



March 2, 2009

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

Re: ENSC 440 – Design Specification for Home Heart Monitor

Dear Mr. Leung,

Heart disease is a growing concern for Canadians. We at VHeart are committed to help Canadians to reduce the occurrences of Cardiovascular diseases by building a portable home heart monitor that will estimates a person's 10-year risk for developing CVD and educates them on how to reduce their risk.

Our device will have two major components: a hardware data collection system, and a software analysis program, which the user will install on their personal computer (PC). The attached document, *Design Specification for the Home Heart Monitor*, contains the high-level design specification of our prototype design.

VHeart consists of four innovative and ambitious engineering students: Michelle Cua, Xiao Han, Louise Linggadaja, and Lilly Pan. If you have any questions or concerns regarding our project, please do not hesitate to contact me by phone at (604) 619-0862 or by email at emc2@sfu.ca. Our team can also be contacted at ensc440.vheart@gmail.com.

Sincerely,

Michelle Cua
CEO, VHeart

Enclosure: *Design Specification for the Home Heart Monitor*

Design Specification for the Home Heart Monitor

ENSC 440 – Capstone Engineering Science Project

Issued Date: March 2, 2009

Revision 1.0



Project Team:
Michelle Cua
Xiao Han
Louise Linggadaja
Lilly Pan

Contact Person:
Michelle Cua
Emc2@sfu.ca

Submitted To:
Patrick Leung – ENSC 440
Steve Whitmore – ENSC 305
Jason Lee
Jamie Westell



Executive Summary

~An ounce of prevention is better than a pound of cure~

Cardiovascular disease (CVD) is a growing concern for Canadians. Recent statistics from Health Canada state that 1/3 of all death are due to CVD and 8/10 Canadians are at risk for developing CVD [1,2]. Fortunately, most of CVD deaths are preventable. At VHeart, we are trying to help individuals and society to reduce CVD preventable deaths, through empowering individuals to take a more active stance in improving their health by assessing their 10-year risk for developing CVD and educating them on how to prevent the development of CVD through taking care of their bodies properly.

This document outlines the design on the VHeart system. It provides the set of detailed high-level description of the prototype model to meet the functional requirements, as listed in the document *Functional Specifications for the Home Heart Monitor*. This document only briefly touches upon the design of the functionalities of the production model.

The prototype phase shall have the following components:

- ECG and blood pressure data acquisition and analysis
- Database for efficient data storage and retrieval
- User-friendly application software

The first phase is scheduled to be completed by April 17, 2009.

The second phase of product development shall also be capable of acquiring and analyzing body fat. It shall also have a fully functional nutritional and physical activity input and assessment. At completion of the second phase, the product will also adhere to all standards and regulations set forth by FDA and the Standards Council of Canada.



Table of Contents

Executive Summary.....	iii
List of Tables	vi
List of Figures	vi
Glossary.....	vii
1. Introduction	- 8 -
1.1. Scope.....	- 8 -
1.2. Intended Audience.....	- 8 -
2. System Overview	- 9 -
3. Hardware Data Collection System Design.....	- 11 -
3.1 ECG Acquisition System Design.....	- 11 -
3.2 Blood Pressure Acquisition System Design.....	- 14 -
3.3 Body Fat Acquisition System Design	- 17 -
3.4 Microcontroller Design	- 18 -
4. Software Program System Design.....	- 21 -
4.1 ECG Analysis Program Design	- 21 -
4.2 Blood Pressure Analysis Program Design.....	- 25 -
4.3 Body Fat Analysis Program Design.....	- 27 -
4.4 Personal Information Data Design.....	- 27 -
4.5 Risk Stratification Scheme.....	- 28 -
4.5.1 Framingham CVD Risk Profile.....	- 28 -
4.5.2 Framingham Stroke Risk Profile	- 29 -
4.6 Educational Report System Design	- 29 -
4.6.1 Risk Assessment Results.....	- 29 -
4.6.2 Physical Activity Assessment.....	- 31 -
4.6.3 Nutritional Assessment	- 31 -
4.6.4 ECG Results	- 32 -
4.6.5 Printer-friendly Report.....	- 32 -
4.7 Track Progress Design	- 32 -



Design Specification
for the Home Heart Monitor

4.8 Database Design..... - 32 -

4.9 Application Software Design..... - 34 -

5. Environment..... - 36 -

6. Conclusion..... - 37 -

Reference - 38 -

Appendix 1: Framingham CVD Risk Profile - 40 -

Appendix 2: Framingham Stroke Risk Profile..... 43



List of Tables

Table 1: Multiplexer Configuration	- 12 -
Table 2: ECG Circuit Gain and Cutoff Frequencies	- 13 -
Table 3: Blood Pressure Circuit Gain and Cutoff Frequencies	- 16 -
Table 4: Standard ECG Parameters [7].....	- 21 -
Table 5: BMI Classifications and Significance [14]	- 30 -
Table 6: BP Classifications and Significance (from correspondence with Dr. Scott Lear).....	- 30 -
Table 7: Smoking Assessment [15].....	- 31 -

List of Figures

Figure 1: System Overview	- 9 -
Figure 2: Home Heart Monitor Block Diagram	- 9 -
Figure 3: ECG Lead Configuration	- 11 -
Figure 4: Electrodes connection to ECG circuitry.....	- 12 -
Figure 5: ECG Circuit Schematic	- 13 -
Figure 6: ECG Circuit Frequency Response	- 14 -
Figure 7: Motor and Pump Powering Diagram	- 15 -
Figure 8: Blood Pressure Circuit Schematic	- 16 -
Figure 9 Blood Pressure Circuit Frequency Response.....	- 17 -
Figure 10: High Level Microcontroller Flow Chart	- 18 -
Figure 11: ECG Data Acquisition Flow Chart	- 19 -
Figure 12: BP Data Acquisition Flow Chart	- 20 -
Figure 13: Standard ECG Waveform [6]	- 21 -
Figure 14: Axis Determination	- 24 -
Figure 15: Typical Blood Pressure Acquisition Waveform	- 25 -
Figure 16: DBP Measurement.....	- 26 -
Figure 17: Envelope Detection for Blood Pressure Measurement	- 26 -
Figure 18: Database Diagram.....	- 33 -
Figure 19 Application Software Design Overview.....	- 34 -
Figure 20 Application Software Flowchart.....	- 35 -



Glossary

Term	Definition
BP	Blood Pressure Blood pressure is the pressure blood exerts against the arteries, and falls under systolic and diastolic. Systolic blood pressure is the blood pressure when the heart is pumping, and diastolic blood pressure is the pressure at rest.
BPM	Beats Per minute The number of times the heart beats per minute.
CVD	Cardiovascular Disease Diseases that involve the heart and blood vessels (1) which includes heart attack, stroke, high blood pressure, etc.
ECG	Electrocardiogram The electrocardiogram is a non-invasive measurement of the electrical activity of the heart.
FDA	Food and Drug Administration US Food and Drug Administration, and agency in the Department of Health and Human Services responsible for regulating safety of medical devices in US, among other things .
GUI	Graphical User Interface Software Interface which used graphics as opposed to command lines
ISO	International Organization for Standardization ISO is an international standard setting organization composed of various national standards organizations.
MAP	Mean Arterial Pressure The mean arterial pressure is the average blood pressure of a person during one cardiac cycle.
MI	Myocardial Ischemia Myocardial ischemia is the term given when there is reduced blood flow to the heart due to partially blocked arteries.



1. Introduction

The home heart monitor is a device that estimates the user's relative risk for developing CVD within the next 10 years through various user inputs and gives practical suggestions on how to decrease their risk. The design specifications of this device are outlined in this document.

Home Heart Monitor's development is divided into prototype stage and production stage. The prototype stage will span over a four months period which will end in on April 17, 2009. After careful testing and validation, production stage will soon follow in the coming year.

1.1. Scope

This document outlines the design choices of the Home Heart Monitor. It explains the detail of design and implementation strategies of our hardware data collection system as well as our software analysis program. This document will also list and detailed the tests needed to be done to satisfy our functional specification as outlined in *Functional Specification for the Home Heart Monitor*. The design specifications for the production model will only be partially outlined in this document.

1.2. Intended Audience

This design specification is intended for the use of VHeart members in implementing and testing project's prototype. Furthermore, it will align engineers' goal as they work on different aspect of the project.

Test Engineers will also use this document to ensure that our prototype meets all design specifications.



2. System Overview

Our system consists of a hardware data collection system and a software analysis system.

This system is shown in the system overview and system block diagram in figures 1 and 2 below.

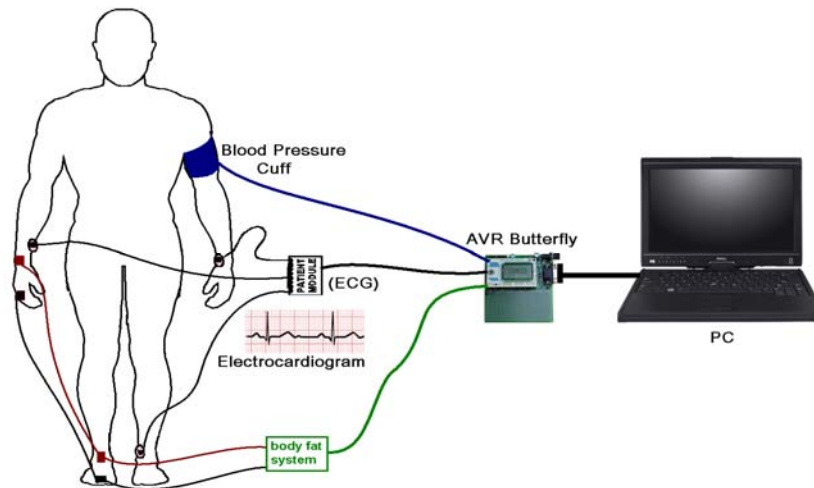


Figure 1: System Overview

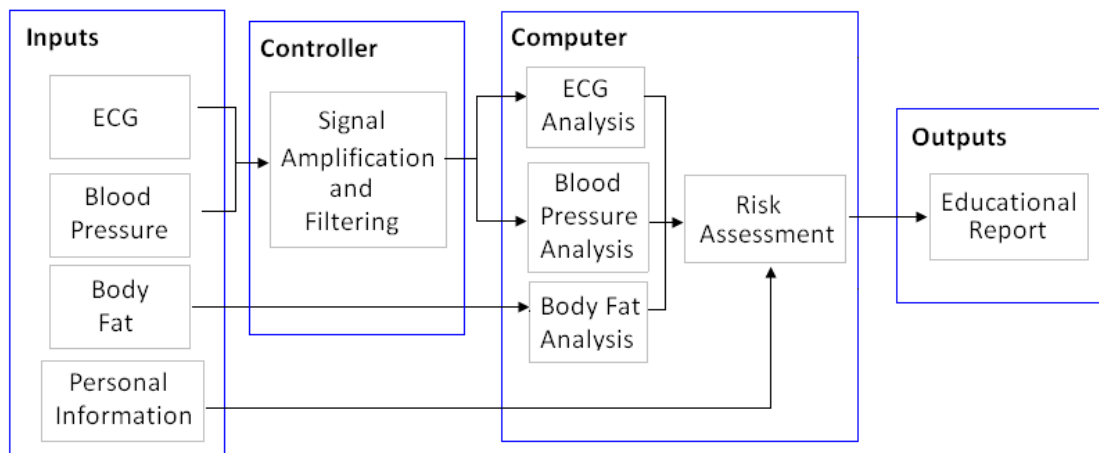


Figure 2: Home Heart Monitor Block Diagram

The ECG, body fat, and blood pressure (BP) module will collect data from individuals. Based on this collected data, along with the user's personal information, the user's risk of developing CVD is estimated using published risk score assessments. The ECG data is also analyzed to see whether or not the person has any other heart problems that might require some medical attention.



