Proposal for a low-cost high fidelity ventilator for COVID 19 pandemic

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Abstract

The COVID-19 pandemic situation has called for an urgent need for the development of low cost respiratory ventilators across the globe. Such ventilators must include functionalities to cater to the patients experiencing severe respiratory illnesses, such as ARDS, where lung compliance and patient breathing cycles are dynamic, and require an accurate and controllable ventilator design. A low cost ventilator design is presented here which offers essential pressure and volume control ventilator modes for critical patients while being cost-effective as compared to all other presently available commercial alternatives which provide similar functions. The presented design is currently in the conceptual stage, and is presented here to elicit feedback for further refinement, prototyping, medical approval and large scale manufacturing.

1 Introduction

The COVID-19 pandemic has affected more than 1.5 million people across the world, leading to an acute shortage of respiratory ventilators in many countries [1]. In response to this surge in demand, a number of low cost ventilator designs have been proposed [2,3], prototyped [4,5], and put into production [6–8]. While many of these designs remain low cost [2,3,6], such bag-valve-mask (BVM) based designs are limited on the level of controllability of several essential parameters required in an intensive-care-unit (ICU) ventilator. Besides the lack of precision in pressure and volume supplied to the patient, such ventilators also present an absence of pressure based feedback mechanisms which can lead to ventilator-induced complications on long-term usage, such as barotrauma and volutrauma [9], resulting in irreversible lung injury. At the same time, existing high fidelity designs remain either confidential or exorbitant, making them impractical for rapid proliferation. Thus, a low cost and high fidelity design of a ventilator is presented as a potential supplement to the currently available commercial ventilators.

A standard ICU ventilator operates with a number of breath sequence modes largely categorized as pressure control (PCV) and volume control ventilation (VCV) targeting the control parameter of either inspiration pressure or volume, respectively. Most essential breathe sequence modes required for critical ARDS patients are Pressure Regulated Volume Control (PRVC), Assist control (AC), Synchronized Intermittent-Mandatory Ventilation (SIMV), and Continuous Positive Airway Pressure (CPAP) mode [10]. Such patients also require an accurately controlled Positive End Expiratory Pressure (PEEP) to prevent the collapse of alveoli and maintain a healthy oxygen exchange rate. Thus, the key operating parameters for the present ventilator are identified below and meet the requirements prescribed by the ARDSNET protocol [11].

- Adjustable peak inspiration (PIP - up to 50cmH2O) and expiration pressures (PEEP - upto 25cm H2O)
- Adjustable respiration rate (6-40 breaths/ minute)
- Patient initiated breathing cycles
- Adjustable inspiration to expiration ratio (I:E ratio - 4:1 to 1:4)
- Adjustable FiO2 up to 100%
- Humidity control
- User friendly interface for parameter readout and control
- Adjustable tidal volume (100 ml to 800 ml)

An overview of the conceptual design is illustrated in Fig. 1. The size of the compactly designed device is comparable to the size of a small travel bag, making it conveniently portable. The following sections discuss the detailed conceptual design and the feasibility for prototyping. Sect. 2 presents the pneumatic circuit, control algorithms, and user interface. Sect. 3 lists the essential components of the present design along with an estimation of the cost. Sect. 4 discusses the potential calibration procedure for various sensors required for an optimal functioning of the device.

