

DESIGN AND PROTOTYPE OF AN AUTOMATED POSITIVE SUCTION MECHANICAL VENTILATOR UNDER AN ECONOMIC AND SOCIAL PROJECT ANALYSIS IN LOW-INCOME PATIENTS

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Abstract

The design and prototype of a low-cost portable positive pressure mechanical ventilator for use in cases of mass disasters and resource-limited environments are described. The ventilator provides breaths by compressing a conventional valve bag mask (AMBU) using a pivoting lever, eliminating the need for a human operator for the AMBU. An initial prototype was constructed using acrylic, with measurements of 285 x 350 x 250 mm and a weight of 4.1 kg (9 lb). It is powered by a 12V DC battery-operated electric motor and features an adjustable air volume of up to a maximum of 750 ml. Control is achieved through a human-machine interface using a 16x2 LCD screen displaying RPM and percentage speed data, which are adjusted using an easy-to-use potentiometer. The prototype also includes an overvoltage safety control mode and pilot lights to indicate the equipment's status. Iterations of the device will include a controllable inspiration-to-expiration time ratio, a pressure relief valve, and a battery bank system that allows for 4 hours of autonomy. The prototype manufacturing cost is only \$820. Through this ventilator prototype, it is demonstrated that the lever-driven AMBU compression strategy is a viable option to achieve a low-cost, low-consumption portable technology that provides essential ventilator features at a fraction of the cost of existing technology

Keyword: Ventilator, Bag valve mask (BVM), Low cost, Low consumption, Portable and Automatic

INTRODUCTION

Trauma-induced respiratory disease and failure are a major public health problem in both developed and developing countries. Asthma, chronic obstructive pulmonary disease and other chronic respiratory conditions are widespread and are currently more visible since the SAR-COV 2 pandemic. These conditions are exacerbated by air pollution, smoking and the burning of biomass as fuel around the world. Patients with underlying lung disease may develop respiratory failure under a variety of challenges and may receive mechanical ventilation. These are machines that mechanically help patients breathe in and out, allowing the exchange of oxygen and carbon dioxide to occur in the lungs, a process called artificial respiration. While ventilators used in hospitals are highly functional and technologically sophisticated, their acquisition costs are correspondingly high (as much as US\$30,000 to US\$150,000).



High costs make such sophisticated technology a constraint for use in resource-poor countries. In addition, these mechanical fans are often fragile and vulnerable during continued use, requiring expensive service contracts from the manufacturer. In developing countries, this led to practices such as sharing ventilators between hospitals and purchasing less reliable refurbished units. Since medical resources in these countries are concentrated in the main urban areas while in hospitals in rural and peripheral areas they do not have access at all to this type of mechanical ventilators. Therefore, the need for a mechanical and economical fan is a priority. In the developed world, where well-stocked medical centers are widely available, the problem is of a different nature. While there are enough ventilators for regular use, there is a lack of preparedness for cases of mass casualties, such as influenza pandemics, natural disasters, and massive toxic chemical emissions.

The costs of storing and deploying state-of-the-art mechanical ventilators for mass casualty scenarios in developed countries are prohibitive. As an example, according to President Bush's November 2005 national preparedness plan, the United States would need up to 742,500 ventilators in a worst-case scenario. When compared to the 100,000 fans currently in use, it is clear that the system is deficient. Thus, this shortage occurred during Hurricane Katrina, when there were not enough 5 fan numbers and staff were forced to resort to BVM6 manual ventilation measures for since then measures have been enacted to improve preparedness; most notably the Centers for Disease Control and Prevention (CDC) recently purchased 4,500 portable emergency ventilators for the strategic national reserve. However, considering the low number of fans stored and their currently high cost, there is a need for an economical portable fan for which production can be expanded according to demand.

A clear example is the one currently experienced since the end of 2019, a group of cases of pneumonia of unidentified cause at that time was reported in the People's Republic of China, which would later be recognized as Severe Acute Respiratory Syndrome of Coronavirus 2 (SARS-CoV2).¹⁻³ This entity more commonly known as coronavirus disease 2019 (COVID-19) (term applied to patients who have laboratory-confirmed symptomatic cases without manifestations apparent radiological). Noncommunicable disease (NCD) prevention and treatment services have been severely affected since the beginning of the COVID-19 pandemic in the Region of the Americas, according to a survey by the Pan American Health Organization/World Health Organization (PAHO/WHO). The virtual survey, which was completed globally by 158 countries and regionally by 28 PAHO Member States, confirmed that the impact is global and that the disruption of health services.