Design Specification
for the Home Heart Monitor

Using the ECG, body fat, blood pressure, and personal information collected from the individual, the software program shall estimate the user's risk of developing CVD and give an educational report on actions the user can take to prevent CVD from occurring. The device shall also be able to track the progress of the individual over time by storing previous data collected and/or inputted by the user.

Due to time and budget constraints, our prototype device will not contain the body fat measurement, nor will it contain a full nutritional and physical activity input data and assessment.

3. Hardware Data Collection System Design

The hardware data collection system consists of ECG, BP, and body fat data acquisition. The following section describes the design of each of these three systems.

3.1 ECG Acquisition System Design

The ECG Acquisition system measures the electrical activity of the heart, through a 6-lead (3 limb leads, and 3 augmented leads) ECG configuration, as shown in the figure below.

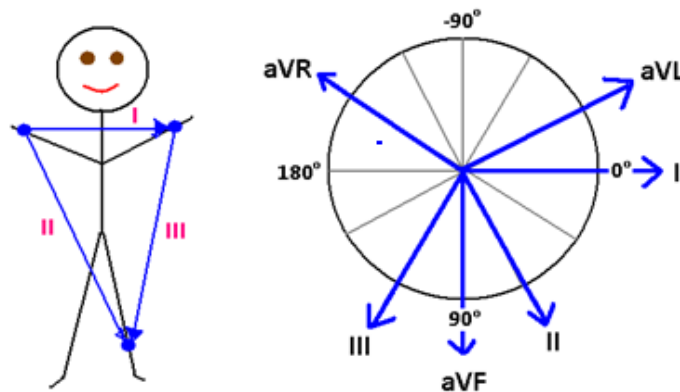


Figure 3: ECG Lead Configuration

The three limb leads are on shown in Figure 3, in the picture on the left. The three augmented leads (aVR, aVF, aVL) can be obtained through Eithoven’s law, by:

$$aVF = 0.5 * (II + III) \tag{1}$$

$$aVR = -0.5 * (I + II) \tag{2}$$

$$aVL = 0.5 * (I - III) \tag{3}$$

The limb leads are a measurement of the potential differences between the respective limb electrodes (eg. for lead I, between the two arms), and the central terminal, where the central terminal is defined as the average of the potentials from all the limb leads. Three 4:1 multiplexers will be used to allow the ECG circuitry to measure the three different potential differences needed for analysis. The following figure and table describes the multiplexer configuration.

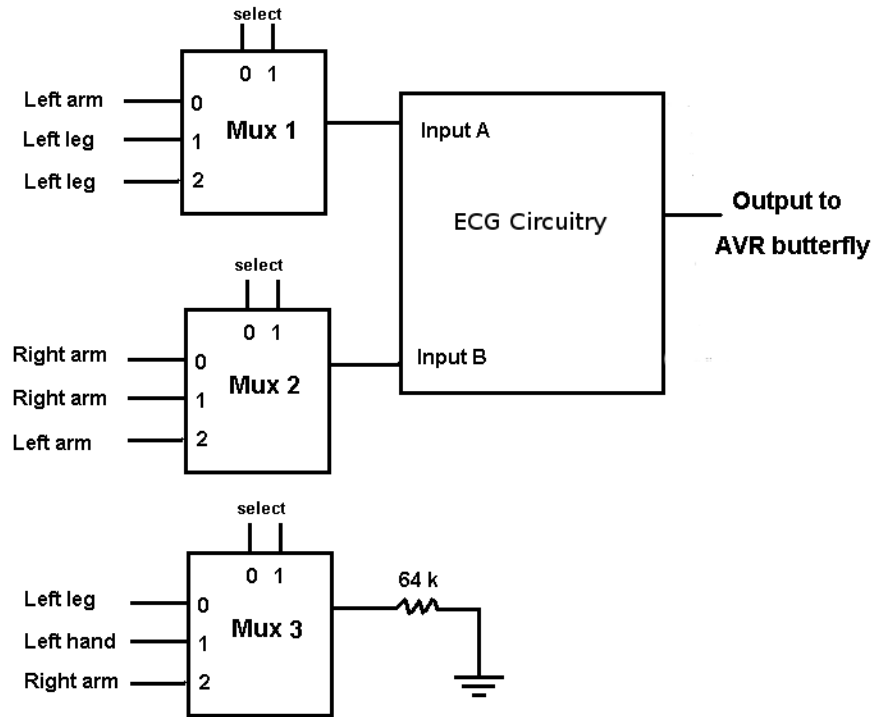


Figure 4: Electrodes connection to ECG circuitry

Table 1: Multiplexer Configuration

Multiplexers Signal Control	Potential Difference (Lead) Measured
[0,0,0]	I
[1,1,1]	II
[2,2,2]	III

Since the electrical activity of the heart is very small (μV range) and is subject to a lot of noise (movement artifacts, power line noise, EMG activity, respiration to name a few), the acquisition circuitry needs to have a very high input impedance, high amplification, and filtering. While there are some signal content in the very high and very low frequency ranges, most of the signal content lies in the 0.5 – 50 Hz.. Below is the schematic of our circuit, with component values.



Design Specification
for the Home Heart Monitor

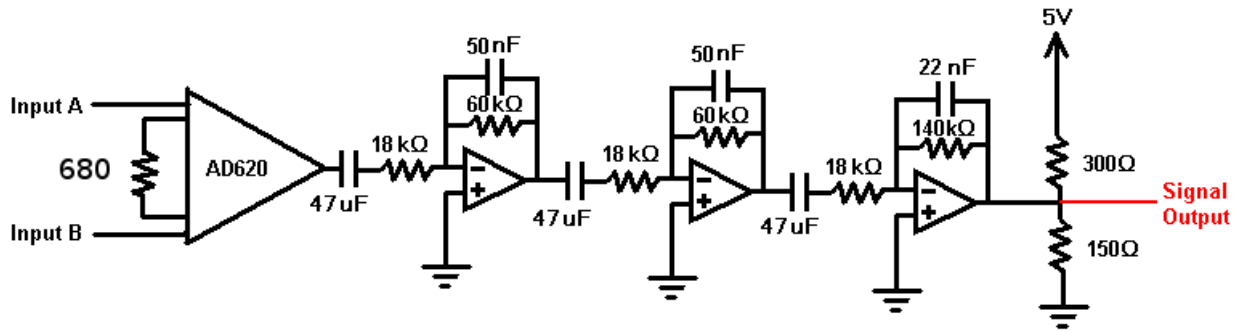


Figure 5: ECG Circuit Schematic

There are three stages of circuit in the schematic. Circuit is started with instrumentation amplifier. This instrumentation amplifier has a very high input impedance and high amplification and therefore meets our expectation. The gain of the instrumentation amplifier can be calculated using the following equation

$$G = 1 + \frac{49.4k}{R_G} \quad (4)$$

Using the equation and R_G of 680Ω, our calculated gain is 73.65.

The theoretical frequency cutoff frequencies of the bandpass filters in our circuit is calculated using the equation:

$$f = \frac{1}{(2\pi RC)} \quad (5)$$

While the gain can be obtained by the following equation:

$$G = -\frac{R_{Feedback}}{R_{Forward}} \quad (6)$$

From the component values given in figure above, the resulting gain and cutoff frequency of the various stages and our overall circuit is summarized in the table below.

Table 2: ECG Circuit Gain and Cutoff Frequencies

Lower Frequency Cutoff	$f_{low} = \frac{1}{2 * \pi * 47\mu F * 18k\Omega} = 0.188 \text{ Hz}$
Higher Frequency Cutoff	$f_{hi1} = \frac{1}{2 * \pi * 50nF * 60k\Omega} = 53.05 \text{ Hz}$
	$f_{hi2} = \frac{1}{2 * \pi * 22nF * 140k\Omega} = 51.67 \text{ Hz}$



Filter Gain

$$G_1 = -\frac{60k}{18k} = -3.33$$

$$G_2 = -\frac{140k}{18k} = -7.78$$

Patient isolation is achieved by attaching diodes at every input point to ground. By attaching diodes, we ensure that the voltage and current applied to the patient is never greater than 0.7V and 0.1A respectively, as the patient will start to experience discomfort when there is a current of more than 0.1A flowing through their bodies.

From the calculations conducted previously, our total gain is 6353.9 or 76.06 dB

Figure 6 below shows the frequency response of our circuit.

