Detailed Design Specifications Document

for

Portable, Single-Lead ECG Monitor

Version: 4.00

Prepared by:

Truc Do, Matthew Nepo, Vignesh Ravindranath, Jacob Scheftel

Last modified: 5/4/2019

Portable, Single-Lead ECG Monitor

Detailed Design Specifications Document Concurrence

The undersigned acknowledge that they have reviewed and approve the Portable, Single-Lead ECG Monitor Detailed Design Specifications Document. Changes to this document must be coordinated and approved by the undersigned of their designated representatives.

Matthew Nepo_____ UT Austin: Department of Biomedical Engineering
TITLE ORGANIZATION

_____ _____
SIGNATURE DATE

Jacob Scheftel_____ UT Austin: Department of Biomedical Engineering
TITLE ORGANIZATION

_____ _____
SIGNATURE DATE

Vignesh Ravindranath_____ UT Austin: Department of Biomedical Engineering
TITLE ORGANIZATION

_____ _____
SIGNATURE DATE

Truc Do_____ UT Austin: Department of Biomedical Engineering
TITLE ORGANIZATION

_____ _____
SIGNATURE DATE

Table of Contents

1.0 General Information

1.1 Purpose

The Design Specifications Document tracks the necessary information required to effectively define architecture and system design in order to give the development team guidance on architecture of a Portable, Single-Lead ECG Monitor.

1.2 Scope

Included in this document is an overall description of the project, a Portable, Single-Lead ECG Monitor; along with any assumptions required in designing the device, as well as constraints and risks associated with the design. The document also includes a detailed specification of design elements affecting the entire system (system architecture; user interface; packaging and labeling; and instructions for installation, use, and servicing) as well as the design of individual components (hardware, circuitry, software, and data format/contents). The intended audience of this document is the developers, designers, and software testers of the Portable, Single-Lead ECG Monitor.

1.3 Referenced documents

- Customer Needs Document
- Requirements Traceability Document

1.4 Acronyms and Abbreviations

- AC – Alternating Current
- ADC – Analog to Digital
- CS – Chip Select
- DC – Direct Current
- ECG – Electrocardiogram
- GB – Gigabit
- I/O – Input Output
- LCD – Liquid Crystal Display
- MB – Megabit
- MOSI – Master Out Slave In
- PCB – Printed Circuit Board
- RTC – Real Time Clock
- Rx – Receive
- SCK/SCL – Serial Clock
- SD – Secure Digital
- SDA – Serial Data
- TFT – Thin Film Transistor
- Tx – Transmit

2.0 Overall Description

With cardiovascular disease remaining the number one killer in the United States, understanding cardiovascular health is more important than ever. The goal of this project is to build an easy to use, portable ECG device for patients with history of atrial fibrillation. Along with this, the venture aims to introduce low cost ECG technology to the general public, as well as improve ease of access for physicians to cardiographic data. The ECG will measure one or two leads rather than the traditional 12-lead ECG machines, thus allowing for the device to be compact while still maintaining accuracy and specificity comparable to that of a 12-lead device.

The aim of this endeavor is to make healthcare more accessible to the average consumer by providing a device capable of presenting ECG data in an easy to understand, aesthetic format. Consumers are expected to use the device multiple times as advised by physicians, requiring a lasting battery life throughout the day. The patient can expect to use our device to quickly and accurately monitor their ECG data.

2.1 Assumptions

- The frequency range of the normal human PQRST wave is from 0.5 Hz to 20 Hz
- The capacitive touch sensor will have sufficient sensitivity, such that ECG data can be collected.

2.2 Constraints

- The device shall serve as biometric data monitor for non-emergency monitoring use only, not as a diagnostic device.
- The device shall require the user to remain stationary during use.
- The device must cost under $100 to construct.