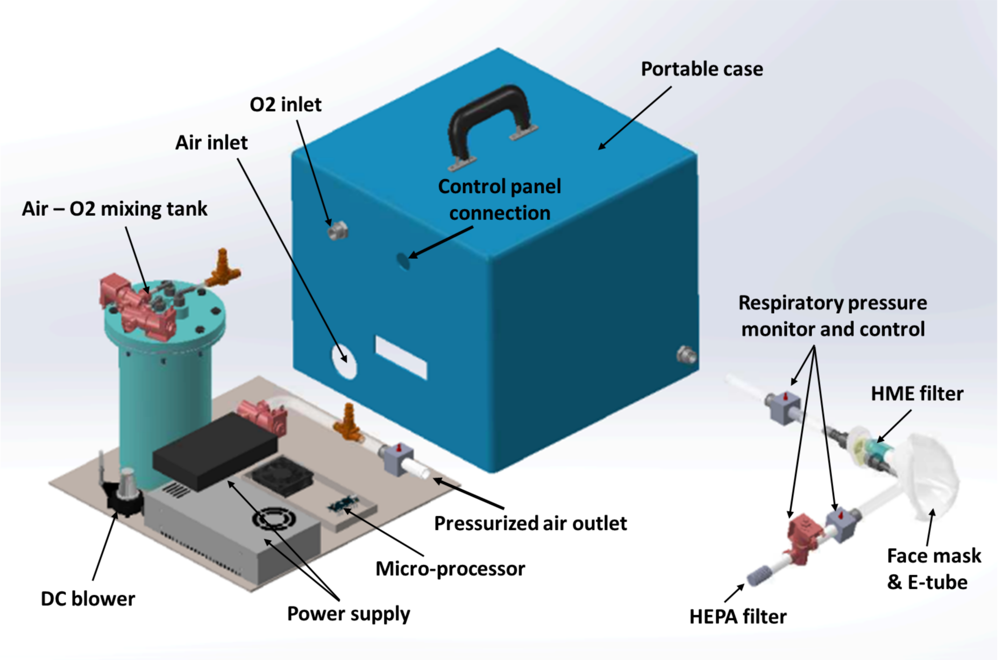

Figure 1: CAD model of the ventilator.

2 Conceptual Design

The conceptual design of the pneumatic circuit for the ventilator is presented in Fig. 2. The system consists of two gas inlets for hospital supplied O_2 and ambient air supplied through a blower assembly respectively, a mixing tank with safety valves, sets of solenoid valves and pressure sensors, humidity exchanger,

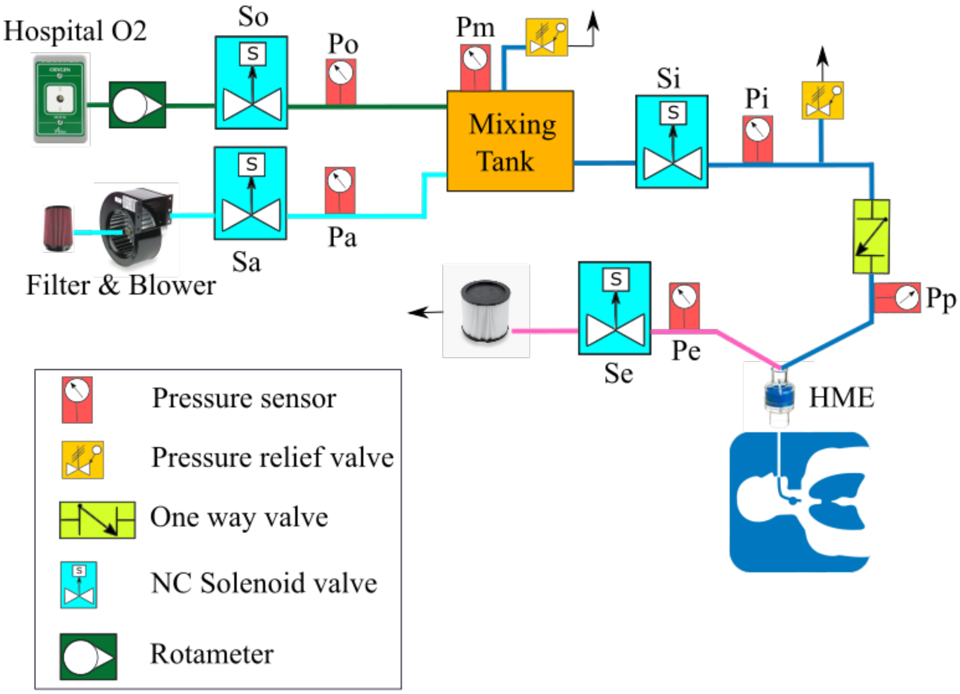

Figure 2: Pneumatic circuit of the proposed ventilator. Solenoid valves: So - O_2 inlet, Sa - air inlet, Si - inspiration tube, Se - expiration tube. Pressure sensors: Po - O_2 inlet, Pa - air inlet, Pm - mixing tank, Pi - inspiration tube, Pp - patient inlet, Pe - expiration tube. Lines: green - O_2 supply, light blue - room air, dark blue - oxygen-air mixture, pink - exhaled air.

filters and standard inhalation/exhalation tubes with a Y-connector. A low cost processor (Raspberry Pi) monitors the pressures at six stations in the circuit and operates on four proportional solenoid valves using standard control mechanisms, such as pulse width modulation (PWM) and proportional-integral-derivative control (PID). This enables the ventilator to operate both pressure and volume controlled modes with a variety of breath sequence modes such as Assist Control (AC), Synchronized Intermittent Mandatory Ventilation (SIMV), Spontaneous/Timed (S/T) ventilation mode combined with patient inspiration triggers, as well as the Continuous Positive Airway Pressure (CPAP) mode.

