Alternative Design #2

Accessible Home Vital Signs Monitor

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Project For
RERC National Design Competition

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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.

Our three clients that are in need of an accessible home vital signs monitoring system are Mat, Sani, and Dolores. Mat is a blind 52-year-old male who just had a small stroke and lives with his vision-impaired wife, who loves the internet. Sani is a 31-year-old female who recently experienced a head injury from an automobile accident. This accident left the right side of her body paralyzed (her dominant side). Her doctor monitors her vital signs by a computer system that is installed in her home, but she does not want to appear sick to her family and friends. She would like a vital signs monitoring device that blends in with the other furniture in her home. Our last client is Dolores. She is an 86-year-old female who lives with her son, his wife, and their son. Dolores is deaf and has severe arthritis. She also has heart problems that cause her to receive infusions at home. These infusions are normally administered by one of her family members. Dolores' grandson Tyler is 11 years old, and he likes all kinds of electrical gadgets. He loves to help his grandmother collect her vital signs and send them to her doctors on the computer.

To maximize the simplicity of our design and make it accessible to 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.

To collect the data, medical transducers will be commercially purchased and integrated into the accessible vital signs monitoring system. The items to be purchased are a finger pulse oximeter probe, an oral temperature probe, and an automatic blood pressure cuff. On the next page is an illustration of our design (Fig. 1) followed by a flowchart of our system operation (Fig. 2).

