

**DESIGN AND PROTOTYPING OF A LOW-COST PORTABLE
MECHANICAL VENTILATOR**¹ Patil Amol Devidas , ²Patil Prashant RajeshDepartment of Electronics and Telecommunications, GCOE Dhule^{1,2}pamol473@gmail.com¹, prashantrpatil2016@gmail.com²**ABSTRACT**

This paper describes the design and prototyping of a low-cost portable mechanical ventilator for use in mass casualty cases and resource-poor environments. The ventilator delivers breaths by compressing a conventional bag-valve mask (BVM) with a pivoting cam arm, eliminating the need for a human operator for the BVM. An initial prototype was built out of Wooden, measuring 11.25 x 6.7 x 8 inches (285 x 170 x 200 mm) and weighing 9 lbs (4.1 kg). It is driven by an electric motor powered by a 14.8 VDC battery and features an adjustable tidal volume up to a maximum of 750 ml. Tidal volume and number of breaths per minute are set via user-friendly input knobs. The prototype also features an assist-control mode and an alarm to indicate over-pressurization of the system. Future iterations of the device will include a controllable inspiration to expiration time ratio, a pressure relief valve, PEEP capabilities and an LCD screen. With a prototyping cost of only 6 K, the bulk-manufacturing price for the ventilator is estimated to be less than 5 K. Through this prototype, the strategy of cam-actuated BVM compression is proven to be a viable option to achieve low-cost, low-power portable ventilator technology that provides essential ventilator features at a fraction of the cost of existing technology.

Keywords: Ventilator, Bag Valve Mask (BVM), Low-Cost, Low-Power, Portable and Automatic.

1. INTRODUCTION

Respiratory diseases and injury-induced respiratory failure constitute a major public health problem in both developed and less developed countries. Asthma, chronic obstructive pulmonary disease and other chronic respiratory conditions are widespread. These conditions are exacerbated by air pollution, smoking, and burning of

Biomass for fuel, all of which are on the rise in developing countries^{1,2}. Patients with underlying lung disease may develop respiratory failure under a variety of challenges and can be supported mechanical ventilation. These are machines which mechanically assist patients inspire and exhale, allowing the exchange of oxygen and carbon dioxide to occur in the lungs, a process referred to as artificial respiration³. While the ventilators used in modern hospitals in the United States are

Highly functionally and technologically sophisticated, their acquisition costs are correspondingly high (as much as 1.5 lack). High costs render such technologically sophisticated mechanical prohibitively expensive for use in resource-poor countries. Additionally, these ventilators are often fragile and vulnerable during continued use, requiring costly service contracts from the manufacturer. In developing countries, this has led to practices such as sharing of ventilators among hospitals and purchasing of less reliable refurbished units. Since medical resources in these countries are concentrated in major urban centers, in some cases rural and outlying areas have no access at all to mechanical ventilators. The need for an inexpensive transport ventilator is therefore paramount.

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 casualty such as influenza pandemics, natural disasters and massive toxic chemical releases. The costs of stockpiling

and deployment of state-of-the-art mechanical ventilators for mass casualty settings in developed countries are prohibitive. According to the national preparedness plan issued by President Bush in November 2005, the United States would need as many as 742,500 ventilators in a worst-case pandemic. When compared to the 100,000 presently in use, it is clear that the system is lacking⁴. One example of this shortage occurred during Hurricane Katrina, when there were insufficient numbers of ventilators⁵, and personnel were forced to resort to manual BVM ventilation⁶. Measures to improve preparedness have since been enacted; most notably the Center for Disease Control and Prevention (CDC) recently purchased 4,500 portable emergency ventilators for the strategic national stockpile⁷. However, considering the low number of stocked ventilators and their currently high cost, there is a need for an inexpensive portable ventilator for which production can be scaled up on demand.

2. PRIOR ART

While many emergency and portable ventilators are on the market, an adequate low-cost ventilator is lacking. A cost-performance distribution is depicted in Figure 1 with manually operated BVMS on the low end of cost and performance, and full-featured hospital ventilators on the other extreme. The middle section of the chart includes the existing portable ventilators which can be broadly categorized as pneumatic and electric. Pneumatic ventilators are actuated using the energy of compressed gas, often a standard 50 psi (345 kPa) pressure source normally available in hospitals. These ventilators have prices ranging from 50.5k -1 lack. This category includes products such as the *VORTRAN Automatic Resuscitator (VAR™)*, a single patient, disposable resuscitator, and the reusable *Lifesaving Systems Inc.'s Oxylator, O- Two Handheld Resuscitators* and *Ambu bag*. However, these systems cost an order of magnitude more than our target price and depend on external pressurized air, a resource to which our target market may not have access.