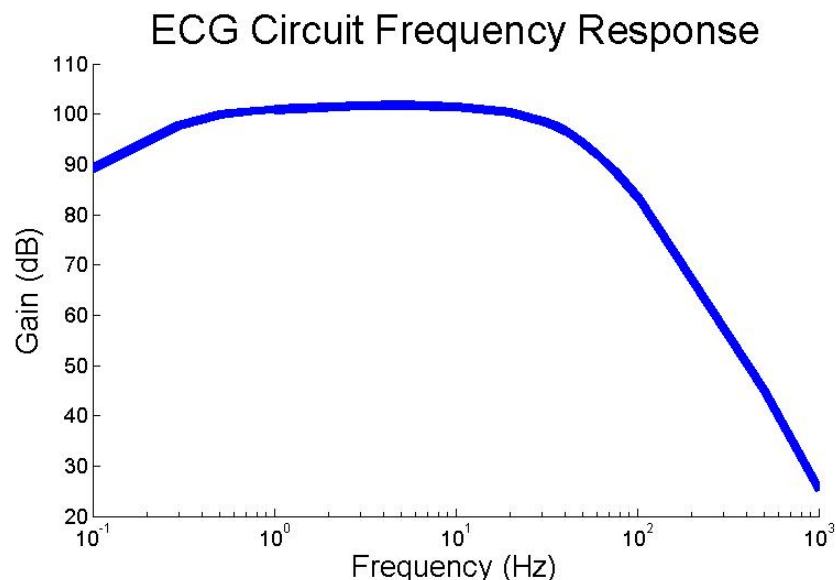


Figure 6: ECG Circuit Frequency Response

3.2 Blood Pressure Acquisition System Design

Our blood pressure acquisition system measures the systolic and diastolic blood pressure of the user, and consists of a blood pressure cuff with corresponding pump motor, an air pressure sensor, and the signal processing circuitry.

The motor used in the blood pressure system is a brush motor with a diaphragm pump. This pump has an operating voltage of 3V DC and has 2 valves, for air intake and outflow. Using this motor/pump, we can then control the cuff pressure of the blood pressure system. A 3V regulator will be used to supply power to the motor. [3] Figure 7 below diagrams the motor and cuff configuration.

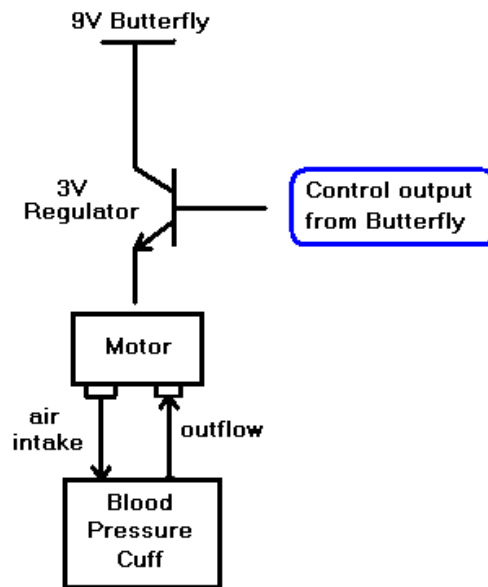


Figure 7: Motor and Pump Powering Diagram

The air pressure sensor is MPX2050, which operates on 5V DC. This air pressure sensor is designed with a range of 0 – 375 mmHg. Out of the 375 mmHg range, our blood pressure system will only go to a maximum of 160 mmHg, as the user will start to experience discomfort when the cuff pressure exceeds 160 mmHg. A 5V regulator will be used to power our air pressure sensor as well as Vcc for all of the opAmps. [4]

The pressure sensor is connected to an instrumentation amplifier, which increases the CMRR and has the advantage of greatly reducing any noise induced onto the output lines of the sensor. The subsequent stages in the amplifier further amplify and filter the signal, to remove high frequency noise and DC offset.

The blood pressure circuit schematic is given in the figure below.

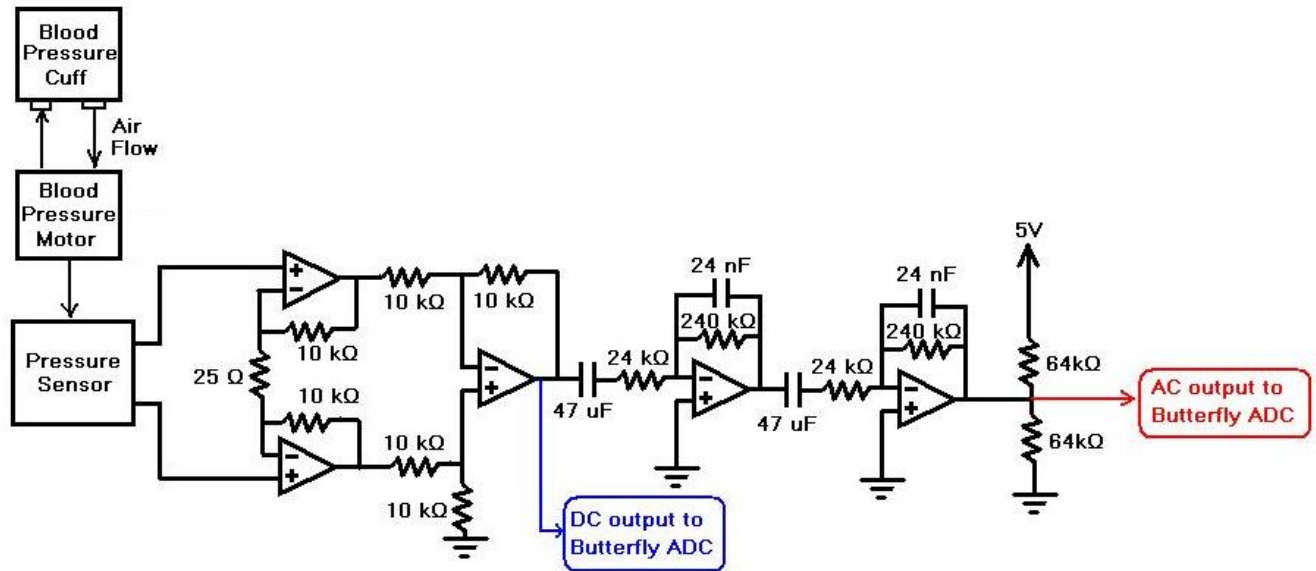


Figure 8: Blood Pressure Circuit Schematic

The useful content of the blood pressure signal is within the 0.5-25 Hz frequency band. Using equations 5 and 6, the cutoff frequency of the filters is calculated and given in the table below. The gain of our home made instrumentation amplifier can be calculated using the following equation:

$$G = 1 + \frac{2 * R}{R_G} \quad (7)$$

Table 3: Blood Pressure Circuit Gain and Cutoff Frequencies

Instrumentation Amplifier Gain	$G = 1 + \frac{2 * 10k}{25} = 801$
Filter Lower Cutoff Frequency	$f_{low} = \frac{1}{2 * \pi * 47uF * 24kOhm} = 0.141 \text{ Hz}$
Filter Higher Cutoff Frequency	$f_{hi} = \frac{1}{2 * \pi * 24nF * 240kOhm} = 27.6 \text{ Hz}$
Filter Gain	$G = -\frac{240k}{24k} = -10$

The frequency response of our blood pressure circuit is given in the figure below. As seen in Figure 9, the cutoff frequencies of 0.5 and 25 Hz, and the maximum gain of 80100 V/V, or 11.29 dB, is achieved within reasonable tolerance.

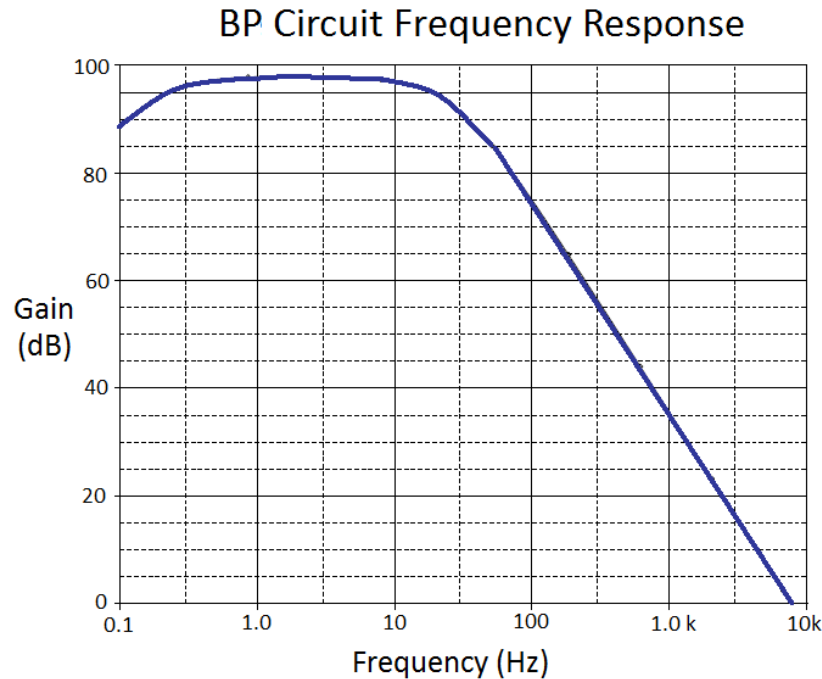


Figure 9: Blood Pressure Circuit Frequency Response

The DC voltage signal from the air sensor is proportional to the cuff pressure. The cuff pressure can be calculated from the DC voltage signal by the following equation:

$$P_{cuff} = \frac{V_{DC}}{G_{DC}} * \frac{50 \text{ kPa}}{0.04 \text{ V}} * 7.5 \frac{\text{mmHg}}{\text{kPa}} \quad (8)$$

where P_{cuff} is the measured cuff pressure (mmHg), V_{DC} is the DC voltage at the output of instrumentation amplifier (V), and G_{DC} is the DC gain of the instrumentation amplifier (experimentally determined).

The cuff is placed around the upper arm (brachial artery), and inflated from supra-systolic to sub-diastolic pressure. The DC signal is used to measure the cuff pressure at any time, while the AC signal is used to determine where the cuff pressure reaches the user's systolic blood pressure (SBP) and diastolic blood pressure (DBP).

3.3 Body Fat Acquisition System Design

The Body Fat acquisition estimates the user's percentage body fat by measuring its bioelectrical impedance. It is based on the principle that different body tissues (muscle, bone, fat) have different electrical resistances.

To measure the bioelectrical resistance, bipolar electrodes are placed at the hand and feet. A small current is placed through the electrodes, and the resulting voltage drop is measured. Through voltage and current, the resistance is calculated through Ohm's law ($V = IR$).



Since the body fat acquisition will not be implemented for the prototype model, the design of the system is not described in detail.

3.4 Microcontroller Design

For data collection, the AVR Butterfly evaluation kit is used. This evaluation kit comes with peripherals such as 10 bit Analog/Digital Converter, LCD display, joystick control, RS232, timer/counters, and 4Mbit of external data flash. Other feature such as low power consumptions makes this evaluation kit ideal for our system. [5]

As prototype for design, the microcontroller will act as the brain of our data collection system; very little data processing will be done on board. Data will be streamed to the PC as soon as it arrives on the butterfly kit. The high level microcontroller flow chart is given in Figure 10 below, while shows the ECG and blood pressure data acquisition algorithms respectively.