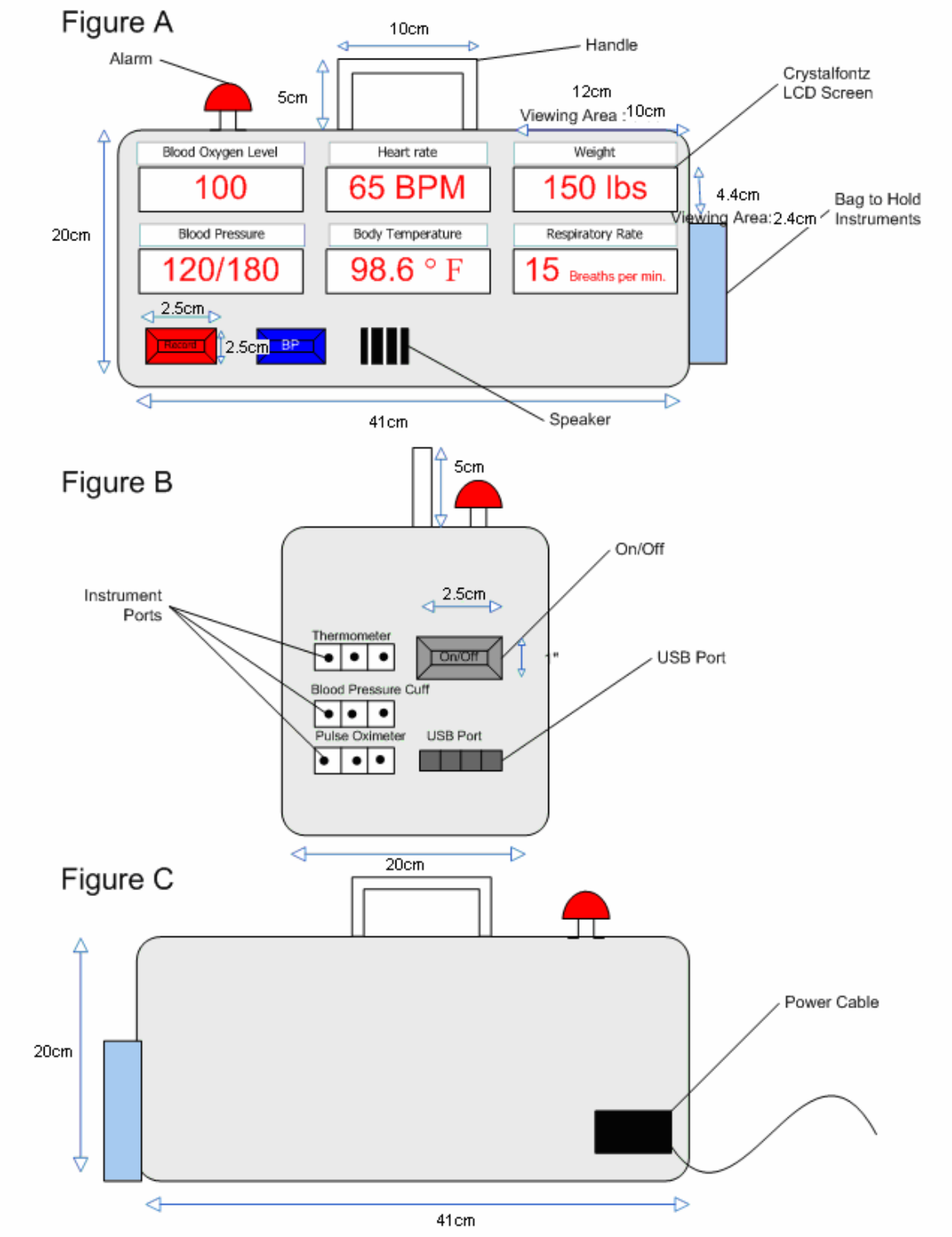


Figure 1: Illustration of Design

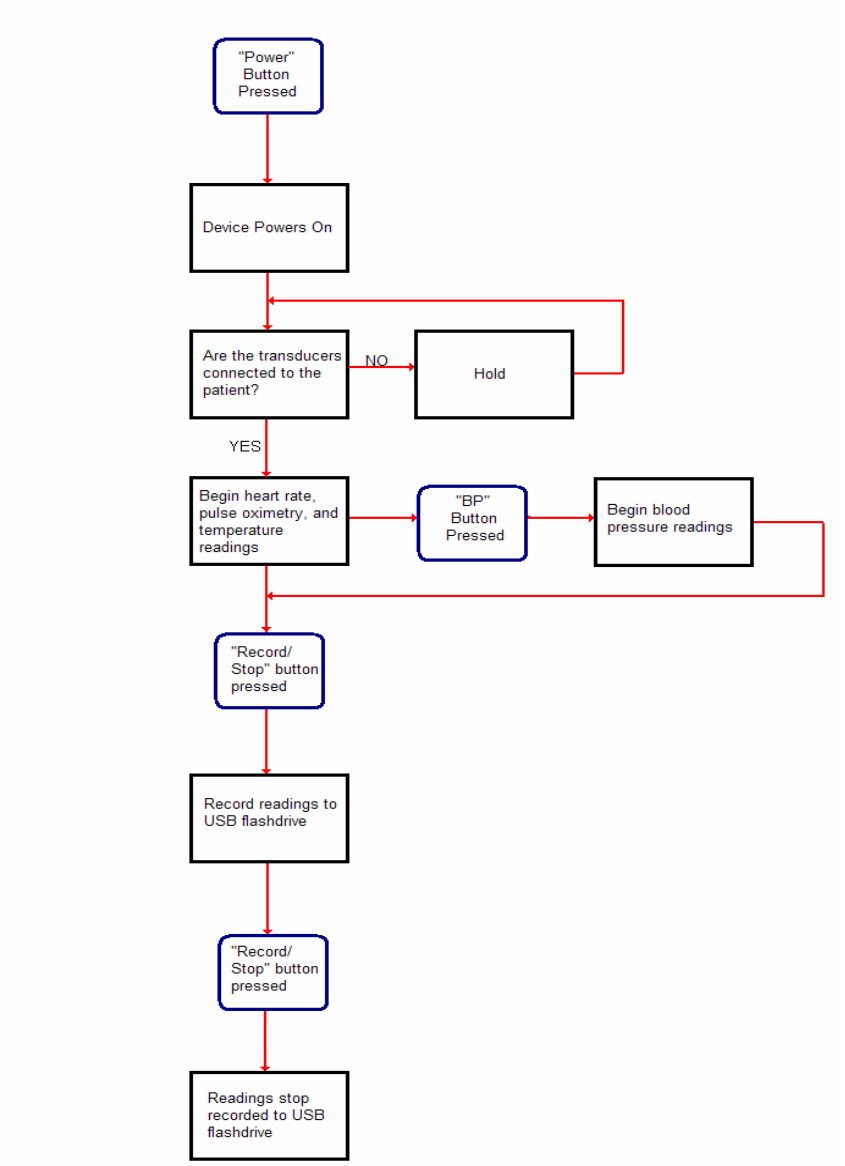


Figure 2: Flowchart of accessible vital signs monitor operation

The following design differs from the first design in a few important ways. First, this new design is for a vital signs monitor that will measure 6 different vital signs. Our last design only measured 4 vital signs (heart rate, blood oxygen saturation, blood pressure, and temperature), but this design adds the equipment to measure two more vital signs, weight and respiratory rate. The thermometer linearizing circuit has been changed from a resistor to a Wheatstone bridge, which is more common in medical instrumentation and reduces heat created by the circuit itself. Instead of purchasing an automated noninvasive blood pressure monitor and incorporating it into our device, this report includes a design for an automated blood pressure system that will be part of the system itself. Finally, in this design we are using a Blackfin microprocessor instead of a PIC 16F877. The Blackfin was chosen for its superior processing capabilities and its ability to be programmed through LabVIEW™.

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. This output can be linearized through the use of a Wheatstone bridge (Fig. 4).

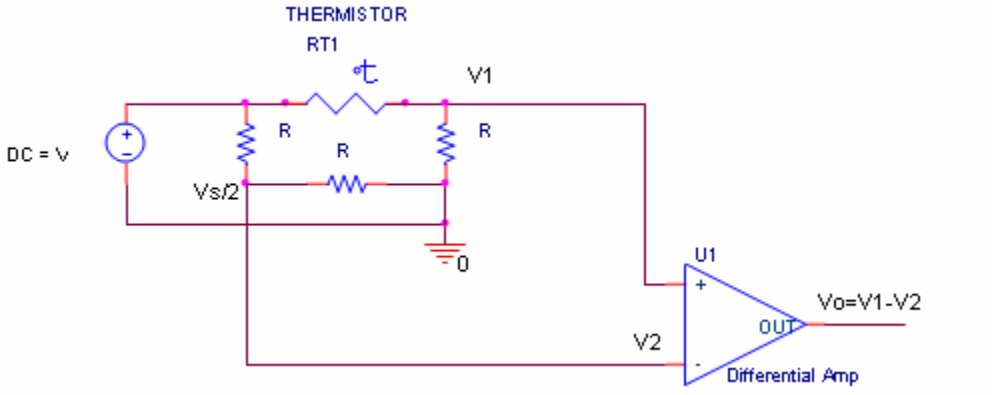


Figure 4. Thermistor Linearizing Circuit

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

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

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 ($\Delta T = T - T_o$) 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 [8]. 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 (± .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 ($f_c = \frac{1}{2\pi R_2 C}$) [6]. Possible values for R2 and C are 1820Ω and 2.2μF. 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).

