Continuous Positive Airway Pressure (CPAP) Performance Verification Device

Design Review

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2/24/17

1. Introduction

1.1 Objective

CPAP (Continuous Positive Airway Pressure) machines are commonly used to treat many breathing-related sleep disorders. Once a patient puts on the mask, they should be able to sleep in peace. What happens if, during the middle of the night, the machine malfunctions? The problem would remain untreated and could even be catastrophic for the patient. Currently, there are machines for the home that can measure and verify that the CPAP machine is working properly for the full sleep period, but they come with a hefty price tag that turns many consumers away.

Our goal is to design a low-cost hose attachment to the traditional CPAP machine for use in a home setting.The attachment will allow the user to obtain measurements on the machines operation throughout the night. The data will be saved to a SD card that will then be read into a program on the consumer's personal computer. We will also create a program for use on the user's computer that will read the data and allow the patient to see the CPAP machine's activity and verify that the machine performed to specification during the patient's sleep period.

1.2 Background

CPAP machines are regarded as the best treatment for obstructive sleep apnea. The machine consists of a mask connected to a hose that leads to the machine that produces air pressure to help keep the airway open during the sleep period. If the machine is adjusted correctly and used consistently, studies have shown that patients experience less daytime sleepiness, depression, and fewer heart issues[3,4]. The problem with CPAP machines is that, in order to have your machine adjusted, you must participate in an overnight sleep study.[5] During this time, the doctor does a titration study with a mask and machine to obtain the proper pressure for sleep apnea events.[5] Adjustments can be necessary for reasons such as weight change, sinus congestion, increased fatigue, and more.[5] Many CPAP machines change pressures during each breath cycle. Patients who do not have an automatically adjusting CPAP machine have a higher chance of needing to make adjustments at one point or another. The device that we are proposing will allow the patient to better track that the CPAP machine they own is benefitting them and treating their sleep disorder properly.

1.3 High-level requirements

- The device should sample air pressure (60-200 mmH_2O column) at a rate of 16 samples per breath, giving a sufficient speed of 16 samples per 1.5 seconds to detect maximum and minimum values during each breath cycle to within +/- 3 percent.

- The device must cost less than $50 to manufacture.

- The home application should provide the user with verification of device functionality, in the form of a plot of pressure versus time. This range will usually fall within a 16 hour window and allow the user to see smaller segments of time as well.

2. Design

In order for our device to meet the requirements, a power supply, control unit, sensor, and computer application are necessary. These components will be selected to meet the requirements at the lowest cost. The power supply ensures that the control unit and sensor can function by providing the right current and voltage. The control unit contains a microcontroller to handle sensor data, as well as on/off and start/stop operation of the device. The control unit also contains an SD card for storage of sensor data, which will be exported to the computer application for further processing. Finally, a pressure sensor is responsible for providing a measurement of the pressure delivered by the CPAP. A block diagram is provided in figure 1.