2.3 Risks

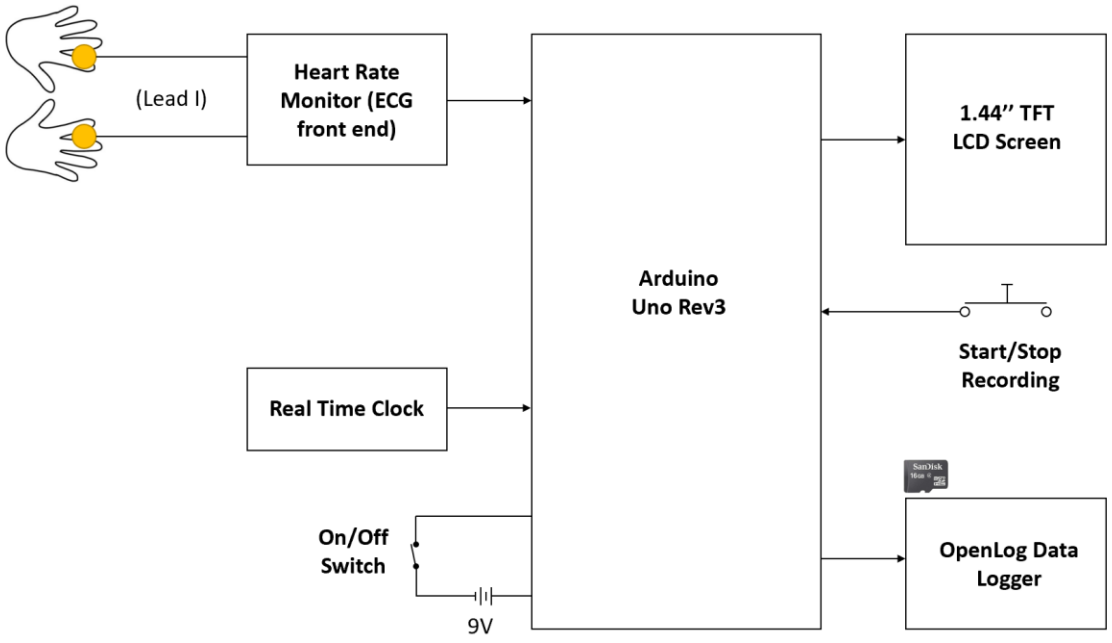
Contact with the touch capacitive sensors for an extended period of time can irritate or slight burn the skin in contact with the electrodes due to the presence of reactive metals. If fingers are wet, an electrical shock could occur when contacting the electrodes.

3.0 System Design

3.1 System Architecture

The primary computer for the portable ECG is an Arduino Uno Rev3, which takes a filtered ECG input from an ECG front end device (AD8232 Heart Rate Monitor by SparkFun) as well as a momentary data recording pushbutton. The Arduino Uno Rev3 outputs the ECG data to an LCD monitor (ST7735 1.44'' Color TFT LCD Display by Adafruit) and an OpenLog (DEV-13712 by SparkFun) with a 64MB – 32GB SD card for external storage. The Heart Rate Monitor will receive inputs from two capacitive touch sensors (one for each hand), which represents Lead I from a standard 10-electrode, 12-lead ECG. The Arduino Uno Rev3 also has a real time clock (DS3231 Real Time Clock) to output date and time onto the LCD output monitor. Lastly, a 2-solder lug rocker on/off switch will be available to power on and off the Arduino board.