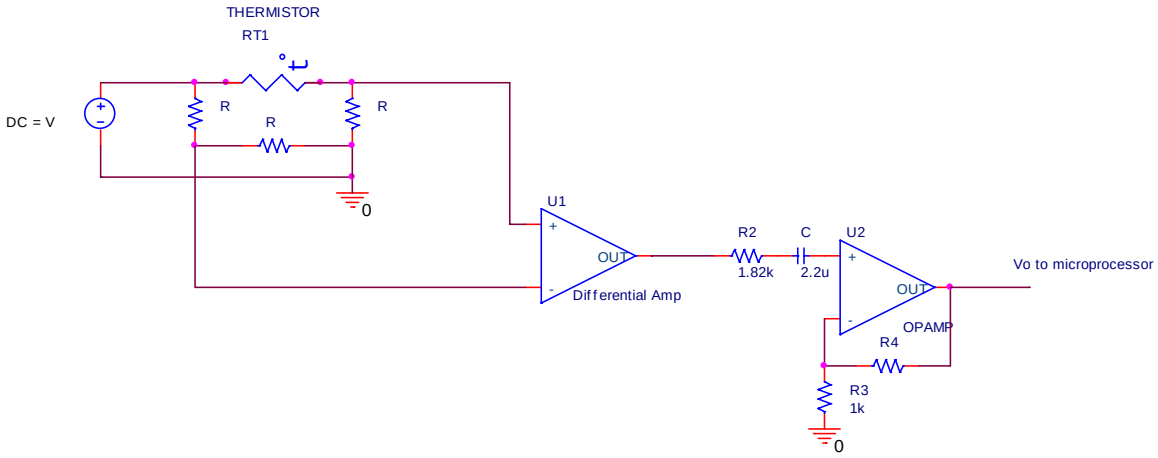


Figure 5. Thermometer Circuit

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

$$\frac{V_{out}}{V_{in}} = 1 + \frac{\mathrm{R}_f}{\mathrm{R}_{in}}.$$

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. 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 (SpO_2) is defined as the ratio of oxyhemoglobin (HbO_2) to the total concentration of hemoglobin in the blood ($Hb + HbO_2$):

$$\mathrm{SpO}_2 = \frac{[\mathrm{HbO}_2]}{[\mathrm{Hb} + \mathrm{HbO}_2]}.$$

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 HbO_2 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:

$$I_1 = I_{in1} 10^{-(\alpha_{o1} C_o + \alpha_{r1} C_r) l} \text{ at wavelength } \lambda_1, \text{ and}$$
$$I_2 = I_{in2} 10^{-(\alpha_{o2} C_o + \alpha_{r2} C_r) l} \text{ at wavelength } \lambda_2,$$

where C_o is the concentration of HbO_2, C_r is the concentration of Hb, α_{on} is the absorption coefficient of HbO2 at wavelength λ_n, and α_{rn} is the absorption coefficient of Hb at wavelength λ_n. Therefore, if

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

then blood oxygen saturation can be calculated from

$$\mathrm{SpO}_2 = \frac{C_o}{C_o + C_r} = \frac{\alpha_{r2} R - \alpha_{r1}}{(\alpha_{r2} - \alpha_{o2})R - (\alpha_{r1} - \alpha_{01})}.$$

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).

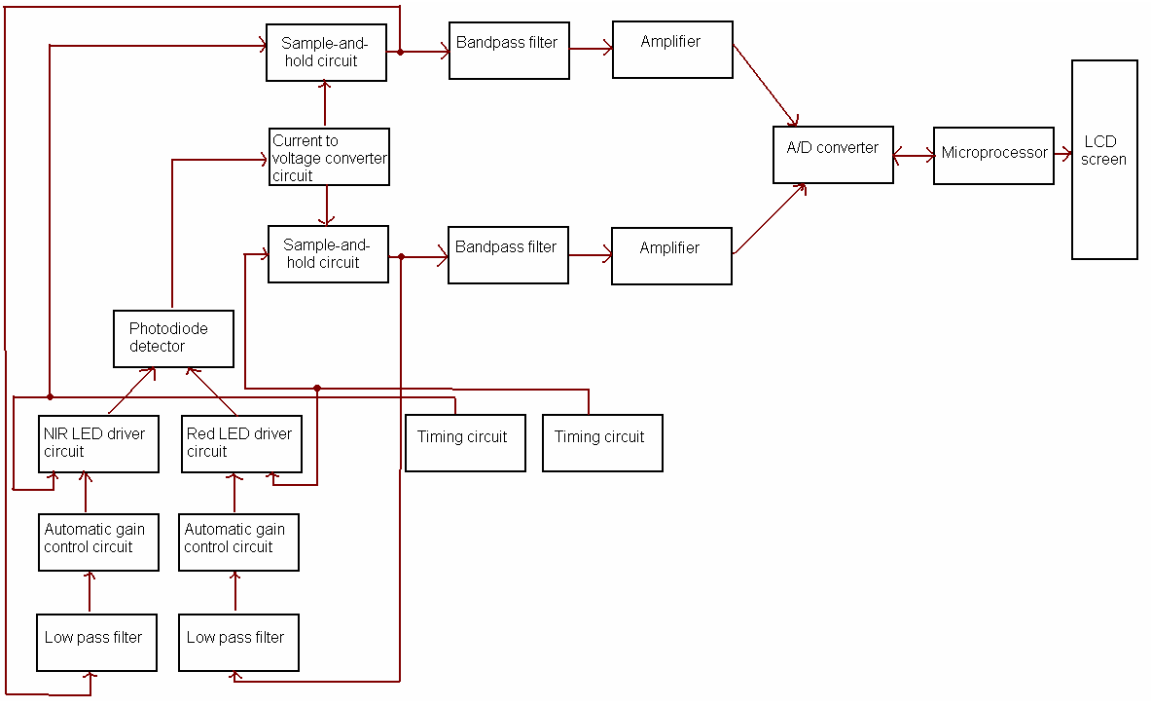


Figure 6. Pulse Oximeter Circuit Block Diagram

The pulse oximeter finger probe that we will use is the DRE Datascope compatible SpO2 finger probe with 8-pin connector for $165.00 (price before shipping and tax) from DREMed.com (Fig. 7).