The situation was so serious that it affects not only developing countries, but also developed countries that enjoy very good care services for conditions of "normality". Several countries, including the United States of America, have already experienced a shortage of ventilators. Acute care hospitals in the U.S. currently have about 62,000 full-function ventilators and about 98,000 basic ventilators, with an additional 8,900 in the Office of the Undersecretary for Preparedness and Response of the National Strategic Reserve.

The Centers for Disease Control and Prevention estimates that 2.4 million to 21 million Americans will require hospitalization during the pandemic, and experience in Italy has been that about 10 to 25% of hospitalized patients will require mechanical ventilation, in some cases for several weeks.⁸ Based on these estimates, the number of patients needing ventilation could range from 1.4 to 31 patients per ventilator. Whether ventilators will need to be rationed will depend on the pace of the pandemic and how many patients need ventilation at one time, but many analysts warn that the risk is high.

It is very likely that 53 years ago, in 1967, when Ashbaugh et al. first described ARDS¹⁷ they did not imagine that they were laying the first stone for the construction of modern mechanical ventilation (MV), since, the advances achieved in this half century have been motivated in large part by the fight against acute breathing syndrome by its acronym ARDS, accompanies COVID-19 as one of the maximum manifestations of complication, severity and death. In the absence of specific studies on COVID-19- induced ARDS, ventilatory management should be consistent with established



guidelines for ARDS. WHO has published similar guidelines for severe respiratory infections from COVID-19.

Once the patient is intubated, MV should be applied with pulmonary protection standards using low tidal volumes (4 to 6 mL/kg of weight) exerting monitoring and control of plateau pressure keeping it below 30 cmH₂O. The driving pressure value (plateau-PEEP pressure) should be below 15 cmH₂O, which has been associated with lower mortality.²⁰ PEEP titration should be based on compliance, oxygenation, dead space and hemodynamic status. PEEP can also be titrated by estimating transpulmonary pressure with esophageal catheter or electrical impedance tomography.²¹ It could also be titrated from the formula (PD=P_{plateau}-PEEP) taking into account that physiological mathematical coupling is logical (which would result in a PEEP of 15 cmH₂O if the plateau pressure is 30 cmH₂O). PEEP titration requires consideration of benefits (reduced atelectrauma and improved alveolar recruitment) versus risks (final inspiratory overdistension leading to lung injury and increased pulmonary vascular resistance).

The automation system of the prototype consists of a cam that presses the ambu, eta cam is driven by a direct current motor with a power supply, this system is controlled by a 10k ohm potentiometer, this potentiometer makes a change in the control input to which it is by modulation of pulse width this control through the potentiometer modifies the width of this pulse which increases or decreases The speed of the motor, this change of speed is shown on the LCD screen 16x2 where the percentage of the pulse width of the current state of the engine and the revolutions per minute at which it is rotating at that moment is indicated, this helps to calculate the number of times the AMBU is pressed for each minute as required by each patient.

The prototype has a safety system against over voltages, consists of a 5 amp fuse, a mushroom type emergency stop in addition and a power switch, this system helps us protect the prototype against over current and over voltages, also consists of a battery bank system that gives all the equipment an autonomy of 4 hours of operation at full load. The systems implemented both in the control part and in the autonomy part provide the prototype with a degree of automation and security against possible damage.

DESIGN STATUS

While many emergency and portable ventilators are on the market, the lack of a suitable fan at low cost is indispensable. Figure 1 shows a cost-performance distribution of manually operated Ambu BVM ventilators at the lower end of cost and performance, relative to full- featured hospital ventilators at the other end. The middle section of Table 1 which includes existing portable fans that can be broadly classified as pneumatic and electric. Pneumatic fans are activated using compressed gas energy, often a standard pressure source of 50 psi (345 kPa) normally available in hospitals. These fans have prices ranging from 20,000.00 to 100,000.00 US dollars. This category includes products such as the VORTRAN automatic resuscitator (VAR),TM a single-patient disposable resuscitator and Lifesaving Systems Inc.'s reusable Oxylator, the OTwo CAREvent® and Ambu® Matic portable resuscitators. However, these systems cost an order of magnitude more than our expected price and rely on external pressurized air, a resource that our target market may not have access to.

