Alternative Design #3

Accessible Home Vital Signs Monitor

Team #3

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Project For

RERC National Design Competition

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Table of Contents

1. Introduction.	3-5
1.2. Subunits	
1.2.1 Thermometer	
1.2.2 Pulse Oximeter.	
1.2.3 Non Invasive Blood Pressure.	
1.2.4 Respiratory Rate	
1.2.5 Weight.	
1.2.6 Microprocessor.	
1.2.7 LCD Screens.	
1.2.8 Speech Output.	
1.2.9 Alarm	
1.2.10 Secure E-mail System	
1.2.11 Power Supply	
1.2.12 Bluetooth	
1.2.13 Pushbuttons	
1.2.14 Casing	26
2. Realistic Constraints	26-28
3. Safety Issues.	29-30
4. Impact of Engineering Solutions.	30-32
5. Life-Long Learning.	32-33
6. References	33-34
Figures and Tables	
1. Illustration of Vital Signs Monitor	4
2. Flowchart of Vital Signs Monitor Operation	5
3. Oral Temperature Probe.	
4. Thermometer Linearizing Circuit.	
5. Thermometer Circuit.	
6. Pulse Oximeter Circuit Block Diagram	
7. Pulse Oximeter Finger Probe.	
8. Circuit for Constant Current LED Driver.	
9. Timing Circuit.	10
10. Circuit to Pulse the LEDs.	
11. Current to Voltage Photodiode Conversion Circuit	
12. Sample-and-hold Circuit.	
13. Pulse Oximeter Circuit Diagram.	
14. Pulsatile Signals Found in the Intensity of Detected Light	14

15. Blood Pressure Cuff	15
16. Blood Pressure Waveform.	15
17. Block Diagram of Blood Pressure System	16
18. Thermocouple Nose Clip.	
19. Digital Scale	
20. Blackfin Image	19
21. EZ–Kit Lite Evaluation Board	20
22. JTAG Emulation	20
23. LCD Screen.	21
24. SpeakJet IC	22
25. Pin Diagram of TTS256.	22
26. Small Speaker for Audio Output	23
27. Alarm Light	
28. Rechargeable Battery	
29. EmbeddedBlue eb100-SER OEM Bluetooth Serial Module	25
30. Bruising Caused by One Use of an Automatic Blood Pressure Cuff	28
31. Table of Current Home Heath Care Patients with Aides and Devices in 2000	
32. Table of Home Care Cost Savings.	31
Table 1. Disable Cresifications	1.0
Table 1: Blackfin Specifications.	19

1. Introduction

Due to the increasing number of chronic illnesses, along with the shortage of nurses, home monitoring is becoming more and more of a necessity. Patients that require frequent healthcare monitoring can now have this done in the comfort of their own home. An important tool for home health monitoring is the vital signs monitor. Our accessible home vital signs monitoring system will have the capability to non-invasively gather a patient's heart rate, blood pressure, blood oxygen level, body temperature, weight, and respiratory rate, and then send this data to their corresponding healthcare provider. To send this data, we will create a password protected encrypted website to which patients can upload their vital signs. This accessible home vital signs monitoring system design is an accurate and consistent way to obtain a patient's vital signs, regardless of the caregiver's skill level. To accommodate all users, including our clients, the monitoring system was designed as simple and user friendly as possible.

To maximize the simplicity of our design and make it accessible to all of our clients, the buttons on the front panel of the monitor will be large and printed with either Braille or a universal symbol, allowing patients who are vision-impaired or have arthritis to successfully operate the monitor. Also to accommodate vision-impaired clients, a text-to-speech function will be implemented to allow the monitor to audibly tell the patients what their current vital signs are. In addition, four bright LCD screens with wide viewing angles will be used to display the patients' vital signs. A visual and audio alarm will be installed to alert clients if their vital signs are abnormal. An illustration of our design followed by a flowchart of our system operation can be seen in Figs. 1 and 2.

In our last two designs, we purchased a pulse oximeter probe to incorporate into our vital signs monitor. To save money, this report includes a design for a pulse oximeter probe that we will build. The respiratory belt used in the last design to measure respiratory rate has been replaced by a thermocouple, a more cost effective but just as accurate solution. Bluetooth wireless communication has been used in this design to transmit collected vital signs from the monitor to the client's computer. This removes the USB flashdrive and the need to physically transport vital signs data to the computer which was part of previous designs. We also explored an effective way to enclose the inner circuitry of our design. An AutoCadTM drawing of our casing will be sent to Toolless Plastic Solutions, who will take that file and manufacture a plastic casing. Buttons will be customized to increase accessibility and ordered through Grayhill Co. Finally, in this design we have included a method to transmit the vital signs data to the healthcare professional through a secure e-mail system rather than a website.

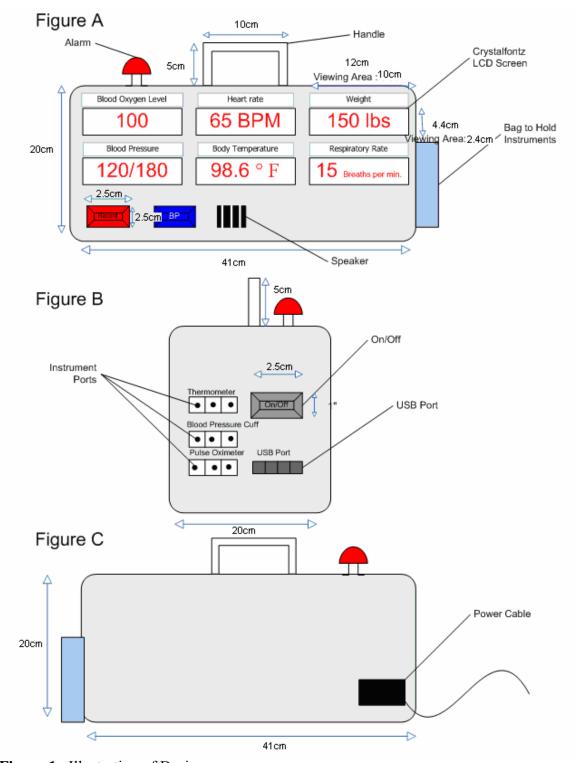


Figure 1. Illustration of Design

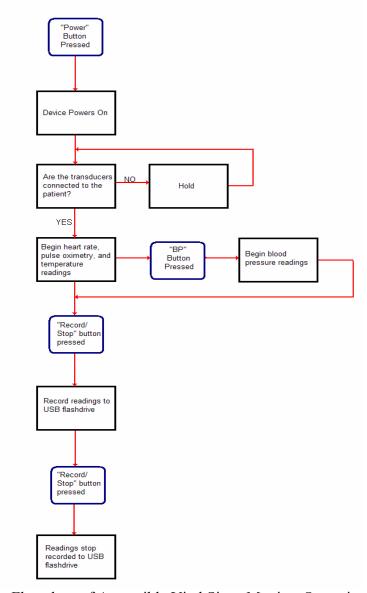


Figure 2. Flowchart of Accessible Vital Signs Monitor Operation

In the following section we discuss the subunits of our accessible home vital signs monitoring system. This includes information on our apparatus for collecting vital signs, how will we process this data, how we will transmit it to a computer, and the method in which we will communicate with healthcare providers.