http://www.dremed.com/catalog/product_info.php/cPath/205_210/products_id/435

Figure 7. Datascope Compatible SpO2 Probe

It contains two LEDs, one that works at a red wavelength and the other at a near-infrared (NIR) wavelength. Also, in the probe is a photodetector that will detect the light transmitted through the finger. The red LED used in the probe has been manufactured to give high intensity output, and the NIR LED is 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 $I_{LED}=V_{in}/R$.

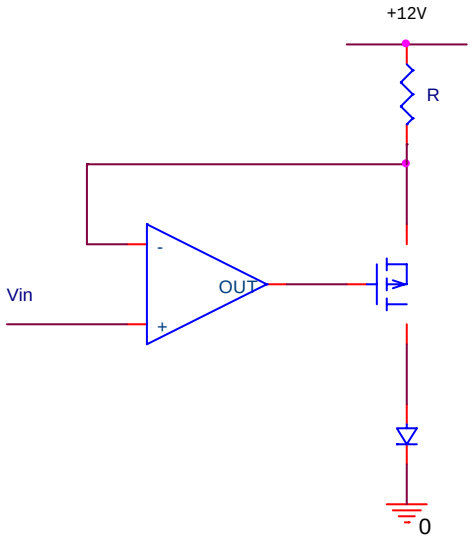


Figure 8. Circuit for constant current LED driver

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.

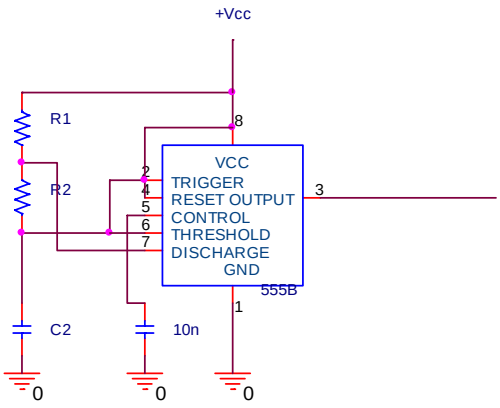


Figure 9. Timing circuit

The values of the resistors can be determined from

$$T_1 = .7(R_1 + R_2)C_2 \text{ and } T_2 = .7R_2C_2$$

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 56kΩ, 3.3kΩ, and 22nF respectively.

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

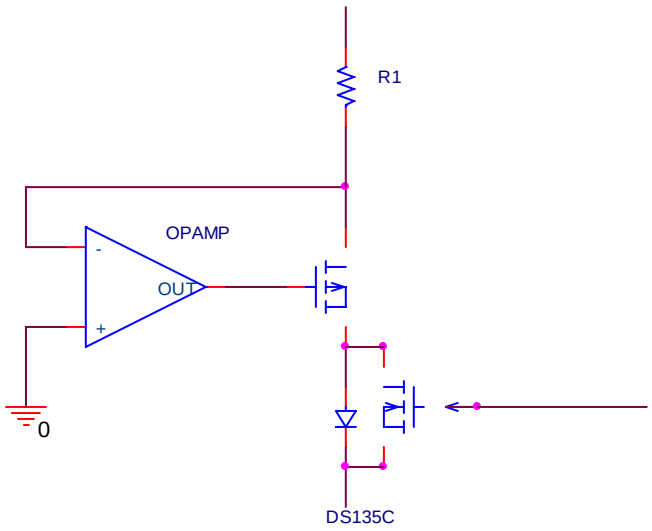


Figure 10. Circuit to pulse the LEDs

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).

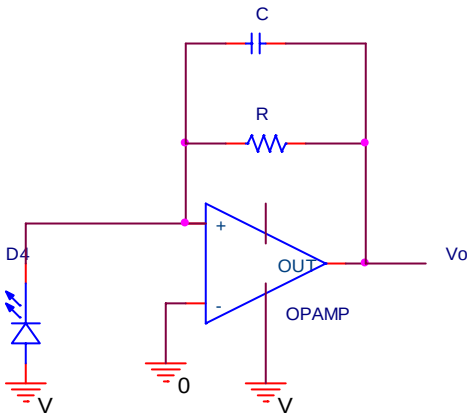


Figure 11. Current to voltage photodiode conversion circuit

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).

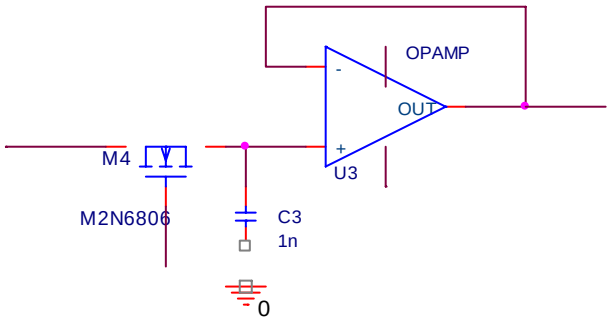


Figure 12. Sample-and-hold circuit

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 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 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].