Notably, all the above modes depend on timing the operations of the solenoid valve (Si) to achieve various set-points prescribed by the doctor, which is enabled via the control algorithms programmed in the controller (Fig. 3(b)). Similarly, Positive End Expiratory Pressure (PEEP) of a prescribed value is enabled in the circuit by throttling the solenoid valve S_e using a PID control algorithm using pressure sensor Pe (Fig. 3(a)). In presence of a separate oxygen meter, the inlet valves Sa and So are also controlled using independent PID controllers to achieve the prescribed FiO2. In addition, the inspiration and expiration *hold* pressures are also achievable by implementing the PID control on the solenoid valve S_i based on pressure sensor Pi and Pe respectively. These plateau pressures are frequently monitored by doctors particularly for critical patients in order to identify their lung compliance. The processor consists of an on-board memory to enable storage of data collected from various pressure monitors. Additional pressure monitors are provided at critical locations in the circuit, which interrupt the standard cycle to revert to a fail-safe mandatory ventilation mode when an anomaly is detected. Such anomalies trigger alarms in the form of LED lights and sounds to attract the medical personnel.

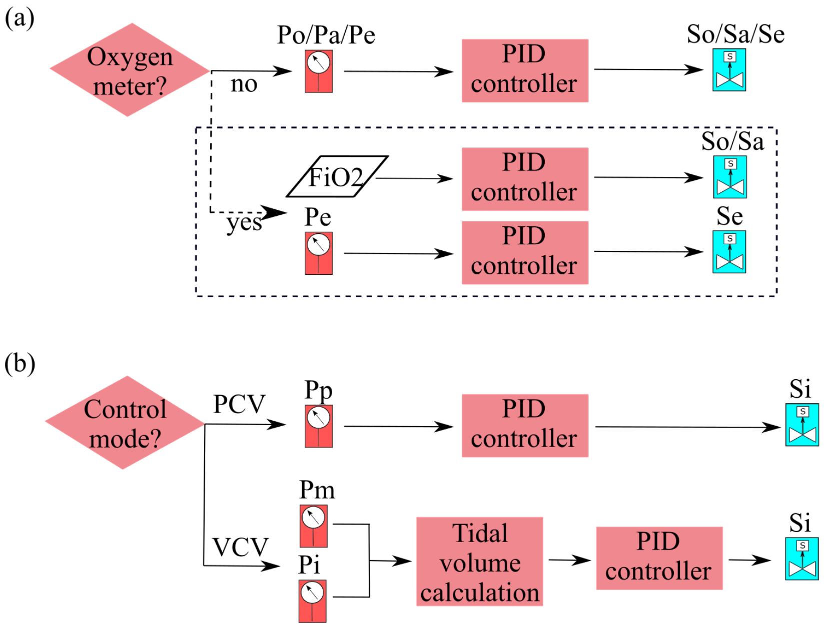

Figure 3: Control strategies for controlling the flow through the solenoid valves. (a) Control of valves So, Sa, and Se at the absence and presence of oxygen meter; (b) Control of valve Si under the volume control mode (VCV) and pressure control mode (PCV).

The typical operation of the inspiration flow controlling solenoid valve S_i is shown in Figs. 4(a) and 4(b) corresponding to the volume control and pressure control modes, respectively. They are complemented with the expected pressure signal measured via Pp. Volume signal is derived by integrating the instantaneous flow rate computed using the Bernoulli's principle [12] between the stations Pm and Pi respectively. The first two cycles in each figure represents a timed AC cycle, whereas the third cycle shows a patient trigger received from the pressure sensor Pp as patient starts inhaling before the end of the mandatory cycle. This low pressure patient trigger over-rides the mandatory timed cycle and restarts the timing cycle by opening Si to promptly meet the patient's need to inhale. Similar patient triggers are available in other ventilator modes available in this device reducing the discomfort caused by timed breath sequences.

Interfacing between the hardware and the user is enabled with the Raspberry Pi processor as illustrated in Fig. 5. The control program is divided into three major blocks - user interfacing, hardware control, and interrupts requiring immediate attention. Before initiating the ventilator, the doctor prescribes the operating mode and various set-points (out of PIP, PEEP, Tidal Volume, FiO2, I/E ratio, Respiratory Rate) as mandated by the chosen mode via a touchscreen display panel. The processor sets up the required timing and the initial PID tuning parameters based on the prescribed set-points. These parameters are updated in every cycle depending on the real-time response to achieve the prescribed set-points. Limits for low and high pressures, and various other alarm thresholds are also initiated based on prescribed set-points. The device initiates upon authentication by an authorized user and displays the required monitors (pressure, volume, flow rate, FiO2). Additional security measures for preventing misuse by unauthorised users are incorporated within the software. Using an advanced processor such as the Raspberry Pi also allows the doctor to remotely access the device to view the patient's current and past response as well as transfer the collected data on other local/cloud servers.