1.2 Subunits

1.2.1 Thermometer

To measure body temperature, a thermistor circuit will be used. The thermistor will be in the form of a commercially purchased, oral temperature probe. The probe we have chosen for this is the Welch-Allyn # 02893-000 Sure Temp 690 Oral Probe from DREMed.com for a cost of \$74.00, before shipping and tax (Fig. 3):



http://www.dremed.com/catalog/product_info.php/products_id/1214 **Figure 3.** Welch-Allyn Sure Temp 690 Oral Temperature Probe

The thermistor within the probe will convert changes in temperature to changes in voltage. Unfortunately, thermistors are inherently non-linear. The Steinhart-Hart equation describes the resistance-temperature curve of a thermistor [16]:

$$\frac{1}{T} = a + b\ln(R) + c\ln^3(R)$$

where T is the temperature in kelvins, R is the resistance in ohms, and a, b, and c are constants called the Steinhart-Hart parameters which will be provided by the thermistor manufacturer. This output can be linearized through the use of a Wheatstone bridge (Fig. 4).

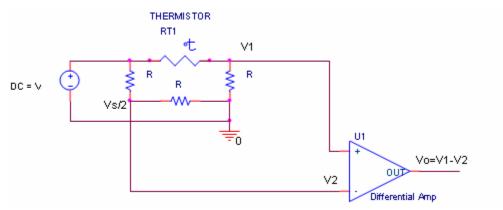


Figure 4. Thermistor Linearizing Circuit [10]

Thus, the resistance of the thermistor, RT1, can be modeled by the first order equation [10]:

$$R(T_1) \cong R[1 + \alpha \Delta T],$$

where R is the resistance of the other resistance in the Wheatstone bridge, α is the temperature coefficient, and ΔT is the change in temperature from the reference temperature (ΔT =T-T_o) in degrees Kelvin. The reference temperature (T_o) of the thermistor is given by the manufacturer and for medical thermistors it is usually around 300°K. The temperature coefficient, α , can be calculated from the following equation:

$$\alpha = \frac{\frac{d(R(T_1))}{dT}}{R(T_1)} = -\frac{\beta}{T^2},$$

where β is a temperature constant, typically around 4000°K [9]. The value of the resistors, R, used to linearize the thermistor will be determined from the reference temperature and other values given by the manufacturer (β or α) using the above equations. For our use as an oral temperature probe, the thermistor needs to be linearized (calibrated) around 98.6° F (37°C), for a temperature range of at least 90-104° F (32-40°C). When linearizing the thermistor, we must be careful to keep the accuracy of the thermometer high (\pm .1°C) so as to be able to take appropriate measurements.

After being linearized, the signal will be sent to a low-pass filter to remove any noise. The cutoff frequency for the filter should be less than 40Hz to remove any noise from room lights and other sources $(f_c = \frac{1}{2\pi R_c})$ [8]. Possible values for R2 and C are

 1820Ω and $2.2\mu F$. The signal will be sent to a non-inverting amplifier to be amplified and then passed to the microprocessor where it will be analyzed and sent to an LCD screen to be displayed (Fig. 5).

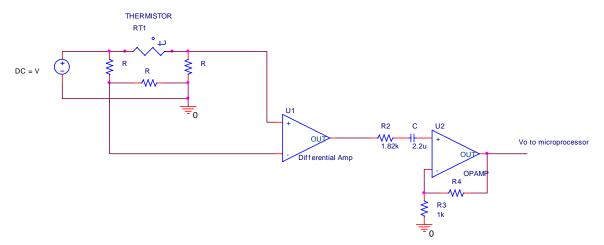


Figure 5. Thermometer Circuit

Values for R3 and R4 will be determined from gain equation for non-inverting amplifiers:

$$\frac{V_{out}}{V_{in}} = 1 + \frac{R_f}{R_{in}}.$$

The target gain for the amplifier will be based on the input current for the microprocessor.

The thermometer will be tested by placing the probe in a beaker of water heated to a certain temperature and comparing the resulting temperature given by the thermometer to the actual temperature of the water. This will be done over a range of temperatures to determine the thermometer's actual operating range and to assure that is within the appropriate range to measure body temperature. We feel an appropriate temperature range to test this would be from 10°C to 80°C. It will be made sure not to test with a temperature so hot that it burns the thermometer. Final testing will be done by taking group members' temperature with the thermometer and comparing the reading with that taken by a commercial digital thermometer.

1.2.2 Pulse Oximeter

To measure blood oxygen saturation, a pulse oximeter will be used. Pulse oximetry uses the optical properties of blood to determine oxygen saturation. Blood oxygen saturation (SpO₂) is defined as the ratio of oxyhemoglobin (HbO₂) to the total concentration of hemoglobin in the blood (Hb + HbO₂):

$$SpO_2 = \frac{[HbO_2]}{[Hb + HbO_2]}.$$

This can be determined by measuring the difference in the light absorption spectra of oxyhemoglobin and deoxyhemoglobin [15]. Assuming that the transmission of light through the arterial bed in the finger is only influenced by the concentrations of Hb and HbO₂ and their absorption coefficients at two measurement wavelengths (red and near infrared), then the light intensity will follow the Beer-Lambert Law. Thus, for an artery of length l, through which light of intensity I_{in} passes:

$$I_1 = I_{in1} 10^{-(\alpha_{o1}C_o + \alpha_{r1}C_r)l}$$
 at wavelength λ_1 , and $I_2 = I_{in2} 10^{-(\alpha_{o2}C_o + \alpha_{r2}C_r)l}$ at wavelength λ_2 ,

where I_1 and I_2 are the intensities of the light passing through the artery at each wavelength, C_0 is the concentration of HbO₂, C_r is the concentration of Hb, α_{on} is the absorption coefficient of HbO2 at wavelength $\lambda_{n,\cdot}$, and α_{rn} is the absorption coefficient of Hb at wavelength $\lambda_{n,\cdot}$. Therefore, if

$$R = \frac{\log \left(\frac{I_1}{I_{in1}}\right)}{\log \left(\frac{I_2}{I_{in2}}\right)},$$

then blood oxygen saturation can be calculated from

$$SpO_{2} = \frac{C_{o}}{C_{o} + C_{r}} = \frac{\alpha_{r2}R - \alpha_{r1}}{(\alpha_{r2} - \alpha_{o2})R - (\alpha_{r1} - \alpha_{01})}.$$

Circuit Design

The block diagram of the pulse oximeter below shows an overview of the circuits that are involved and will be included in the vital signs monitoring device (Fig. 6).

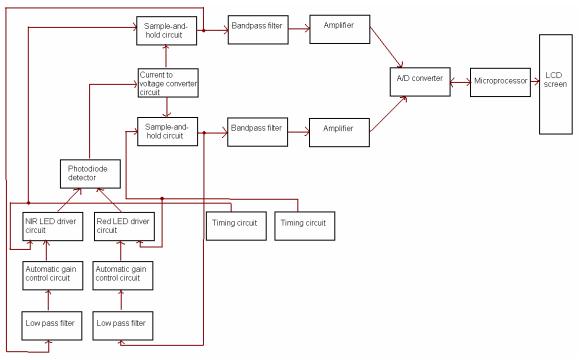


Figure 6. Pulse Oximeter Circuit Block Diagram

To build the finger probe that we will use with our device, we will need a red LED, a NIR LED, and a photodiode. The LEDs will be placed opposite the photodiode within a casing that can be clipped to a finger (Fig. 7).

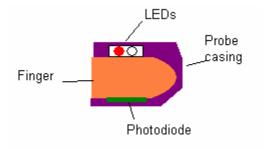


Figure 7. Finger Probe Diagram

One LED will work at a red wavelength (660nm) and the other at a near-infrared (NIR) wavelength (910nm). Also, in the probe is a photodetector that will detect the light transmitted through the finger. The red LED used in the probe will have been manufactured to give high intensity output, and the NIR LED will have been designed to be pulsed, so that its peak power can be increased without increasing its average power. By pulsing both light sources, only one photodiode is needed to detect the light transmitted through the finger [15].

