Continuous Positive Airway Pressure (CPAP) Performance Verification Device

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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 (6-20 cm H2O column) at a rate sufficient to detect maximum and minimum values during each breath cycle to within +/- 3 percent.
- The device must cost less than $100 to manufacture.
- The home application should provide the user with verification of device functionality, according to a desired range specified by the user.

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.

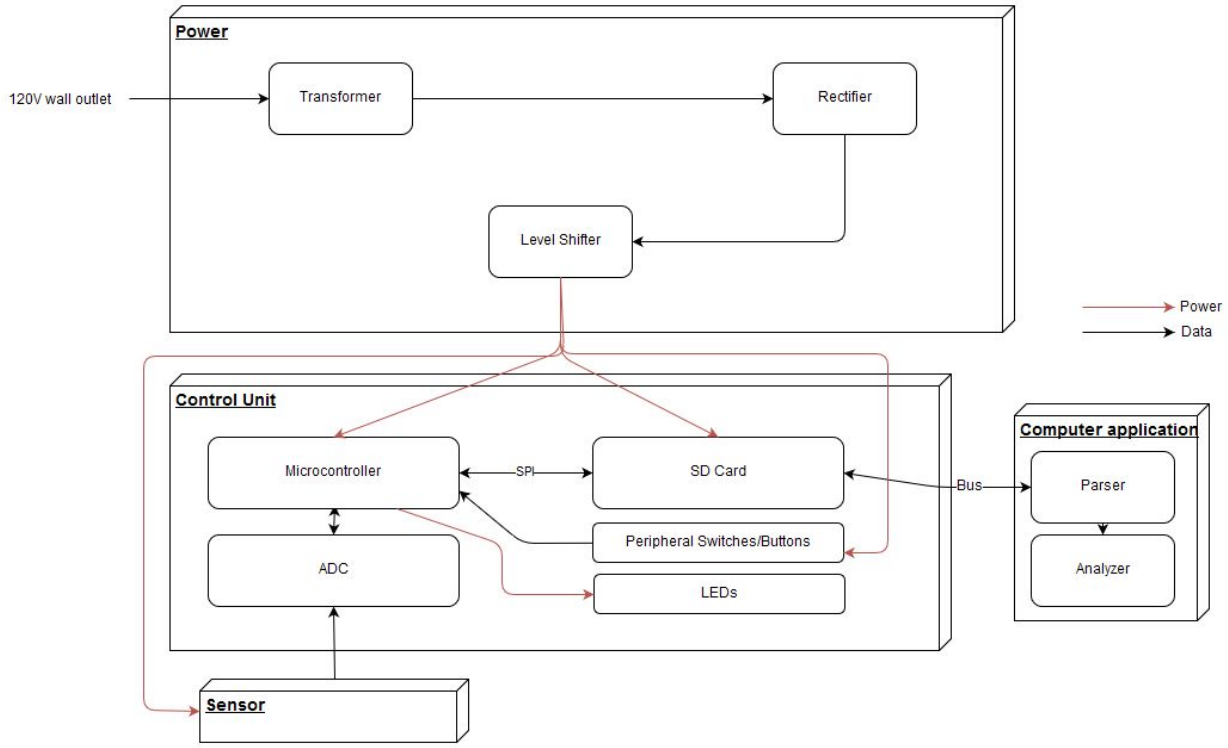

Figure 1. Block Diagram

The physical design will be in box form, with threading to accommodate flow generator connection and mask hose connection. 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 rough sketch is provided in figure 2.

