# Bi-PAP Monitoring System Using Low-Powered Microcontroller

## Abstract

Under extreme medical circumstances, such as the COVID-19 pandemic, limited access to ventilators is a major concern as most hospitals and other medical facilities are not equipped for large scale outbreaks. However, similar devices such as Bi-level Positive Airway Pressure (BiPAP) machines, which are widely available and comparatively cheaper, offer a platform for conversion to a ventilator. The primary difference between a ventilator and BiPAP device is the BiPAP’s inability to monitor the patients’ respiratory functions to provide necessary feedback such as pressure, flowrate, and tidal volume to medical professionals. In addition, there are no alarms equipped to alert medical personnel based on individual patients' breathing needs. Therefore, the current work presents a novel, cost effective device for monitoring flow produced by the BiPAP machine using a low-powered micro-controller equipped with multiple pressure sensors. The flowrate of the system is determined by implementing a bi-directional, 3D printed venturi tube with two differential pressure transducers, and a single static pressure transducer to provide additional monitoring capability for physicians and nurses. Next, the instantaneous flowrate is determined using a calibration curve, and tidal volumes, during the inspiration and expiration portions of the breathing cycle, which are determined by integrating the flow rates. Alarm limits, such as high and low flow, static pressure, and prolonged zero flow are continually compared to measured data and if limits are exceeded, an audible alarm is generated to notify the medical staff. The microcontroller then relays data to the PC via serial communication, which displays a graph of the flowrate over time, user defined alarm limits, and static pressure. The collected information is also saved for each session and readily accessible on the PC. The device is designed to be battery powered or powered via USB, and it has the option to operate without the PC to provide only an audible alarm to doctors and nurses if user defined alarm limits are exceeded. Overall, the materials chosen for the BiPAP-Ventilator device are relatively easy to procure and cost effective, which further contributes to the device's accessibility under unique circumstances.

## Introduction

COVID-19 is a disease caused by the SARS-CoV-2, which is a highly contagious form of coronavirus that has affected millions around the world. Within months, the WHO declared the spread an outbreak in January, then a pandemic in March 2020, which continued to disrupt the daily life and health of individuals. Many people only experience mild symptoms; however, there are populations at risk for severe illness. Some of these groups include those who are older or who have pre-existing conditions. According to the WHO, 14% of patients may require ventilator support due to COVID-19, which has increased the demand for ventilators beyond the supply of many hospitals [1]. Although critically ill patients may require invasive mechanical ventilation support, others can be treated with non-invasive ventilation methods.

To help relieve the pressure of ventilator shortage, efforts can be dedicated to improving devices with similar functions, such as CPAP and BiPAP devices that are commonly used for treating sleep apnea. CPAP, or Continuous Positive Airway Pressure devices apply pressure during the inhale to keep the airway open. BiPAP, or Bi-level Positive Airway Pressure devices offer the same functionality but for both inhale and exhale conditions. Currently, there are methods for converting V60 BiPAP machines into invasive ventilation devices from Northwell Health by introducing special T adapters to interface with existing ventilation components. [3] The device can then be monitored using the existing V60 computer interfaces that provide the patient ventilation flow rate information. However, not every patient requires invasive ventilation and an article from the Elsevier Public Health Emergency Collection describes successful treatment 77% of patients with severe symptoms using noninvasive methods [4]. Thus, the high demand for ventilators may be reduced by allowing some patients to follow a treatment plan using CPAP or BiPAP machines. To properly execute this treatment, control panels displaying important medical information is crucial to its success according to the 10-step guide to convert a surgical unit into a COVID-19 unit [5]. Additionally, surgeons and surgical nurses require frequent training on ventilation, which proposes the need for dedicated user interfaces that are concise while providing necessary patient information.