To transmit light, the LEDs need to be driven by a constant current source. This can be done by a non-inverting op amp combined with a FET (Fig. 8). In this circuit, the current driving the LED is given by $I_{LED}=(V_{in}-1.5V)/R$, because LEDs usually need 1.5V to turn on.

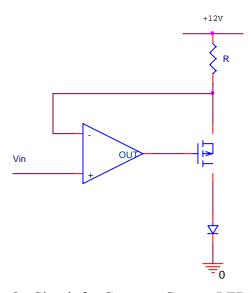


Figure 8. Circuit for Constant Current LED Driver

To control the pulsing of the LEDs, timing circuits need to be used. For this, we will use 555 timer circuits (Fig. 9). The 555 timers will supply 50µs pulses to the LEDs at a rate of 1 kHz. This is well above the maximum frequency in the arterial pulse, which is never more than a few Hz.

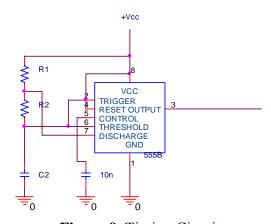


Figure 9. Timing Circuit

The values of the resistors can be determined from

$$T_1 = .7(R_1 + R_2)C_2$$
 and $T_2 = .7R_2C_2$

where T_1 is the pulse length (50µs) and T_2 is the rate (1kHz or 1ms). Thus, values for R1, R2, and C2 are $56k\Omega$, $3.3k\Omega$, and 22nF respectively. The 10nF capacitor connected to the control will be used to eliminate any electrical noise from the timer.

Finally, an n-channel enhancement-mode MOSFET connected across the each LED is used to pulse the output from them (Fig. 10).

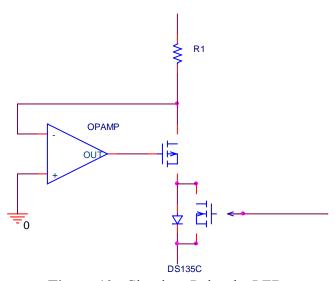


Figure 10. Circuit to Pulse the LEDs

In the receiving end of the circuit is the photodetector. The photodetector used in pulse oximetry probes is a photodiode. The photodiode detects the light transmitted through the finger as current [15]. To amplify the signal, the photocurrent must be converted into a voltage with moderate output impedance. This can be done by using an op-amp configured for current-to-voltage conversion (Fig. 11). The photodiode provides a high junction resistance, so the op amp should be a FET type with high input impedance [15]. The negative input of the op amp acts as a virtual ground, making the output of the op amp $v_o = IR$. Thus, it is common practice to make the value of R as high as tens of M Ω with the value of C as 47pF [15].

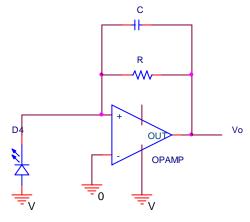


Figure 11. Current to Voltage Photodiode Conversion Circuit

Because the LED light is pulsed, sample-and-hold circuits are needed to reconstitute the waveforms at each of the two wavelengths. The timing circuits that were used to control the red and NIR LED drivers also are used to provide the control pulses for their corresponding sample-and-hold circuits [15]. A simple sample-and-hold circuit can be created from a FET switch, capacitor, and op amp (Fig. 12).

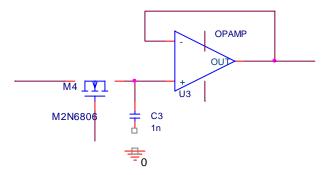


Figure 12. Sample-and-hold Circuit

Once the signal goes through the sample-and-hold circuit, it is sent through a band pass filter with cutoff frequencies .5Hz and 5Hz to eliminate high frequency noise and the d.c. offset. Then, it is amplified (resistor values to be determined) and sent through an A/D converter and the microprocessor to be analyzed. A lookup table stored in the microprocessor will be used to calculate SpO_2 values. This signal is also sent through a low pass filter ($f_c = .1Hz$) to extract the d.c. value of the transmitted signal, which is then sent to an automatic gain control circuit. The gain control circuit adjusts the light intensity from the LEDs so that the d.c. level always remains at the same value, whatever the thickness of the patient's skin, tissue, etc. This circuit is implemented by feeding the d.c. signal to one input of a differential amplifier. The other input to the amplifier is a constant reference voltage. The output of the differential amplifier, the voltage difference between the two inputs, is used to generate the voltage that sets the value of the LED currents [15]. The complete schematic (Fig. 13) of the pulse oximeter shows how each of the different circuits previously described will be integrated into a whole.

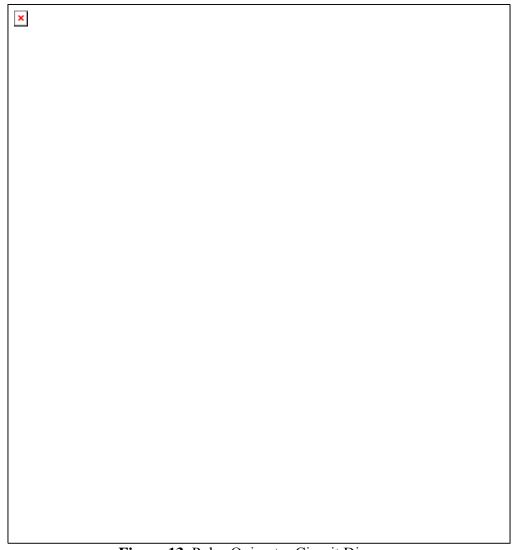


Figure 13. Pulse Oximeter Circuit Diagram

Calibration of the pulse oximeter will be done through the lookup table stored on the microprocessor. Due to the scattering effects of blood, Beer's Law does not apply for a pulse oximetry system [18]. Therefore, the blood oxygen saturation equations explained previously are good for theory but not for practice. As such, pulse oximeters are usually calibrated by comparing the oximeter R value (SpO₂ ratio) to the oxygen saturation ratio obtained from *in vivo* samples using human test subjects. Manufacturers of pulse oximeters do this and determine calibration curves or lookup tables for their devices. The pulse oximeter will be calibrated tested through a pulse oximeter simulator, a device designed to test the accuracy of pulse oximeters. We plan to find a simulator to use at a local hospital or the UConn Health Center.

Heart Rate

Pulse oximetry will also be used to determine heart rate. There are pulsatile signals detected in the intensity of the detected light by the photodiode (Fig. 14).

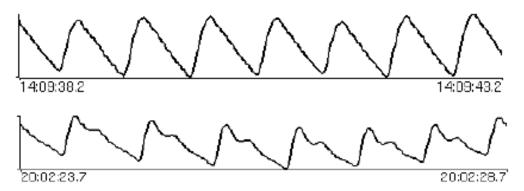


Figure 14. Pulsatile Signals Found in the Intensity of Detected Light [15].

One pulse is one cardiac cycle. The microprocessor will count the pulses to determine heart rate (beats per minute), which will be displayed on an LCD screen.

The microprocessor will be programmed (calibrated) to count the peaks of the signal for 10 seconds. Multiplying this by 6 will give the heart rate in beats per minute. This function will be tested by comparing the heart rate given by the pulse oximeter to that of a group member taken manually.

