for our needs, which enables us to make upgrades to our design without the need for a more complex microcontroller. The PIC16F877A is also software compatible with the entire PIC16 microcontroller family, which will allow us to chose a less sophisticated microcontroller with the ideal amounts of memory and I/O pins for the final product, without minimal hardware and no software changes. The development tools for the PIC16F877A are very easy to work with which will cut development time and make for quicker debugging of the prototype.

4.2 RS-232 Driver

In order to change the output of the microcontroller from TTL into the ±9V signal that are used by the RS-232 standard a MAX232 IC is used. This IC is the industry standard and can be used for up too four signal lines, but the main reason it was chosen is that it can be used with the same power supply as the microcontroller with only a few external capacitors. A connection diagram for the MAX232 can be found at the manufacturer's website, http://www.maximic.com.

5 RF Transmission and Reception

5.1 Transmission

The RF transmitter will receive a digital signal from the microcontroller between 3V to 5V. In order to minimize power consumption a stable design with a 3V input is desired, however because the shirt sensors will be running at 5V, a balance between design complexity and power consumption might mean a 5V operating range for the RF transmitter as well.

The transmitter will operate at 56,000 bps and transfer packets 512 bytes long using a sync byte, start byte, data packet format. The data will be transmitted as an FSK, FM signal to reduce the effects of noise, and increase reliability.

The transmitter will be powered by the shirt power supply (battery) at 5V and draw approximately 6uA of current while operating. In order to minimize power consumption the RF transmitter will be powered down when not needed.

Although the transmit power of the transmitter can be lowered, it will not be in order to reduce both debugging time and the probability of a signal loss. Because there is only a transmitter on the shirt, data packets will each contain a checksum and be sent a minimum of two times for error correction purposes.

5.2 Receiving

Since the receiver will be powered from a wall outlet DC supply, power consumption is not a major design consideration.

The receiver will receive an FSK, FM signal at 56,000 bps and will never be powered down.

5.3 Interface

Although the ES series chip provides a clock output, it will run at 4MHz and is not fast enough to give us the processing time we need on our PIC16 microcontroller. The output from Port E of the shirt's microcontroller will be connected to the RF transmitter's input signal port.

The receiver chip will be connected to the microcontroller via an external circuit to provide data hysteresis and squelching.

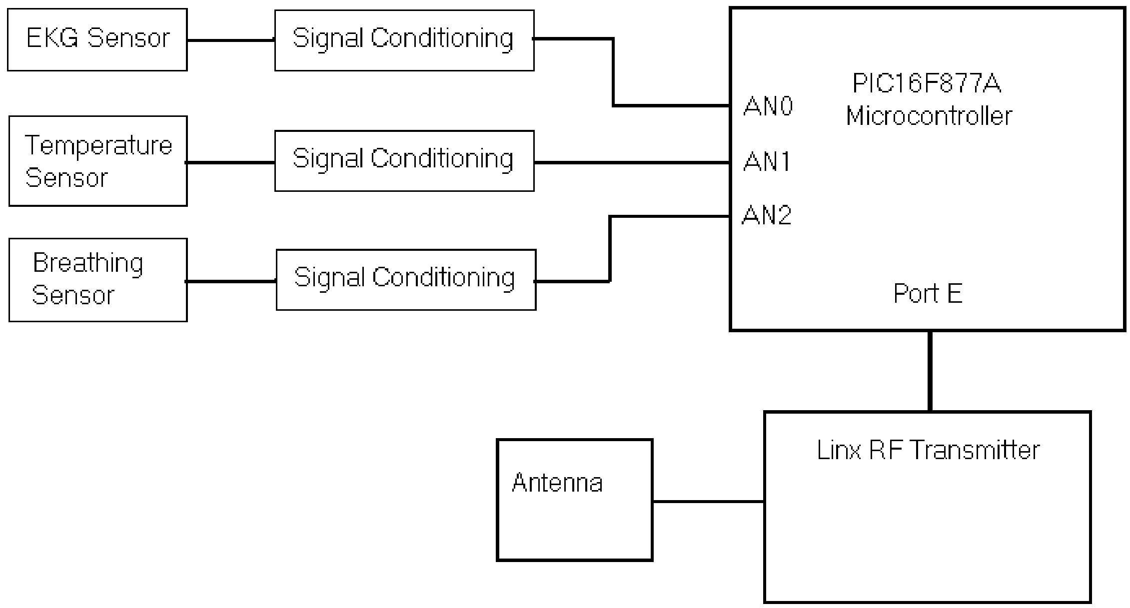

Figure 9 Block diagram for the RF Transmitter interface.