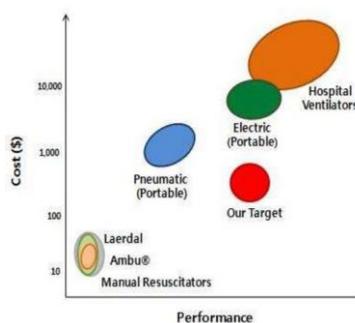


Figure 1: Fan cost-performance distribution



On the other hand, there are electric fans that can work anywhere, therefore, they are not subject to this restriction. Fans of this type, such as CareFusion LTV 1200, LTV® 1200 which even weighs 6.3 kg (13.9 lb) and includes standard features as well as the ability to interrupt or slowly remove the mechanical fan support. Its complexity raises its cost to several thousand dollars, an order of magnitude above our target retail price. As an example, the U.S. Department of Defense has also developed several rugged portable electric fans. One of these fans is the Johns Hopkins University (JHU) Applied Physics Laboratory (APL) Miniventilation Unit (JAMU), which weighs 6.6 pounds (3.0 kg), measures 220 cubic inches (3600 cubic cm), and can run for up to 30 minutes on a battery. This device was patented by JHU/APL and licensed to AutoMedx. The trading device features a one-button operation. Its simplicity comes with a compromise, as the user cannot adjust tidal volume, respiratory rate and other parameters, making it not suitable for many patients who cannot tolerate fixed tidal volume, frequency or ventilation per minute. Nor can it be operated for prolonged periods in an environment of scarce resources. Plus, priced at over

\$2000, it costs several times more than our given target price.

Another device, the FFLSS, weighs 26.5 pounds (12 kg) and can run for an hour powered by a battery. It also includes additional physiological sensors and fits into a

U.S. standard military backpack. While these devices are functionally suitable, their compressors require high power, which limits battery life. In addition, its numerous pneumatic components are expensive and cannot be easily repaired in a resource-poor environment.

MEDICAL DEVICE REQUIREMENTS

In anticipation of the aforementioned limitations, mechanical, medical, economic, user interface and reliability functional requirements have been developed under ASTM F920-939 requirements and are summarized in Table 1.

Doctor	<ul style="list-style-type: none"> - User-specified minimum breathing - Inspiration/expiration ratio - Current volume - Attendance control - Positive end-expiratory pressure (PEEP) - Maximum pressure limitation - Moisture exchange - Infection control - Limited dead space
Mechanic	<ul style="list-style-type: none"> - Portable - Independent operation - Robust mechanics, electricity and software - Parts that are easy to obtain and repairable - Minimum energy requirement - Charged battery
Economic	<ul style="list-style-type: none"> - Low cost (<\$500)
Interface	<ul style="list-style-type: none"> - Alarms for loss of energy, loss of integrity of the breathing circuit, high pressure in the airways and short battery life. - Viewing settings and status - Standard connection ports
Repeatability	<ul style="list-style-type: none"> - Indicators within 10% of the correct reading - Breathing rate with an accuracy of one breath per minute

Table 1: Device functional requirements



DEVICE DESIGN

Air supply technology

Two main strategies for the fan air supply system were identified. One strategy uses a constant pressure source to deliver air intermittently while the other provides breaths by compressing an air reservoir. The latter approach was adopted because it eliminates the need for continuous operation of a positive pressure source. This reduces energy requirements and the need for expensive and difficult-to-repair pneumatic components.

Where most portable and emergency fans are designed with all custom mechanical components, we chose to take an orthogonal approach when building on top of the economical BVM, an existing technology that is the simplest realization of a volume displacement fan. Due to the simplicity of their design and production in large volumes, BVMs are very economical (approximately \$10) and are frequently used in hospitals and ambulances. They are also readily available in developing countries, equipped with an air reservoir and a complete valve system, inherently providing the basic necessities required for a fan.

The main drawback of BVMs is their manual operation that requires continuous operator involvement to hold the mask to the patient and tighten the bag. This operating procedure induces fatigue during prolonged operations and effectively limits the usefulness of these bags to temporary relief. In addition, an untrained operator can easily damage a patient's lungs by compressing the bag too much. Our methodology, therefore, was to design a mechanical device to drive the BVM. This approach results in an economical machine that provides the basic functionality required by mechanical ventilation standards.