1.2.3 Non Invasive Blood Pressure

Blood pressure will be automatically measured through the oscillometric method [14]. This is done by wrapping a blood pressure cuff around the upper arm and inflating it until the pressure around the arm due to the cuff collapses (or occludes) the brachial artery. The cuff is then slowly deflated. As the cuff deflates, blood starts pumping through the brachial artery causing minute vibrations of .5 to 1 mmHg in the cuff [3]. The pressure at which these vibrations start is the systolic pressure, and the pressure at which they stop is the diastolic pressure [4]. The block diagram in Fig. 17 illustrates how this method will be used to measure blood pressure in the accessible vital signs monitoring system. Each system in the flow chart is described in more detail in the following paragraphs.

When the blood pressure "Start" button on the vital signs monitor is pressed, the blood pressure cuff will be inflated to about 40mmHg above normal (160mmHg). The blood pressure cuff used will be a DRE Adult single lumen cuff from DREMed.com at a cost of \$37.00, before shipping and tax (Fig. 15).



 $http://www.dremed.com/catalog/\ product_info.php/cPath/56_121_241_242/products_id/194$

Figure 15. DRE Adult Single Lumen Blood Pressure Cuff

The cuff will be inflated by a Sensidyne AA Series Micro Air Pump. A microprocessor, second to the microprocessor controlling the rest of the device, will control the inflation of the cuff. The sensor used to sense cuff pressure will be the NPC-1210 low-pressure sensor from GE. Once the pressure sensor determines that the cuff has been inflated to 160mmHg, the cuff will deflate slowly at a rate of 2-3mmHg/sec. Deflation will occur through a release valve (brand to be determined).

As blood begins flowing through the brachial artery again, it will cause small pulsations that will be picked up by the pressure sensor in the cuff (Fig. 16). This waveform will be analyzed by the microprocessor to determine the systolic and diastolic pressures.

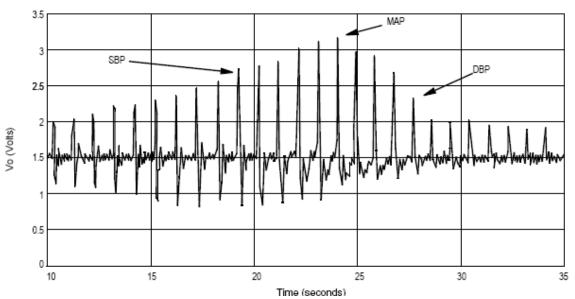


Figure 16. Blood Pressure Waveform Picked Up by Pressure Sensor[17]

Where: MAP = Maximum Arterial Pressure SBP = Systolic Blood Pressure

DBP = Diastolic Blood Pressure

A threshold voltage level will be set. This will be done by experimentally comparing blood pressure readings from a sphygmometer or other commercial device to those

detected by our pressure sensor. Once 4 pulsations peak above the threshold level, the voltage will be recorded and from that value the systolic pressure determined. The microprocessor will continue to monitor the blood pressure readings and diastolic pressure will be taken when the voltage drops below the threshold voltage for 2 pulsations. After the diastolic pressure is determined, a command from the microprocessor will deflate the cuff quickly and completely.

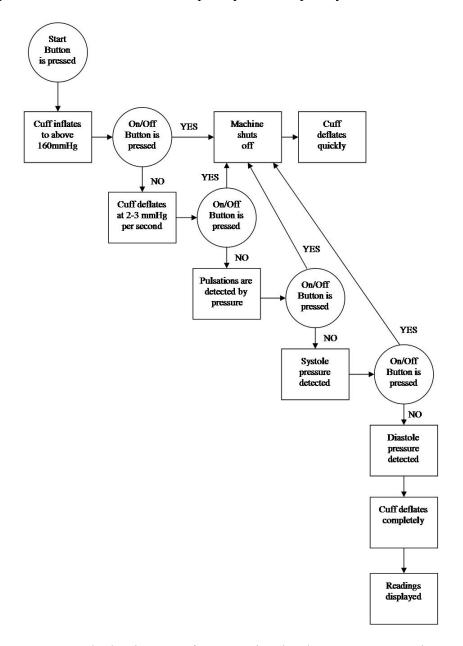


Figure 17. Block Diagram of Automatic Blood Pressure Measuring System

Due to the safety issues that arise with automatic blood pressure systems, we have incorporated a "kill switch" into our design (Fig 17) [17]. If at any time during the blood pressure measurement the user wants to stop the inflation of the cuff and rapidly deflate it, they just need to press the vital signs monitor "On/Off" button. This will cut power to

the whole device and open the pressure release valve. This method bypasses the microprocessor, avoiding any software bugs that an emergency stop button might encounter.

As stated previously, the automated blood pressure system will be calibrated experimentally. This will be done through establishing a threshold voltage by which correct pressure measurements for systolic and diastolic pressures can be made. Final testing of the device will be done by comparing its blood pressure readings to those of a sphygmometer. In the testing, the sphygmometer will be operated by a nurse or other individual who is familiar with manually measuring blood pressures and does so often. Nevertheless, we expect to see some slight differences in the measurements from our device and the sphygmometer because of the inherent degree of imprecision in manual blood pressure measurement. This is why it is important to have a professional operating the sphygmometer. Their experience with the device and the art of blood pressure measurement should reduce the likelihood of human error. Finally, the rapid cuff deflation will be tested by experimentation (turning the vital signs monitor off during use).

1.2.4 Respiratory Rate

Respiratory rate will be measured using a thermocouple. The thermocouple will be clipped to the client's nose and will measure the change in temperature caused by inspiration and expiration (Fig. 18). The thermocouple will convert the changes in temperature it detects to changes in voltage. Through experimentation, voltages thresholds will be set to define the changes in temperature that correspond to inspiration and expiration. By counting the number of inspiration and expiration pairs that occur in a given period of time, we can determine respiratory rate.



Figure 18. Image of Thermocouple Nose Clip

The circuit for the thermocouple will be powered by the battery. The voltage from the thermocouple will be linear over our range (approx. 65°F to 98°F), so the signal from the thermocouple only needs to be filtered and amplified (resister and capacitor values to be determined) before being A/D converted and processed by the microprocessor.

As mentioned previously, this circuit will be calibrated experimentally. Voltage output from the thermocouple will be measured for inspiration and expiration (most likely from being tested on group members). From these measurements voltage thresholds will be set for inspiration and expiration. Experiments will also be done to determine the optimum time period for measurement. Testing will be done by comparing the readings from our respiratory rate monitor to those taken by the Biopac respiratory belt from the Biopac software used in the ENGR 166 lab.

1.2.5 Weight

Weight is an important vital sign to monitor. In addition to ensuring proper eating habits, weight is used to determine medication doses. We will include weight monitoring into our vital signs monitor by buying a digital scale that exists on the market and connecting it to our device. The scale that will be used is the Homedics SC-200 Digital Scale (Fig. 19).



Figure 19. Homedics SC-200 Digital Scale

This scale was chosen because it fits quite well with our project. We figured with our clients we will have to build handles onto the scale so people will be able to hold on and not fall. The reason for this is that some of our clients are elderly and might not be able to stand steady on their own. Also since this scale already has a main waist high base, it should not be difficult to connect handles or rails. The scale was also chosen because it is very inexpensive at \$24.95 and it can be found at wholesalepoint.com. The scale has an on/off switch and requires only one 9V batters for power. As of now our main approach to connecting the scale to our device is a very simple and straight forward approach. We plan on taking apart the scale and breaking the connection between the circuit and its digital display. From here we just plan on simply connecting the scales circuit to one of our output displays instead.

