CPAP Monitoring

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1 Introduction

1A Objective

Obstructive Sleep Apnea is a very prevalent disease among adults in the United States, which is caused by the obstructions of the upper airway (from nose / mouth to throat) [1]. Leading to repetitive episodes of shallow or paused breathing (which is called “apneas” here) during sleep, despite the effort to breathe, this syndrome may lead to a reduction in blood oxygen saturation. Due to the paused breathing during night sleep, the patient may suffer from daytime sleepiness and fatigue, together with significant sleep disturbance that last for decades without identification due to the hardship to identify obvious daytime syndrome [1]. The key to alleviate the impact of Obstructive Sleep Apnea on patients, is to continuously open their airway to ensure they may have a good breathing during the whole night. It is usually done by a ventilation device that keep “pushing” air into the patient, which is called CPAP, the abbreviation for continuous positive airway pressure [1]. Usually, this system use ventilation to maintain a positive pressure of around 2 centimeters of water (which is around 200 Pa) to 20 centimeters of water (which is around 2000 Pa). Under this pressure, the patient will be able to breath normally without obstacles.

However, the major inconvenience of CPAP system is that it lacks an accurate monitoring system to keep an eye on its performance. This inconvenience may lead to inconsistent air pressure in the patient’s airway, which is usually associated to uncomfortable sleeping experience. This inconvenience leads to our plan, which is aimed to provide a continuous monitoring and recording tool for the pressure in the CPAP system. By continuously monitoring and recording the air pressure data inside the air tube, we can provide a detailed analysis for its user to monitor how their CPAP system is performing, and an immediate warning if they need to fix their CPAP system due to the malfunctional or inconsistencies.

1B Background

One of the common solution before is what called “Auto CPAP”. It is an integrated solution that provide a continuous monitoring over the air pressure, and provide instant adjustment based on that monitoring. However, it is not an economical (a typical CPAP cost you around $350, while an automatic one cost you $700). Also, the need for an “auto CPAP” is not permanent: people can manually change their CPAP settings once several weeks, leave no reason to adopt such an “automatic” device to work. Another disadvantage of such design is that it increased the failure rate of the whole system, with the reduction of reliability. The failure of “auto” module could severely impact the ability to provide a continuous airway pressure. Another uncomfortable thing is the time and labor. Usually, the patient has to bring the CPAP machine back to their physicians to diagnose and fix it [2]. For patient living far away from the clinic, the time cost is so high that many people choose to tolerate rather than fix.

Thus, here we should provide a simple, accurate and reliable solution that can keep record of airway pressure for further analysis. The system should have the capacity of continuously recording of airway pressure for at least eight to ten hours; The data should be easy to access for computers for further analyses; Also, the installation and usage should be simple and our device should be compatible to almost all CPAPs available in the market.

1C High-Level Requirements

The theoretical ground of our plan is the continuous monitoring of air pressure: according to reference, a good CPAP device should keep the pressure in a range about four to twelve centimeters of water, which is about 39 to 118 Pascal. Thus, the precise measurement of air pressure is the key to implement our plan. Also, since we must monitor the pressure for at least eight hours (which covers the whole night), our plan should also have the ability of continuous recording. The last requirement for our plan is the ability to export data into Personal Computers or Cellphones for convenient display.

Based on these key requirement, we have proposed three main key technological requirements for our plan.

1) Accuracy: the measurement of air pressure provided by our plan should be with a range from 0 Pascal to 150 Pascal, with a minimum resolution of 1 Pascal;
2) Durability: our plan we used should ensure at least ten hours of continuous pressure sensing and storing, without the usage of external power supply;
3) Permanent Storage Ability: our plan should provide functionalities to store and export the measurement for further retrieval and analysis.

2 Design

The overall design is based on a branch on the CPAP hose that connected to the mask and the machine. We designed five major independent parts:

1) a power supply chip, which converts various power source into regulated voltage for chips and equipment;
2) a sensor unit, which records the pressure information;
3) a control unit, which converts the raw sensor data into human-readable format;
4) a storage unit, which temporarily store the data for later retrieval; and
5) an output unit, which provides output onto PCs or cellphones via serial port.