6 Software Analysis and Monitoring

6.1 Programming Language

The software for the analysis and monitoring of incoming vital signals needs to run on a Windows platform and will include a graphical user interface. The software will be implemented using Visual Basic 5.0 as this language allows for fast and effective development of GUI's.

6.2 Communication

The software will communicate with the base station via the computer's serial port, using the RS-232 protocol. Serial communication was chosen over parallel to conserve I/O pins on the PIC microcontroller. RS-232 is the standard serial port protocol, and it can be carried out in Visual Basic by using the MSComm control. Under this protocol, data is sent and transmitted at a constant frequency, which must be agreed upon on both ends of the communication. The RxD and TxD lines are used to transmit the data. A constant logic '1' is sent while idle, and a '0' is used as a start bit. The following bits, either 6, 7, or 8, will be used as data bits. A parity bit can follow for error detection. Last comes the stop bit, a logic '1', of length 1, 1.5, or 2 cycles. A sample transmission is shown in Figure 10.

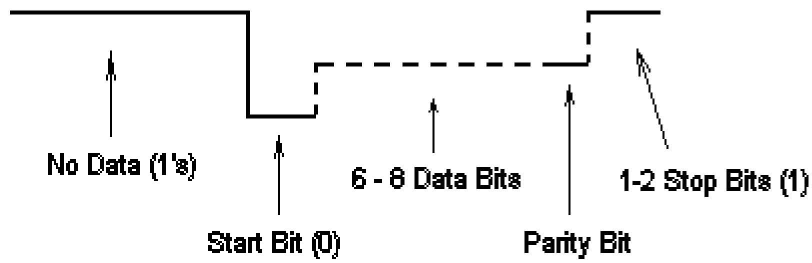

Figure 10 Sample RS232 transmission waveform.

We have chosen to transmit and receive data at a baud rate of 57,600, as this is a standard value and is reasonable for us based on our amount of data to transmit and the oscillator frequency of our base station microcontroller. We will not send a parity bit, as we have are using a checksum. We will use a stop bit length of 1 cycle, and will transmit 8 data bits at a time (the maximum).

To verify the received data, we will send a single checksum packet after every data transmission. If the checksum indicates that incorrect data was received, we will send a request to the base station to re-send the data. If the base station no longer has the data, a special packet will be sent to the computer to indicate this condition. The first packet of every data transmission will indicate the type of data being transmitted, as well as the number of packets to follow. An example of a simple data transmission is shown below in Figure 11.

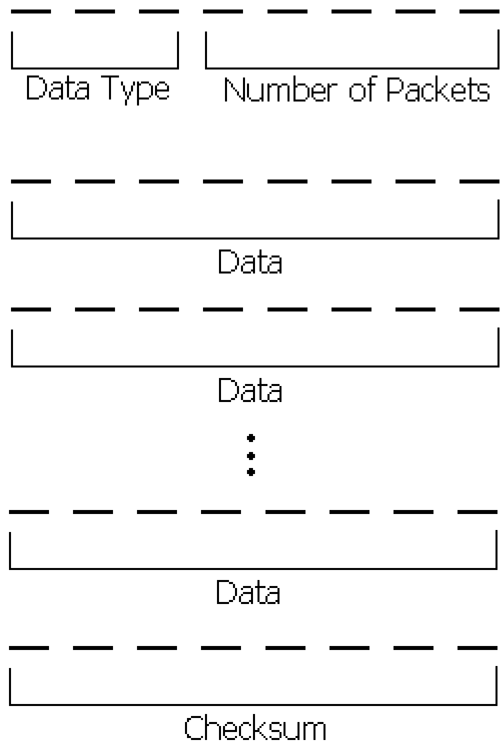

Figure 11 Sample data transmission packets.

6.3 Graphical User Interface

The user interface will be consistent with a typical Windows application. It will present ECG data in a chart, with an indicator of beats per minute. Current temperature will be displayed as a numerical value, with a chart indicating the history of temperature values over the past hour. Breathing will be presented as breaths per minute, also presented in a chart. Figure 12 presents a preliminary sample of the GUI.