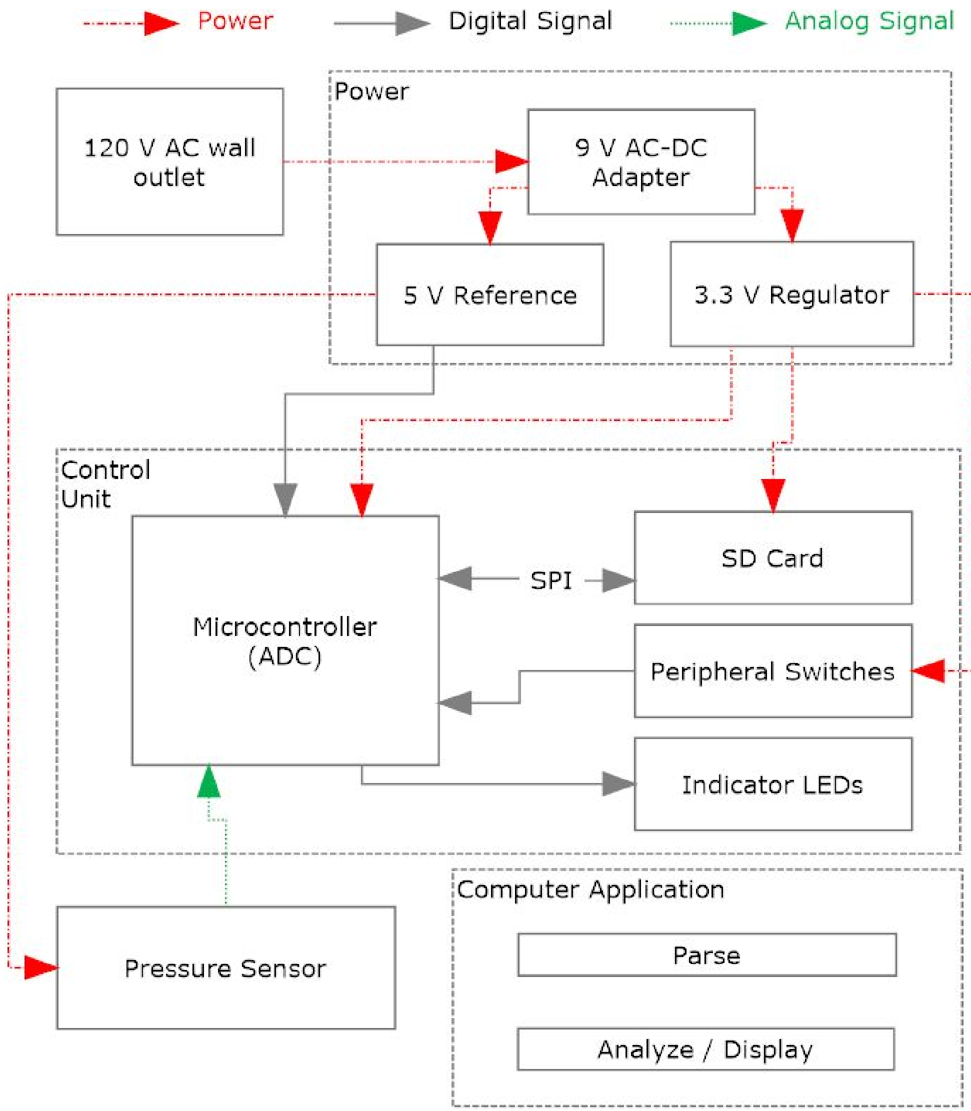

Figure 1. Block Diagram

The physical design will be in box form, with threading to accommodate flow generator connection and mask hose connection. A “T” style coupling will be used to connect the device to the CPAP pressure tube. The main chamber will have a pressure sensor placed inside, connected to the control circuitry, which will be placed outside of the CPAP system. The chamber connected to the CPAP flow generator will be designed to be airtight, with no change in the pressure from that supplied by the generator. The control circuitry will also have LEDs, buttons, and switches that will be exposed from the housing of the device for user interaction. A sketch of the user panel, device housing and connection to the CPAP is provided in figures 2-4 with rough dimensions.