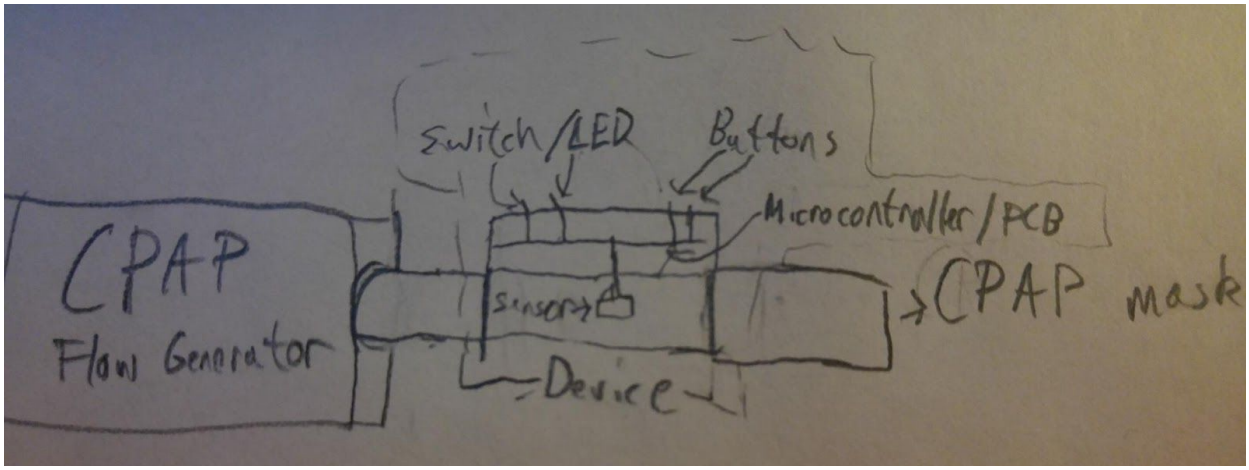

Figure 2. Physical Diagram

2.1 Power Supply

2.1.1 Transformer

The transformer will convert the line voltage to a lower voltage value usable by the modules in the device.

Requirement: Must convert 120V AC to ~5V AC

2.1.2 Rectifier

The rectifier will convert the AC voltage to DC voltage for the components in the device.

Requirement: Must convert ~5V AC to ~5V DC

2.1.3 Level Shifter

The level shifter will provide varying voltages as needed to each component in the device

Requirement: Must output ~5V DC, ~3.3V DC

2.2 Control Unit

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.

Requirement: Must support communication via SPI

Requirement: Must cost less than $20

2.2.2 SD Card

The SD Card will store sensor data for extraction to the computer application. The SD card must have enough capacity for 14 nights of data storage.

Requirement: Must have a capacity higher than 512 Mbits

2.2.3 Analog-to-Digital Converter (ADC)

The ADC will convert analog voltages from the pressure sensor to quantized values sufficient to maintain higher than 97 percent accuracy.

Requirement: Must have a resolution of at least 8 bits

2.2.4 Peripheral Switches/Buttons

The peripheral switches and buttons will allow the user to start and stop data collection, as well as switching the power on and off.

Requirement: Must utilize a supply voltage of less than 5V

2.2.5 Indicator LEDs

The peripheral switches and buttons will allow the user to start and stop data collection, as well as switching the power on and off.

Requirement: The LEDs must be clearly visible from a distance of 1 meter away

2.3 Sensor

The sensor will measure the pressure delivered by the CPAP in the range of 4 cm water column to 22 cm water column and deliver a voltage to the ADC.

Requirement: Must have an error of less than 3% in the range of 4 cm water column to 22 cm water column

2.4 Computer Application

2.4.1 Parser

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

Requirement: Must be able to read data format exported from SD card.

2.4.2 Analyzer

The analyzer will take data from the parser and return a verdict on whether or not the device is performing to specification. The user can specify a desired pressure range**.**

Requirement: Must provide a verification of device functionality.

Requirement: Must have a runtime of less than 3 minutes.

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 wall wart 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 5V. If the transformer burns out, it can create a domino effect and burn out all circuitry. The rectifier poses a threat as well. It is susceptible to corrosion and upon failure can leave us without current. 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.

3. Safety and Ethics

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. 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 is 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.

References

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[6] Langelund, E. S. (2013). Fundamentals of Rectifier Operation, Monitoring, and Maintenance. http://www.materialsperformance.com/articles/cathodic-protection/2016/03/fundamentals-of-rectifier-operation-monitoring-and-maintenance [Accessed: 8-Feb-2017]