The scale will already have been calibrated and tested by its manufacturer. We will do additional testing by comparing known weight values (dumbbells) to the values displayed by the scale when we place the weights on it

1.2.6 Microprocessor

The processor we are going to use for our design is the Blackfin ADSP-BF535P Digital Signal Processor by Analog Devices (Fig. 20). This processor is extremely versatile due to the fact that it can function as both a microcontroller and a DSP (Digital Signal Processor), allowing for either 100% DSP, 100% microcontroller, or a combination of the two [7]. This makes the Blackfin ideal for our design due to the fact that we are going to input and output the data like a microcontroller, but use the digital signal processing features to analyze and filter the signals (FIR and IIR filters). The Blackfin will function like the traditional microcontroller, taking the electric signals from

the transducer, passing them through an analog to digital converter, and processing the information. Like the PIC microcontrollers, the Blackfin contains an internal analog to digital converter. There are many advantages for us in using digital signal processing rather than traditional 100 % microcontroller functions. Microcontrollers can be cheap and easy to assemble, but are difficult to calibrate and modify. Using DSP, one can more easily design and modify their work due to the fact that it is all computer based. Thus, one can rely on their software based filters much more. DSPs are also much faster than microcontrollers. A typical PIC microcontroller has a clock speed of about 20 MHz, whereas the Blackfin has a clock speed of 350 MHz (Table 2). We will use the PF pins (I/O ports on microcontrollers) on the Blackfin to function as inputs for the transducers and outputs for the LCD screens and speaker. Due to the Blackfin's abilities, it should be the only microprocessor we need for our device.

We also chose to use the Blackfin due it its versatility in programming code. The Blackfin can take C/C++ code as well as LabVIEW VI's. Since we have had more experience using LabVIEW, we felt that LabVIEW would be a more suitable code to program the processor. When designing a product with Blackfin, many helpful tools are provided to the engineer to aide in the design, which has already been purchased by the Biomedical Engineering department. These include simulation software, an evaluation board, and an emulator. Before the processor is even programmed, VisualDSP++ software will be used to simulate the behavior of the DSP chip. Using this software we will be able to build, edit, and debug our DSP program before we even have the actual processor, which is done solely on the computer. After the simulation is complete, evaluation of the simulation is performed using the EZ-KIT Lite evaluation system to determine the specific Blackfin processor that fits our needs. This board (Fig. 21) connects up to the computer via a cable, allowing us to run our simulation program. After the evaluation process, the JTAG emulation board (Fig. 22) will be used to serially scan the I/O status of each pin on the device as well as control internal operations of the device. This hardware connects our PC to the actual process target board via a USB cable.

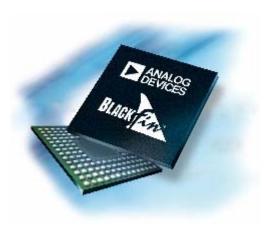


Figure 20. Blackfin Image

Table 1. Blackfin Specifications

Blackfin Specifications		
Clock Speed (MHz)	350MHz	
MMACS (MAX)	700	
RAM Memory (Kbytes)	308	
External Memory Bus	32bit	
Parallel Periph Interface	No	
PCI	Yes	
USB Device	Yes	
UARTs, Timers	Yes	
Watchdog Timer, RTC	Yes	
Core Voltage (V)	1.0-1.6	
Core Voltage Regulation	No	
Package	260 PBGA	



http://www.analog.com/images/Product_Descriptions/60475542243306341558700011339bf535_hardware.jpg

Figure 21. EZ-Kit Lite Evaluation Board



 $http://www.analog.com/images/Product_Descriptions/3050239190340284911841682443833402744562989117500 usb_emulator.jpg$

Figure 22. JTAG Emulation

1.2.7 LCD Screens:

The digital information from the output of the microcontroller will be sent to six character LCD screens (Fig. 23).



http://www.crystalfontz.com/products/1602l/CFAH1602L-YYH-JP_front_bl_on.jpg

Figure 23. LCD Screen

The CFAH1602L-GGH-JP LCD screens are ideal for our design due to its easy to read characters, ideal size, and wide viewing angles. It measures 122mm x 44mm, with a viewing area of 99mm x 24mm, and a character height of 8.06mm. These LCD screens were chosen due to the fact that many of the features meet the specific needs of our clients. Since the majority of our clients will be viewing the monitor from their bed, it is important that the screens should be viewable from a wide variety of angles. Since these screens have a wide viewing angle, patients will have no problem seeing their vital signs from their bed. Also, the yellow backlight makes this LCD screen easy to read, especially in dark or dim-lighted areas. Also, a viewing area of 99mm x 24mm makes the screens easy to read from a distance.

1.2.8 Speech Output

Our vital signs monitor will contain a text-to-speech function which will allow the monitor to say what the vital signs are once they have been recorded. This function will be useful for our client Mat, who is blind and cannot see the monitor. Even though his wife is around to help him, she is also vision-impaired. The output text from each pin on the microcontroller will need to be converted to sound. To do this, we will use the Magnevation SpeakJet IC (Fig. 24). It is an 18 pin IC which uses a mathematical sound algorithm to control an internal five channel sound synthesizer to produce sound. The SpeakJet can be controlled by a single I/O line from the Blackfin [12]. Since this microchip requires phonetics and not text, the TTS256 Text to Code IC will have to be used in conjunction with the SpeakJet. The TTS256 is an 8-bit microprocessor programmed with letter-to-sound rules. This built-in algorithm allows for the automatic real-time translation of English ASCII characters into allophone addresses compatible with the Magnevation SpeakJet Speech Synthesizer IC. This IC is Compatible with Basic Stamp, OOPic, Pic and any processor with a serial port, like our microchip [12]. We will use pin #5 (TX) to output the phonetics from the SpeakJet, and pin #18 (RX) to receive the data from the Blackfin (Fig. 25). The pin diagram of the TTS256 is shown below. The final sound will be sent from the Voice Output pin (#18) of the SpeakJet using +5V and a speaker. Since the SpeakJet is preconfigured with 72 speech elements, 43 sound effects, and 12 DTMF touch tones, we will also use the SpeakJet to produce an alarm when the vital signs are out of range (range to be determined). This chip will be tested

experimentally by providing to it a series of inputs to confirm that it is giving the correct outputs.



http://www.speechchips.com/images/SpeakJetIC.jpg **Figure 24.** SpeakJet IC

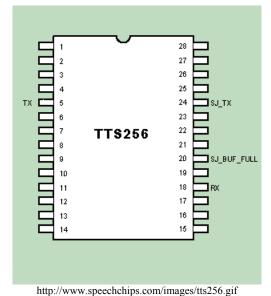


Figure 25. Pin Diagram of TTS256

To play these computer generated sounds, a speaker from Futurelec (Fig. 26) will be purchased and attached to the microcontroller. This speaker was chosen due to its small size and affordable price. This speaker will be used to play the data output from the

microprocessor, as well as sound an alarm when the patients' vital signs become irregular.



http://www.futurlec.com/Pictures/Sm Speaker.jpg

Figure 26. Small Speaker for Audio Output

Features

Small Size

Power rating: 0.5WImpedance: 8 ohm

• Dimensions: 50mm Diameter, 16mm High, 28mm base diameter

1.2.9 Alarm

To assist our clients, we will install an alarm system to alert them when their vital signs have become irregular or dangerous. On top of the monitor will sit a light that will flash when these signs become abnormal. A light we have chosen is shown below (Fig. 27). In addition, an alarm sound generated by the SpeakJet will also serve as an alert. The majority of the alarm design will be done by programming the microprocessor. We will have a set of defined limits for each vital sign, and if these signs fall out of range, a signal from the microcontroller will be sent to the SpeakJet and alarm light.



http://img.alibaba.com/photo/50538513/Alarm_Lights__Warning_Lights_.jpg

Figure 27. Alarm Light

1.2.10 Secure E-mail System

In the first couple designs the way we decided to send data was through a secure website that was password protected. After looking at a few different options we decided that another good idea to send data is through a secure e-mail system. By doing this it would send information directly to the host, making it very tough for someone to hack into it. We decided the best way to accomplish a secure e-mail system is through a website, http://www.certifiedmail.com. This website provides the software necessary to protect e-mail using transparent encryption. It provides easy to use software that the recipient of the e-mail does not need to download in order for complete security to occur. There are some advantages to having a secure e-mail system to send data this way. For starters there is no password required and information is automatically secured every time with the Certified Mail software. Also it is possible to send information from anyplace with an internet hookup. It is also made possible to track the e-mail to determine that the e-mail was received and who opened it. The Certified Mail software is also very easy to use and rather inexpensive. All it requires is a one time download and just clicking the send certified button every time after that. The whole Certified Mail System costs only \$10 per month.