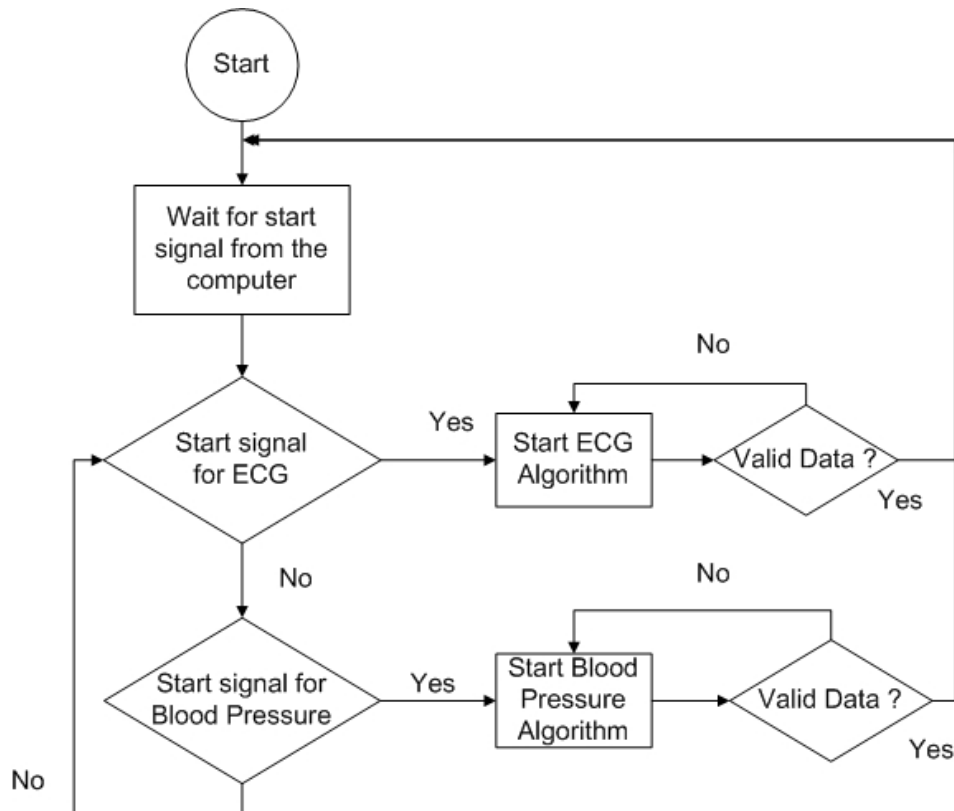


Figure 10: High Level Microcontroller Flow Chart

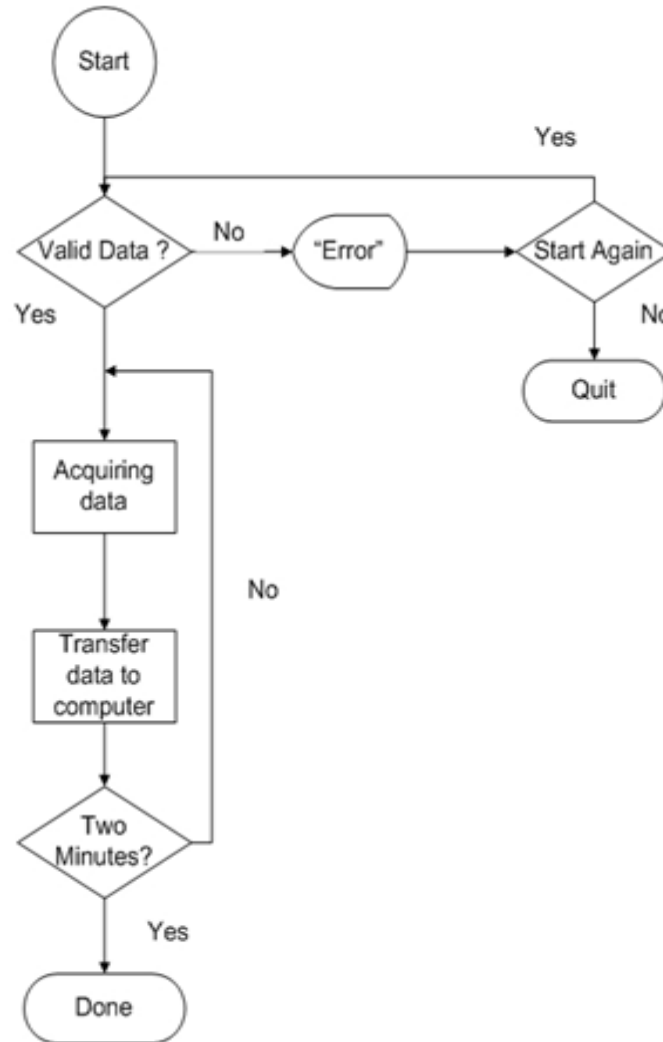


Figure 11: ECG Data Acquisition Flow Chart

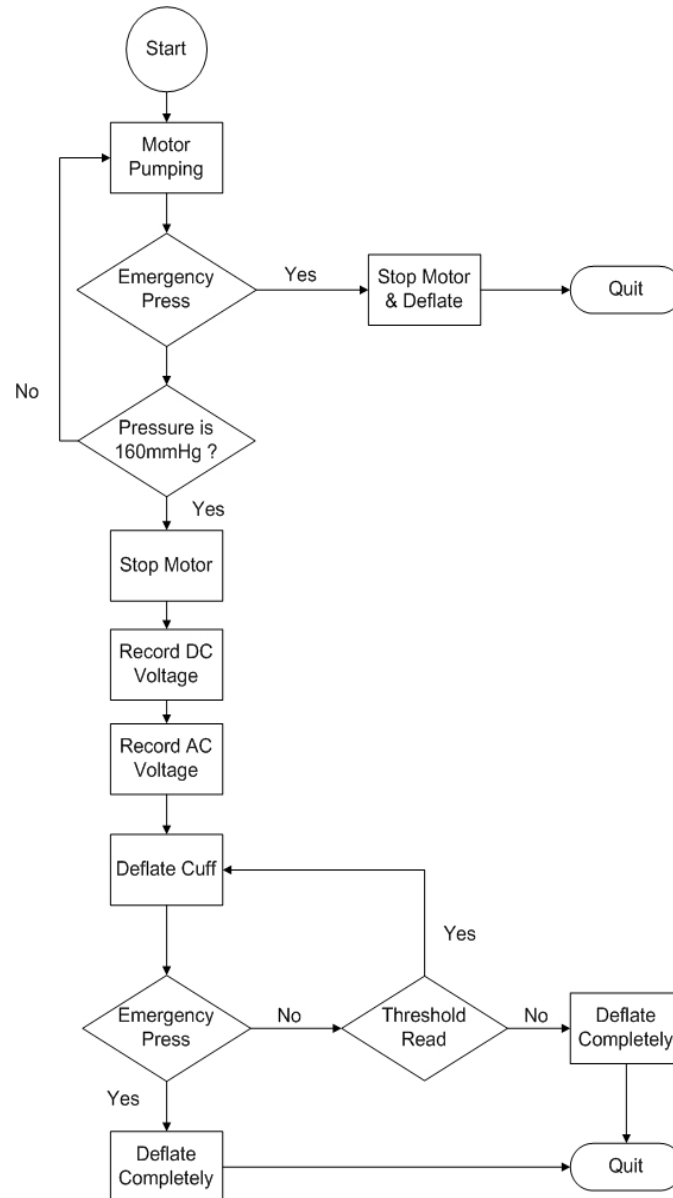


Figure 12: BP Data Acquisition Flow Chart

In order for the AVR Butterfly kit to control data acquisition, it will need to read 3 signals – 2 output signals and 1 bidirectional signal – to the computer. The signals read are the 0-5V analog signal from BP circuitry, the 0-5V analog signal from the ECG circuitry, and the emergency stop signal from user. The output signal from the AVR butterfly will be used to control the multiplexers which will choose which lead to measure. The bidirectional signal to the computer will be done via UART port. Signals through this port that go from the computer to the AVR kit include start ECG and start BP measurement signals, while the signals that go from the AVR to the PC include the ECG and BP signals, as well as the error signal.

Just as describes in previous section, AVR Butterfly powering will be done using 3V regulator.

4. Software Program System Design

The software analysis system consists of the ECG, body fat, and BP data analysis; the personal information database; the risk stratification scheme; the educational report; and track progress. This section also includes the design of the application software and the data structure used to manage the data of our project (ECG, body fat, BP, personal information).

4.1 ECG Analysis Program Design

The ECG analysis program analyzes the ECG signal measured from the user by the ECG acquisition system.

The interior of the heart muscle is negative with respect to its extracellular environment. Every beat, the heart undergoes a wave of depolarization (interior becomes positively charged) that initiates the contraction of the heart muscle. In order to return to its resting state, it undergoes repolarization. The depolarizations and repolarizations of the heart muscle each pulse is measured as waves on the ECG.

Since the anatomy (structure) of the normal healthy heart is the same between people, there is a standard ECG. Problems with the heart, such as electrical blockages or arrhythmias, affect the electrical signal of the heart; thus, we can diagnose certain heart conditions by analyzing a person's ECG and seeing if and how it deviates from the normal pattern and timing. Figure 13 below shows the standard ECG waveform, with normal amplitude and time intervals given in Table 4.