In our plan's general physical design, immediately on the branch there will be a pressure sensor that monitor the continuous change in the main hose; the signal will be passed to control unit for the conversion, and then temporarily stored in the storage unit. Once retrieved an appropriate signal from computer or phone, the stored data will be transmitted via the output unit.

Please refer to the block diagram for more information.

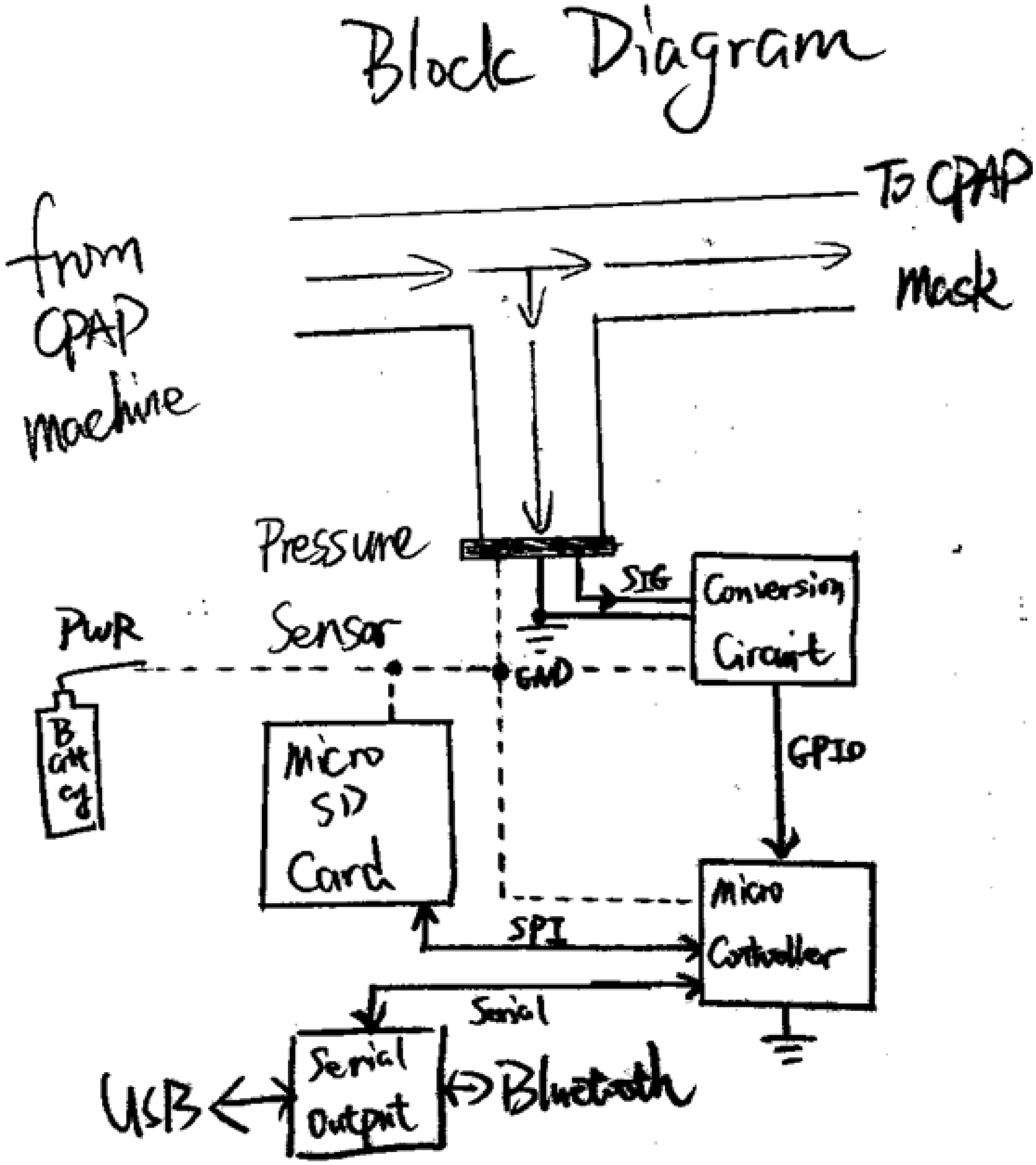

Figure 1 Block Diagram which makes of six main components.