Unlike the V60 BiPAP machine, many BiPAP devices are designed to also accommodate in-home treatment by the patients themselves who may not necessarily have a medical background. Thus, the information provided on these user interfaces may not provide the monitoring needed for COVID-19 treatment. Therefore, to fill the gap in monitoring ability, CPAP and BiPAP devices can be fitted with an intermediary monitoring device such as a computer to measure flow characteristics such as flow rate, pressure, and tidal volumes. Furthermore, alert systems based on these measurements can improve the device’s ability to monitor patient ventilation. Additionally, designing more specialized user interfaces for treating COVID-19 patients can improve the ease of use for medical professionals and volunteers by reducing the training needed to operate the machine.

Offering alternative methods to ventilation is important in preventing ventilator supply shortages, especially in less developed countries or if another pandemic occurs. Thus, this paper presents a novel flow monitoring device, using low-cost materials that are relatively easy to procure with specific, provides an overview of the design approach, and provides all information needed to replicate the design for use with BiPAP devices in order to alleviate the demand for ventilators. This device includes a bi-directional venturi flow meter, two differential pressure sensors, one static pressure sensor, and a microcontroller that feeds information to a PC based software to display crucial flow information. The location of the device intersects the flow between the BiPAP and patient to offer real time monitoring of the ventilation. Furthermore, the user interface can be adjusted to accommodate specialized treatment procedures to provide the information needed for quick conclusions that are valuable during a pandemic.

Important design considerations included ensuring that the device was compatible with most medical hoses normally connected to BiPAP devices. Additionally, the device needed the capability to connect to common PCs. Therefore, the ports are designed to specially connect to the standard 22mm inner diameter corrugated tubing and PC connection is a standard USB-A. Furthermore, medical settings require frequent sanitization especially between different patients, thus the airflow component containing the Venturi for flow monitoring is removable and autoclavable.

## Design Calculations and Calibration

To measure the flow of the system, pressure sensors were implemented to measure the differential pressure within the Venturi tube. Since the BiPAP machine offers air flow assistance in both directions two differential pressure transducers were included to monitor the inhale and exhale as illustrated in Figure X. In addition, a single static pressure transducer provides additional information for monitoring capabilities for medical personnel. The differential pressure measurements were then converted to a flowrate using Equation X which was adapted from the Bernoulli’s principle. Since the geometry of the Venturi tube stayed constant, the area terms were replaced with a single constant as shown in Equation X, which was determined through calibration procedures.

To develop the calibration constant, a pressure vs. flow rate chart was determined by sending known flowrates and measuring the corresponding pressure through the BiPAP conversion device. Since the BiPAP device only supplied pressures up to 25 cm H2O, the chosen flow rates were between 0-140 SLPM for an air mixture and 0-125 SLPM for a 50% N2/O2 mixture to accommodate the difference in composition. The calibration test procedure consisted of compressed air that was controlled with a manual valve and monitored using an Alicat MCR-Series mass flow rate controller, which allowed for data collection through a LABVIEW program. Then, the flow was directed to the BiPAP device’s venturi tube, which had an open end for the flow to exit the device. The general setup of the calibration procedure is depicted in Figure X.

For each trial,

~~To supply the correct flowrate, a mass flow controller was connected to the system to monitor the flowrate as a valve was manually adjusted. Figure X offers an illustration of the calibration set-up and where the device was set up as well as the adjustment points. For each flowrate, both the flowrate measurements coming from the MFC and the pressure measurements coming from the device were recorded for 20 secs after returning to steady state. This procedure was completed for three trials, twice by sweeping up from 0 SLPM and once by sweeping down from the maximum flowrate.~~

~~After data collection, the flow rates and pressures were averaged over the 20 seconds and used to develop a pressure flow curve as illustrated in Figure X. By fitting the curve to Equation X, a nominal constant was determined for use in the control code written in the microcontroller. In addition, a 95% confidence interval was also developed to ensure that the constant value accurately included the tested data points. Overall, the resulting calibration constant was X, with a range from Y to Z. Furthermore, the calibration was also done with a 50% N2/O2 mix to verify the results determined from the air mixture. After including the N2/O2 mixture data to the confidence interval found from air, the points fell in between the interval, verifying the original calibration constant value.~~