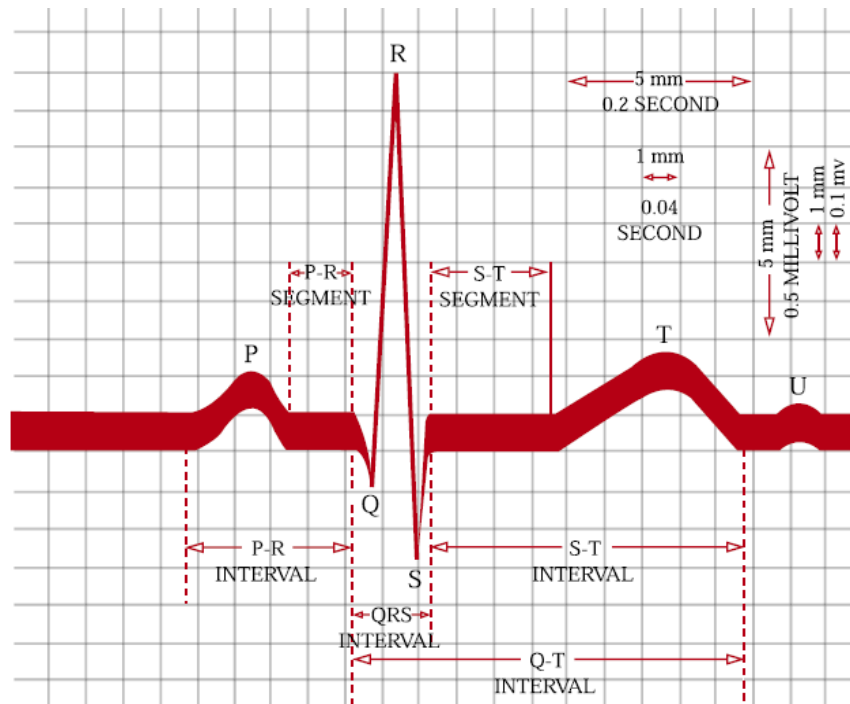


Figure 13: Standard ECG Waveform [6]

Table 4: Standard ECG Parameters [7]



Feature	Normal Value	Normal Limit
P Width	110 ms	± 20 ms
PQ/PR Interval	160 ms	± 40 ms
QRS Width	100 ms	± 20 ms
QT Interval	400 ms	± 40 ms
P Amplitude	0.15 mV	± 0.05 mV
QRS Height	1.5 mV	± 0.5 mV
ST Level	0 mV	± 0.1 mV
T Amplitude	0.3 mV	± 0.2 mV

The P wave is associated with atrial depolarization, the QRS wave is associated with ventricular depolarization, and the T wave is associated ventricular repolarization. While atrial repolarization does cause a wave on the ECG, it is covered by the large signal coming from ventricular depolarization and thus cannot be seen.

The ECG analysis program measures the parameters given in Table 4. It first analyzes the ECG through the following steps:

1. Preprocessing
2. QRS detection
3. ECG segmentation
4. Spectral Analysis
5. T-wave Analysis

Preprocessing is required to further remove noise from the ECG and smooth the waveform for easier analysis. Noise falls under two categories – high-frequency and low-frequency noise – and can be attributed to baseline wander caused by respiration, body movement, power line interference, muscle activity, and poor electrode contact [7]. Preprocessing is done through bandpass filtering, passing only the signal content in the range of 0.5-50 Hz.

QRS detection and ECG segmentation can be done through a variety of published methods, including the use of non-probabilistic methods such as thresholds and OFM transforms; or statistical pattern recognition using hidden markov models. [7]

Since both hidden markov models and non-probabilistic methods have errors associated with them, the program combines both methods in order to get a better result.[7]

After ECG segmentation, the values of the ECG parameters given in Table 4 can be calculated. Certain heart conditions can then be determined based on whether or not the values are standard or not.

Here is the order of analysis of ECG, one it is segmented [8]:



1. Rate:

From the QRS detection, we can get the heart rate, in beats per minute. Normal heart rate is 60 bpm. If it is not 60 bpm, it falls under one of these two categories:

- Sinus Bradycardia – heart rate < 60 bpm
- Sinus Tachycardia – heart rate > 60 bpm

2. Rhythm:

First, the beat-to-beat QRS time intervals is generated and analyzed to see if there is any large variability in the value. If there is, it can be due to escape beats, premature beats, atrial bigeminy, or trigeminy. An escape beat occurs when there is a pause in pacing, and can be:

- Atrial escape beat (60 – 80 bpm)
- Junctional escape beat (40-60 bpm)
- Ventricular escape beat (20-40 bpm)

These are differentiated based on the morphology of the escape beat, and the length of the pause. In contrast with escape beats, premature beats are due to an irritable automaticity focus.

If the heart rate variability is not due to escape or premature beats, but instead has a regular pattern, then it can be due to bigeminy or trigeminy. Both of these have large heart rate variability, but unlike the premature or escape beats, these have a regular pattern associated with them. For example, bigeminy occurs in couplets.

Next, the software analyzes for any blockages by noting the P and QRS locations. The software checks to see if the ratio of P waves to QRS waves is 1:1, and calculates the length of the PR interval, and QRS complex. From there, it can determine, based on the results:

- Primary AV block – PR interval > 0.2 sec, but P:QRS is 1:1
- Secondary AV block – P:QRS is not 1:1
 - Weinckebach block if beat-to-beat PR interval gradually increases until there is 1 missing QRS
 - Mobitz block if P:QRS is constantly not 1:1, but PR interval is normal
- Tertiary AV block – P and QRS rates are independent; heart rate between 20-60 bpm

The naming of the block (primary or secondary AV) refers to the location of the block. These AV blocks affect the conduction from the atria to ventricles.

Bundle branch blocks occur at the bundle branch. These are assessed if the QRS interval > 0.12 sec.



3. Axis:

Axis refers to the mean direction of movement of depolarization as it spreads throughout the heart. The normal mean QRS vector points downwards and towards the patient's left. Figure 14 below shows how the axis is measured.

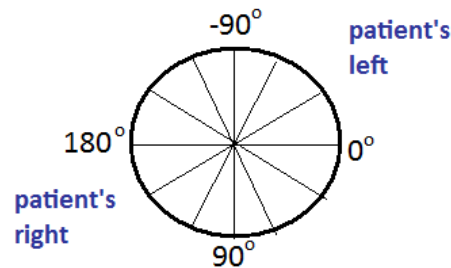


Figure 14: Axis Determination

The normal range is from 0° to 90° . Right Axis deviation is from 90° – 180° , extreme right axis deviation is from 180° to -90° , and left axis deviation is from 0 to -90° . This is determined by looking at the QRS complexes in leads I, II, and aVF to see whether they are mainly positive or negative. It can also be determined by looking at which lead is the most isoelectric (out of the limb and augmented leads).

4. Hypertrophy:

Hypertrophy refers to abnormal thickening of the heart muscle. There is atrial and ventricular hypertrophy. To assess atrial hypertrophy, the software looks at the morphology of the P waves. Using sign counting, if it is diphasic, then there is atrial hypertrophy.

For ventricular hypertrophy, the axis deviation is in the direction of ventricular hypertrophy.

5. Infarction or MI

Infarction or MI occur when there is little or no blood flow in one or more parts of the heart. It is diagnosed on the ECG by looking at the morphology of the T-waves and the ST segment level. An inverted T wave is associated with MI. ST-segment elevation or depression, defined as above or below the isoelectric line, is associated with infarction.

Spectral analysis computes the power spectral density (through Fourier analysis), and is used to assess arrhythmias, in particular atrial or ventricular fibrillation and flutter, since these show up as a shift of the power spectral density to higher frequencies.

Finally, T-wave alternans refer to beat-to-beat differences in the shape, amplitude, and timing of T-waves and are associated with ventricular arrhythmias [9] and sudden cardiac arrest [10]. These alternans are detected through highpass linear and nonlinear filtering methods [7].



4.2 Blood Pressure Analysis Program Design

The Blood pressure analysis program analyzes the signal measured by the air pressure sensor in the air cuff to determine the systolic and diastolic blood pressure of the user. Figure 15 below shows a screenshot of the signals from the air pressure sensor of a normal blood pressure reading.

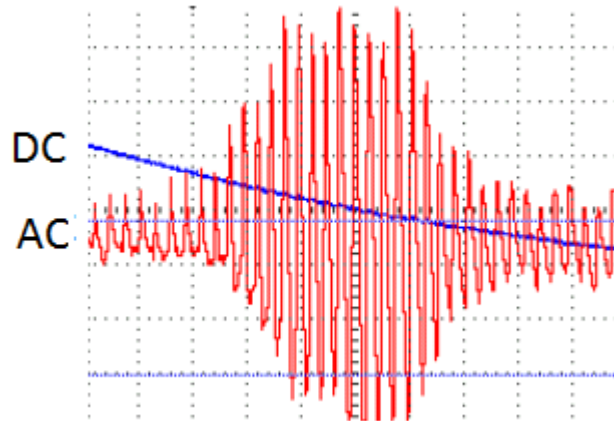


Figure 15: Typical Blood Pressure Acquisition Waveform

The DC value gives the air pressure in the cuff, while the AC value shows the fluctuations due to blood. The conversion of voltage to pressure (in mmHg) is given in appendix.

As the cuff pressure is deflated from supra-systolic to sub-diastolic pressure, the oscillation amplitude (of the AC signal) increases then decreases. The point of maximum amplitude is taken to be when the cuff pressure is equal to the mean arterial pressure (MAP).

There are two basic methods of determining the cutoff point for SBP and DBP: the amplitude threshold and the differential method [11]; both these methods are based on the measurement of MAP.

The amplitude threshold determines SBP and DBP by priority set factors. SBP and DBP are determined where the ratio of their amplitude to MAP amplitude is equal to the systolic and diastolic ratios respectively. That is,

$$\text{Systolic Ratio} = \frac{\text{SBP Amplitude}}{\text{MAP Amplitude}} \quad (9)$$

$$\text{Diastolic Ratio} = \frac{\text{DBP Amplitude}}{\text{MAP Amplitude}} \quad (10)$$

The DBP is always lower than MAP, while SBP is always larger than MAP. The systolic ratio is typically 0.5, while the diastolic ratio is typically 0.7 [11]. The DC voltage value at the time where the amplitude equals the systolic and diastolic ratios is taken to be the pressure reading. For example, determination of DBP is shown in the figure below.

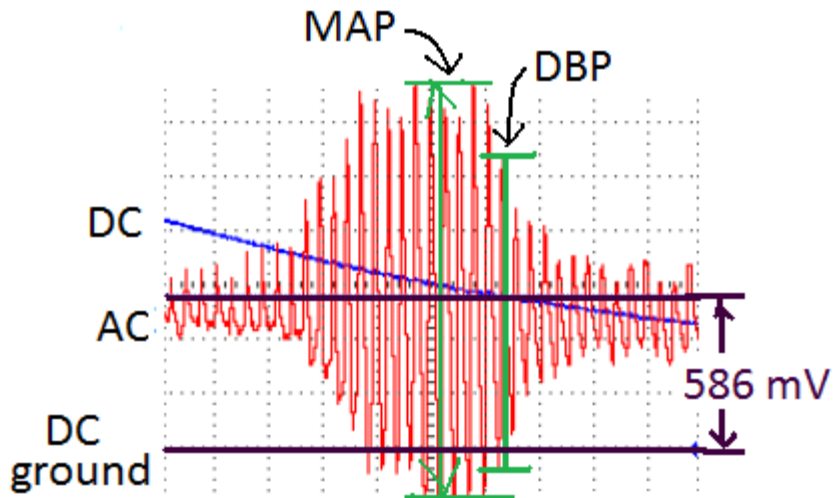


Figure 16: DBP Measurement

DBP is the point past MAP pressure where the oscillation amplitude is 0.7 of the MAP amplitude. The DC voltage value at that point is 586 mV. Using equation 8, this DC voltage value can be converted to pressure (mmHg) to determine the DBP of the user.