1.2.11 Power Supply

When designing this project we found it rather important to include two different types of power. The device will mainly be run from an external power source by using a power cord. It will also be equipped with rechargeable backup batteries in case of a power failure (Fig. 28). For the power supply, we plan on using a very generic universal power cord which will plug into the back of our device and then also plug into the wall. This cord will only fit into the socket designated for it on the device to prevent any accidental power surge or electrocution. For the backup power supply we determined the best way would be to use nickel cadmium rechargeable batteries. Although lead acid batteries can sometimes produce more voltage, nickel cadmium batteries are safer and will recharge a lot quicker. The need for a backup battery is so the patient can take signs even if the power is gone. Also if power is lost that means the alarm will also be shut off causing the patient to possibly miss a time. This could be life threatening to some patients so we felt it was very important to include a backup supply.



Figure 28. Image of Rechargeable Battery

1.2.12 Bluetooth

To increase accessibility, we will transmit the data collected by the vital signs monitor to the client's computer wirelessly using Bluetooth. We will purchase the EmbeddedBlue eb100-SER OEM Bluetooth Serial Module from A7 Engineering for \$40 to integrate into our vital signs monitor to provide Bluetooth connectivity (Fig. 29).



Figure 29. EmbeddedBlue eb100-SER OEM Bluetooth Serial Module

This module contains all the components of the Bluetooth stack on the board so that no additional host processor code is needed. The interface between our host processor and the eb100-SER radio will be done through UART communication. When a connection is made to another Bluetooth device, the link will appear as a cabled serial connection which eliminates the need for any special wireless protocol knowledge. Assuming that our clients' computers are not Bluetooth ready, a USB Bluetooth dongle will be purchased (usually at \$10-\$20) to provide connectivity on the PC end. These USB dongles are easy to use and come with software to install on the PC to allow Bluetooth connectivity.

Bluetooth communicates data via low-power radio waves on the 2.4 GHz frequency. This is the ISM frequency band. It has been internationally agreed upon to be used only for industrial, scientific, and medical devices (ISM). Many devices make use of the ISM band, but Bluetooth has precautions in place to prevent interference with these other systems, making it and ideal technology for our use. One way in which Bluetooth prevents interference is by only sending out very weak signals (of about 1 milliwatt). This limits Bluetooth's range to about 10m (although advances in the technology have made it possible for transmission ranges up to 100m). This is an acceptable range considering that our device is meant only for home use. However, because of this, we do advise that users ensure they are within a 10 m radius of their computer when using their vital signs monitor. Another way in which Bluetooth limits interference is through frequency hopping. This also helps ensure the security of the data being transmitted. Bluetooth transmitters use 79 randomly chosen frequencies and "hop" between them 1,600 times per second.

Our Bluetooth communications system will be calibrated through UART communication with any extra equipment necessary provided by the BME 252 lab. It will be programmed to set up a network with the Bluetooth USB dongle when it detects it. The Bluetooth system will be tested by acquiring vitals signs from the monitor and sending them to a computer in the design lab to which the USB dongle is installed. The

vital signs monitor will be placed at different ranges within 10 meters to determine signal strength at different ranges and the optimum range for data transmission.

1.2.13 Pushbuttons

One important feature of our design is the buttons that involved. We need to have our buttons customizable so we can include a universal sign and Braille so they can be used by individuals with vision impairment. A company that offers customizable buttons is Grayhill. The model button from Grayhill that fits our project the best is a rectangular button that is about 15 by 20 millimeters. These buttons are very easy to secure by a short simple process. The buttons require a proper size whole to be drilled in the area where the buttons will be place. The buttons will then be snapped into the whole. Once the button is snapped into the whole it has wings which will then open causing the button to not be removed. The only visible problem with this product is that the button may be too small and also that we are not yet aware of the price. We are awaiting a price quote from the Gray Hill Company. It may tend to be a little pricey because we have the option to customize the details of the button. The main factors we tend to look at when determining what button option we will be using are the price and size of the buttons.

Our buttons are basically going to act like a switch either turning the power on or off. The start button will be connected to the beginning of the circuit. There will be a switch in the circuit that will either be open if the circuit is not working or closed if power is wanted to be given to the entire circuit. When the start button is pressed the switch on the circuit will close allowing for the power supply to be sent to and power the rest of the circuit. When the patient feels the process is complete they will be able to press the stop button which will allow for the circuit to open disallowing any power to get through to the circuit.

1.2.14 Casing

In order to safely enclose the internal circuitry of our design, a plastic enclosure needs to be manufactured. We will use the company Toolless Plastic Solutions to manufacture our casing. In order for this company to manufacture our case, we need to submit an AutoCadTM drawing of the final casing design. Since we will not know the exact size and placement of all 6 holes for the LCD screens, and the various I/O ports in the casing, the design will be submitted in the spring semester when all the parts have been ordered and more about the final design is known. Toolless Plastic Solutions requires no tooling or molds, and therefore will be a cost-effective way to obtain an enclosure for our design [6]. The company uses CNC (Computer Numerical Control) machining and fabrication process to build plastic casings. We will not know the exact price of the casing until a design is sent for a quote.

2. Realistic Constraints

The main source for medical instrumentation standards is the Association for the Advancement of Medical Instrumentation (AAMI). They provide for purchase the current standards of medical device design and use. These standards must be followed in

the design and production of our device to ensure that it is acceptable and safe for our clients and the health care community.

This device has been designed with the economic constraint of cost in mind. We have a maximum budget of \$2000 to build a working prototype of our device, so parts were chosen carefully. A balance had to be maintained between using parts that meet the needs of our design and not overspending our budget. It may be especially important to have room left in our budget next semester when we begin the actual construction of our device. We may need to order replacement parts or additional parts as we go and we cannot do that if we have no money left within our budget.

Our accessible home vital signs monitor is meant for use in the home, so varying environmental conditions are not a large concern of the device. However, being used in the home, there were a few things we needed to keep in mind as we made our design. Our device will be exposed to dust, sunlight, food, and water. Though it is not meant to withstand an onslaught of any of these things, it was designed to be relatively robust in these conditions. No parts were used that are very sensitive to movement or other household factors that could affect their use. The device will have a durable plastic casing has been designed to withstand the typical rigors of home electronic life (movement, animals, children, cleaning, spills, etc.). That being said, the device is not a toy, nor was it designed to be one, and the user should keep in mind the device's purpose when using it. There are little to no concerns over our device's effect on the environment. As it is a piece of home electronics, it has very little effect on the environment as a whole.

Offshoots of the environmental constraints laid on our device are the accessibility constraints that it needs to meet. Our device was designed to be properly accessible so that it will be of use to our clients and meet their needs. Audio and visual output, along with Braille and raised universal symbols were used to make the device user friendly to anyone with vision or hearing impairment. Also, the simple user interface of the device allows it to be used by individuals of all ages and technological savvy.

