Team Breathe Eazy - Design Proposal

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Executive Summary

The team has chosen a ventilator that can be built in any low resource environment that has access to a 3D printer and generic OTS parts. It operates mainly by mechanical means which provides such benefits as simpler manufacturing ability. It is 3D printed at its core to be easily reproduced at any location. The initial and any subsequent altering of the design are further simplified with minimal and strategic use of electrical components, especially added where they increase patient safety by narrowing the margins on the control range validation requirements. The system's operation will be regulated with pneumatically actuated control valves which reduce electrical power consumption should the main power supply go out causing the backup power to be needed to run the alarm system for an extended period. The pump will be a single cylinder with a dual silicone sealed partition creating two chambers. One chamber has an inlet of conditioned low pressure air and oxygen mix that is used to expand the same chamber during the patient's expiration cycle in preparation for being compressed by the movement of the partition during the inhalation cycle. The outlet pressure of this same chamber is precisely controlled via a relief valve automatically opening at the correct threshold. The pressure is attained in the chamber via valves opening in the other chamber thus pressurizing it to a higher degree and moving the partition accordingly. The partition movement is controlled to an adjustable distance that correlates to the prescribed tidal volume. Any excess pressure is mitigated via a blow off valve for each pneumatic circuit. All design requirements were evaluated and accounted for accordingly. For a prototype, the cost is estimated to be around $500.00 meanwhile a prototype that is only tested mechanically with parts like cheaper valves, the cost is estimated to be $1500.00. For a full prototype that can be medically tested, the cost is estimated to be $5000 when manufactured and certified. However, costs may be subject to change depending on the addition of parts upon feedback and as more information and expertise is sought out.

1.0 Introduction

1.1 Design Problem

A ventilator is a machine that supports breathing by getting oxygen into the lungs and removing carbon dioxide out [1]. These machines are very commonly used in the healthcare field during surgeries, for individuals who have lost the ability to breathe on their own, or just overall need help breathing easier due to medical conditions [1]. These machines play a vital role in the treatment and care of patients and thus it is important they work with accuracy and precision to fit patient needs. Low-cost ventilators are often used in developing countries as they are not able to afford high-end units. These lower-cost machines have drastically improved the treatment and care for individuals from these countries. However, due to COVID-19, the need for higher quantities of ventilators is most important now than ever.

1.2 Objectives

The goal of this project is to provide a high quantity of life sustaining ventilator systems that can be made outside of the normal production cycle and at any location given minimal generic OTS parts with the assistance of 3D printers on site. They will be of minimalist design and materials, but must meet the specific guidelines laid out by the event organizers as they pertain to medical requirements.

1. 3 State of the Art

The low-cost portable mechanical ventilator prototyped and designed by Husseini *et al.* is one of the current existing technologies. The cost to make the prototype is $420 and to create it in the future in larger quantities is less than $200 [2]. Their ventilator design runs on an electric motor driven by a 14.8 VDC battery and it is constructed on the bag-valve mask (BVM) since it is affordable [2]. Their main model is a mechanical device that controls the BVM without the need of an operator [2]. Their ventilators air delivery system would compress an air reservoir which would assist patients in exhaling and inhaling air [2]. This approach decreased power requirements and the necessity for high-priced and hard to fix air ventilator parts [2]. The method they chose to operate the BVM utilized an arc shaped cam to squeeze the BVM, since it can deliver air constantly in a steady manner [2]. The quantity of air volume transferred can be precisely managed by adjusting the cam's angle [2]. Their first prototype included a spirometer to determine volume and flow rate, a hand dynamometer to determine the force applied on the cam, a revolving motion sensor to determine the angular displacement of the cam, and a pressure sensor to determine the air pressure inside [2]. The highest amount of air volume transferred per stroke was about 750mL [2]. The second prototype also included a potentiometer that was connected to the tip of the shaft to be utilized as a "position feedback sensor" [2]. Breath rate, inhalation to exhalation time relationship, and tidal volume can all be modified using the three analog dials fixed onto the exterior side of the ventilator [2]. Lastly, their prototype can deliver between 200 to 750mL of tidal volume and 5 to 30 "breaths per minute (bpm)" [2].