Compression mechanism

The most obvious means of actuating a BVM is to mimic the hand movement for which the bag was designed. This requires the use of linear drive mechanisms (e.g. feed screw or rack and pinion) which, despite being simple to implement, require additional linear bearings and accessories. Other compression techniques were sought to take advantage of the cylindrical shape of BVM. However, since BVMs were designed for manual operation, their compressible outer surface is made of high-friction material to maintain contact with hands with minimal slippage.

This eliminates the option of tightening a belt wound around the bag as a means of drive. To avoid the problems associated with high surface friction, the two main candidates for the drive were a roller chain and a compression cam. These options employ rolling contact with the bag instead of sliding contact, eliminating losses due to kinetic friction between the actuator and the bag.

Roller chain concept

The roller chain concept uses roller chains with roller diameters greater than the width of the link. Figure 2 shows the chain winding around the circumference of the bag and, as a result, saves a lot of space. A sprocket is connected to the motor shaft; Its clockwise/counterclockwise rotation compresses and expands the bag for breath delivery.

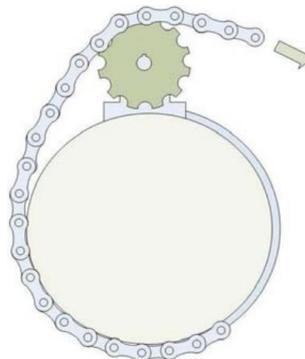


Fig. 2: Schematic of the roller chain device

While this idea initially seemed feasible, preliminary experiments revealed that radial compression



of a BVM requires significantly greater force than the vertical compression for which the bag was designed. Additionally, its operation was noisy and the bag crumpled under radial compression, inhibiting the desired pure roll motion and preventing a precise and repeatable tidal volume from being administered.

Compensation was found; While small-pitch/roller diameter chains are more space-efficient and produce higher angular resolution for compression, bag crumpling becomes a problem. On the other hand, a chain of higher pitch/roller diameter overcomes crumpling, but takes up more space and decreases angular resolution. In any case, the use of roller chains added a significant amount of weight to the system, suggesting the need for a more effective mechanism that needs a smaller contact area.

Concept of leads

The cam concept uses a crescent-shaped cam to compress the BVM, allowing for uniform and repeatable deformation to ensure a constant air supply shown in Figure 3. As it rotates, the cam makes a rolling contact along the surface of the bag and, unlike the roller chain, achieves a low noise level operation. By controlling the angle of the cam shaft, the amount of air volume delivered can be precisely controlled. It was found that the cam mechanism took up less space and required less energy than the roller chain concept, so it was the method of choice.

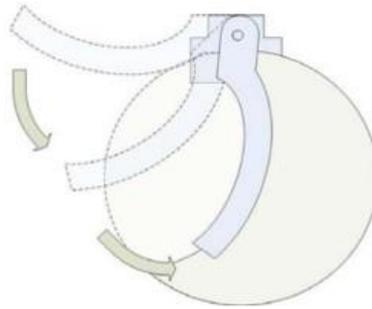


Figure 3: Sketch of the cam-based device

Results Prototype design

Design of the first prototype

With the cam concept selected as the best method for BVM compression, an initial prototype was built to measure force and power requirements. The cabinet frame consists of four vertically mounted sections of 1/2" (12.5 mm) clear acrylic, each mounted on the bottom section of the frame with interlocking companions.

The material is easily laser cut and allows visibility of internal components. The two inner sections (ribs) have U-shaped grooves made to conform to the contour of the BVM's surface, while the end sections feature openings to accommodate the valve neck and oxygen reservoir of the BVM.

The pivoting cam assembly was mounted on top of the hinged aluminum lid and consisted of two crescent-shaped pieces of 2.5" (63.5 mm) radius attached to a 5/16" (8 mm) aluminum shaft mounted with nylon bushings.

Experiment of the first prototype

A bank-level experiment was conducted on the first prototype to determine performance characteristics. Data was collected using our prototype's cam mechanism to compress an adult-sized Ambu® BVM shown in Figure 4. The test apparatus included a spirometer to measure flow (and volume, by integrating over time), a manual dynamometer to measure the force exerted on the cam, a rotary motion sensor to measure the angular displacement of the cam and a pressure sensor to measure the internal air pressure. The experimental setup is shown in Figure 5.