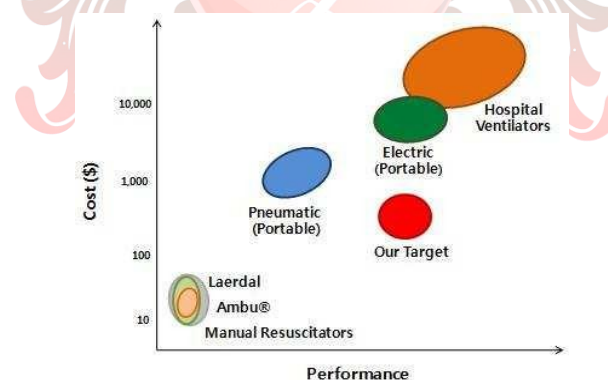


Figure 1: Cost-performance distribution of ventilators

Medical	- User-specified breath/min insp./exp ratio, tidal volume - Assist control - Positive end-expiratory pressure (PEEP) - Maximum pressure limiting - Humidity exchange - Infection control - Limited dead-space
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Mechanical	- Portable - Standalone operation - Robust mechanical, electrical and software systems - Readily sourced and repairable parts - Minimal power requirement - Battery-powered
Economic	- Low-cost (<6 K)
User- interface	- Alarms for loss of power, loss of breathing circuit integrity, high airway pressure and low battery life - Display of settings and status - Standard connection ports
Repeatability	- Indicators within 10% of correct reading - Breath frequency accurate to one breath per minute

Medical Device Requirements

In light of the aforementioned constraints, a set of mechanical, medical, economic, user- interface and repeatability functional requirements were developed. These include the ASTM F920-93 standard requirements⁹, and are summarized in Table 1.

3. DEVICE DESIGN

1) Air Delivery Technique

Two main strategies were identified for the Ventilator's air delivery system. One strategy uses a constant pressure source to intermittently deliver air while the other delivers breaths by Compressing an air reservoir. The latter approach was adopted as it eliminates the need for the continuous operation of a positive pressure source. This reduces power requirements and the need for expensive and difficult to repair pneumatic components.

Where most emergency and portable ventilators are designed with all custom mechanical components, we chose to take an orthogonal approach by building on the inexpensive BVM, an existing technology which is the simplest embodiment of a volume-displacement ventilator. Due to the simplicity of their design and their production in large volumes, BVMs are very inexpensive (approximately 1k) 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, they inherently provide the basic needs required for a ventilator.

The main drawback with BVMs is their manual operation requiring continuous operator engagement to hold the mask on the patient and squeeze the bag. This operating procedure induces fatigue during long operations, and effectively limits the usefulness of these bags to temporary relief. Moreover, an untrained operator can easily damage a patient's lungs by over compression of the bag. Our methodology, therefore, was to design a mechanical device to actuate the BVM. This approach results in an inexpensive machine providing the basic functionality required by mechanical ventilator standards.



2) Compression Mechanism

The most obvious means to actuate a BVM is to mimic the hand motion for which the bag was designed. This requires the use of linear actuation mechanisms (e.g. lead screw or rack and pinion) which despite being simple to implement, require linear bearings and extra space. Other compression techniques were sought to take advantage of the cylindrical BVM shape. However, since BVMs were designed for manual operation, their compressible outer surface is made from high-friction material to maintain hand-contact with minimal slippage. This eliminates the option of tightening a strap wrapped around the bag as a means of actuation. To avoid the problems associated with high surface friction, the two main candidates for actuation were a roller chain and cam compression. These options employ rolling contact with the bag rather than sliding contact, eliminating losses due to kinetic friction between the actuator and the bag.

4. PROTOTYPE DESIGN

Human lungs use the reverse pressure generated by contraction motion of the diaphragm to suck in air for breathing. A contradictory motion is used by a ventilator to inflate the lungs by pumping type motion. A ventilator mechanism must be able to deliver in the range of 10 – 30 breaths per minute, with the ability to adjust rising increments in sets of 2. Along with this the ventilator must have the ability to adjust the air volume pushed into lungs in each breath. The last but not the least is the setting to adjust the time duration for inhalation to exhalation ratio.

Apart from this the ventilator must be able to monitor the patients' blood oxygen level and exhaled lung pressure to avoid over/under air pressure simultaneously. The ventilator we here design and develop using arduino encompasses all these requirements to develop a reliable yet affordable DIY ventilator to help in times of pandemic.