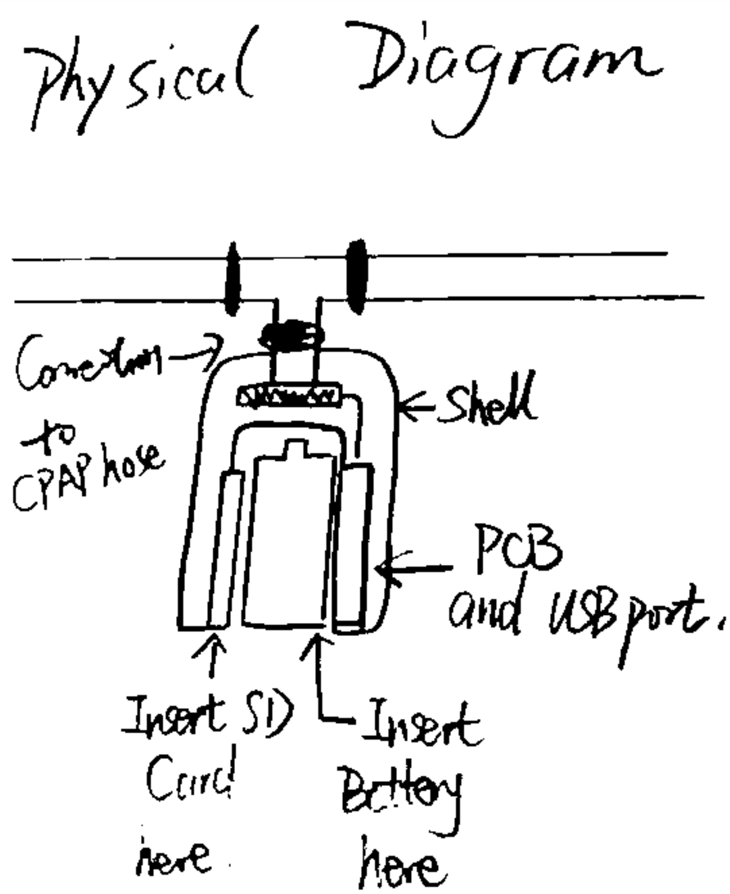

Figure 2 Preliminary Physical Diagram that shows the arrangement of elements.

In our preliminary design of physical arrangement, we designed the product to be in the form of a small cylinder. At the top, there is a T-connector that connect the cylinder to the CPAP hose between the machine and the mask. Immediately under the connector is the pressure sensor to monitor the pressure in the tube. To save some space, we place the SD Card, the battery and the main PCB (which includes all other chips and circuits) parallel to each other.

2B1 Sensor Unit

The sensor unit is the core item in our design. It measures the air pressure in the CPAP hose that connected the mask and the machine, and transmitted the measurement value in an appropriate form to the conversion circuit.

We here have the following desire for the sensor:

1. The air pressure sensor shall fit in the size of the CPAP tube, which is with an internal diameter of 19mm, and a cuff size of 22mm [2]. Since it is a circle, its area should be around 284 square millimeters to 380 square millimeters.
2. The sensor shall have the range capacity to measure pressure from 200Pa to 2000Pa, with suggested minimum division of about 1Pa. Setting up on the surface of our hose, it should be really a small force: from 0.08 N to 0.76N [3].

3. The output unit, if needs individual power supply, should accept 5 V or 3.3 V as its input voltage, and have a maximal power of 1 W.

2B2 Conversion Circuit (Optional)

Depending on the sensor we finally choose, there may be possibility that the output electrical signal is not in linear relationship of the input pressure signal. Also, the input signal is analog, but we need digital signal to process in the microcontroller. Thus, the conversion circuit converts the analog input signal into a formatted digital input.

This circuit may be implemented as an independent circuit, or a portion of the central microcontroller. We desire following performance on this portion of circuit, if implemented independently:

1. The conversion circuit shall provide a continuous digital signal output with the sampling rate at 50 Hz or more;
2. The circuit shall be able to digitize the analog signal without the loss of precision, i.e. the precision should be at least 1Pa.
3. The output unit, if needs individual power supply, should accept 5 V or 3.3 V as its input voltage, and have a maximal power of 2 W.