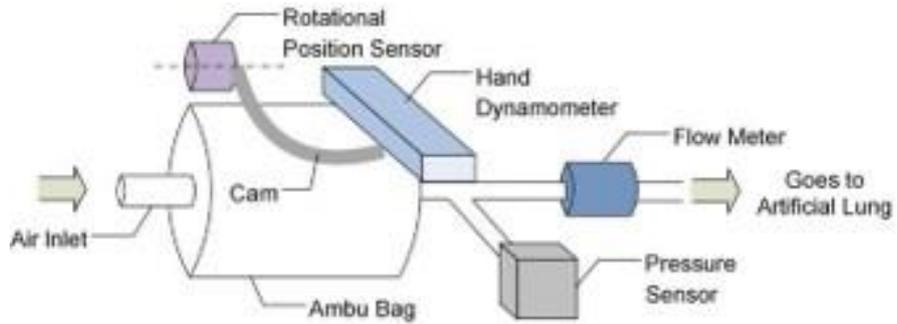


Fig. 4: Schematic of the experiment configuration

A second prototype was built in which all the moving components were moved within the enclosure. The dimensions of the cabinet were increased to accommodate the range of motion of the cam arm and to make room for the motor, microcontroller and battery pack. The lid of the enclosure was made of acrylic and hinges from the side of the unit to better restrict the top of the bag. The support ribs inside the cabinet also serve as mounting blocks for the camshaft hubs. A potentiometer was attached to the end of the shaft for use as a position feedback sensor. Figure 7 shows an isometric view of the CAD model of the second prototype, and Figure 8 shows the built device.

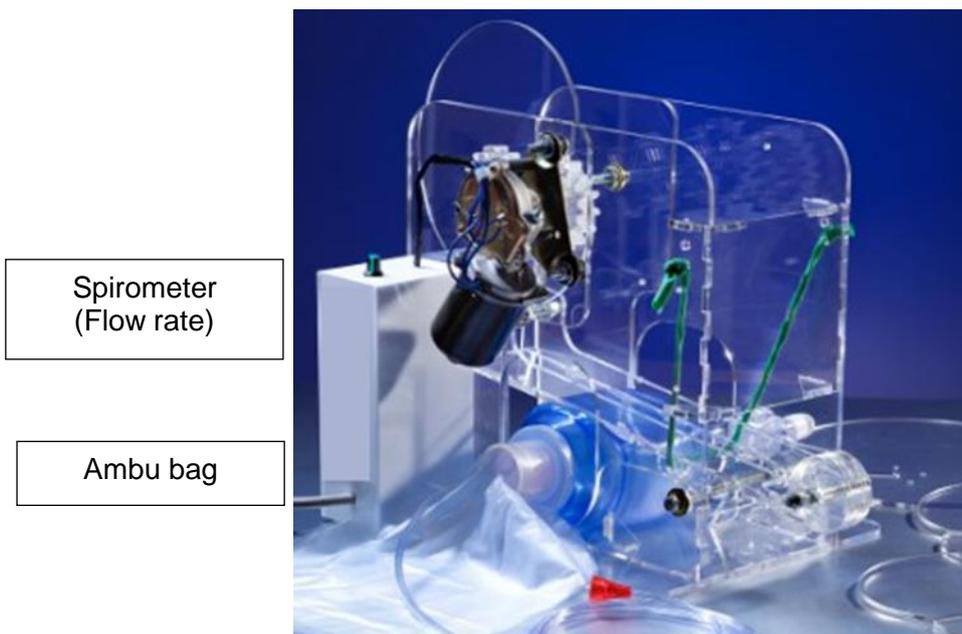


Fig. 5: Setting up the actual experiment

The volume of air supplied was measured as a function of the cam angle integrating the flow over time. The results indicated that the relationship between the administered volume and the cam angle is approximately linear (Figure 6). Data analysis showed that the maximum power required was 30 W and the maximum torque was 1.5 Nm. The maximum volume administered per stroke was approximately 750 ml. The target tidal volume is 6-8 ml/kg for adult human use, making it suitable for most clinical situations.