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 (SpO_2 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. Because we are using a Datascope compatible probe, we will obtain and load Datascope's lookup table onto our microprocessor. The pulse oximeter will be 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. 13).

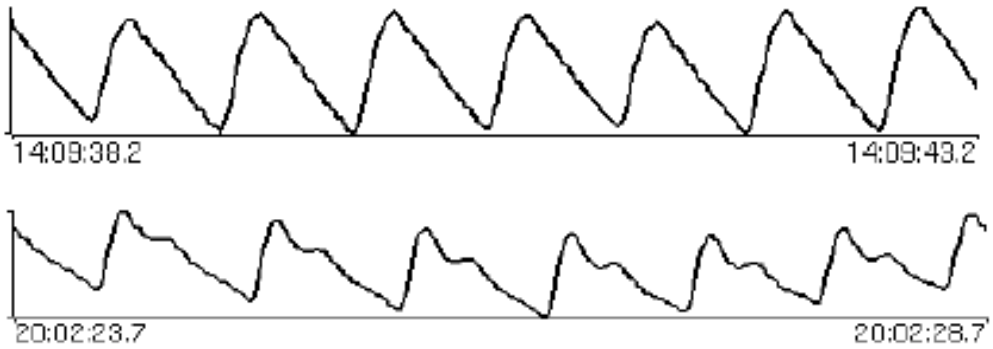


Figure 13. Pulsatile signals found in the intensity of detected light [15].

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.

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 [2]. The pressure at which these vibrations start is the systolic pressure, and the pressure at which they stop is the diastolic pressure [3]. The block diagram in Fig. 16 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. 14).

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

Figure 14. 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. 15). This waveform will be analyzed by the microprocessor to determine the systolic and diastolic pressures.

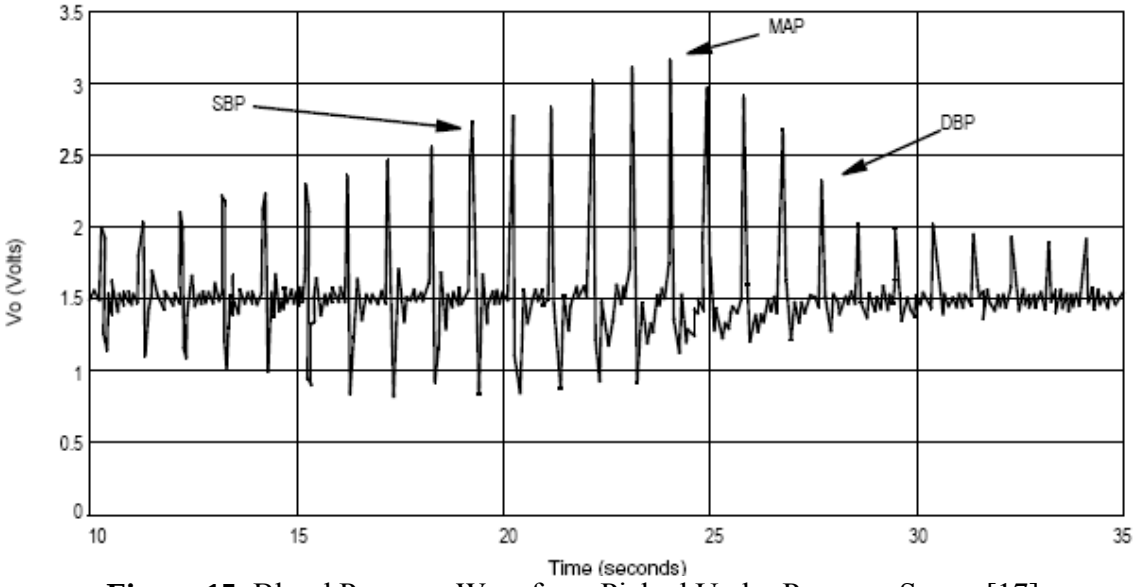


Figure 15. Blood Pressure Waveform Picked Up by Pressure Sensor[17]

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.