In the differential method, the envelope of the oscillations is first detected, as shown in figure below.

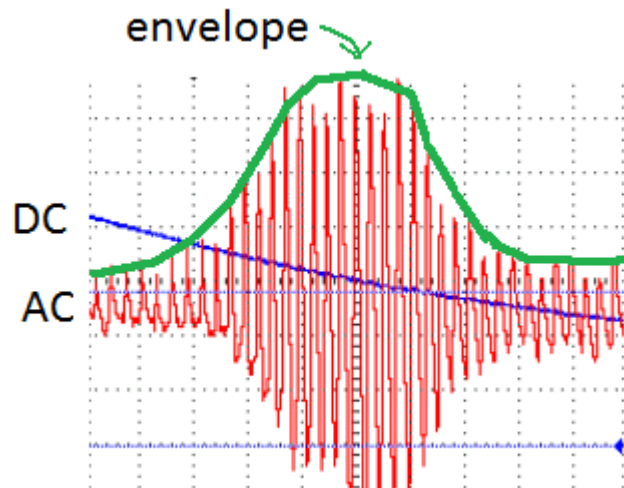


Figure 17: Envelope Detection for Blood Pressure Measurement

The maximal and minimal envelope slopes are used to determine DBP and SBP respectively, where MAP is the point of zero slope [11]. Similar to the other method, the DBP is found at a pressure lower than MAP while SBP is greater than MAP.



The blood pressure of the user is displayed on both the hardware LCD (for quick viewing) and in the software report. Most commercial products use the amplitude threshold method, but the differential method is more accurate. Since the differential method takes more processing power for the envelope detection, the hardware uses the amplitude threshold while the software uses the differential method to analyze blood pressure.

4.3 Body Fat Analysis Program Design

The body fat analysis program takes the electrical resistance of the body to estimate the user's body fat content, since the resistance is related to the total body water content, which can be used to estimate the fat mass when body mass is taken into consideration, through anthropometric equations which relate proportion of fat to fat-free tissue mass in the "standard" human.

Since body fat analysis is not included in the prototype model, this section is only briefly described.

4.4 Personal Information Data Design

The personal information data takes into account demographic data in order to be able to assess their risk for CVD. It also optionally records the person's physical activity levels and nutrition level.

The demographic data included in this database are: age, weight, height, gender, family history of CVD, and whether or not they smoke or are diabetic, and their ethnic history. The personal information database also prompts the user for any previous/present medical condition and whether or not they are on any medications or drugs. This is done via an editable form in the GUI that the user, once verified, can access and modify at any time.

Estimation of physical activity level can be done two different ways:

- 1 week prospective recording of all physical activity
- Fitness assessments for VO_2 max, flexibility, and strength

Both methods have their respective advantages and disadvantages. While the first method is more ideal, in that it records every single physical activity the person does, it is more time consuming. The fitness assessments are easier for the user to do and take less time, but are more indicative of physical fitness in certain areas as opposed to level of physical activity, which are not the same.

Recording of nutrition is optional for the user, but important assessment in making healthy lifestyle changes. The nutrition is recorded via 2 ways:

- 1 day food log, plus dietary frequency intake
- Daily food log for user-specified duration of at least 1 week

The information above is used in both the risk stratification and the final educational report.



The 1 day or daily food log asks the user to right down, in as much detail, everything consumed (food and drink) for that day. The 1 day food log is for one day, while the daily food log is for every day from the start day to user-specified end day.

The dietary frequency intake form asks the person, on a weekly basis, how often he/she consumes the various food types and groups. For example:

- How many servings of fruits and vegetables do you usually get in one day?
- How many days in the week do you eat fish?

A fully functioning physical activity and nutrition assessment is not included in the prototype model, and, as such, any design specifications pertaining to them are only partially described, and tentative.

4.5 Risk Stratification Scheme

The risk stratification scheme assesses the user's relative risk for heart disease and stroke using the user's personal information and tests done by users using Home Heart Monitor data acquisition equipment. Method used to analyze user's risk is based on Framingham Heart Study. The following sections describe the information needed and limitations of Framingham Risk Profile for CVD and stroke.

4.5.1 Framingham CVD Risk Profile

Framingham CVD Risk Profile on Home Heart Monitor device will attempt to detect user's probability of acquiring CVD in the next 10 years. It is most accurate if used on individuals 30 to 74 years old without any underlying heart disease(s). [12]

The following information is needed to calculate user's probability of acquiring CVD in the next 10 years:

1. User's age?
2. User's gender?
3. User's height and weight?
4. Is user a smoker?
5. Does user has diabetes?
6. User's blood pressure?
7. Is user taking any hypertensive medication?

Information such as age, gender, height, weight, smoking habit, hypertensive medication, and diabetes, is acquired by user input through the personal information page on the Home Heart Monitor's GUI. Blood pressure is acquired through measurement by the blood pressure acquisition system.

Using Framingham CVD risk profile, each data will be converted into Framingham CVD risk score as shown in Appendix 1. The score will be totaled and converted to user's 10 years probability of developing CVD.



4.5.2 Framingham Stroke Risk Profile

Framingham Stroke Risk profile on Home Heart Monitor will calculate user's 10 probability of stroke if users lie in the 55 to 84 years old population. Calculation result is invalid if user has a history of stroke. [13]

The following information is needed to calculate user's probability of acquiring CVD in the next 10 years:

1. User's age?
2. User's gender?
3. Is user a smoker?
4. Does user has diabetes?
5. User's systolic blood pressure?
6. Is user taking any hypertensive medication?
7. Does user has any prior CVD?
8. Is atrial fibrillation and/or ventricular hypertrophy detected in ECG reading?

Information such as age, gender, height, weight, smoking habit, hypertensive medication, and diabetes, is acquired by user input through the personal information page on the Home Heart Monitor's GUI. Blood pressure and heart problems (atrial fibrillation and left ventricular hypertrophy is acquired through measurement and analysis by the respective hardware acquisition systems.

Using Framingham stroke risk profile, each data will be converted into Framingham stroke risk score as shown in Appendix 2. The score will be totaled and converted to user's 10 years probability of developing stroke.

4.6 Educational Report System Design

The educational report system takes into account the users' risk assessment, ECG findings, physical activity level, and nutritional intake and compares it with current established guidelines for healthy living. It also

This section breaks down the educational report and describes the assessment of each of the aforementioned components, as well as the components involved in the printer-friendly results. Since the prototype will not have a full physical activity and nutritional assessment capability, the design described in their respective sections are only tentative.

4.6.1 Risk Assessment Results

The results of the risk assessment give show their risk for CVD categorically (high, moderate, or low). The relationship between the percent risk and categorical risk is:

- High: >20%
- Moderate: 10-20%
- Low: <10%



For people with an extremely high risk of developing CVD (>50%), the report will also suggest they go to the doctor for a more complete checkup.

The educational report then goes on to describe their results, and how they can improve it.

It first explains their BMI and blood pressure results, how it compares to “healthy values”, and its significance. This information is summarized in Table 5 and Table 6 below.

Table 5: BMI Classifications and Significance [14]

BMI	Classification	Significance
>30	Obese	Your BMI is too high. Normal BMI range is from 18.5 – 24.9 A high BMI can be indicative of high body fat percentage. It is recommended that you reduce your BMI through lifestyle changes.
25-29.9	Overweight	
18.5-24.9	Normal Range	Your BMI is within the normal range. Good Job!
< 18.5	Underweight	Your BMI is too low. A low BMI can cause health problems. Try to increase your BMI through lifestyle changes.

Note: For Asians, BMI \geq 23 is the cutoff point for overweight.

Also, “lifestyle changes” referenced here shall be described in the report.

Table 6: BP Classifications and Significance (from correspondence with Dr. Scott Lear)

Systolic	Diastolic	Classification		Significance
>210	>120	Hypertensive	Very Severe	Blood pressure is higher than normal, which means your heart has to work hard than normal to pump blood through your body, increasing your risk for CVD. Please see the doctor.
180-209	110-119		Severe	
160-179	100-109		Moderate	
140-159	90-99		Mild	
121-139	81-89	Pre-hypertensive		You are at risk of developing high blood pressure. It is suggested that you lower your blood pressure, through lifestyle changes.
<120	<80	Normal Range		Your blood pressure is normal. Good Job!

Note: For pre-hypertensive users, the “lifestyle changes” shall be described in the report.

It then checks whether or not the person is diabetic or smokes. If the person smokes, the report posts a link to the smoking cessation program, which interactively decides which stage of change the person is at, and suggests actions to move them to the next stage. The stages of change, along with the corresponding computer actions, are given in Table 7 below.



Table 7: Smoking Assessment [15]

Stages of Change	Description	Computer Action
Pre-contemplation	Has not considered changing	Raises doubt and tries to persuade user to stop smoking by listing pros and cons of smoking
Contemplation	Ambivalent	
Determination	Committed to change	Educates user on smoking cessation aids and steps user through process of making the change
Action	Attempts to change	

Finally, if the person is diabetic, the report will highlight the effect of diabetes on heart health, and remind the user of what they can do to not further worsen their condition.

This is only the first part of the assessment; the second half of the educational report is education on how the person can change their lifestyle, with respects to physical activity, nutrition, and smoking. The first two are described in the section below, while the last one has already been described.

4.6.2 Physical Activity Assessment

Physical activity is important as it affects blood pressure and body composition, and has a greater bearing on heart health than body composition. An active lifestyle is important in reducing risk for CVD.

From the physical activity intake, the computer can assess a) whether or not they are sufficiently physically active and b) how their fitness scores compare to others their age.

The computer explains the results, the importance of an active lifestyle for those who are not yet physically active, and how to improve their results.

Since a full physical activity assessment is not included in the prototype model, this is only a partial and tentative description of the design of the physical activity assessment.

4.6.3 Nutritional Assessment

Based on the food intake record given by the user, the software analysis estimates the number of calories consumed per day, and the proportion of calories coming from each nutrient group (carbohydrates, proteins, fats, dairy). If possible, it shall also estimate the amount of vitamins and minerals coming from the food.

It then compares calories consumed to the amount needed (based on calculations of basal metabolic rate). It also compares proportion of food intake to those established by Canada Food Guide. Finally, it compares the amounts of vitamins and minerals to the recommended intake values.