This leads into sustainability. Our device was designed with its ability for future and continued use in mind. Not only must the device be designed so that it can last and function properly for years, but it also needs to use up-to-date parts and technology so that it does not become outmoded. An example of this was the selection of the rechargeable battery for our device. In many vital signs monitors being used, rechargeable lead batteries power the device. However, lead materials are currently being phased out of medical devices so we chose to use a nickel cadmium rechargeable battery in our design. This is one step that was taken to ensure that our device will still be acceptable for use years from now.

Because this is a medical device and will have direct contact with our clients, client/patient safety was an important constraint in our design process. All circuits and power sources must be properly grounded to prevent accidental electrocution and safety measures had to be put in place to prevent an injury use of the device might cause. Since this is a medical monitoring device, one of its safety constraints is that it should be explosion proof. It should not spark or create flames to prevent explosion used in the presence of pure oxygen. Most components of our design are relatively benign (provided that basic electrical safety is followed), but a major point of health and safety constraint was the design and incorporation of the automatic blood pressure measuring device.

Self-inflating blood pressure cuffs can cause injury if not properly calibrated and used (Fig. 30).



Figure 30. Bruising Caused by One Use of an Automatic Blood Pressure Cuff [14].

Bruising can result if the cuff inflates too much. Pain and circulation cutoff can occur if the cuff does not deflate, and at the extreme this could lead to tissue death.

Our accessible vitals signs monitoring system has really no political constraints, but it does have social and privacy constraints. Part of our system includes the transmission of vitals signs of the internet to a health care provider. To protect patient privacy and abide by the Health Insurance Portability and Accountability Act (HIPAA), the transmission of vital signs will be done via a secure, password protected website. This will protect our clients' personal information while still giving them flexibility in the transmission of their vital signs to their physicians or HMOs. This is an important and valid constraint in our device design. The internet provides rapid transfer of information, but it is filled with predators and opportunists who like to access the private information of others. It is important for us to protect our clients when they are contacting their physicians so that their medical information does not end up all over the World Wide Web.

By paying heed to these constraints and working with them, not around them, our accessible home vital signs monitoring system has been designed with the best interests of our clients and society at heart. This ensures that we have designed an economically feasible device, affordable for our clients. Our device is appropriately designed for the environment which it will be used in, and with careful part selection it will sustain and continue to be appropriate for the home monitoring of vital signs.

3. Safety Issues

Safety plays a crucial role when designing a product, especially one that contains electrical components. Because our design will be comprised mainly of electrical components, we strive to effectively enclose the inner circuit of our final design with a durable, non-conductive, completely enclosed casing. The casing of our final design will show no wires, circuit boards, or any part of the inner circuitry. Loose wires will have the potential to not only cause the device to operate ineffectively, but could also be hazardous to the patient. Any moisture from the air, or water accidentally spilled near the device, could cause a spark and start a small fire. It is for this reason that it will be recommended that all liquids be kept off of and way from the monitor, regardless of how good the casing. Also, it is important for the casing to be made of a non-conductive material (such as plastic), so that if the "hot" side of the power system touches the side of a casing, there is no danger to the user of the monitor. The inner part of the monitor should be designed so that neither the "hot" or "neutral" part of the power cord touches the casing, but if the "hot" wire does accidentally touch the casing, then this could be dangerous. If the casing is conductive and the "hot" wire touches the side of the case, then the case will be made electrically common to the wire, and touching the case will be iust as hazardous as touching the wire bare.

In addition, it is always important for an electrical design to have a solid connection to earth ground. A power system with no secure connection to earth ground could pose a safety hazard. There is no way to guarantee how much or how little voltage will exist between any point in the circuit and earth ground. By grounding one side of the power system's voltage source, at least one point in the circuit can be assured to present no shock hazard. One way to ensure proper ground is to use a three prong plug. The third prong on the power cord provides a direct electrical connection from the appliance case to earth ground, making the two points electrically common with each other. If they're electrically common, then there cannot be any voltage dropped between them. Even if the "hot" wire accidentally touches the metal casing, it will create a direct shortcircuit back to the voltage source through the ground wire. The patients' skin plays an important resistive role in protecting the body from such hazards. But when the skin becomes wet or broken, this resistive value drops to 1% of its original value putting the patient in serious harm if the correct electrical safety precautions are not followed correctly [1]. A circuit that is not properly grounded will have the potential to cause microshock. Microshock is defined as the passing of high current from one body part to another, such as from arm to arm and therefore directly through the heart. Such high doses of current can cause difficulty breathing, and even ventricular fibrillation [1].

Choosing the correct gauge wire is also an important factor to consider. An electrical hazard exists when the wire is too small a gauge for the current it will carry. If a wire is too small for the current it is supposed to carry, the wire will heat up. The heated wire could have the potential to cause a fire inside the monitor. After selecting the correct wire gauge, it is important to make sure that all wires are properly insulated and cleanly soldered to its respective position on the circuit board. Frayed wires have the potential to interact with other wires causing the monitor to not work properly or cause a fire.

In addition to the electrical safety issues, it was also made sure that the operator of the monitor does no harm to the patient while taking measurements. Each instrument used to obtain measurements was carefully chosen to be as simple and safe as possible. Out of the four vital signs being obtained, the only one which needs skill to operate would be blood pressure. Using the blood pressure cuff incorrectly could not only cause the monitor to record the wrong vital signs, but also harm the patient. Squeezing the blood pressure cuff too tightly could injure the patient. To minimize this potential hazard, we will use an automatic blood pressure cuff, allowing the person who is taking the readings to have no prior skill. Since the people taking the vital sign readings are elderly or young, the automatic blood pressure cuff makes gathering data relatively simple. Even though the automatic blood pressure cuff is simple to use, it is still not completely foolproof.

4. Impact of Engineering Solutions

Much of the technology used in our design for an accessible home vital signs monitoring system is not new, but the manner in which it is being employed is valuable. There are few, if any, accessible vital sign monitors currently available. Patent and web searches have not devices on the market comparable in that regard to the device that we have designed. The design of an accessible vital signs monitor will improve the quality of life for those individuals with hearing and vision impairment who need to have their vital signs monitored. This device will allow those individuals the ability to go home to recuperate while still being effectively monitored by their health care provider. This is especially important in cases where home health care would be a treatment option for someone without visual or hearing impairments but not for someone with them.

Home health care is a growing industry. Approximately 7.6 million individuals receive home care in the United States. The Center for Disease Control reported that in the United States in 2000, 317,600 individuals in home care were using medical devices (Fig. 31).

Medical							
Total with medical devices	317,600	15,900	31,700	58,300	74,300	84,800	52,600
Blood glucose monitor	132,500		11,800	19,200	38,600	37,300	25,000
Enteral feeding	30,700			•	•	•	
Intravenous therapy	52,300		17,100				
Oxygen ⁶	114,600			18,200	25,700	43,400	19,900
Other respiratory therapy	45,300			*15,000			
Other aids	187,500	11,600	23,600	33,100	28,200	58,600	32,400

Figure does not meet standard of reliability or precision because the sample size is less than 30 if shown without an estimate. If shown with an estimate, the sample size is between 30 and 59, or the sample size is greater than 59 but has a relative standard error of 30 percent or more

Figure 31. Excerpt from Table of Number of Current Home Heath Care Patients with Aides and Devices in 2000 [11].

⁻ Quantity zero.

Age is the patient's age at the time of survey.

Numbers will not add to totals because a patient may be included in more than one category

³Total number of home health care patients.