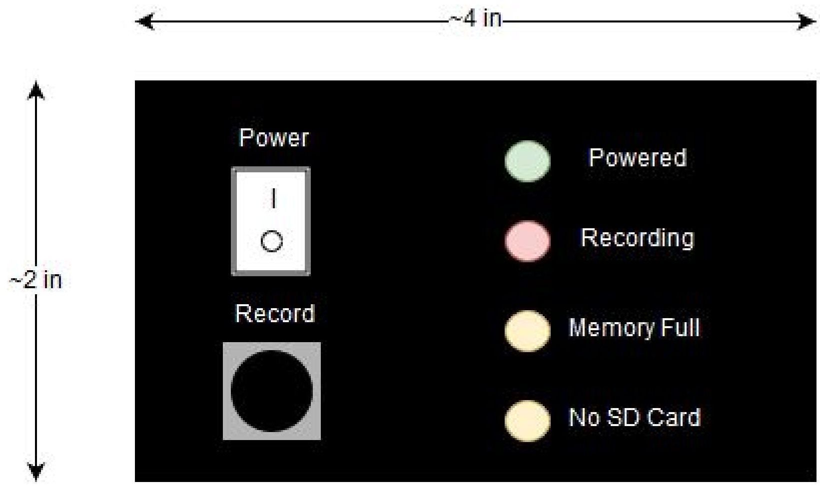

Figure 2. Top view of user panel

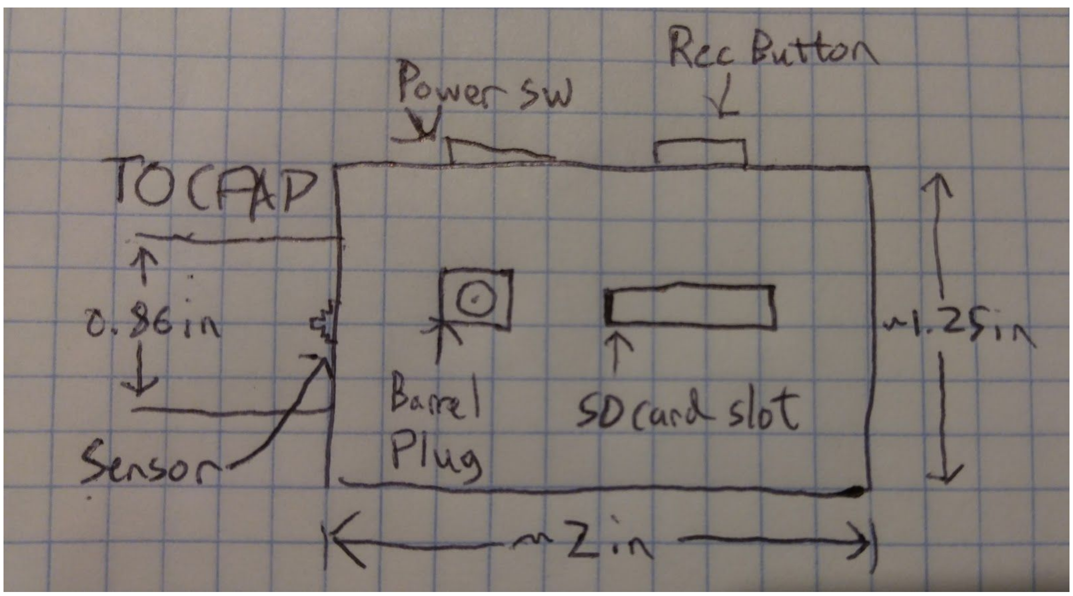

Figure 3. Side view of housing and connection to CPAP

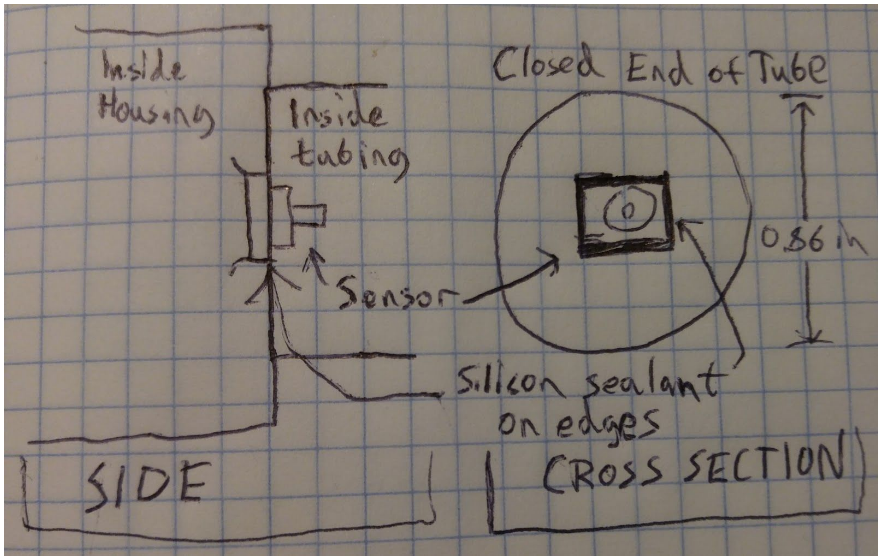

Figure 4. Side and cross-sectional view of sensor placement

2. Block Description/ Requirements and Verification

2.1 Power Supply

The power supply will be required in order to provide power to the various modules of the CPAP Device. The sensor, microcontroller, SD card reader, and switches will all be wired to the power supply, as illustrated in Figure 1 and X. We will need a 3.3V line and a 5V line depending on the module power is being supplied to. The sensor will be supplied 5V, while the microcontroller and SD card slot will be supplied 3.3V. Since we are using a 120V wall outlet, voltage spikes are an issue that must be dealt with before power is supplied to the components in the device. To get the desired voltage, we are using a 9 volt AC-DC adapter, and two additional chips to reach a precise 5 volt reference and a 3.3 volt line. Our device will be supplied voltage from the power supply at all times while in use, so we won’t have to worry about losing power overnight.

2.1.1 AC Adapter

The AC-DC adapter we are using will convert the power coming from the standard wall outlet from 120V AC, down to ~9V DC. We will be using a standard 9V AC adapter with a barrel jack that can be replaced if damaged or misplaced. This a necessity for our module in order for our device to be used in homes where CPAP machines are used.

Requirement	Verification
1) Voltage needs to be brought down to between 5.3V - 16V to satisfy the needs of the 3.3V regulator and the 5V shunt 2) Has to supply a current between 50uA and 15mA to operate the shunt	1) Plug the adapter into the wall outlet 2) Use a multimeter to probe the voltage on the breadboard 3) Make sure the measured voltage is ~9V and stable within the range

2.1.2 Shunt Voltage Reference

In order to have two lines of power we will need to utilize a shunt voltage reference IC. We will need a 5V reference. The 5 V line will feed into the pressure sensor which needs to be kept in the range of 4.75-5.25V to ensure accurate data acquisition. The 5 V line must be as precise as possible, as the pressure sensor uses the 5 Volts in the transfer function to measure pressure.