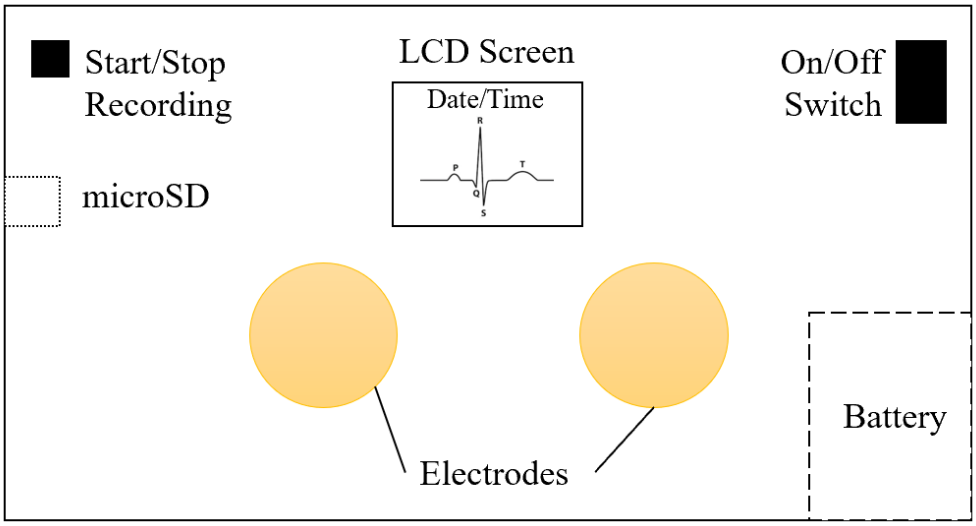
Figure 1: System Architecture Layout



3.2 User Interface

The device has minimal user interaction to increase simplicity and reduce user interaction to a minimum. The user will be able to interface with an LCD display screen, a button, an SD card, a battery, and two capacitive touch sensors.

Figure 2: ECG Front Facing View



3.2.1 Button Interface

The top right of **Figure 2** depicts the location of the start/stop recording button for the device. The initial button 'click' will begin sampling and recording data at 80Hz. The subsequent 'click' will stop recording data. An ECG waveform will continuously be displayed regardless of the button 'click'. The user will be able to see a small red recording circle displayed at the bottom right corner of the screen when data is recording. The small red recording circle will be removed from the screen to indicate data recording has ceased.

3.2.2 On/Off Switch Interface

The user will be able to easily turn on and off the ECG monitor by flipping the toggle switch to the on and off position.

3.2.3 LCD Display Interface

The LCD display (as depicted in **Figure 2**) will map out a PQRST wave (letters will not be show) in real time as the user is taking measurements. At the top of the screen, the date and time of reading will be displayed. When the device is in Sleep-Mode, the LCD screen will be blank (black) and when in On-Mode the LCD screen will display the date, time, and instructions to being recording ECG data.

3.2.4 SD Card Interface

The SD card slot can be found in the middle of the left face of the encapsulation (see **Figure 2** for relative location or **Figure 3 Front View** for more detail). The user will be able to use his or her fingers to pull out or push in a micro SD card into the slot (spring) without having to open the encapsulation. The user or primary care physician can access the data by placing the micro SD card

into a SD card adapter and inserting the adapter into the computer. All files will be stored as .csv files and the data and time of the recording will be displayed in the .csv file (see **4.4 Data Format/Content** for more information).

3.2.5 Battery Interface

1.1 **Figure 2** illustrates the battery compartment (rectangular compartment on the bottom right). The compartment will have a lid (see **Figure 3 Front View**) which can be removed and placed back on by pulling on the indentation. The battery compartment can hold a 9V battery, which can be removed and replaced after battery drainage. The batter is connected to the microcontroller via a battery clip, which can be easily accessed through the battery compartment without having to open the encapsulation.

3.2.6 Capacitive Touch Sensor Interface

The capacitive touch sensors are depicted as the two circles on the front face of the device. The user can place both his or her thumbs on the respective touch sensors for continuous data depiction. If there is no contact with the electrodes, a flatline will display on the screen.

3.3 Instructions for Installation, Use, and Servicing

3.3.1 ECG Monitoring

3.3.1.1 To turn on the Portable, One-Lead ECG by turning the toggle switch to the ON position (I).

3.3.1.2 Once turned on, view instructions displayed on the LCD screen (displayed for 15 seconds). Ensure the device is in the correct position (the LCD screen should be at the top of the device, above the left and right capacitive sensors).

3.3.1.3 Once the instructions have disappeared, place both thumbs on the respective capacitive sensors for as long as desired.

3.3.1.4 To begin recording data, simply press the button on the top left corner once. A small red circle should appear on the bottom right corner to confirm recording.

3.3.1.5 Once you have decided you have collected sufficient data, press the button one more time to end recording, the small red circle on the bottom right corner should disappear.

3.3.1.6 Once you have finished monitoring your ECG signal, turn off the device by turning the toggle to the OFF position (O).

3.3.2 Micro SD Card Access

3.3.2.1 If you would like to access recorded data, take the micro SD card from the slot on the left face of the device. Ensure the device is turned off before doing so.