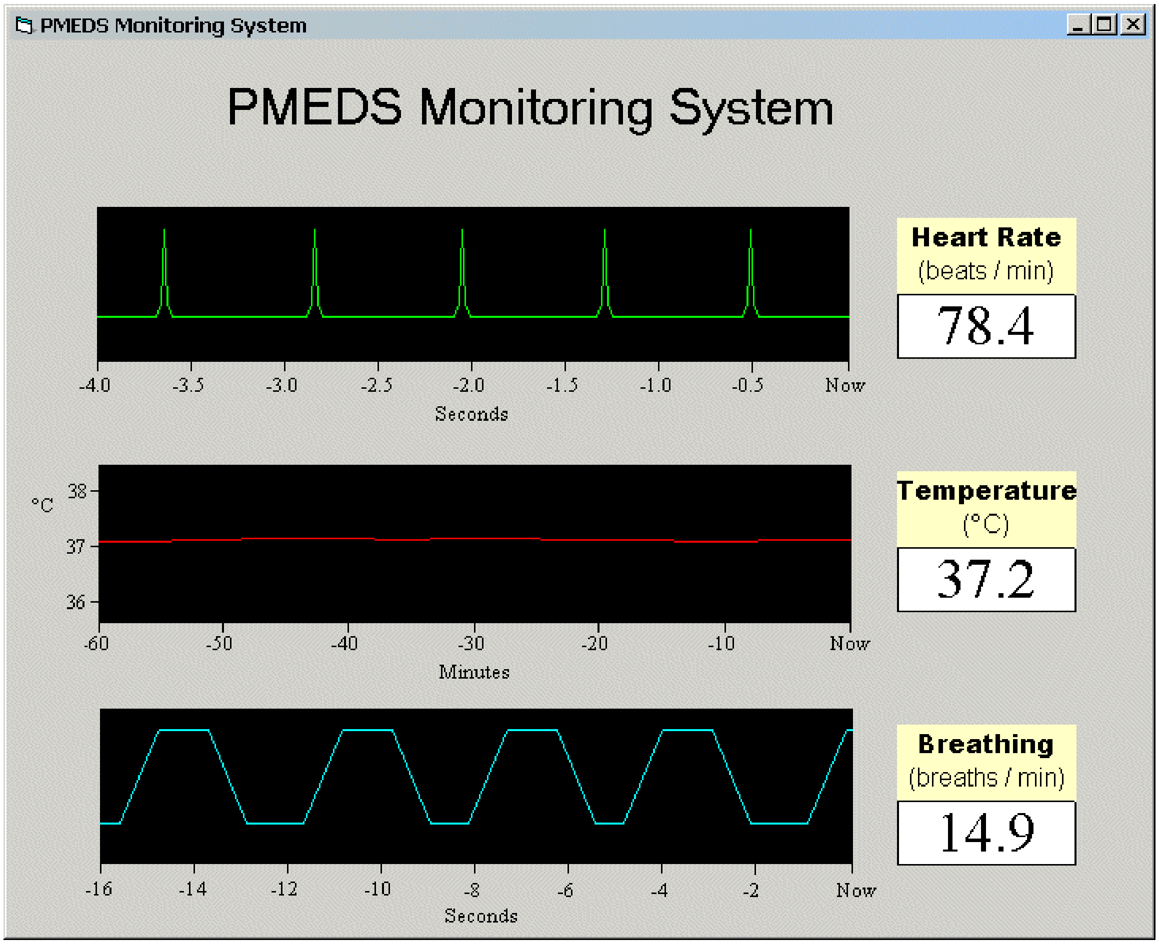

Figure 12 Preliminary sample of PMEDS GUI.

6.4 Monitoring and Alerts

The PMEDS software will receive a notification every time a heartbeat is detected. It will calculate beats per minute by measuring the duration of the current and previous beats in seconds, inverting this number, and multiplying by 60. It will also retain the time between beats for the last five received, and will compare these times to determine if irregularities exist. The duration of the second and third beats received before the current one will be compared to the two durations before and after it. If the duration differs from any of these four by over ten percent, this will be considered irregular. Incoming temperature data will be a numerical value from the microcontroller. Breathing data will be received when the user has started and stopped both inhaling and exhaling. Breaths per minute will be calculated by measuring the duration of the current and previous breath in seconds, inverting, and multiplying by 60.

The software will alert the user when the received data indicates that the user is in danger. A sound will be played, and a message will be displayed on the screen indicating what the problem is. For ECG signals, the alert will happen when heart rate is outside the allowable range specified in the ECG result analysis subsection (Section 3.2.4), or if an irregular beat is detected as described above. A temperature alert will occur when the temperature is outside the allowable range. A breathing alert will occur for a breathing reate below six breaths per minute (the lower-bound for sleeping) and above 30 breaths per minute (an indication of hyperventilation).

7 Test Plan

7.1 Shirt hardware test plan

7.1.1 Body temperature sensing test plan

We will first calibrate the temperature sensing circuitry at approximately 37°C by pressing the AD592CN IC temperature transducer under the armpit so that the axillary temperature of the person can be measured. We will also use an off-the-shelf axillary body thermometer to measure the person's axillary temperature by pressing the thermometer under the armpit in the same region as the AD592CN IC. We will then calibrate the temperature sensing circuitry by adjusting the trimpot until the measured temperature value from the circuitry matches the conventional axillary body thermometer.