2B3 Central Microcontroller

To process the data from sensor to monitor, we need a small microcontroller to allow the read/write of SD Card and USB/Bluetooth serial transmission. The microcontroller will receive the sensor data from our sensor, and then temporarily store it in a Micro SD Card. Then, once the microcontroller received instructions from serial interfaces (USB or Bluetooth serial port in the output unit), it will read the data from SD Card again, and transmit it via serial interface to computer. Depending on implementation details, it may also need to deal with the analog/digital conversion stated in part 2B2.

We here desire following technical performance on the central controller:

1. The central controller should have the ability of multi-task, that may handle the simultaneous reading/writing of SD Card (reading from serial output interface, and writing from the conversion circuit). To handle complicated computing tasks, we suggested that the main frequency should not be less than 2 MHz
2. The central controller should have the ability of SPI interface (for the connection to Micro SD Card), GPIO interface (for the connection to sensor circuit), and serial interface (for the connection to Bluetooth module and USB module). Here we suggested that bus transmission speed should not be less than 1mbps during simultaneous transmission.
3. The central controller should have the ability of serial interface. Here we suggest that the transmission speed should not be less than 1mbps, for a smooth transmission between SD Card and computer.
4. The output unit, if needs individual power supply, should accept 5 V or 3.3 V as its input voltage, and have a maximal power of 5 W.

2B4 Micro SD Card Storage Unit

A storage unit is required to hold the measurement for the later display. To provide maximal compatibility (especially for those who cannot access the serial port), we choose Micro SD Card so that users can transfer the data to computer without serial interfaces (like old devices).

In our design, the storage unit will communicate with our central controller at the speed of 1mbps, which is stated in the technical requirement of microcontroller. Here we here expect two more following performance requirements on the SD Card chip:

1. The chip should be able to handle the reading and writing of FAT / FAT32 filesystem, which is commonly used in Windows and Mac OS, under the SPI interface for the rate of at least 1 Mbps.
2. The chip should have compatibility with different manufacturer and capacity, like those with 2 GB, 4 GB, …, even 32 GB and 64 GB.
3. The unit, if needs individual power supply, should accept 5 V or 3.3 V as its input voltage, and have a maximal power of 1 W.

2B5 Serial Output Unit

Serial Unit is utilized for the output of measurement data. By either wired (USB) or wireless (Bluetooth) transmission, our user could obtain the data from personal computers or smartphones, or make control remotely from them via software (which is out of the scope).

Here are the requirements for the output Unit:

1. The output unit should support the conversion from serial interface to both USB and Bluetooth interface, and accept simultaneous bidirectional transmission.
2. Under both USB mode and Bluetooth mode, the output unit should provide at least 1mbps of transmission speed.
3. The output unit, if needs individual power supply, should accept 5 V or 3.3 V as its input voltage, and have a maximal power of 1 W.

2B6 Power Supply Unit

The power supply of those elements could possibly be the most complicated question in our circuit. To simplify the design of our circuit, we set up an internal standard that restrict the power usage of other units to 5 V or 3.3 V, and overall power consumption to 10 W. To allow the maximum compatibility to variety of power source, including USB power (5 V), AA batteries (4 * 1.5 V = 6 V) or even button cell batteries (2 * 3 V = 6 V). A LED indicator is also included to display the input voltage (green for 5 V to 6 V, yellow for 4 V to 5 V and red for under 4 V)

The requirement for the power supply unit is defined here:

1. The power supply unit should accept a broad range of power sources around 4.5 V and 6 V, and provide a stable supply of 5 V or 3.3 V, with continuous current supply of about 2 Ampere.

2C Risk Analysis

The major risk of our project is the choice of a good sensor. One of the criterium of the sensor is the accuracy to measure. We summarize the factor that may impact the accuracy of sensor into three aspects.

The first aspect will be the mechanical connection from the T-connector to the press sensor. To accurately measure the pressure, we should take appropriate action so that there will be no leakage on the connection between sensor and airway. This is especially important because the air pressure my seriously introduce our system with significant error in the result. One of our possible solution to ensure the seal is using a set of adhesive tape, to make sure that there is no leakage in the contacting interface.