Requirement	Verification
1) 5V IC will supply a voltage that does not exceed the maximum allowable range of 4.75-5.25V 2) Supplies sufficient current for the pressure sensor to run accurately (5-10mA)	1) Build a constant current circuit and draw 100mA 2) Measure output with oscilloscope to ensure output in correct range

2.1.3 Voltage Regulator

We will need to supply a ~3.3V line to supply voltage for the MCU and the SD card slot. The SD card slot must operate in a range of 2.7V - 3.6V for the operation we are using it for and the MCU is the same.We will be using a voltage regulator that supplies 3.3V +/-.033V to keep us in range desired for safe operation of the modules.

Requirement	Verification
1) 3.3V IC will supply a steady signal to not exceed the range of the SD card supply voltage (3.6V)	1) Build a constant current circuit 2) Measure output with oscilloscope to ensure output is within correct range

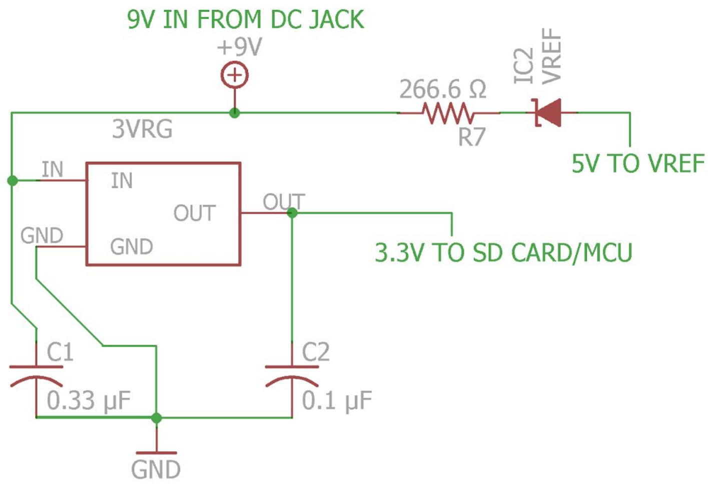

Figure 5. Voltage Regulation Schematic

2.2 Control Unit

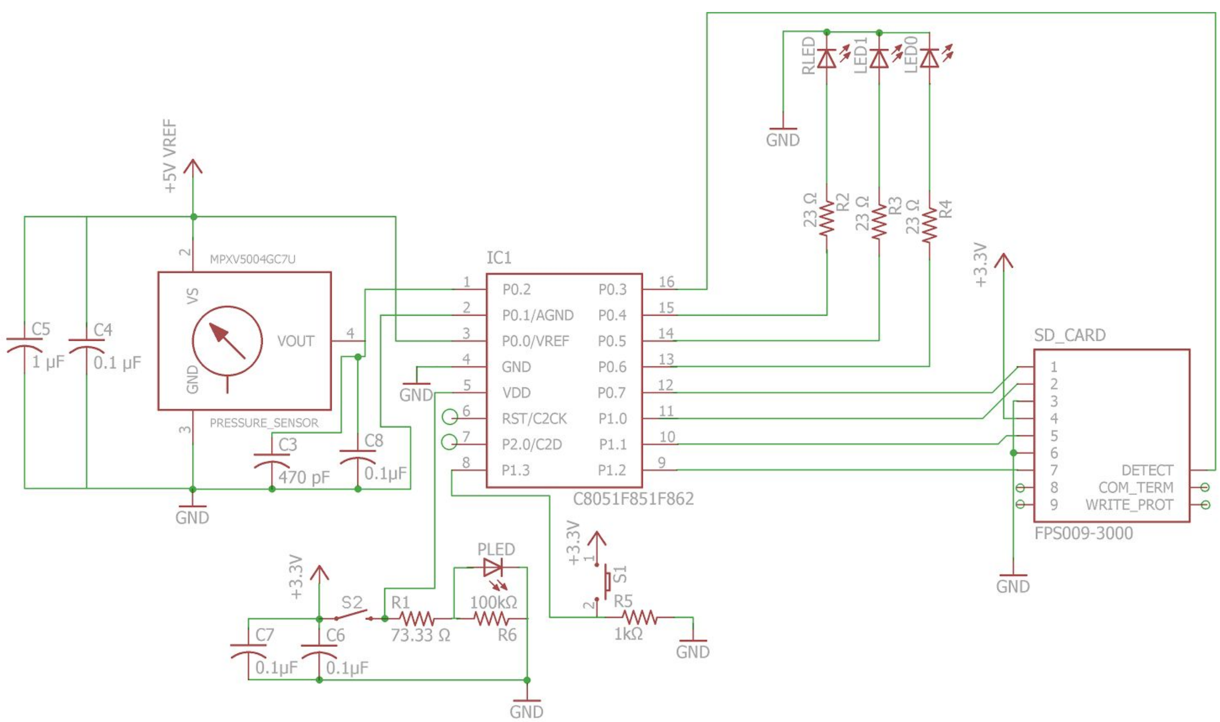

Figure 6. Control Unit Schematic

2.2.1 Microcontroller

The microcontroller will handle sensor output, data storage to the SD card via SPI, peripheral input and output to start/stop data collection and turn the device on/off, and power indicator LEDs. We are using a low level and inexpensive MCU. We will need 9 pins in order to run all modules, which our microcontroller will be able to handle easily. We don't need too much power since we are not sampling the data at a high rate, nor do we need any real-time calculation. The analog-to-digital converter on the microcontroller is a critical component for ensuring that the correct output is stored from the analog sensor. The ADC must be of a sufficient resolution to stay within the 3% error range, and must support an external voltage reference.

Requirement	Verification
1) Must be able to communicate via SPI in order to communicate with the SD card 2) Must have IO pin capable of at least 10 mA drive current	1) Connect MCU to SD card slot a) Preload SD card with 15MB of data b) Read data from SD Card c) (Time) Send data back the SD Card and measure time it takes to transfer 2) Connect pins of MCU to Breadboard a) Use multimeter to measure the current from the MCU

2.2.2 SD Card

The SD Card will store sensor data for extraction to the computer application. The SD card will need to be able to store data for more than 20 nights of 10 hour sleeps. From the calculations we provided in equation 1, we will need around 14 MB for 20 days of data storage.

$$40breaths * 60\frac{min}{hour} * 16\frac{samples}{breath} * 12\frac{bits}{sample} * 12\frac{hours}{night} * 20nights$$

$$= 110592 * 10^3 bits \approx 14MB$$

Requirement	Verification
1) Must be able to store device functionality software and 2 weeks of data	1) Access SD card on computer and verify SD drive has 14MBs of storage and can hold all required data and software.