Once this procedure is completed, we will repeat this process again on the same person, and then on other persons to ensure that the results given by the temperature sensing circuitry consistently match or are similar to the results measured by the conventional axillary body thermometer.

7.1.2 ECG test plan

In order to test the ECG we will need to determine whether the average heart rate as determined from the ECG output is within, at most, 5% of the actual heart rate as measured from the person's pulse.

In order to determine if our ECG output meets this requirement, we will low pass filter the output of the ECG and then display the result on an oscilloscope. From this output, we will determine the average frequency of QRS peaks in terms of beats per minute by analyzing the ECG output over 5 to 10 second periods. Concurrently, we will determine the heart rate by counting the number of heartbeats by palpating the person's pulse on the wrist. We will then repeat this entire process several times on different persons in order to ensure that the ECG output closely and consistently matches the pulse-determined heart rate.

7.1.3 Ventilatory (breathing) rate sensing test plan

We will test our ventilatory rate sensing system by putting the apparatus/shirt onto the test subject and then observing the measured ventilatory rate value (in breaths per minute) from the base station. We will also have the test subject mentally count the number of breaths they have taken, and another observer will visually observe and count the number of breaths taken by the test subject. These three ventilatory rate values will then be compared to see if they are similar and consistent. This test will be repeated once again, and the whole test, including the repetition, will be performed for cases where the test subject is either breathing normally, breathing very slowly, hyperventilating, or not breathing at all (i.e. the test subject is not wearing the shirt).

7.2 Base station hardware test plan

In order to test the base station's RS-232 serial communication link with the PC we will setup up the microcontroller to send a known series of packets that adhere to the standard that we have outlined. The PC will know the expected set of packets and will compare the received packet with the expected packet for constancy and reliability.

7.3 RF transmission and receiving test plan

To test the performance of the RF transmitter and receiver pair, a test data signal that is known to both the transmitter and receiver microcontrollers will be transmitted. Both maximum line of sight indoor range and maximum through-wall indoor range will be tested, while maintaining at least 99.9% data packet integrity. Testes will be repeated using multiple transmitter power so that our functional specification of 100 feet line of sight is met with minimum practical power consumption.

7.4 Software analysis and monitoring test plan

The software will be tested by sending known heart rate, breathing rate, and temperature values from the microcontroller and verifying that these values show up correctly on both the charts and the numerical displays. This will ensure that serial communications are working correctly, and that the vital sign displays are functioning.

Next, we will test the three alert conditions. A temperature both above and below the threshold will be given, and the alert sound and message should occur. A slow, fast, and irregular heart rate will be generated via software, which should also produce an alert. Finally, a dangerous breathing rate will be generated, and the appropriate alert should occur.

8 Conclusion

The design 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 practical. The design requirements specified for the final product clearly state the expected technical parameters and performance characteristics expected of the PMEDS that we intend to implement. We believe that with these design specifications, our project will be practical and feasible, while providing an effective proof of concept mock-up that will clearly demonstrate the capabilities of the PMEDS.

9 References

Hugo Villeneuve, RS232 Specifications,
http://eintr.net/serial/electrical_spec.html

Stephen Seiler, Understanding Heart Rate and Exercise,
http://home.hia.no/~stephens/hrchngs.htm

Maxim Integrated Products, Homepage,
http://www.maximic.com

Microchip, Homepage,
http://www.microchip.com

Linx Technologies, Homepage,
www.linxtechnologies.com

Texas Instruments, Op-amp datasheet,
http://focus.ti.com/lit/ds/symlink/tl072.pdf

Bristol-Meyers Squibb Company, The Electrocardiogram,
http://www.cardioliving.com/consumer/Heart/Electrocardiogram.shtm

British Heart Foundation, Heart rate Monitoring,
http://www.bhf.org.uk/questions/index.asp?secondlevel=370&thirdlevel=707

Jason Nguyen, Homemade Electrocardiograph,
http://www.eng.utah.edu/~jnguyen/ecg/ecg_index.html

Linx Technologies, Evaluation Board Specifications,
http://www.linxtechnologies.com/ldocs/pdfs/es-beval.pdf

Linx Technologies, Receiver Specifications,
http://www.linxtechnologies.com/ldocs/pdfs/esrxman.pdf

Linx Technologies, Transmitter Specifications,
http://www.linxtechnologies.com/ldocs/pdfs/estxman.pdf