3.3.2.2 Place the micro SD card into a SD card adapter and insert the adapter into a computer.

3.3.2.3 Open the respective .csv file to view various recordings (each recording will generate its own .csv file with the respective time stamp).

3.3.3 Battery Instructions

3.3.3.1 To remove the battery, slide open the battery box lid on the bottom right corner.

3.3.3.2 Unclip the battery from the battery clip and dispose of drained battery.

3.3.3.3 Place a new 9V battery onto the battery clip and place battery into the battery box.

3.3.3.4 Close the enclosure by sliding the battery box lid over the battery box.

4.0 Component Design

4.1 Hardware Design

Figures 3 and 4 below depicts various views of the 3D encapsulation of the electronics and wiring and places for interface. Note that all measurements in **Figures 3 and 4** are in mm and are the minimum required dimensions to completely enclose all hardware components.

Figure 3: Views From Bottom Surface of ECG Box

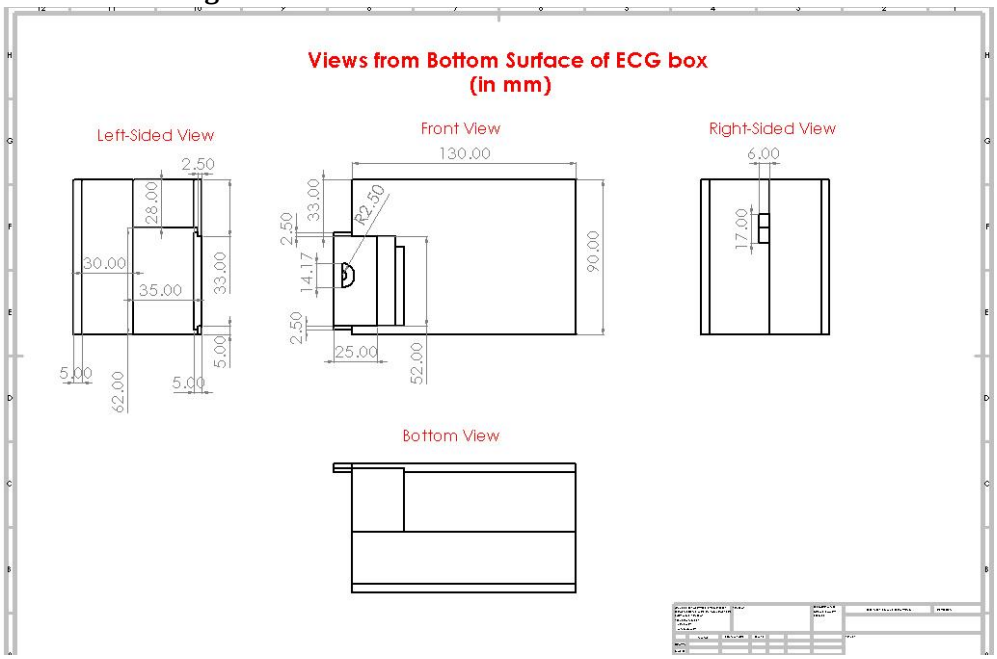
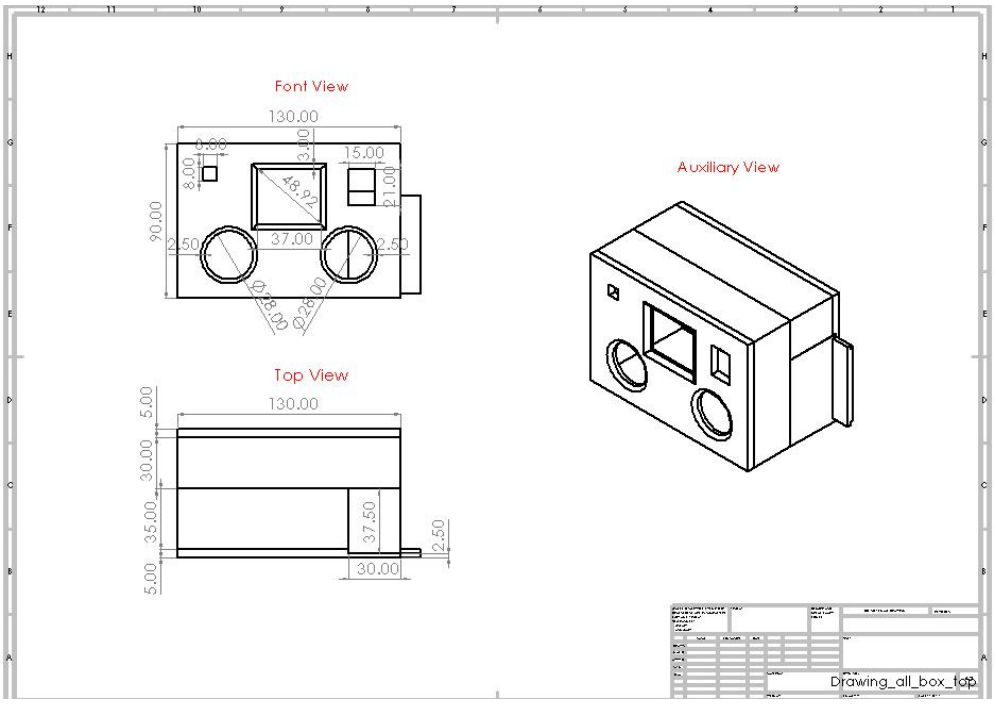