Another possibility of failure is the sensitivity of our sensor. The accurate measurement of air pressure depends on the sensitivity of our sensor. One of the possible failure is the situation when our sensor cannot react to the sudden pressure change in the tube, which may lead to inaccurate value during the measurement. One of our possible solution is to carefully select from our sensor candidates, and make comprehensive laboratory test to ensure their reaction. If the measurement is not significant, an amplifier may be required to improve the visibility.

The last possible weakness is the relationship between input pressure and output voltage. There are several different types of pressure sensor available on the market. One typical type of these sensor is based on variable resistance, which does not require an external power input, while the other typical type of sensor is based on variable voltage, which requires an external power input. The resistance type of sensor may have nonlinear reaction for the change in pressure while the voltage type of sensor may require additional power input.

Here we summarized the major risk on the pressure sensor. Thus, during the design, the choice and laboratory test of our candidate is important.

3 Ethics and Safety

We have examined some possible safe, ethical and environmental risk that may occur in our plan.

3A Safe

According to IEEE Code of Ethics [4], #1 and #9, our work should “make decisions consistent with the safety, health, and welfare of the public”, and “avoid injuring others, their property, reputation, or employment by false or malicious action”. When designing and manufacturing our work, the most important factor to consider is the safety and health of our user.

There are two possible safe risk on the design of our plan: one is the direct safety risk, lead to fire hazard by the battery that we installed in the plan; The other is the indirect safety risk that may lead to respiratory infection by the tube we installed in the plan.

The direct safety hazard is the risk of a firing battery due to the over discharging, which is the situation when the battery is discharging with a large current. The large current may cause overheat in the cell component of battery, leading to possible fire or even explosion. One of the possible solution is to use an external power supply like USB power, while the other solution is to enhance its heatsink so that the heat accumulation on the chip will be controlled. One of the good news is that this product will be used in door when sleeping, which means that the temperature in its surrounding environment will be relatively controllable within a reasonable range of room temperature.

Another safety hazard, though not acute, is the possibility of bacteria accumulation in the device. The system, which directly connected to the patient's airway, may lead to severe infection if contaminated by bacterium [5]. If there is any colony propagating on the device, the positive airway pressure will keep the air flowing in the tube, transporting bacteria into the airway of our patient. Sometimes there will be no serious impact: there may be just a common cold, or some squeezes; however, if the patient is already sick with respiratory infection, these new bacteria could lead to pneumonia, which is dangerous for their weakened immune system. To deal with this possible failure, we may have to pay specific attention to the selection of tube materials, and use some appropriate measurements, like the cleaning of internal tube, the dehumidification of air to prevent bacteria from propagating, et cetera.

3B Ethic

The other possible risk is the user's privacy. The monitor data of CPAP may lead to speculation on the patient's physical health situation, which may lead to concerns over the privacy. To protect patient's privacy, we must ensure that there will be no unintended or unauthorized access to the CPAP data.

According to IEEE Code of Ethics, #2 [4], we should avoid real or perceived conflicts of interest whenever possible, and disclose them to affected parties when they do exist;

One of the important measurement is to limit the functionality to offline access. In our plan, there will be no need of internet service, so that the privacy data will be kept in user's own devices. We also planned a simple interface so that user can make a choice if they want to share their information for diagnosis usage or other possible services.

3C Environment

According to IEEE Code of Ethics, #1 [4], our work should "make decisions consistent with the safety, health, and welfare of the public", by protecting the environment and carefully our usage of public resources to enhance the public welfare. When designing and manufacturing our work, we should take the environmental impact into consideration.

One of the serious environmental impact is the usage of battery. The battery we used in our daily life may lead to serious contamination of metals and other chemicals. To reduce the usage of battery, we should reduce our power consumption to the lowest available one, so that a battery can last for the longest time. One of the other solution is to accept NiMH batteries in our design, which requires either the design of power supply circuit to accept 4.8 V as input voltage (4 * 1.2 V = 4.8 V), or the battery container to have the ability of holding one more battery (5 * 1.2 V = 6 V). The last solution is to encourage the usage of external power supply like USB Power, which can use the alternative power instead of massive number of batteries during its lifecycle.

Reference

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