We here use a silicon ventilator bag coupled driven by DC motors with 2 side push mechanism to push the ventilator bag. We use toggle switch for switching and a variable pot to adjust the breath length and the BPM value for the patient. Our system makes use of blood oxygen sensor along with sensitive pressure sensor to monitor the necessary vitals of the patient and display on a mini screen. Also an emergency buzzer alert is fitted in the system to sound an alert as soon as any anomaly is detected.

The entire system is driven by arduino controller to achieve desired results and to assist patients in COVID pandemic and other emergency situations

Sketch of experiment setup:

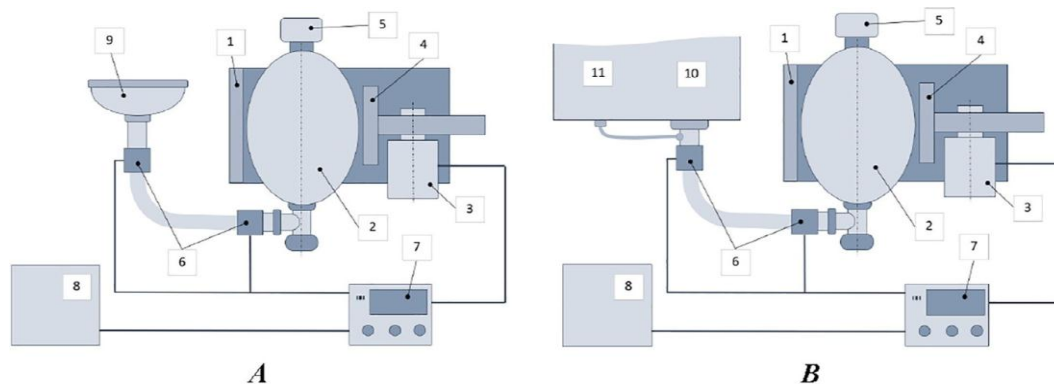


Fig. Portable Ventilator System: A) standalone automated BVM-based resuscitation system, B) testing procedure,

- 1) bag mounting system, 2) self- inflating bag, 3) motor setup, 4) compression mechanism (pusher), 5) Positive End Expiratory Pressure (PEEP) valve, 6) feedback pressure sensors, 7) control system, 8) power supply with backup battery, 9) air mask, 10) mechanical lung, 11) airway pressure sensor.

5. CONTROL IMPLEMENTATION:

CONTROL DESIGN:

This ventilator provides assured tidal volumes using an assist-control (AC) mode. The operator selects the tidal volume appropriate to the patient, usually 6-8 mL/kg of ideal body weight and a minimum respiratory rate. This provides minimum assured minute ventilation (V_e). If the patient is breathing above the set rate, negative inspiratory pressure that exceeds 2 cmH₂O vacuum triggers the ventilator to deliver the set tidal volume.

The advantage of AC mode is that the patient has an assured minute ventilation meet physiologic needs for 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 lung disease, air trapping may occur, raising intra- thoracic pressure with adverse hemodynamic and gas exchange consequences. However, these issues are commonly handled with reductions in respiratory rate and sedation as needed. AC mode, one of the most widely utilized mechanical ventilator modes, is adequate for the management of the majority of most clinical respiratory failure scenarios. This ventilator can be used for patients who are intubated with an endotracheal tube or who would receive non- invasive mechanical ventilation through a mask that is commonly used for provision of continuous positive airway pressure (CPAP).

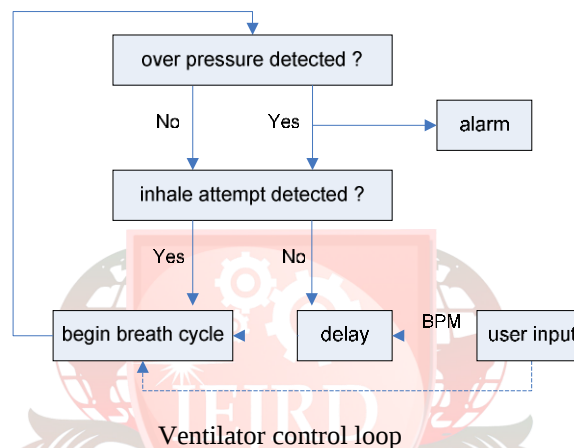
PARAMETERS:

The operator adjusts tidal volume, breath rate, and inspiratory to expiratory time ratio using three continuous analog knobs mounted to the outside of the ventilator. The prototype has a range of 200-750 mL tidal volume and 5-30 breaths per minute (bpm). This yields maximum minute ventilation (V_e) of 21L and a minimum V_e of 1.5L. However, these values do not reflect the limits of the final design only the settings of the prototype. Theoretically, the ventilator is able to deliver anywhere from 0L minute volume to 60L minute volume. However,

this has not been fully tested. I:E ratio was not implemented on the prototype but theoretically could have any desired range within the limits determined by the other parameters. The ranges on the final design will be determined in consultation with respiration specialists to allow for the broadest range of safe settings

CONTROLLER:

An off-the-shelf Arduino Duemilanove microcontroller board was selected to control our device. The microcontroller runs a simple control loop to achieve user-prescribed performance. The control loop is triggered by the internal timer set by user inputs, with the inspiratory stroke initiated at the beginning of the loop. Once the prescribed tidal volume is reached, the actuator returns the cam back to its initial position and holds until the next breath. The loop then repeats to deliver intermittent breaths. If the loop is interrupted by a breath attempt by the patient (sensed through the pressure sensor), the ventilator immediately delivers a breath, interrupting the loop and resetting the timer. A diagram showing this loop is found in Figure



MOTOR:

According to initial experiments, a maximum torque of 1.5 Nm was required for maximum volume delivery. A PK51 DC gear motor with a stall 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 quite enough torque to effectively drive the cam at the slower inhalation cycle rates prescribed to some patients. While a larger motor will be necessary to achieve better speed control, this motor functioned acceptably at 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.

1) Motor Driver:

The motor driver comprises of two H-Bridge circuits. These circuits direct current through the motor in opposite directions, depending on which set of switches on the circuits are energized. Speed of the motor is signaled with a pwm pin. The power is supplied directly from the battery, so the only limit is the current capability of the chip and battery. We opted to use the *motor* driver, which is capable of supplying 5 amps of current to the two circuits. The PK51 motor's stall current is rated at 5.2 amps which means the motor driver will be able to handle the requirements for the system

2) User Interface

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

3) Safety Features:

To ensure that the patient is not injured, the airway pressure is monitored with a pressure sensor connected to a sensor output on the BVM. The same pressure sensor used for initiation of assist control also triggers an alarm if the pressure rises too high, alerting the physician to attend to the patient. As a further safety measure to prevent over-inflation, future iterations of the device will include a mechanical pressure relief valve.

4) Power Delivery:

An AC/DC converter can be used to power the ventilator directly from a wall outlet or a vehicle inverter. When external power is unavailable, the ventilator can run off of any battery capable of delivering 12-15 volt at least 3.5 Amps. For the prototype, we used a 14.8 volt, four-cell Li- Ion battery pack capable of 4.2 Amps (limited by protective circuitry), with a capacity of 2200 mA-hr.

6. CONCLUSIONS:

A working prototype that can be operated on a test lung has been developed. The prototype has user-controlled breath rate and tidal volume. It features assist control and an over-pressure alarm. It has low power requirements, running for 3.5 hours on one battery charge at its most demanding setting. It is portable, weighing 9 lbs (4.1 kg) and measuring 11.25 x 6.7 x 8 inches (285 x 170 x 200 mm), and has a handle and easy to use latches. The prototype can display settings and status on a computer screen. Further development of this proof-of-concept is planned. Future iterations will incorporate changes prompted by the results of our prototype testing. It will incorporate an adjustable inspiratory to expiratory ratio, an option missing in this prototype due to its underpowered motor. We will investigate the effects that changing the motor will cause to cost, weight and battery life. We will also incorporate add-on features including a PEEP valve, a humidity exchanger and a blow-off valve. Since BVM infrastructure already supports commercial add-on, these components can be easily purchased and incorporated. Ways to minimize dead space will be explored; including the option of using a *brand* BVM whose valves can be placed at the patient end of the tubing. In later iterations we hope to be independent from *by* manufacturing our own bags or contracting their production. The design will be changed to be injection molded such that the mass-produced a version would cost less than 1.4 lc to produce. Weight will be minimized and battery-life extended. Consideration to a pediatric version will also be given. Cam arm shape will be optimized to ensure the use of the most efficient rolling contact embodiment. An LCD screen will be included, and alarms programmed for loss of power, loss of breathing circuit integrity and low battery life. Extensive testing of the ventilator's repeatability will be conducted. Finally, we will test the ventilator on a lung model to meet ventilator standards and market the produce.

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