Another current technology is the low oxygen consumption pneumatic ventilator designed by Williams *et al.* Currently, a lot of ICU ventilators take in oxygen at a faster rate [3]. Therefore, they created and assessed a pneumatic ventilator in a modelled lung which would take in minimum oxygen [3]. Their prototype is a cheap "self-inflating bag squeezer" which can provide nitric oxide (NO) at a constant concentration in the respiring gas [3]. Their goal is to create an easily portable gas-efficient ventilator that would run entirely on gas and that could help a patient live for at least six hours without requiring more oxygen cylinders or power reserves [3]. The driving force, for their second design, that provides air to the lungs is the energy extracted roughly from oxygen compressing at a rate of 1 $1.min^{-1}$ at a pressure of two to four bars [3]. Following the use of the reserved energy to provide the driving force of the ventilator, the unusable oxygen would get reused again to enhance the air going into the ventilator before being sent to the lungs [3]. Thus, most of the breathable oxygen comes from the surrounding air [3]. Their third design consisted of a modification made to the first pneumatic ventilator which continuously squeezed a "single-use self-inflating bag" instead of a huge costly piston providing the motive force [3]. To add to that, this design also examines whether NO could be sent to the ventilator at a constant proportion to the "minute volume" with respect to volume [3].

According to the article written by Kacmarek, the most current mechanical ventilators would be the "Fourth-Generation ICU ventilators" [4]. This specific ventilator is a "Positive-Pressure Invasive Ventilator" [4]. This ventilator is expensive compared to the ones mentioned above. The one feature that differentiates these ventilators from others is the excess of modes present for ventilation [4]. One of the most complicated modes in this device tries to set up an appropriate breathing pattern for each patient derived from the “Otis work-of-breathing model” [4]. All the doctor would have to do is enter in the individuals appropriate body weight, the airway pressure limit and the minute volume and the device would automatically calculate their tidal volume and breathing rate and modify the pressure exerted by the ventilator [4].

1.4 Design Requirements

Table 1 outlines the requirements that were needed to be fulfilled and the requirements that the team was able to satisfy. There were primary and secondary requirements. This design focuses on the primary requirements.

2.0 Methodology

The team compared three different approaches; purely mechanical components, bag valve mask (BVM) ventilation, and a mix of mechanical and electrical components for ventilation. The team decided that the BVM ventilation does not address all the variables associated with ventilation effectively as automating the motion of a BVM is not sufficient. The team desired to make the ventilator purely mechanical, but soon realized that in order to achieve accuracy and precision some electrical components will be required. After researching many different designs, mechanical and electrical components, the team chose to design a ventilator with mostly mechanical components and a few electrical components, in turn maintaining simplicity and functionality.

Figure 1 outlines the general flow of the proposed mechanical ventilator concept.

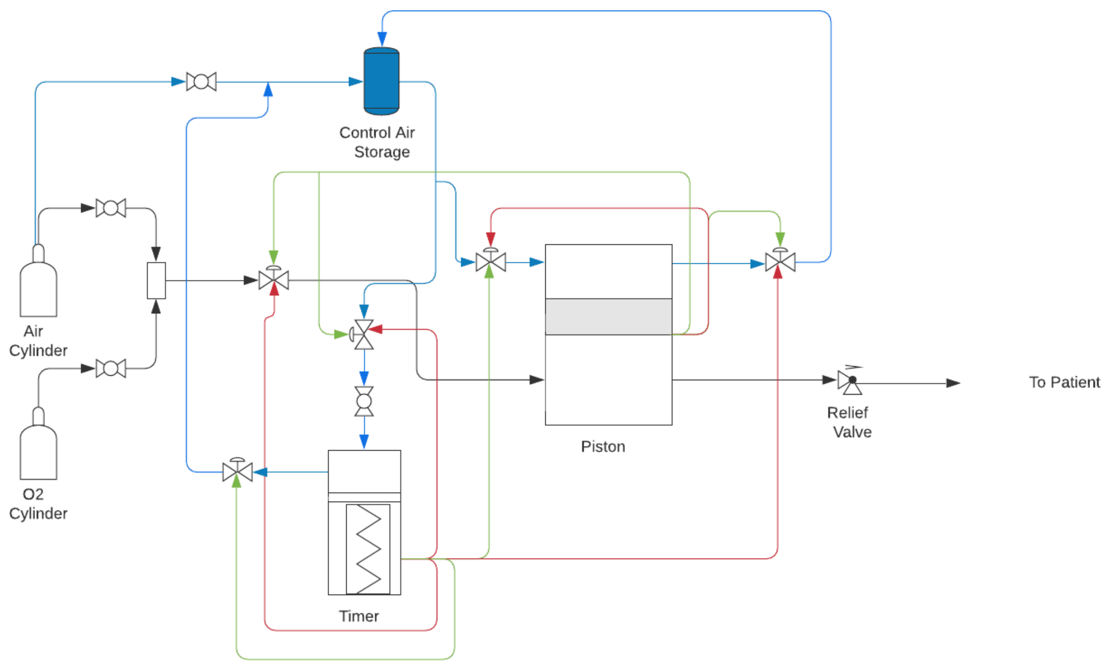

Figure 1: Ventilator flow diagram

3.0 Final Design

In order to achieve the two main modes of ventilation, mandatory ventilation and volume control, there are two variables to control, tidal volume and respiratory rate. To achieve these two conditions, a piston design was selected. Accurate volume control is achieved by a mechanical adjustment screw on the top of the unit that limits or extends travel distance.