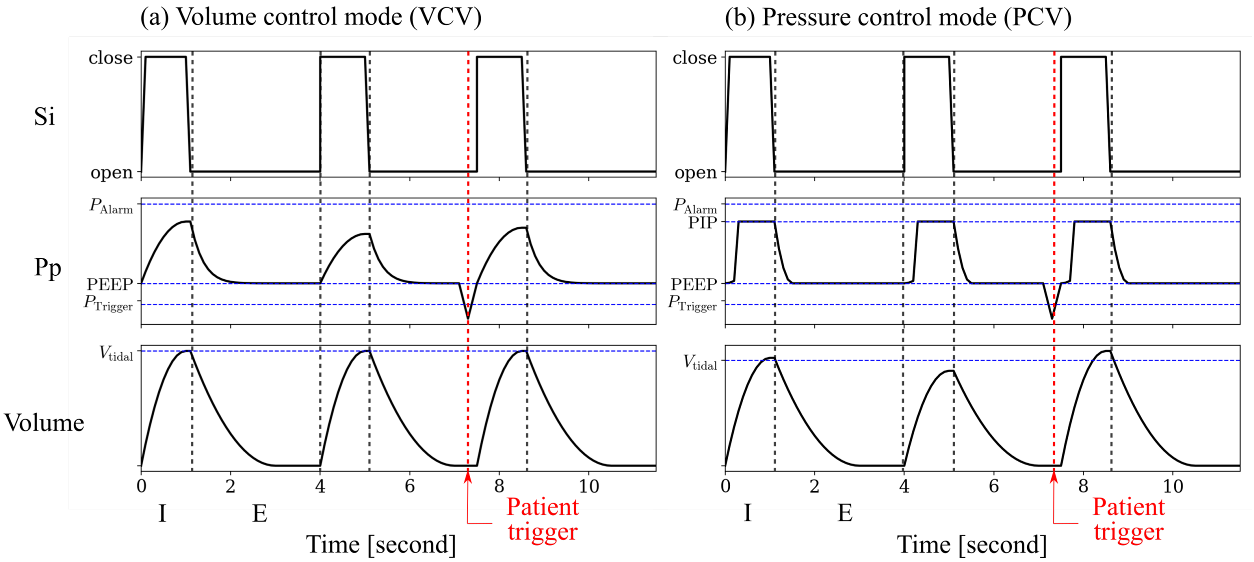

Figure 4: Timing diagram of the (a) volume control mode (VCV) and (b) pressure control mode (PCV) of a typical AC mode ventilation with a respiratory rate of 15 and I:E = 1:3. Row 1: trigger signal for solenoid valve Si; Row 2: pressure signal measured by pressure sensor Pp; Row 3: volume provided to the patient. Red dashed lines mark the patient trigger signal, which is a low pressure signal detected when the patient inhales before the end of the cycle.

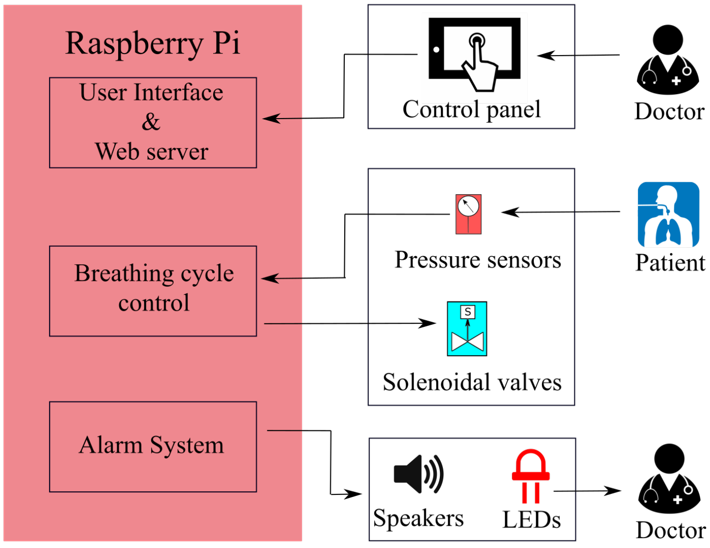

Figure 5: Control diagram for the interactions between doctors, patients and the ventilator. Raspberry Pi is used for both the user interface and communications with the electronics.