2.2.3 Analog-to-Digital Converter (ADC)

The ADC will convert analog voltages from the pressure sensor to quantized values. We need the ADC to have a quantization of less than .5% as to not exceed the total sensor error limit of 3%. The ADC will need to be running in 12 bit mode to reduce the error.

Requirement	Verification
1) Has to operate at a speed of >16Hz to get all the samples from the pressure sensor during the breathing cycle 2) Should sample at a rate faster than 128 bits per second so it will process the data from the pressure sensor without delay	1) Set ADC clock to store to register a) Apply any voltage below the ADC's Vref b) Check that we are getting more than 16 samples in the register during 1 clock cycle 2) Corresponds to the same measurement above.

2.2.4 Peripheral Switches/Buttons

The peripheral switches and buttons will allow the user to start and stop data collection, as well as to switch the power on and off. The on/off switch will be used to indicate the status of the device. The switch and buttons will be the full extent of the user interaction with the device on a nightly basis. We wanted to make use as easy as possible so the switch/button will be accompanied by status LED's.

Requirement	Verification
1) Button must be easily pressable	1) Test button by pressing repeatedly determine if it causes strain

2.2.5 Indicator LEDs

The LED's on the user interface of the device will serve as visual verification for the device. We will have LED's that indicate whether the device is on or off. Also on for whether the device is recording or not. Lastly we will have an LED to signal that the memory on the SD card has run out.

Requirement	Verification
1) LED must be able to accept a 15 mA current	1) Connect LED in series with the multimeter a) Set desired current and voltage to test if LED will work at our conditions

2.3 Sensor

The sensor will measure the pressure delivered by the CPAP in the range of 40mmH_20 water column to 220mmH_20 water column and deliver the corresponding voltage to the ADC. As a design constraint we must be able to sense the voltage to with a 3% error. To satisfy this range we are using a pressure sensor rated for 100-400mmH_20 at an error of +/-2.5% when auto zeroed at a standard pressure for normal operation. This auto-zero condition will calibrate the sensor to a "zero" pressure upon device startup, guaranteeing low error. This is covered in the tolerance analysis.

Requirement	Verification
1) Measures the pressure within 3% accuracy of the actual pressure supplied to the patient	1) Connect U-tube column to the sensor column 2) Read "zero" pressure reference voltage 3) Measure voltage from the pressure sensor when U-tube is at 40mmH20 increasing to 220mmH20 4) Examine voltage curve, ensuring linear behavior that maintains +/-3% accuracy according to transfer function in figure 8.