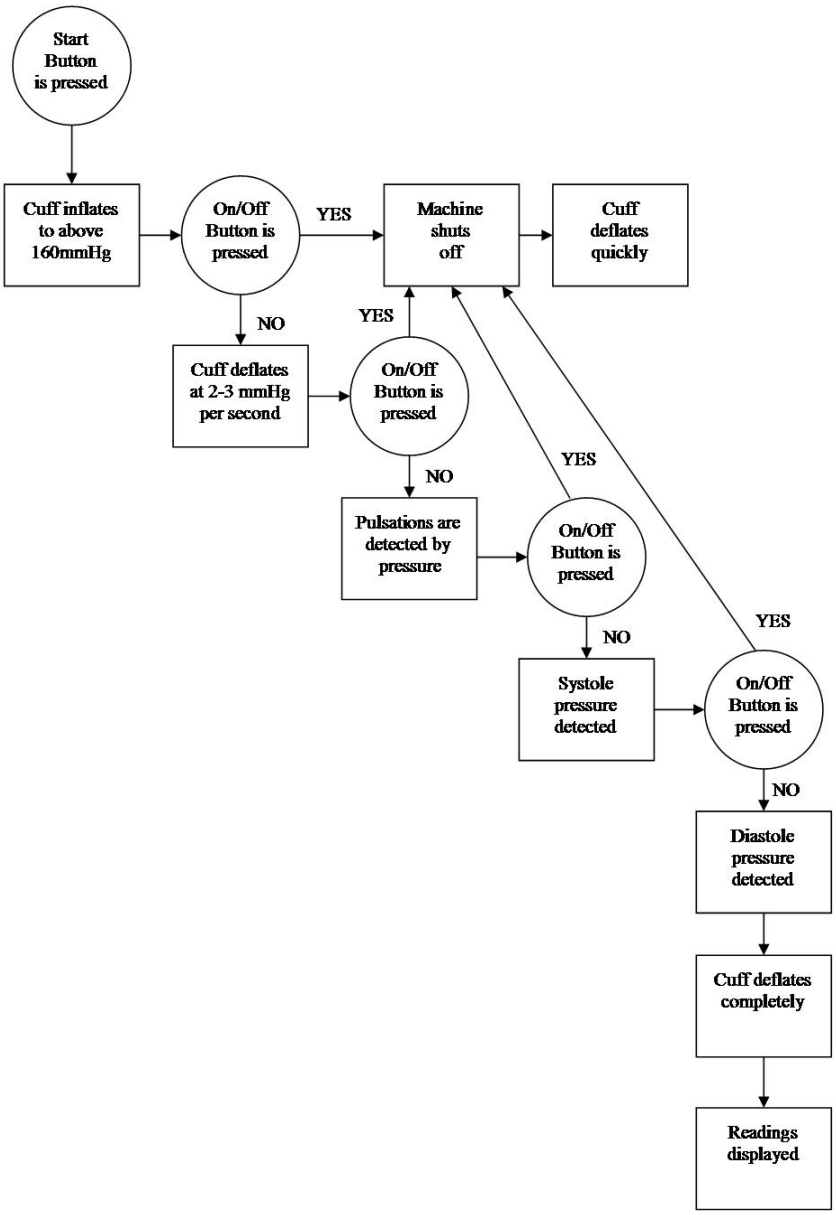


Figure 16. Block Diagram of Automatic Blood Pressure Measuring System

Due to the safety issues that arise with automatic blood pressure systems, we have incorporated a "kill switch" into our design (Fig 16) [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

To measure the respiratory rate of patients, the MLT1132 Piezo Respiratory Belt Transducer from AD Instruments will be used (Fig. 17). Using a piezoelectric sensor placed between two strips, this belt measures the changes in thoracic or abdominal circumference due to respiration inhalation and exhalation. By stretching the elastic due to respiration, strain is placed on the sensor which generates a voltage. Piezoelectricity is the ability of crystals to generate voltage in response to applied mechanical stress. In a piezoelectric crystal, the positive and negative electrical charges are separated, but symmetrically distributed, so that the crystal overall is electrically neutral. When a mechanical stress is applied, such as the stress applied to the straps as respiration occurs, this symmetry is disturbed and the charge asymmetry generates a voltage across the material. The voltage produced responds linearly to the mechanical stress applied to it. This voltage is then sent through the transducer and converted into digital signals to be processed by the Blackfin. In plotting the voltage sent from the transducer, we can count each breath as a peak on the graph which corresponds to the maximum distance the belt traveled for that breath. In monitoring a patient's respiratory rate, the adult patient should have an average of 12-20 breaths per minute. Below is a picture of the respiratory belt. With an adjustable belt length of 3.9 feet (Table 1), it can accommodate all sizes of patients. To test the accuracy of this transducer, we will compare our results obtained from using this respiratory belt to the results obtained the BioPac software. Any modifications can be made using the software internally. Calibrating the respiratory belt can be done by knowing the voltage of the piezoelectric sensors at rest. Ideally, there should zero voltage because there is no stress on the sensors. If the sensors do exhibit some voltage, the device will be zeroed at that corresponding voltage reading.

http://www.adinstruments.com/products/dataimages/MLT1132Web.jpg

Figure 17. MLT1132 Piezo Respiratory Belt

Table 1. Respiratory Belt Specifications

Respiratory Belt Specifications	
Signal Source	Piezo-electric
Output Range	20 mV to 400 mV
Sensitivity	4.5 +/-1 mV/mm
Device Capacitance	2.2 uF
Device Resistance	10^8 Ohms
Natural Frequency of Belt	>35 Hz
Connector	BNC
Rest Length	300 mm (11.8")
Maximum Elongation	100 mm (3.9")
Width	45 mm (1.8")
Belt Length	1200 mm (3.9')
Cable Length	2800 mm (9.2')

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. 18).

Figure 18. 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. 19). 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 [5]. 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. 20) connects up to the computer via a cable, allowing us to run our simulation program. After the evaluation process, the JTAG emulation board (Fig. 21) 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.

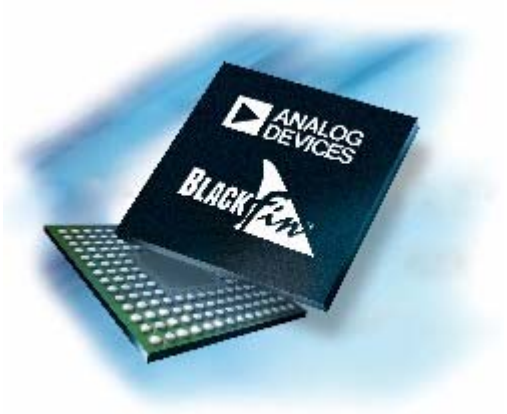


Figure 19. Blackfin Image

Table 2. 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/6047554224330634155870001133 9bf535_hardware.jpg

Figure 20. EZ-Kit Lite Evaluation Board

http://www.analog.com/images/Product_Descriptions/30502391903402849118416824438334027445629891175 00usb_emulator.jpg

Figure 21. 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. 22).

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

Figure 22. 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.