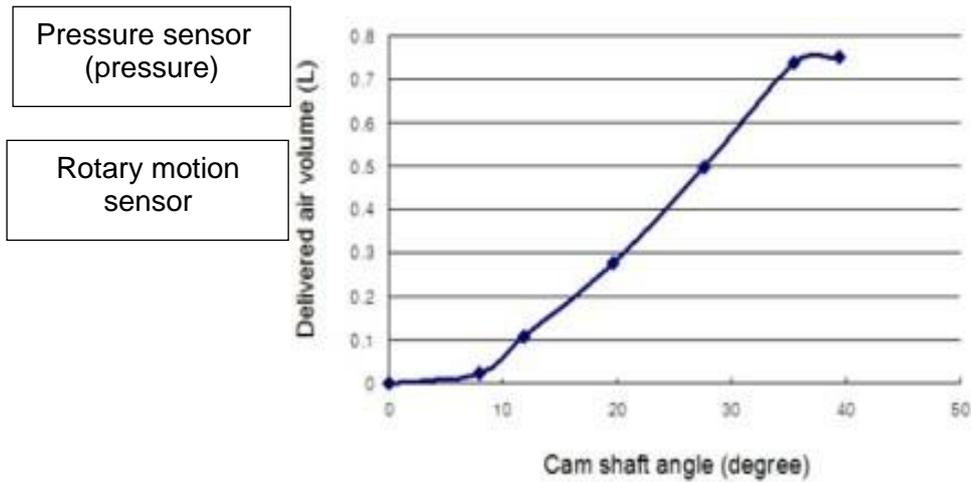


Fig. 6: Volume vs. cam angle

Implementing controls

Control Design

This fan provides guaranteed tidal volumes through an assisted control (AC) mode. The operator selects the appropriate tidal volume for the patient, usually 6-8 mL/kg of ideal body weight and a minimum respiratory rate. This provides a minimum assured ventilation per minute (V_e). If the patient is breathing above the frequency set, the negative inspiratory pressure exceeding 2 cmH₂O vacuum activates the ventilator to deliver the set tidal volume.

The advantage of AC mode is that the patient has assured ventilation per minute to meet the physiological needs of adequate gas exchange. A disadvantage is that if the patient is tachypneic or breathing too fast, respiratory alkalosis may develop or, for those with obstructive pulmonary disease, air trapping may occur, raising intrathoracic pressure with adverse hemodynamic and gas exchange consequences. However, these problems are commonly managed with reductions in respiratory rate and sedation as needed. AC mode, one of the most widely used modes of mechanical ventilation, is suitable for the management of most clinical scenarios of respiratory failure. This ventilator may be used for patients who are intubated with an endotracheal tube or who would receive noninvasive mechanical ventilation through a mask that is commonly used to provide continuous positive airway pressure (CPAP).

Parameters

The operator adjusts tidal volume, respiratory rate, and inspiratory-expiratory time ratio using three continuous analog knobs mounted on the outside of the ventilator. The prototype has a tidal volume range of 200 to 750 ml and 5 to 30 breaths per minute (bpm). This produces a maximum ventilation per minute (V_e) of 21 L and a minimum V_e of 1.5 L. However, these values do not reflect the limits of the final design but the adjustments of the prototype. Theoretically, the fan can supply from 0 l volume per minute to 60 l volume per minute. However, this has not been fully proven. The I:E ratio was not implemented in



the prototype, but could theoretically have any desired range within the limits determined by the other parameters. The ranges of the final design will be determined in consultation with breathing specialists to allow for the widest range of safe configurations.

Controller

A ready-to-use Arduino Duemilanove microcontroller board was selected to control our device. The microcontroller runs a simple control loop to achieve the performance prescribed by the user. The control loop is activated by the internal timer set by the user's inputs, with the inspiratory stroke initiated at the beginning of the loop. Once the prescribed tidal volume is reached, the actuator returns the cam to its initial position. position and hold until the next breath. The cycle is then repeated to administer intermittent breaths. If the loop is interrupted by an attempt at breathing by the patient (detected through the pressure sensor), the ventilator immediately delivers a breath, interrupting the loop and resetting the timer. A diagram showing this loop is in Figure 9.