Additionally, the variation of temperature on the density was analyzed using a sensitivity analysis to understand the error introduced into the system from temperature variations in inhaled and exhaled air. During the final calibration, temperature data was gathered using a digital thermocouple located between the MFC and the prototype. Using this data, we were able to calculate the difference between the estimated value on the GUI and the actual temperature of the gas, and thus the percent error of the resulting flow rate measurement. With this procedure we found that the error in the flow rate measurement was 1% for every 8°C (14.4°F) of ΔT. Therefore, implementing a temperature measuring device would increase costs and complexity without a substantial increase in accuracy.

~~SInce the devices does not have a temperature~~

~~It was determined that the temperature had a very small effect on the density of the mixture, with a 1% change for every 8°C (14.4°F) of temperature variation. Therefore, it was unnecessary to measure temperature data and add complexity to the model.~~

[Insert Ryan’s findings] From the resulting calibration constants, the differences were negligible (<X%) and still supported the original calibration constant with the 95% confidence intervals.

After verifying the calibration constant, the equation was ready to incorporate into the microcontroller code for converting the pressure readings to flowrates. In this study, an MSP432 microcontroller was used along with C code developed on Code Composer Studio.

* Add section about why we chose the ranges for the sensors

## Embedded System Architecture

## Packaging Design

* Function
* What it’s made out of and why
* How it’s made
* Modularity and why
* Dimensions and how it interfaces with rest of system
* Other design considerations (hole for switch, finger, reset, wires)
* Potential improvements for design
* Talk about including o-rings to prevent leaks
* Shake test

The enclosure was designed to hold each component and package them neatly together so that the product could be easily operated by the end user, and easily maintained. The main enclosure has space for the battery on/off switch, a reset switch, and a USB slot. To accommodate the microcontroller, 4 standoffs are in the main body of the enclosure, each standoff has space for a heat set insert to secure the microcontroller to the enclosure. The standoffs allow for the microcontroller to be in a range of places to ensure tight tolerances do not affect the assembly of the prototype. Since the enclosure is entirely custom the team decided to 3D print the enclosure. The design allows for the enclosure to be printed from any standard 3D printer, with a thermoplastic. The enclosure also has a dedicated spot for the venturi tube which uses a friction fit to keep the venturi tube in place. This allows the venturi tube to be taken out very quickly to sanitize. The venturi is also a 3D printed part but should be made from an autoclavable material such as Ultem if intended to use with an autoclave. This way the venturi can be taken out for cleaning and swapped if the device is needed immediately. The venturi can only be printed from a 3D printer that can print soluble support materials since it's impossible to get the supports out of the tube, so it does not obstruct the flow and influence the functionality of the device. The venturi is unable to be printed without internal supports because the venturi has taps that are built into the part for pressure measurements, since the tubes axes are perpendicular to each other, the current iteration of the part will have to have interior supports. To interface the venturi with the enclosure, it had to be designed in such way that constrained it motion in the axial, and circumferential directions. Annular fins were used to constrain the motion in the axial direction, while a vertical tab contacted the walls of the enclosure to constrain circumferential motion. The pressure taps are set at an angle of 30 degrees from the horizontal to allow the width of the box to be shortened slightly and keep the hoses from interfering with the microcontroller. With all components installed into the enclosure the full prototype measures at 5.75” x 5.75” x 1.75 not including the hose connections.

The main barrier for this device to be used is the need for a dual extruder 3D printer with the ability to print soluble supporters. To resolve this problem, the venturi could be redesigned as a 2-piece design that is fixed by some sort of glue to stop leaks and remove the need for interior supports.