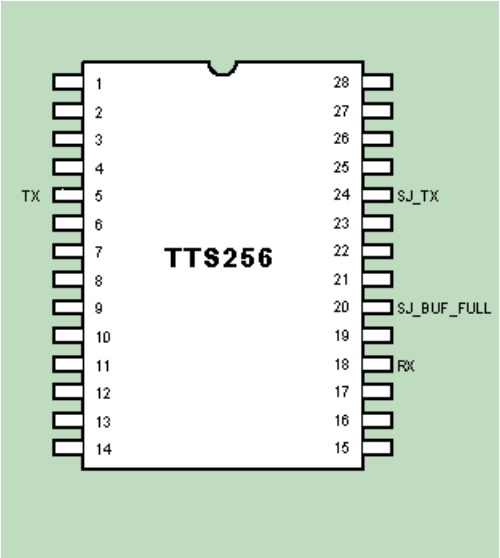
1.2.8 Speech Output

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. 23). 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. 24). 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 23. SpeakJet IC



http://www.speechchips.com/images/tts256.gif

Figure 24. Pin Diagram of TTS256

To play these computer generated sounds, a speaker from Futurelec (Fig. 25) 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 25. Small Speaker for Audio Output

Features
• Small Size
• Power rating: 0.5W
• Impedance: 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. 26). 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 26. Alarm Light

1.2.10 Secure Website

After the patients vital signs have been gathered and recorded, they need to be sent to their primary healthcare provider. To maximize patient privacy we have devised a way to securely transmit the patients' health information, minimizing the risk of interception. We will create an encrypted, password protected website to which the patient uploads the information from their USB stick. To ensure that the website is secure, HTML encryption software will be used to encrypt the contents of the website, allowing only those with the correct username and password to access it. We will use encryption software such as TagsLock Pro v 2.22 to hide the source code of our HTML documents. To encrypt HTML using TagsLock PRO, you need to create a new project once, and re-use it later when the site content gets modified and needs re-uploading. In order to use this encryption software, a website using the UCONN Biomedical Engineering server will have to be created for the prototype accessible home vital signs monitoring system.

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. 27). 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 27. Image of rechargeable battery

1.2.12 USB Port

The USB device is a very important part to include in this project. The main job of the USB device is to store the readings taken by the machine. This device will then be connected to a computer in which it is possible to send the readings to any computer that has an internet connection. The USB device that we decided to use is the Philips. PDIUSBD11 (Fig. 28). This device uses I2C technology to be able to connect to the microcontroller. This allows for easy communication between the two. By writing a computer program in the microcontroller we will be able to send the data received by the machine to the USB device and then to the computer. The following image shows the schematic of a how the USB device will connect with the microcontroller.

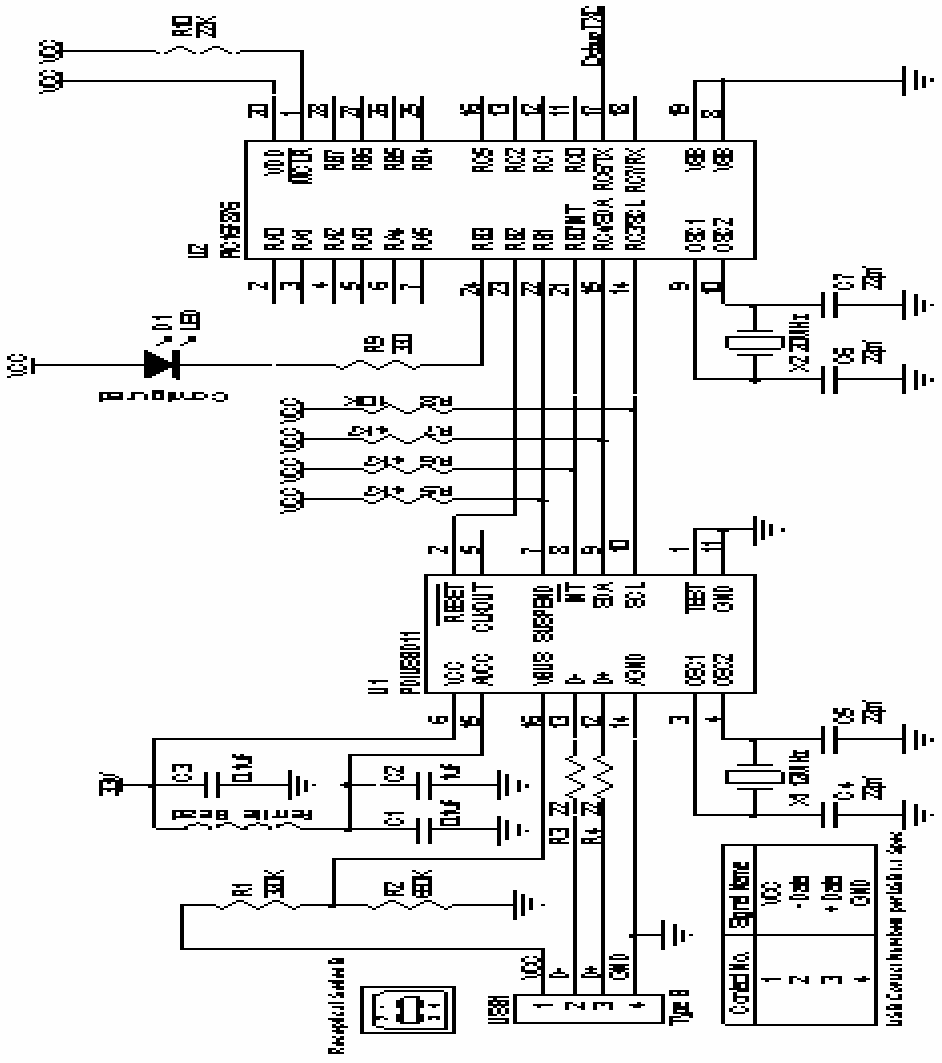


Figure 28. USB Schematic

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 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. 29).