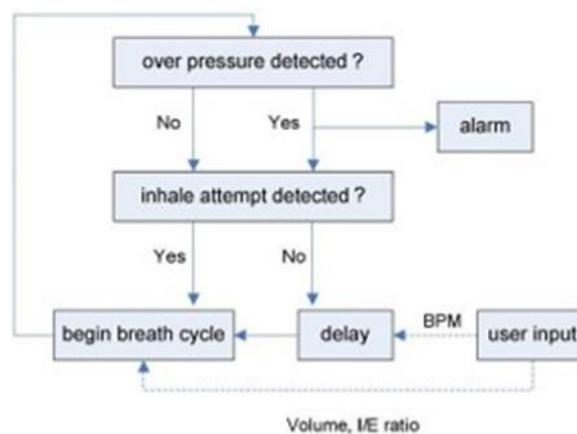


Figure 7: Fan control loop

Motor

According to initial experiments, a maximum torque of 1.5 Nm was required for maximum volume delivery. A PK51 DC gearmotor with a torque of 2.8 Nm was selected for the prototype. Despite the lower torque value measured in our experiment, we found that this motor did not provide enough torque to effectively drive the cam at the slower inhalation cycle speeds prescribed for some patients. While a larger motor will be necessary to achieve better speed control, this engine performed acceptably in the proof-of-concept phase. It was desirable for its gear reduction ratio of 51:1 and an operating speed in the required range of 50-70 rpm.

Motor controller

The motor controller consists of two H-Bridge circuits. These circuits direct current through the motor in opposite directions, depending on the set of switches in the circuits that are activated. The motor speed is indicated by a pin pwm. Power is supplied directly from the battery, so the only limit is the current capacity of the chip and battery. We opted to use the Solarbotics® motor controller, which is capable of supplying 5 amps of current to both circuits. The PK51 motor current station is rated at 5.2 amps, which means that the motor controller will be able to handle the requirements for the system.

User interface

The three user inputs (tidal volume, bpm and I:E ratio) are configured via three potentiometer knobs. Future iterations of the device will include the addition of an LCD display to display input settings as well as airway pressure level and battery power status.



Security features

To ensure that the patient is not injured, the airway pressure is controlled with a pressure sensor connected to a sensor outlet in the BVM. The same pressure sensor used to initiate attendance monitoring also triggers an alarm if the pressure rises too high, alerting the doctor to attend to the patient. As an additional safety measure to prevent overinflation, future iterations of the device will include a mechanical pressure relief valve.

Power supply

An AC/DC converter can be used to power the fan directly from a wall outlet or vehicle inverter. When external power is not available, the fan can run on any battery capable of delivering 12-15 volts at least 3.5 amps. For the prototype, we used a 14.8-volt four-cell lithium-ion battery pack capable of generating 4.2 amps (limited by a protection circuit), with a capacity of 2200 mA-hr.

Analysis and Testing

The battery life of the second prototype was tested by running the fan in the test lung until the battery voltage dropped to a level insufficient for operation. The device was set to maximum volume and frequency of BPM (30 breaths/minute). The total duration of the test was three hours and thirty-five minutes, at which point the battery ran out. Based on battery capacity and voltage, electrical power consumption during this test averages only 9 watts (this includes downtime between breaths).

CONCLUSIONS

A working prototype has been developed that can be operated on a test lung. The prototype has user-controlled respiratory rate and tidal volume. That features attendance control and an overpressure alarm. It has low power requirements, runs for 3.5 hours on a battery charge in its most demanding configuration. It weighs 9 pounds (4.1 kg) and measures 11.25 x 6.7 x 8 inches (285 x 170 x 200 mm), and has an easy-to-use handle and latches. The prototype can display the configuration on a screen, planned with further development of this proof of concept. Future iterations will incorporate changes brought about by the results of our prototype testing. It will incorporate an adjustable expiration-to-expiration inspiration ratio, an option missing from this prototype due to its low-power engine. We will investigate the effects that changing engines will have on cost, weight and battery life. We will also incorporate additional features including a PEEP valve, a moisture exchanger and an exhaust valve. Since BVM's infrastructure already supports commercial add-ons, these components can be easily purchased and incorporated. Ways to minimize dead space will be explored, including the option of using a Laerdal-branded® BVM whose valves can be placed at the end of the patient's tube. In subsequent iterations, we hope to be independent of Laerdal® by manufacturing our own bags or contracting their production. The design will be changed to be injection molded so that the mass-produced version costs less than \$200 to produce.

Weight will be minimized and battery life will be extended. The shape of the cam arm will be optimized to ensure the use of the most efficient rolling contact realization. An LCD display and programmed alarms will be included for power loss, loss of breathing circuit integrity, and low battery life. Extensive fan repeatability testing shall be performed. Finally, we will test the ventilator on a lung model to meet ventilator standards and market the product.

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