Finally the program reports the results to the user and lists how the user can improve their diet to meet Canadian guidelines.

As a fully functioning nutritional assessment is not included in the prototype model, the design specification outlined here is only partially described, and tentative.



4.6.4 ECG Results

If there are any abnormal ECG findings, the educational report does not go into detail, but mentions that the user does have an abnormal ECG, and suggests that the person prints off the measured ECG and seek clinical advice for more accurate assessment.

4.6.5 Printer-friendly Report

Once the educational report has been generated, it is displayed on the screen. The user has the option to convert it into a printer-friendly format, while will be displayed in .pdf format.

Two versions of the printer-friendly report are given: full and concise. Both versions include the results, but only the full version includes the explanations and significance of the results.

The ECG measured from the person can also be displayed in a printer-friendly .pdf format. This report includes the 6-lead ECG signals, as well as the annotation by the computer. The annotation consists of computer-calculated parameter values (segment lengths and wave amplitudes), as well as the computer's interpretation of the ECG (based on the ECG analysis algorithm given previously).

4.7 Track Progress Design

This section describes in brief the design of the track progress option.

Once the results are saved into the database, the user has the option of tracking their progress over time. To do so, the user specifies time duration (from start to end date) they want to see their progress. The computer checks to see that the time duration give is valid (that there are records available between the time period given). The program then pulls up the records of BP, CVD risk, and BMI from during that time period and plots it over time so that the user can see how their present risk compares to past values.

4.8 Database Design

Our database is implemented using a relational database model; as such, it can be conceptually viewed as a collection of tables. The diagram given in Figure 18 below shows the tables and their relation to each other.

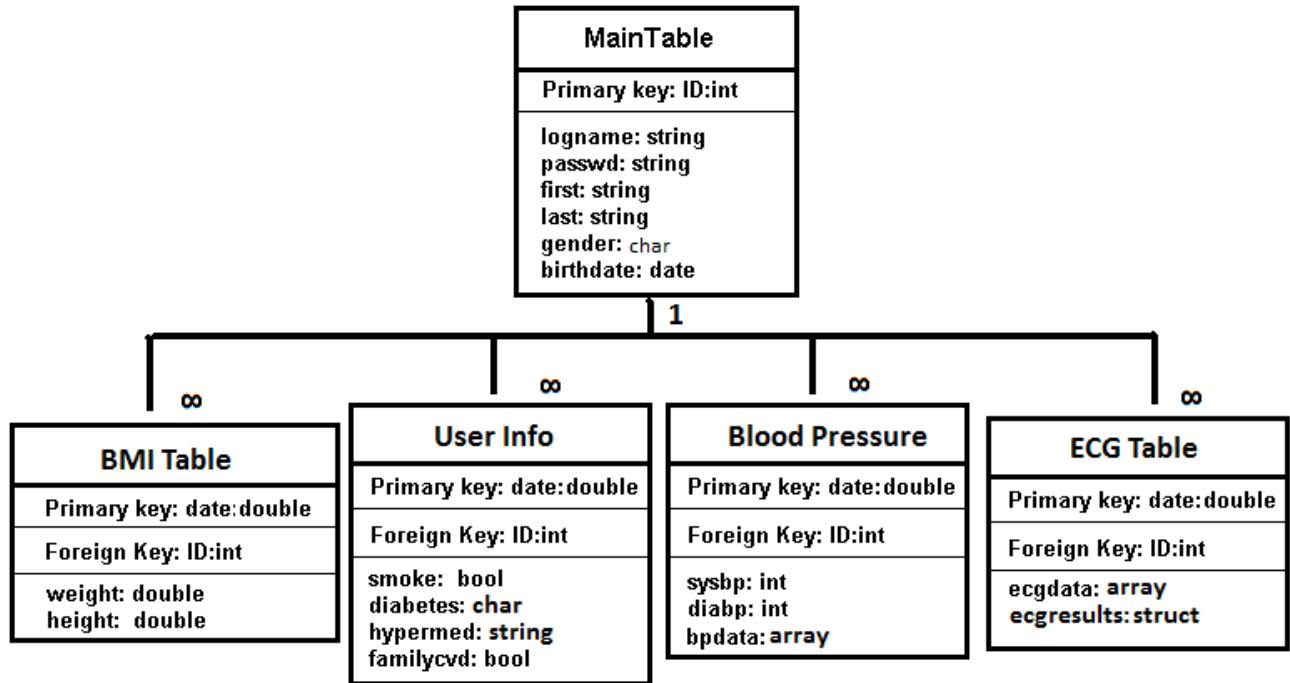


Figure 18: Database Diagram

The database consists of 5 different tables. The main table consists of user information (login, password, name). The ID is the primary key, and is a unique identifier given to each user. The other four tables are connected to this main table via the ID. Since the entities in each of the other four tables can change over time, we are using date as the primary keys. The date consists of the month, day, year, and time, converted to numerical format based on the whole and fractional number of days since Jan 1, 1990.

The next two tables, BMI and user info, store the rest of the personal information. The entities of each of these two tables are shown in Figure 18. Since both weight and height are expected to change, and it is important to track these changes in order to show the participant their progression over time and the effect of their lifestyle, the entities in the BMI table are saved every time they change values, which is why they are separated from the main table.

Similarly for the user info, whether or not a person is a smoker, diabetic, etc. can change over time, though not as much as BMI. Every time these changes occur, it is good to keep a record. Diabetic is given in char format as there are 3 types of diabetes: type I, type 2, and gestational. Hypermed, which stands for hypertensive medication, is stored as a string as there are a variety of categories of medications one can be on.

For the BP and ECG tables, both the waveform and the results after analysis are saved into the database for future reference, according to the time they were measured and transferred to the computer. Since both waveforms (BP and ECG) take up quite a bit of space, they shall be stored in a compressed format. ECG shall be compressed by wavelets, and only the limb leads (leads I, II, III) shall be stored.



For the ECG table, the results have been shown simply as “ECGresults:struct” for ease of viewing, as there are many results associated with this, such as the parameter values in Table 4, presence and type of arrhythmias, any other rhythm and rate problems, etc. as described in section 4.1.

4.9 Application Software Design

This section discusses the design specifications for the software in the computer that communicates with the AVR butterfly microcontroller via RS232. This application software will be run as a Windows program with user interactions. The software design overview and flowchart are shown in the figures below.

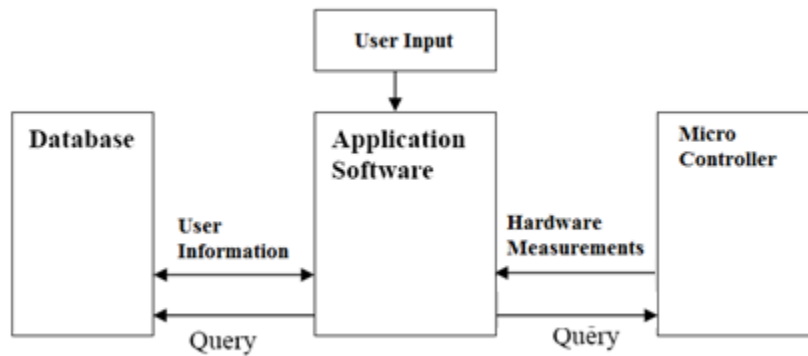


Figure 19: Application Software Design Overview

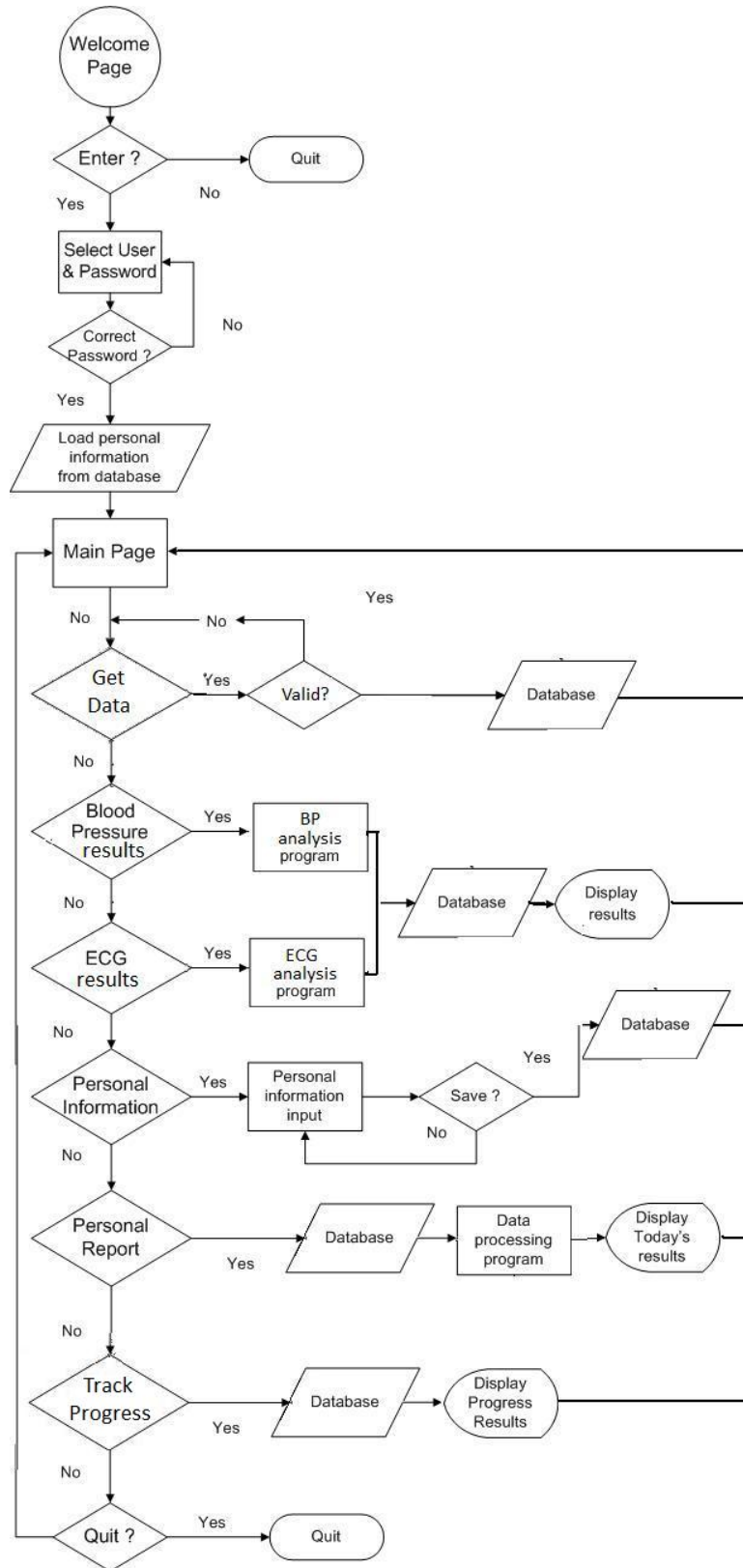


Figure 20: Application Software Flowchart



The application software, as shown in Figure 20, consists of the following options:

- Log in menu – manages users , and verify user through password verification
- Get data – downloads BP, Body fat, and ECG data from the microcontroller
- ECG results – analyzes the ECG and displays the ECG waveform and results
- Blood Pressure results – analyzes and displays resulting blood pressure reading(systolic/diastolic)
- Personal Information – allows user to input, view, and modify personal information
- Educational report – assesses user’s risk for CVD, and interprets the results in a meaningful way to the user
- Track Progress – plots the progression of BMI, BP, and risk over user-specified time period

5. Environment

The following section outlines the considerations we have made in trying to make our product as environmentally friendly as possible.