~~A 3D printed, modular housing was used to package the MCU, sensors and venturi tube. The housing is modular in that the venturi tube is removable for replacement and cleaning purposes. The venturi should be printed from an autoclavable material for easy cleaning while the rest of the housing should be made of any thermoplastic since heat-set inserts are used in the final product to secure some parts together. The prototype was made with Ultem 9085 because of its ability to be sterilized in an autoclave and its thermoplastic. The prototype was made with a Stratasys?? 3D printer for its ability to print with soluble supports. The venturi tube would be virtually impossible to print without the use of soluble supports since its design uses tubes whose axes are perpendicular to each other.~~

## Results

The combined electrical system, packaging, and interfacing hardware resulted in a compact and easy to assemble device for improved airflow monitoring. Due to the modular design of the 3D printed enclosure, the venturi tube was easily removable from the rest of the system for cleaning purposes and sterilization in medical settings. Additionally, the added O-rings to interface with the medical hoses provided a leak-proof seal to prevent pressure losses from the ventilation source. The flow rates determined from the calibrated constant was tested over a sweep between the minimum and maximum pressures, 0 to 2500 Pa. For each point, the value was compared to the flow rate collected from the mass flow rate controller to determine the percent error. As a system, the measured flow from the microcontroller displayed values that were within X% of the values on the mass flow rate controller, which supported the calibration constant and model fidelity. [We have not calculated this] Furthermore, the user flexibility in customizing the level of oxygen concentration in the graphical interface ensured that any prescribed level of oxygen was compatible with the calculated flow rate values.

Following the completion of the BiPAP-Ventilator prototype, the component was also verified against the measurement values on a full ventilator with a medical mannequin. This ventilator offered both flow rate and tidal volume which was compared to the prototype values. Since this test did not allow data collection on the ventilator, the test points were visually sampled every X seconds. Overall, the prototype produced values within X% of the ventilator data, which (supports/ does not support) the data collection and calculation methods. [How we might verify the prototype with an actual ventilator]

Additionally, there were some aspects of the design that may become a set back for the user. For instance, since the computer program was developed within a Python environment, the user would also need to have a compatible version of Python installed on the local computer to run the executable. Furthermore, since the venturi was designed using support material, the immediate completion of the 3D printed part may have remaining residue that requires diligent cleaning before use. Despite the setbacks, the device still carries value as these issues only require special care before the initial use. The implementation of this device will allow the cheapest and most widespread ventilation devices without precise flow monitoring an opportunity use in more advanced medical procedures. Additionally the prototype could offer further benefits in reducing the strain on the hospital system by allowing patients to transition to home care early, since the BiPAP ventilator is portable and easy to use.

## Conclusion

In summary, the team was able to create a working prototype that accurately measures flow parameters in response to the COVID19 pandemic. This device can equip a standard BiPAP machine with functionality that allowed doctors to monitor the patient's condition over time. In testing, the prototype device was able to measure the mass flow rate of air in the patient within a BLANK % error as compared to a mass flow controller. The device also has functionality to alter the composition of the air in the system based on the oxygen content. The resulting device was low cost and easy to operate, utilizing 4D printing and microcontrollers to provide a framework for the device. Using a modular design and autoclavable material the hardware team was able to meet a major design goal which was to ensure easy cleaning of the device, while the software team was able to ensure the accuracy of the device and usability with the interactive GUI. The goal of this device is to produce a low-cost alternative to a ventilator that can still provide essential functionality that doctors need in the event that ventilators are not feasible to procure. Our prototype allows medical personnel to maintain the standard of care while drastically reducing the price.

Sources

(<https://www.who.int/docs/default-source/coronaviruse/clinical-management-of-novel-cov.pdf>).

CPAP Helmet

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7270556/>

Successful non-invasive ventilation

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7386290/>

Other BiPAP related projects

<https://ieeexplore.ieee.org/abstract/document/9121830?casa_token=vYc2TkSdhjYAAAAA:YkRWc77RZ5ErXFpWhmEr8fEoT6mV1znCcBVI7sWcOBcQuFtdEm-yP2lC3B3ui3_5w1de8hEToIc>

A 10-step guide to convert a surgical unit into a COVID-19 unit during the COVID-19 pandemic

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7185019/>