Medical air and oxygen are mixed in the lower chamber of the piston to a set FiO2 level. A galvanic oxygen sensor measures the FiO2 and monitors for incorrect O2.

The housing contains all the pneumatics and control circuitry. The housing leverages additive manufacturing in its design with built in low pressure pneumatics components and mounting points for hardware. A simple stand has been designed to allow the unit to sit in the correct position next to an ICU bed and allows for a humidifier to be attached.

The user interface was designed to be user friendly as in an emergency, the staff may be inexperienced and exhausted. Large mechanical pressure and volume gauges clearly communicate these key variables to the user. A simple panel of 6 knobs adjusts the control variables (Mode, RR, IE Ratio, Pplat, FiO2, PEEP) - volume is set mechanically. The alarm status is shown with LEDs and a text label. Optional controls include Alarm Mute and Measure Pplateau (inspiratory hold maneuver).

To meet the alarm and control requirements of modern ventilators, a simple electronic controller was designed. The design separates critical functions such as the respiratory rate, from monitoring and alarm functions. A backup watchdog and battery is provided in case of power failure.

A discrete circuit based on a 555 timer controls valve timing. This is adjusted directly through the potentiometer dials on the front of the unit. With no software, the basic function of the unit is maintained in case of a higher level system failure, software bug or sensor failure.

A simple circuit board with a microcontroller monitors pressure and oxygen sensors. The microcontroller could be extended with higher level functions such as SIM-V modes, digital displays and networking. A separate watchdog circuit, with audible alarm and a long-life li-ion battery monitors control circuit and power failure.

Supply constraints and manufacturing methods were considered for the Breathe Eazy ventilator. With stocks of critical components already exhausted, off the shelf components were selected from other industries and interchangeability of components was strongly considered.

To meet the ventilator requirements for a low pressure, high volume inhalation and exhalation valves, a 2/2 pilot operated diaphragm valve was designed. For rapid testing, the valve can be made with PolyJet and OTS silicone o-rings and sheeting. The valve is low cost, fully sterilisable and easy to clean between patients.

Additional mechanical components for the patient airway circuit were designed, such as a check valve, filter holder, wye junction. These can be made for end use or testing using additive manufacturing.

To streamline the regulation process, all materials in the Breathe Eazy ventilator were carefully selected for their biomedical compatibility, ability to be sterilised and chemical compatibility. The following materials were selected::

- Stratasys MED610 Polyjet
- Stratasys PC-ISO, ABS-M30i, ULTEM 1010 FDM
- 316 Stainless Steel
- Silicone o-rings, sheet and tubing
- Polycarbonate

Manufacturing methods we considered for rapid prototyping and scalability. This design can be made quickly using commonly available off-the-shelf parts and additive manufacturing. Further refinement and optimisation of the design for injection moulding will enable manufacturing at scale.

In summary, the Breathe Eazy ventilator is a modern ventilator that combines a simple mechanical design with low cost electronics and solenoid valves to provide accurate ventilation for modern ICU use over an extended period of time. The design incorporates all specified alarm checks and has multiple redundancies to reduce the risk of critical system failure. The user controls are simple and familiar to the operator so that is easy to operate in challenging conditions. The ventilator is compatible with off-the-shelf airway circuits and valves; similar components have been designed in case of supply disruption. All materials and components have been selected to be easily sterilized and replaced.

3.1 Components

- A cylinder with a sealed partition providing two chambers
- Pneumatically actuated control valves
- User interface for ventilator control
- Gauges - mechanical components clearly show pressure and flow rate
- Venturi Valve
- Needle Valves
- Silicone Tubing
- Patient piping kit
- Knobs and switches - Replaceable or easily withstanding sterilization
- Y-Connector
- Thermometer
- Rolling tripod with vertical ventilator mounting rod
- Disposable filters
- Plexiglass enclosure
- LEDs
- Audible alarm buzzers
- Humidifier
- 3D printed parts

The heat and moisture exchanger (HME) filter is used to prevent drying within the patient's airways and the filter helps prevent bacterial infections from occurring. The Y-connector is used to connect the inhalation and exhalation pathways to the patient. There are two check valves in place to reduce backflow from the two distinct channels.