2.4 Computer Application

2.4.1 Parser

The parser will take the data from the SD card and prepare it for analysis**.**

Requirement	Verification
1)Extract data from SD card and load into analyzer	1)Store test data on SD card. Run parser and verify the correct data is extracted from the SD card

2.4.2 Analyzer

The analyzer will take data from the parser and return a plot to display to the user, with some data so the user can screen their CPAP.

Requirement	Verification
1)Must have runtime of under 3 minutes 2)Display data from SD card for user to verify CPAP functionality	1) Run the analyzer 20 times with different amount of data in the SD card and manually time the runtime to confirm runtime is under 3 minutes 2) First, manually verify the data displayed is the same as the data in the SD card. Then, during the testing phase of our device, receive feedback from device users that the data display format is understandable.

2.4.3 Software Flow Chart

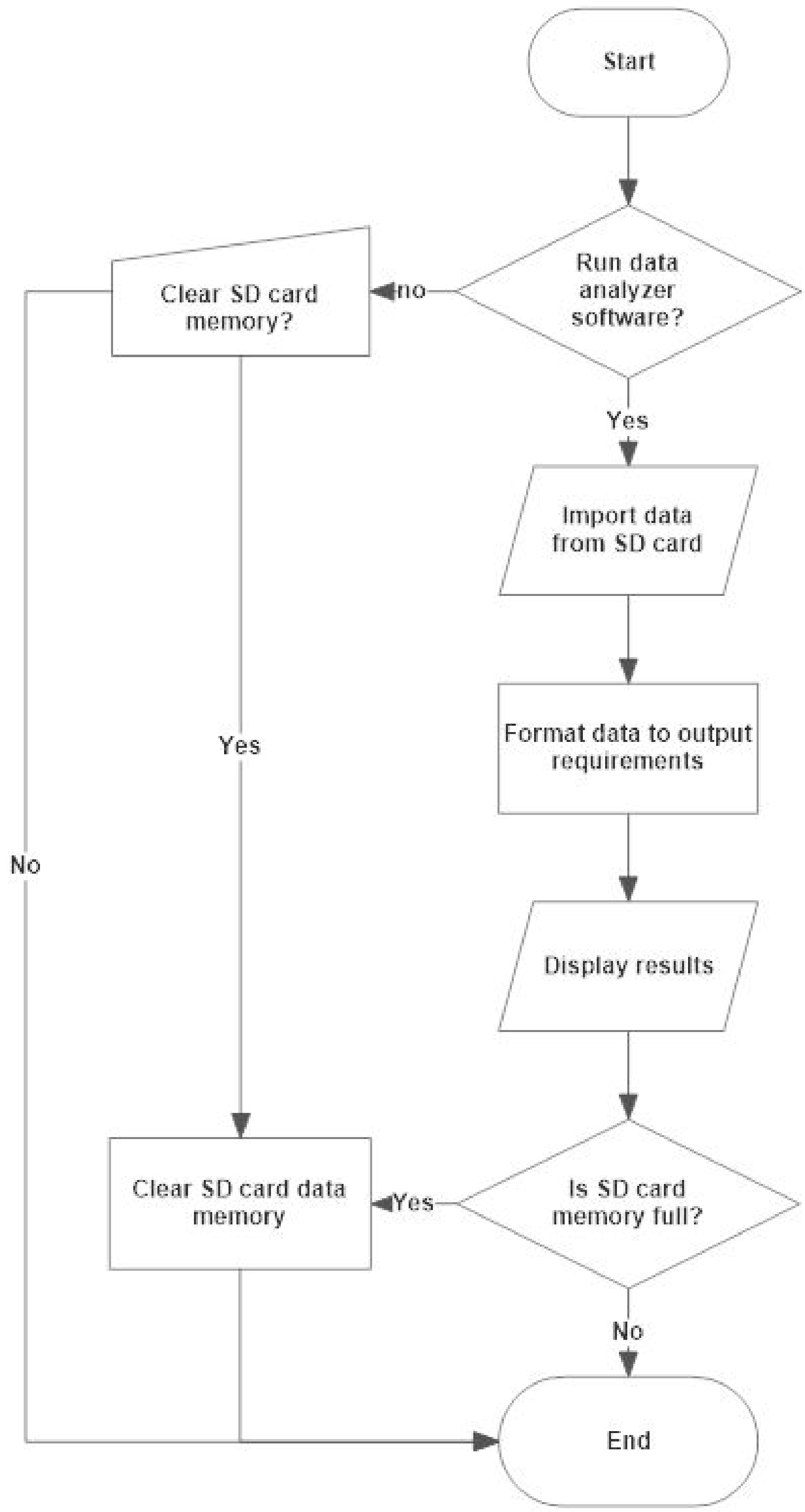

Figure 7. Flowchart for Computer Application

2.5 Risk Analysis

Since the device we are proposing will be in-line with the hose of the CPAP machine there is a concern that the flow through the attachment may alter the pressure sent from the base. The attachment will be designed to work on a hose of any size with an appropriate adapter and should not alter the pressure in the hose. If the attachment does change the airflow and/or pressure then the whole device will create a problem instead of help to fix the issue at hand. We will need to account for this when designing the housing unit for the sensor and circuitry.