Includes manual and motorized wheelchairs

Includes geri-chairs, lift chairs, and other specialized chairs.

Includes oxygen concentrator.

As such, it is important to have reliable technology to support home care. Home care can not only save patients and insurance companies money (Fig. 32), but living at home can provide patients a welcome and comfortable environment in which to recover and be monitored.

	Per-patient Per-month	Per-patient Per-month	Per-patient Per-month
Conditions	Hospital Costs	Home Care Costs	Dollar Savings
Low birth weight ¹	\$26,190	\$330	\$25,860
Ventilator-dependent adults ²	21,570	7,050	14,520
Oxygen-dependent children ³	12,090	5,250	6,840
Chemotherapy for children with cancer ⁴	68,870	55,950	13,920
Congestive heart failure among the elderly ⁵	1,758	1,605	153
Intravenous antibiotic			
therapy for cellulitis, Osteomyelitis, others ⁶	12,510	4,650	7,860
and Cheang, M.S. "Earlier Disch Randomized Trial." <i>Pediatrics</i> 9 ² Bach, J.R., Intinola, P., Alba, A Institutionalization vs. Rehabilita ³ Field, A.I., Rosenblatt, A., Polla Technology-dependent Children ⁴ Close, P., Burkey, E., Kazak, A Chemotherapy for Children with daily charges for chemotherapy multiplied by 30 days reflecting ⁵ Rich, M.W., Beckham, V., Witt Intervention to Prevent the Read <i>Journal of Medicine</i> 333, no. 18 ⁶ William, D.N., et al. "Safety, Et <i>Clinical Therapy</i> 15 (1993): 169 with Home Intravenous Cefotaxi <i>The American Journal of Medici</i> \$417 and the estimated savings/of per-patient per-month costs.)	2, no. 1 (1993): 128-134. S., and Holland, I.E. "The ation and In-home Managen ack, M.M., and Kaufman, J." American Journal of Dise. Danz, P., and Lange, B. ". Cancer." Pediatrics 95, no were \$2,329±\$627 in the hot the above per-patient per-m tenberg, C., Leven, C., Freedmission of Elderly Patients (1995): 1190-1195. Efficacy, and Cost Savings in 1-179, cited in Williams, D., time Treatment: Results with the 97, no. 2A (1994): 50-55	Ventilator-assisted Individual nent." Chest 101, no. 1 (1992) "Home Care Cost-Effective passes of Children 145 (1991) A Prospective Controlled Ev. 6 (1995): 896-900. (Note: Tospital and \$1,865±\$833 at hooth costs.) diland, K., and Carney, R.M. with Congestive Heart Failur an Outpatient Intravenous A "Reducing Costs and Hospita a Computerized Ambulators. (Note: The estimated hosp	l: Cost Analysis of 2): 26-30. ness for Respiratory : 729-733. aluation of Home The study found that the ome. These charges were "A Multidisciplinary re." The New England antibiotic Program." ral Stay for Pneumonia y Drug Delivery System." ital cost/day/patient is

Figure 32. Table of Home Care Cost Savings [2].

When patients choose (or have the option) to enter home care, they free up hospital beds for more acute cases, give doctors more time to work with sicker people, and many times patients they are happier at home than in the hospital. But patients can not be cared for at home unless they have the proper technology to do so. Our accessible vital signs monitoring device is a simple, easy-to-use method to monitor patients' health at home. It can be operated by patients, their families, and physicians, making it an ideal device for the home environment. Since vitals signs are saved on a USB flashdrive to be uploaded to a secure website, patients are not even stuck at home, but can take their rechargeable battery powered vital signs monitor with them if they need to monitor their vital signs. This offers flexibility and comfort to patients.

Economically, the design for our device will reduce some of the costs of healthcare. Vitals sign monitors (and many of these are not accessible) currently range in cost from \$2500 up to \$5000. Most of the monitors that measure the same four vitals

signs as our device (heart rate, blood oxygen saturation, blood pressure, and temperature) cost closer to \$5000. If a patient's health insurance will not cover this cost than it becomes a large out-of-pocket expense for them, or they may not be able to afford the device at all. This is detrimental to their health and recovery. By designing a monitor that's expected cost is \$700 (a third of the cost of the cheapest monitors currently available), we will be able to alleviate some of this financial stress and provide more comprehensive health care and monitoring to more people.

Globally, this design may translate into an affordable piece of medical equipment for undeveloped countries. With its two-button user interface, detachable transducers, and simple design, it may be useful in countries with a low level of technology. Our device is designed for home use, but in countries and areas with poor healthcare systems and little to no medical equipment, it would be useful in a hospital or emergency room. Because it is lightweight and has a rechargeable battery, and because vital signs are saved onto a USB flashdrive, our accessible vital signs monitoring system is an excellent option for remotely monitoring patients in areas where there are few trained medical personnel. A layperson (with no medical training) could use our device to visit a patient who does not have access to a hospital or doctor and record their vitals signs on a USB flashdrive. These measurements could then be uploaded to the secure website and accessed by doctors anywhere.

5. Life Long Learning

During the research of this design, we were introduced to new and challenging engineering applications. In updating our processing technique, we learned about the Blackfin and digital signal processing. Although we have already learned about FIR and IIR filters thus far in our engineering curriculum, we were now able to apply these concepts to a real life situation. Through researching digital signal processing we were able to compare it to traditional microcontroller design and see the differences. Digital signal processing is not only substantially faster, it also eliminates additional hardware associated with analog circuits. Although analog circuits are cheap and easy to assemble, software based DSPs provide flexibility in modification and maintenance. We learned to integrate microcontroller based data gathering with digital signal processing to achieve a cheaper, more efficient way of data analysis.

Also, the text-to-speech function in our design was a new and exciting function to learn about. Since none of us have ever worked with such a unique and advanced tool, it made the research enjoyable and informative. There are many devices out there used for speech synthesis, but we needed to find the one that would be compatible with the microcontroller we selected, as well as capable of converting the text output from the microcontroller to sound. Most algorithms associated with speech chips cannot convert English text straight to audio, which is why we integrated the TTS256 Text to Code microcontroller to convert text to phonetics, which is compatible with the SpeakJet.

Through designing the thermometer for the accessible vital signs monitor, we have learned about the Steinhart-Hart equation and the properties of thermistors. It is important to realize that thermistors behave nonlinearly and to understand what effects this has on designing a thermometer. In order to use the thermistor output, it must be linearized. This can be done over a small temperature range, but any readings outside the

temperature range will be increasingly inaccurate the farther away they are. This means that one should only use an oral thermometer to measure oral body temperature, not air temperature or a cold beverage.

We learned about the optical properties of blood and the Beer-Lambert law to design a pulse oximeter circuit. Also from the pulse oximeter, we saw the application of transistors to switching and timing. Research into an automated blood pressure measurement system highlighted the importance of control systems in medical devices. Even for something as seemingly benign as an automatic blood pressure cuff system, safety precautions have to be taken to ensure that a patient is not harmed through the use of the device. This design also required us to learn about pressure sensors, pressure release valves, and air pumps. Blood pressure waveforms were studied, and the oscillometric method for blood pressure measurement was introduced to us.

In addition to learning new technical engineering applications, senior design has also taught us to work and function as a group. By working as group, we learned to interact and communicate with each other to assess and resolve problems, as well as rely on each other to make deadlines. Since communication is an essential element of being an engineer, working on these skills before we graduate will give us an edge over the majority of graduating engineers. Whether we will be working with an engineering design team, a team of healthcare professionals, or in a corporate environment when we graduate, we will need to use these group skills we are currently developing to drive a successful career.

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