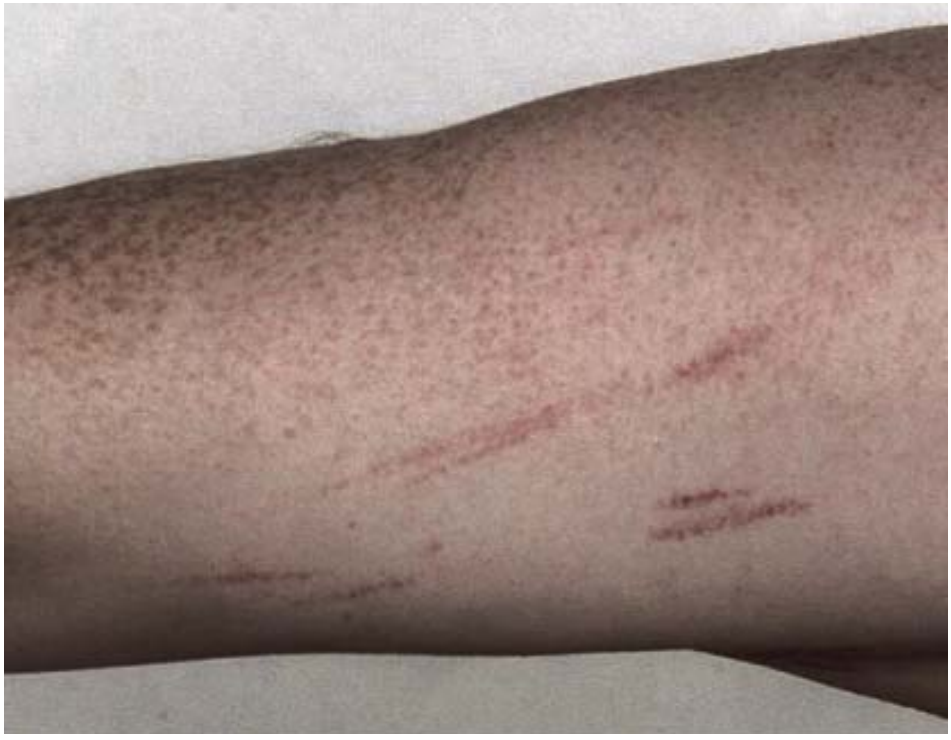


Figure 29. Bruising caused by one use of an automatic blood pressure cuff [14].

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 just 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 short-circuit back to the voltage source through the ground wire.

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. 30).

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.
- Quantity zero.
[1] Age is the patient's age at the time of survey.
[2] Numbers will not add to totals because a patient may be included in more than one category.
[3] Total number of home health care patients.
[4] Includes manual and motorized wheelchairs.
[5] Includes geri-chairs, lift chairs, and other specialized chairs.
[3] Includes oxygen concentrator.

Figure 30. Excerpt from Table of Number of Current Home Heath Care Patients with Aides and Devices in 2000 [9].

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. 31), but living at home can provide patients a welcome and comfortable environment in which to recover and be monitored.

Table 18. Cost of Inpatient Care Compared to Home Care, Selected Conditions

Conditions	Per-patient Per-month Hospital Costs	Per-patient Per-month Home Care Costs	Per-patient Per-month 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

Sources: [1]Casiro, O.G., McKenzie, M.E., McFayden, L., Shapiro, C., Seshia M.M.K., MacDonald, N., Moffat, M., and Cheang, M.S. "Earlier Discharge with Community-based Intervention for Low Birth Weight Infants: A Randomized Trial." *Pediatrics* 92, no. 1 (1993): 128-134.
[2]Bach, J.R., Intinola, P., Alba, A.S., and Holland, I.E. "The Ventilator-assisted Individual: Cost Analysis of Institutionalization vs. Rehabilitation and In-home Management." *Chest* 101, no. 1 (1992): 26-30.
[3]Field, A.I., Rosenblatt, A., Pollack, M.M., and Kaufman, J. "Home Care Cost-Effectiveness for Respiratory Technology-dependent Children." *American Journal of Diseases of Children* 145 (1991): 729-733.
[4]Close, P., Burkey, E., Kazak, A., Danz, P., and Lange, B. "A Prospective Controlled Evaluation of Home Chemotherapy for Children with Cancer." *Pediatrics* 95, no. 6 (1995): 896-900. (**Note**: The study found that the daily charges for chemotherapy were $2,329±$627 in the hospital and $1,865±$833 at home. These charges were multiplied by 30 days reflecting the above per-patient per-month costs.)
[5]Rich, M.W., Beckham, V., Wittenberg, C., Leven, C., Freedland, K., and Carney, R.M. "A Multidisciplinary Intervention to Prevent the Readmission of Elderly Patients with Congestive Heart Failure." *The New England Journal of Medicine* 333, no. 18 (1995): 1190-1195.
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Figure 31. Table of Home Care Cost Savings [1].

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.

We were also introduced to piezoelectric sensors used for converting changes in mechanical stress to voltage. By incorporating a piezoelectric sensor into our respiratory belt, we can obtain a voltage as the symmetry between the crystals change, and pass this voltage through an analog to digital converter. We learned that a respiratory belt responds linearly to changes in length, and we can then use this to analyze a patient's breathing patterns.

6. References

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