The sensing device will be within the hose attachment along with the wiring out to the ADC. Since this is a breathing machine we don't want to contaminate the air of the patients. We don't expect to have issues with this setup because the sensor and wiring are rated for much for much higher conditions.

The AC adapter we will be using has complex circuitry within it. If the adapter is malfunctioning we may not be able to fix the device. We anticipate that if the wall wart is unusable it will take a lot of testing to diagnose the issue, which may cause us to lose us time.The transformer will be pulling down the AC voltage from 120V to 9V. If the transformer burns out, it can create a domino effect and burn out all circuitry. We must follow the National Electric Code for grounding.[6] Since the system will be in a home setting we believe these modules present a lower risk of failure.

2.6 Tolerance Analysis

One of the requirements for our project is to measure the maximum and minimum pressure of each breath cycle within a +/- 3 percent accuracy. We have identified the most critical components to uphold this requirement to be the sensor and its communication with the microcontroller through the ADC.

Ideally, the MPVZ5004 sensor will measure the exact pressure of the CPAP device, but due to temperature, calibration offset, and quantization there could be voltage offset inaccuracies to the output voltage of the sensor. The output voltage of the sensor can be calculated as:

$$V_{OUT} = V_{OFF} + \frac{V_{FSO} - V_{OFF}}{P_{MAX} - P_{REF}}$$

V_{FSO} is the full-scale output, P_{MAX} is the maximum sensor pressure and P_{REF} is the reference pressure, and V_{OFF} is the output measured at the minimum pressure rating [4]. With the sensor we are using the pressure range is zero to 400 mm H_2O. We will be operating in the 40 to 220 mm H_2O range.

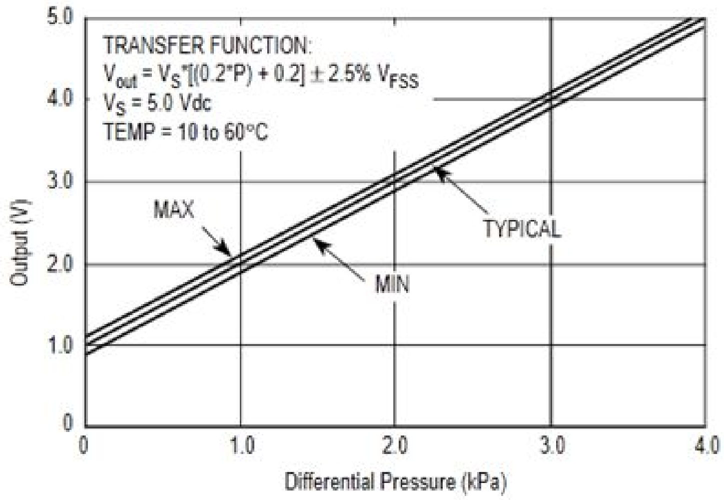

Figure 8. Transfer function of MPVZ5004 between 100-400 mm H_2O with autozero [5]

The transfer function seen in figure 8 is after an autozero calibration method provided by the manufacturer to reduce temperature and factory calibration offsets. The autozero provides the sensor with a “zero” pressure reference voltage, which is sampled at device start-up, and is used to offset the sampled pressure voltages. Since we will be operating within the 10 to 60 °C temperature the manufacturer specified maximum error of +/-2.5 percent holds with autozero.

Other than sensor errors, there can be quantization errors when the sensor data is communicated to the microcontroller through the ADC. Our microcontroller supplies a 12-bit ADC[6] with an external voltage reference of one to five volts.

$$ADCresolves = \frac{5V - 1v}{2^{12}} = 0.9\frac{mV}{bit}$$

$$Sensorsensitivity = 1\frac{V}{kPa} * \frac{1kPa}{101.97mmH_2O} = 9.8\frac{mV}{mmH_2O}$$

$$ADCresolution = \frac{0.9}{9.8} = .092\frac{mmH_2O}{bit}$$

Assuming +/- one least significant bit error during conversion:

$$QuantizationError = \frac{0.092}{400} = 0.023\%$$

With the two concerns falling within our tolerance range we are confident that the device will be able to fulfill our requirement of +/-3 percent pressure measurements.