4.0 Future Work

Future work would include satisfying secondary requirements presented and prototyping. Testing will also indicate whether the 3D printed components can hold up to cyclic loading under high pressure. If necessary, different materials can be evaluated.

References

[1] "Ventilator/Ventilator Support," 26 December 2012. [Online]. Available: https://www.nhlbi.nih.gov/health-topics/ventilatorventilator-support. [Accessed 28 April 2020].

[2] A. M. A. Husseini, H. J. Lee, J. Negrete, S. Powelson, A. T. Servi, A. H. Slocum and J. Saukkonen, "Design and Prototyping of a Low-Cost Portable Mechanical Ventilator," Journal of Medical Devices, vol. 4, no. 2, pp. 1-9, 2010.

[3] D. Williams, D. Flory, R. King, M. Thornton and J. Dingley, "A low oxygen consumption pneumatic ventilator for emergency construction during a respiratory failure pandemic," Anaesthesia, vol. 65, no. 3, pp. 235-242, 2010.

[4] R. M. Kacmarek, "The Mechanical Ventilator: Past, Present, and Future," Respiratory Care, vol. 56, no. 8, pp. 1170-1180, 2011.

Appendix A

Table 1: Primary Design Requirements Fulfilled by Final Design

Identifier	System Requirement	Module	Met or Unmet
SR-01	Mandatory Ventilation	Control	Met
SR-03	Volume Control	Control	Met
SR-07	> 60 liters per minute	Drive	Met
SR-08	5-15 cmH2O in increments of 5cmH2O (+/- 5cmH20)	Control	Met
SR-09	1:2, 1:3, and 1:4 options available (click stop)	Control	Met
SR-10	Respiratory rate: 10-30 breaths/min in increments of 2bpm	Control	Met
SR-11	Option #1: Input height and gender for 6cc/kg TV (+/- 10% or 10mL) Option #2: 350cc (for average woman) and 450cc (for average man) (+/- 10% or 10mL) Option 3: 400cc only (+/- 1-% or 10mL) Option #4: 300-600cc adjustable in 100cc increments (+/- 10% or 10mL)	Control	Option 4 - Met
SR-12	Compatible with high pressure (~50psi) gas source (i.e., pipeline supply) OR low-flow inlet	Air-Oxygen Mixing Chamber	Met
SR-13	Option #1: FiO2 (21%+10%, 50%+/- 10%, 100% -10%) Option #2: adjustable between room air (21%) and 100%	Control	Option 2 - Met

	(+/-10%)		
SR-15	All components coming in contact with patient's breath must be disposable or sterilizable	Breathing	Met
SR-16	0.22um or smaller filter on patient inspiration and expiration pathway	Breathing	Met - filter holder, system pre-filters
SR-17	Ventilator inlet gas to allow filtration	Air-Oxygen Mixing	Medical air and oxygen are mixed in the ventilator
SR-18	All external surfaces must not degrade with application of standard agents for disinfection (e.g. bleach solution)	All reusable touchpoints	Met - chemically resistant plastic body and components, SS316 fittings
SR-19	Inlet Gas (O2) or Power supply failure	Alarm, Air-Oxygen Mixing, and Power Source	Met - electronic controlled mixing, watchdog circuit
SR-20	•Inspiratory airway pressure exceeded limits •Pplat <30-35 cmH2O •Peak P no more than 2 cmH2O greater than Pplat •Fail-safe valve opens at 60cmH2O (powered or un-powered)	Alarm and Monitor	Met - mechanical overpressure failsafe, electronic pressure sensor control
SR-22	Inspiratory and PEEP pressure not achieved (i.e. disconnection)	Alarm and Monitor	Met - electronic pressure sensor
SR-23	Tidal volume not achieved or exceeded (with ~20% tolerance)	Alarm and Monitor	Met - Maximum tidal volume mechanically limited, low pressure alarm for leak detection
SR-24	O2 disconnection	Alarm and Air-O2 mixing chamber	Met - low O2 alarm
SR-25	Alarm Volume 60 to 80 dBA at one meter (+/- 5 dBA)	Alarm	Met - piezo alarm
SR-26	Actual Value (TV, RR, PEEP, FiO2, Flow Rate, PIP)	Monitoring	Met - electronic