3 Components and Prototyping

A majority of the components used in the current design are standardized and RoHS compliant parts available with most wholesale hardware suppliers as verified by the authors. Some parts are suitable for 3D printing and other rapid manufacturing techniques that require minimal workforce which is critical in the current pandemic situation. The components that are 3D printed require a thorough testing for reliability under the extreme operating conditions of the ventilator before deployment. The assembly of the device doesn't require any special tooling or assembly line setups, and thus makes the model prototyping and manufacturing in short time feasible. The entire assembly should further be tested for the different operating modes and edge cases to see how the alarm triggers and overall system behaves. The major components, their quantities, and specifications are given in table 1.

Component	**Specifications**	**Qty.**	**Cost (USD)**
Solenoid valve	12/24VDC Proportional type, normally closed, response time <10ms, dia. 0.5"-1"	4	300
DC blower	12/24VDC, Static pressure >50cmH2O, 5 CFM	1	200
Pressure sensor	MEMS based, gauge pressure, ±1% F.S.	6	30
Mixing tank	3D printed, 2 litres	1	50
Pressure relief valve	∼50cmH2O	2	50
One way valve	dia. 0.5"-1"	1	10
Filters	HEPA filters	2	30
Humidity exchanger (HME)	Replacable on mask/E-tube assembly	1	10
Power supply and switching unit	110/240VAC to 12/24VDC, power>300W	1	40
Battery	Li-Ion, >6000mAh	1	80
Touchscreen display	10"/15", capacitive, LCD/LED	1	100
Tube fittings, tubing, and fasteners	PTC fittings, barbed connectors, dia. 0.5"-1", Tygon tubing, SS fasteners	-	100

Table 1: Bill of material for major components. Costs are representative of retail prices of various components as currently available in Ontario, Canada.

4 Calibration procedures

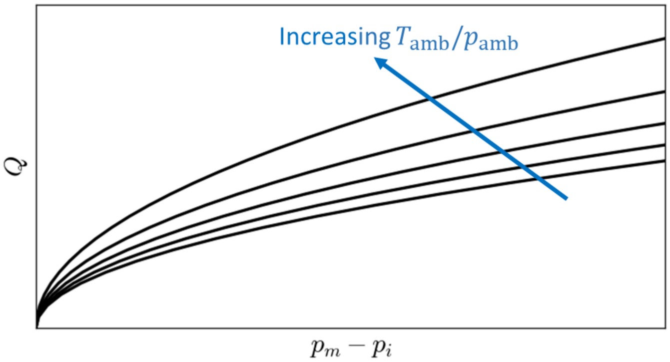

Figure 6: Typical calibration curves relating flow rate Q to pressure difference $(p_m - p_i)$.

Since the performance of the ventilator system is directly dependent on the pressure signals, the calibration of the prototype consists of the two following aspects.

Calibration for the volume measurement will be conducted using a hot-wire based flow meter at the inhalation tube to simultaneously measure of volume flow rate Q provided to the patient, along with the pressure difference between p_m and p_i measured by the sensors Pm and Pi. Following the Bernoulli's principle [12], the relation between flow rate Q and pressure difference $(p_m - p_i)$ can be represented by a calibration curve at given combination of ambient temperature T_{amb} and pressure p_{amb} as shown in Fig. 6. The baseline calibration curves will be generated at controlled ambient pressure p_{amb} and varying temperature in between 15°C to 35°C, at a step of 5°C. These calibration curves are then included in the control algorithms to estimate the flow rate and the volume input during the ventilator operation without the requirement of a separate flow meter in the device. The calibration error associated with the flow rate Q, and the tidal volume V_{tidal} will be retained within 1%.

For ventilator operations without an oxygen sensor, FiO2 is coarsely controlled by tweaking the thresholds Po and Pa corresponding to the solenoid valves So and Sa. The calibration procedure to identify these thresholds is conducted by using a oxygen meter on the mixing tank and provided in the program. It must be noted that the uncertainty of FiO2 with this calibration procedure will be $> 10\%$. Therefore, using an oxygen sensor on the port provided on the mixing tank is highly recommended when a precise control of FiO2 is required.

Open Source Declaration

All the authors consent for this work to be made open source. We also gratefully acknowledge the potential users of the presented design to help the people in need.

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