Figure 4: Front, Top, and Auxiliary Views of ECG Box



4.1.1 Arduino Uno Rev3

Table 1: Adruino Uno Rev3 Features

Microcontroller	ATmega328P
Operating Voltage	5V
Digital I/O Pins	14
Analog Pins	6
Flash Memory	32 KB
Clock Speed	16 MHz
Length	68.6 mm
Width	53.4 mm
Weight	25.0 g

4.1.2 Adafruit ST7735 1.44'' Color TFT LCD Display

Table 2: LCD Features

Operating Voltage	5V
Backlight Current	~25mA
Resolution	128x128
Length	33.0 mm
Width	45.0 mm
Weight	10.6 g

4.1.3 SparkFun DEV-13712 OpenLog

Table 3: OpenLog Features

Microcontroller	ATmega328P
Operating Voltage	3.3V – 12V
SD Card Format	FAT 16/32
Baud Rate	Configurable (up to 115200 bpm)
Idle Current Usage	2mA
Max Current Usage	6mA

4.1.4 SparkFun COM-09190 ROHS Momentary Pushbutton Switch

The momentary pushbutton switch is a 12mm square button. The button requires a 0V terminal (reference) and a variable voltage terminal (supplied by microcontroller). The switch will allow for either high or low voltage across the button.

4.1.5 ZUPAYIPA 2 Solder Lug SPST On/Off Mini Boat Rocker Switch (6A/250V,10A/125V)

The mini boat rocker switch is a 21x15x24mm switch to control the power of the device.