The ECG Electrode Pad: For the ECG electrode, we use reusable electrode pads, instead of disposable ones, to limit waste..

The packaging for the final prototype: We will use recyclable material to build our device package. Other than using plastic container, we could use recycle plastic, which reduce the waste.

The Electronic Waste after its lifecycle: After product life-cycle is completed or users are done using the product, recycling options will be available for those who choose to do so will be available. Working products and plastic parts that are still usable, such as the blood pressure cuff, can be donated to developing and underdeveloped nations for reuse. The unusable or broken parts will be safely recycled to recover its raw material.

Battery: Our final product will require little power when used. The product will also be equipped with long life and rechargeable battery, which will reduce consumer battery consumption and waste.



6. Conclusion

This document describes the proposed design of our product to meet the requirements listed in the functional specification. It only partially outlines the design considerations in the functionalities that are not included in the prototype model. It also includes a brief consideration of how to make our product environmentally friendly as possible. Throughout the developing of our prototype model, we will adhere to this design document as much as possible in order to meet the functional specifications.



Reference

- [1] World Health Organization, "Cardiovascular Disease: Prevention and Control," 2009. [Online]. Available: <http://www.who.int/dietphysicalactivity/publications/facts/cvd/en/>. [Accessed: February 10, 2009].
- [2] Canadian Institute of Health Research, "Health Research – Investing in Canada's Future 2004-2005 – Heart Disease," 2005. [Online]. Available: <http://www.cihr-irsc.gc.ca/e/28901.html>. [Accessed: January 30, 2009]
- [3] Hargraves. "Specification Sheet No. E179-11-030_ Rev_A". July 2003. [Online]. Available: www.hargravesfluidics.com/pdf/CTS/PR_E179-11-030_A.1F02N1.C03VDC_Rev_A.pdf. [Accessed: January 30, 2009]
- [4] Freescale Semiconductor. "50 kPa On-Chip Temperature Compensated and Calibrated Silicon Pressure Sensors". October 2008. [Online]. Available: www.freescale.com/files/sensors/doc/data_sheet/MPX2050.pdf. [Accessed: January 24, 2009]
- [5] ATMEL. "AVR Butterfly Evaluation Kit: User Guide". 2005. [Online]. Available: www.atmel.com/dyn/resources/prod_documents/doc4271.pdf. [Accessed: January 15, 2008]
- [6] R. Mark, "HST.542J/2.782J/20.371J/6.022J Quantitative Physiology: Organ Transport System," HST, 2009. [Online]. Available: <http://ocw.mit.edu/OcwWeb/Health-Sciences-and-Technology/HST-542JSpring-2004/CourseHome/index.htm>. [Accessed: February 11, 2009].
- [7] G. Clifford, F. Azuaje, and P. McSharry, ed. *Advanced Methods and Tools for ECG Data Analysis*. Boston: Artech House, 2006.
- [8] D. Dublin. *Rapid Interpretation of EKG's*. Florida: COVER, 2006.
- [9] J.M. Smith, et al. "Electrical Alternans and Cardiac Electrical Instability," *Circulation*, vol 17, 2001, p 110-121.
- [10] Z. Zheng, et al. "Sudden Cardiac Death in the United States, 1989 to 1998," *Circulation*, vol 104, 2001, p 2158-2163.
- [11] G. Gersak, V. Batagelj, J. Drnovsek, "Oscillometric Virtual Instrument for Blood Pressure Measurement," *Metrology for a Sustainable Development*. Sept 17-22, 2006.
- [12] Framingham Heart Study. "Risk Score Profiles". February 2009. [Online]. Available: <http://www.framinghamheartstudy.org/risk/index.html>. [Accessed: February 13, 2009]
- [13] R. B. D'Agostino, PHD; P. A. Wolf, MD; A. J. Belanger, MA; W. B. Kannel, MD. "Stroke Risk Profile: Adjustment for Antihypertensive Medication – The Framingham Study" *Stroke*, Vol 25, 40-43, 1994



Design Specification
for the Home Heart Monitor

[14] T. Lobstein, N. Rigby, R. Leach. *"International Obesity Task Force EU Platform Briefing Paper,"* EU Platform on Diet, Physical Activity, and Health. European Association for the Study of Obesity, 2005.

[15] S. Brown, ed. Kin-340 Active Health Custom Courseware. SFU Bookstore.



Appendix 1: Framingham CVD Risk Profile

[According to D'Agostino, Vasan, Pencina, Wolf, Cobain, Massaro, Kannel. 'A General Cardiovascular Risk Profile for Use in Primary Care: The Framingham Heart Study']

BMI

BMI will be calculated as follow:

$$BMI = \frac{weight}{height^2} [kg/m^2]$$

Male CVD Index

Points	Age	BMI [kg/m ²]	Systolic Blood Pressure (Not treated)[mmHg]	Systolic Blood Pressure (Treated)[mmHg]	Smoke	Diabetes
-2			<120			
-1						
0	30 - 34	<25	120 - 129	<120	No	No
1		25 - 29	130 - 139			
2	35 - 39	>29				
3			140 - 149	120 - 129		Yes
4			150 - 159	130 - 139	Yes	
5	40 - 44		>159			
6				140 - 149		
7	45 - 49			150 - 159		
8	50 - 54					
9				>159		
10	55 - 59					
11	60 - 64					
12						
13	65 - 69					
14	70 - 74					
15	>75					



Female CVD Index

Design Specification
for the Home Heart Monitor

Points	Age	BMI	Systolic Blood Pressure (Not treated)[mmHg]	Systolic Blood Pressure (Treated)[mmHg]	Smoke	Diabetes
-3			<120			
-2						
-1				<120		
0	30 - 34	<25	120 - 129		No	No
1		25 - 29	130 - 139			
2	35 - 39	>29		120 - 129		
3			140 - 149	130 - 139		
4			150 - 159		Yes	
5	40 - 44		>159	140 - 149		Yes
6	45 - 49			150 - 159		
7						
8	50 - 54			>159		
9						
10	55 - 59					
11	60 - 64					
12	65 - 69					
13						
14	70 - 74					
15	>75					



Conversion Table – CVD score to Percentage Probability of CVD within the Next 10 Years

Points	% Probability for Male	% Probability for Female
≤ -5	< 1	
-4	1.1	
-3	1.4	
-2 for male or ≥ -2 for female	1.6	< 1
-1	1.9	1.0
0	2.3	1.1
1	2.8	1.5
2	3.3	1.8
3	4.0	2.1
4	4.7	2.5
5	5.6	2.9
6	6.7	3.4
7	8.0	3.9
8	9.5	4.6
9	11.2	5.4
10	13.3	6.3
11	15.7	7.4
12	18.5	8.6
13	21.7	10.0
14	25.4	11.6
15	29.6	13.5
≥ 16 for male or 16 for female	> 30.0	15.6
17		18.1
18		20.9
19		24.0
20		27.5
≥ 21		> 30.0



Appendix 2: Framingham Stroke Risk Profile

[According to D'Agostino, Wolf, Belanger, Kannel ' Stroke Risk Profile: Adjustment for Hypertensive Medication ']

Male Stroke Index

Points	0	+1	+2	+3	+4	+5	+6	+7	+8	+9	+10
Age	54 - 56	57 - 59	60 - 62	63 - 65	66 - 68	69 - 72	73 - 75	76 - 78	79 - 81	82 - 84	85
Systolic Blood Pressure (Not Treated)	97 - 105	106 -115	116 – 125	126 - 135	136 - 145	146 - 155	156 - 165	166 - 175	176 - 185	186 - 195	196 – 205
Systolic Blood Pressure (Treated)	97 - 105	106 -112	113 - 117	118 - 123	124 - 129	130 - 135	136 - 142	143 – 150	151 - 161	162 - 176	196 – 205
Diabetes	No	Yes									
Cigarettes	No	Yes									
Previous CVD	No					Yes					
Atrial Fibrillation	No					Yes					
Left Ventricular Hypertrophy	No						Yes				



Design Specification
for the Home Heart Monitor

Female Stroke Index

Points	0	+1	+2	+3	+4	+5	+6	+7	+8	+9	+10
Age	54 - 56	57 - 59	60 - 62	63 - 64	65 - 67	68 - 70	71 - 73	74 - 76	77 - 78	79 - 81	82 - 84
Systolic Blood Pressure (Not Treated)		95 - 106	107 - 118	119 - 130	131 - 143	144 - 155	156 - 167	168 - 180	181 - 192	193 - 204	205 - 216
Systolic Blood Pressure (Treated)		95 - 106	107 - 113	114 - 119	120 - 125	126 - 131	132 - 139	140 - 148	149 - 160	161 - 204	205 - 216
Diabetes	No			Yes							
Cigarettes	No			Yes							
Previous CVD	No		Yes								
Atrial Fibrillation	No						Yes				
Left Ventricular Hypertrophy	No				Yes						



Conversion Table – Stroke score to Percentage Probability of Stroke within the Next 10 Years

Points	% Probability for Male	% Probability for Female
1	3	1
2	3	1
3	4	2
4	4	2
5	5	2
6	5	3
7	6	4
8	7	4
9	8	5
10	10	6
11	11	8
12	13	9
13	15	11
14	17	13
15	20	16
16	22	19
17	26	23
18	29	27
19	33	32
20	37	37
21	42	43
22	47	50
23	52	57
24	57	64
25	63	71
26	68	78
27	74	>84
28	79	
29	84	
30	>88	