3. Costs

The cost estimation for labor will be based off of a 16-week period of work done by three people, for approximately 10 hours per person per week. We will use a $70,000 salary as our baseline for hourly pay, which comes to $33.65 per hour when adjusted for a 40-hour workweek. This is relatively close to the average EE salary out of the university [3].

$$16wks * 10\frac{hrs}{wk} * \$33.65 * 3 = \$16,152$$

The total labor cost for this product is $16,152.

A table of the parts required and their costs is shown in Table 1. Our product will cost $25.80 to prototype, and $14.312 to produce in bulk.

Part	Cost (prototype)	Cost (bulk)
Silicon Labs C8051F862-C-GS MCU	$0.88	$0.648
12mm Square Momentary Pushbutton (Sparkfun Electronics)	$0.50	$0.45
3M SD Card Connector 517-SD-RSMT-2MQ	$2.30	$1.75
ST Microelectronics 511-LF33ABV Regulator	$0.96	$0.353
E-Switch Rocker SPST Switch 612-R1966A	$1.19	$0.778
Phihong 552-PSM03A-090-R 9V AC/DC Wall Adapter	$4.68	$3.51
NXP MPVZ5004GW7U Pressure Sensor	$8.91	$5.94
CUI PJ-102A Barrel Connector	$1.00	$0.255
ADR5045AKSZ-REEL7 5V Shunt Reference	$0.88	$0.378
Assorted resistors and capacitors	$1.00	$0.10
Machine shop parts estimate	$1.50	$0.10

PCB estimate	$2.00	$0.05
Total	$25.80	$14.312

Table 1. Parts and cost

4. Schedule

Week	**Eric**	**George**	**Jamal**
2/26/2017	Finalize schematic design	Begin microcontroller programming, research microarchitecture	Test parts received, help finalize design
3/5/2017	Finalize physical design, gather parts, begin PCB layout	Finish basic microcontroller program for testing sensor to ADC buffer, research testing methods	Begin prototyping on breadboard, gather housing parts
3/12/2017	Finish PCB layout	Start programming for SPI from ADC to SD card	Test prototype for sensor ADC operation, voltage regulation, begin verification
3/19/2017	Calibrate sensors, mount sensor, test calibrated sensor ADC operation	Continue programming SPI for ADC to SD card	Begin soldering components on PCB, finish verification of modules
3/26/2017	Work on computer app with George, explore options for analysis	Finish ADC to SD card programming and debug, start computer app (parse)	Finish soldering PCB and test basic functions
4/02/2017	Finish prototype in mechanical housing	Continue work on computer app (analyze)	Finish prototype in mechanical housing
4/09/2017	Test prototype, test SD card data export, finalize prototype	Finish computer app, test and debug all functions	Test prototype environmental conditions, finalize prototype
4/16/2017	Prepare final presentation	Prepare final presentation	Prepare final presentation
4/23/2017	Work on final paper - focus on overall design details(schematics, etc)	Work on final paper - focus on entire software portion (design, requirements, verification, etc.)	Work on final paper - focus on overall design, requirements and verification
4/30/2017	Finish final paper	Finish final paper	Finish final paper

Table 2. Schedule

5. Ethics and Safety

There are two safety concerns with our project that will be addressed before the completion of the project. The device will be built strictly following UL compliance standards. UL 60950-1 information technology equipment safety states that steady state voltages beyond 42.4 V peak can cause electric shock and energy hazards[1]. We will use the suggested solution of shielding all the wiring and circuitry.

Our project includes a power adapter to power our device. To prevent the power source from being a potential fire hazard the performance and temperature of the power supply will be heavily monitored during the testing phase of our project. The power supply will be monitored through temperature sampling to ensure it is always non-hazardous while active. Other components of the device can also be monitored if suspected of overheating. If any component is determined to be high temperature by UL standards, it will be labelled as a potential energy hazard.

To maintain the safety and welfare of the user we will disclose any factor that might “endanger the public or the environment” in compliance with IEEE Code of Ethics #1[2]. Our project is an indoor device and should not be used outdoors. The device should also never be taken apart during use.

We believe that there are no conflicts of interest between our project and any CPAP manufacturer due to no product in the current market that address the issue we are trying to solve. If at any point there becomes a conflict of interest we will “disclose them to affected parties” as required by IEEE Code of Ethics #2[2].

Our project requires the user to upload their medical data into our software interface to monitor their CPAP usage. There is the risk of user medical data being leaked or stolen. We understand this is a “potential consequence” as stated in IEEE Code of Ethics #5, but we believe the “improve the understanding of technology” factor for our project outweighs this potential risk.

Works Cited

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