4.1.6 SparkFun AD8232 Heart Rate Monitor

Table 4: Heart Rate Monitor Features

Supply Current	170uA
Electrode Configuration	Two or three
Signal Gain	G=100

4.1.7 Adafruit DS3231 Real Time Clock

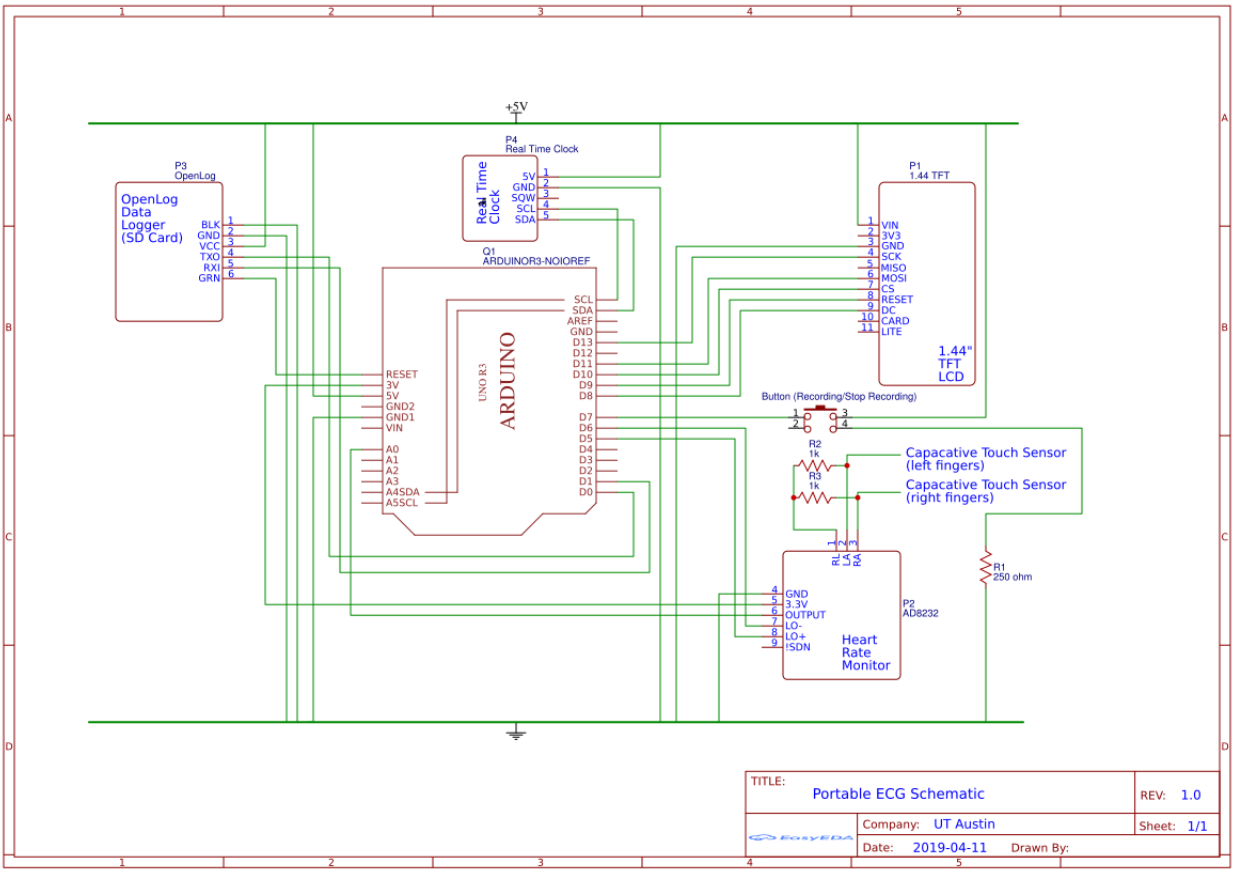
Table 5: RTC Features

Supply Current	Requires battery (incorporated)
Features	Seconds Minutes Hours Day Date Month Year/Leap Year
Clock Speed	400 z

4.2 Circuit Design

Figure 7 below depicts a detailed schematic of pin inputs and outputs for the various hardware components. The hardware components include an Arduino Uno Rev3, a Color TFT LCD Display, an OpenLog, a RTC, a button, and two capacitive touch sensors.

Figure 7: Detailed Circuit Schematic



4.3 Software Design (Pseudocode)

Step 1: Initialize
1.1 Create an `Adafruit_ST7725` (LCD) object
1.2 Initialize input pins for Heart Rate Monitor
1.3 Initialize input pins for RTC
1.4 Initialize input pin for button
1.5 Initialize output pins to LCD
1.6 Initialize output pins to OpenLog
1.7 Calibrate ADC for input voltage from Heart Rate Monitor
1.8 Check if SD card is available (ERROR HANDLING)
1.8.1 If SD card is not available, set SD card flag to false (data will not record)
1.8.2 If SD card is available, set SD card flag to true (data will record)

Step 2: Initialize interrupts
2.1 Create an interrupt routine for the button.
Step 3: Initial Screen
3.1 Display time and date at the top of LCD screen
3.2 Display instructions

Step 4: Wait for input

4.1 Have a busy-wait loop to wait for input voltage above a threshold for at least 15 seconds
4.1.1 Begin recording time as soon as voltage crosses threshold
4.1.2 After a minimum of a 15 second interval enter LCD output interrupt routine

Step 5: Process/Display Input Data
5.1 Display time and date at the top of LCD screen
5.2 `while`(input voltage > threshold)
5.2.1 Save data to SD card
5.2.2 `for` i=0 to i=width of LCD screen
5.2.3 Use `map` function to map input analog voltage to LCD screen
5.2.4 Clear ECG data displayed on screen

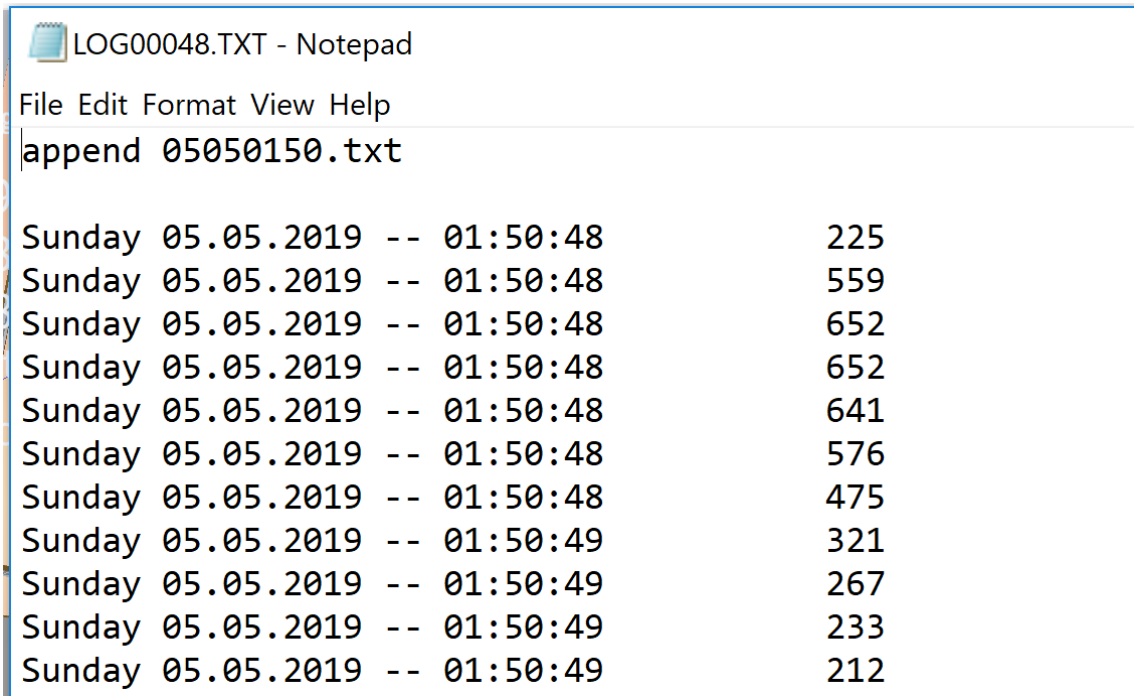
Step 6: Button response
6.1 If button is pressed enter button interrupt
6.2 If in sleep mode, begin steps 1-4
6.3 Else if in on mode:
6.3.1 Clear screen
6.3.2 Ensure all important data is saved to SD card
6.3.3 Enter sleep mode

4.4 Data Format / Contents

The data will be stored as a .csv file. The data will be displayed as:

"DoW Day.Month.Year -- Hour:Minute:Secord Data"

Figure 10: Data File Example



References

(1) Sullivan, T. J.; Deiss, S. R.; Cauwenberghs, G. In *Conference Proceedings - IEEE Biomedical Circuits and Systems Conference Healthcare Technology, BiOCAS2007*; 2007.

(2) Kannathal, N.; Acharya, U. R.; Joseph, K. P.; Min, L. C.; Suri, J. S. In *Advances in Cardiac Signal Processing*; Springer Berlin Heidelberg: Berlin, Heidelberg, 2007; pp 55–82.

(3) Nemati, E.; Deen, M.; Mondal, T. *IEEE Commun. Mag.* **2012**, *50* (1), 36–43.

(4) Mehta, D. D.; Nazir, N. T.; Trohman, R. G.; Volgman, A. S. *J. Electrocardiol.* **2015**, *48* (4), 710–716.

(5) Risks. (n.d.). Retrieved from https://stanfordhealthcare.org/medical-tests/e/ekg/risks.html