DMD2010-3845

Design and Prototyping of a Low-cost Portable Mechanical Ventilator

Abdul Mohsen Al Husseini[1], Heon Ju Lee[1], Justin Negrete[1], Stephen Powelson[1], Amelia Servi[1],

Alexander Slocum[1], Jussi Saukkonen[2]

[1]Massachusetts Institute of Technology, Department of Mechanical Engineering
[2]Boston University, School of Medicine

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 acrylic, 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 $420, the bulk-manufacturing price for the ventilator is estimated to be less than $200. 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 respiration[3]. 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 $30,000). 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 lacking[4]. One example of this shortage occurred during Hurricane Katrina, when there were insufficient numbers of ventilators[5], and personnel were forced to resort to manual BVM ventilation[6]. 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 stockpile[7]. 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.

1.1. 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 $700-1000. 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 CAREvent® Handheld Resuscitators* and *Ambu® Matic.* 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.
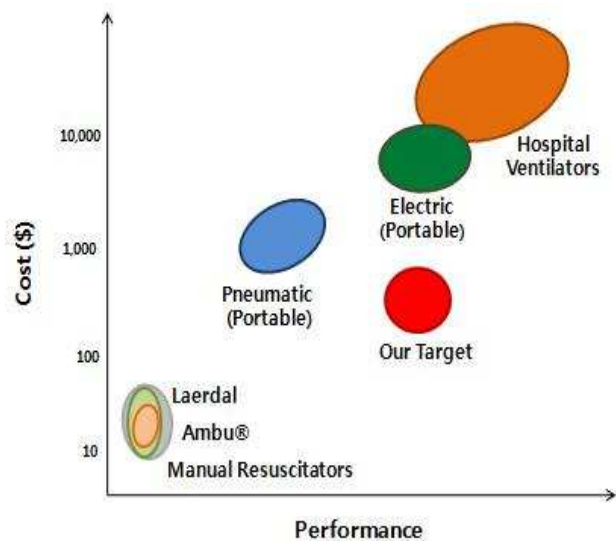

Figure 1: Cost-performance distribution of ventilators

Electric ventilators are capable of operating anywhere, and thus are not bound by this constraint. Ventilators of this type such as *CareFusion LTV® 1200* were the choice of the CDC for the Strategic National Stockpile. The LTV® 1200 weighs 13.9 lbs (6.3 kg) and includes standard features as well as the capability to slowly discontinue or wean off mechanical ventilator support. Its complexity elevates its cost to several thousands of dollars, an order of magnitude above our target retail price.

The United States Department of Defense has also developed several rugged, portable electric ventilators. One such ventilator is the Johns Hopkins University (JHU) Applied Physics Laboratory (APL) Mini Ventilation Unit (JAMU), which weighs 6.6 lbs (3.0 kg), measures 220 cubic inches (3,600 cubic cm) and can operate up to 30 minutes on a battery. This device was patented by JHU/APL, and licensed to AutoMedx. The commercial device features single-knob operation. Its simplicity comes with a compromise, as the tidal volume, breath rate and other parameters cannot be adjusted by the user, making it not suitable for many patients who cannot tolerate the fixed tidal volume, rate or minute ventilation. It also cannot be operated for long periods in a resource-poor environment. Additionally, with a price tag over $2000, it costs several times more than our target price. Another device, the FFLSS, weighs 26.5 lbs (12 kg) and is capable of one hour of operation powered by a battery. It also includes additional physiologic sensors, and fits in a standard U.S. Army backpack [8]. While these devices are functionally adequate, their compressors require high power which limits battery life. In addition, their many pneumatic components are costly and are not easily repairable in a resource-poor environment.

1.2. 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 requirements[9], and are summarized in Table 1.

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
Mechanical	- Portable - Standalone operation - Robust mechanical, electrical and software systems - Readily sourced and repairable parts - Minimal power requirement - Battery-powered
Economic	- Low-cost (<$500)
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

Table 1: Device functional requirements

2. Device Design

2.1. 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 $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, 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.

2.2. 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.

2.2.1. Roller-chain Concept

The roller-chain concept utilizes roller-chains with roller diameters larger than link width. (Figure 2) The chain wraps around the circumference of the bag, and as a result is very space efficient. A sprocket connects to the motor shaft; its clockwise/anticlockwise rotation compressing and expanding the bag for breath delivery.
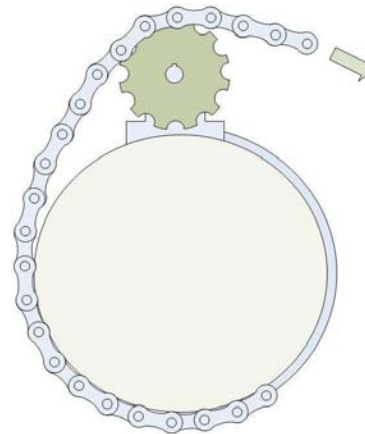


Figure 2: Sketch of roller-chain device

While this idea seemed initially feasible, preliminary experiments revealed that radial compression of a BVM requires significantly higher 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 rolling motion, and preventing an accurate and repeatable tidal volume from being delivered.

A trade-off was encountered; while small pitch/roller-diameter chains are more space efficient and yield higher angular resolution for compression, bag crumpling becomes an issue. On the other hand, a higher pitch/roller-diameter chain overcomes crumpling but takes up more space and decreases angular resolution. In either case, the use of roller chains added a significant amount of weight to the system suggesting the need for a more effective mechanism needing a smaller contact area.

2.2.2. CAM Concept
The cam concept utilizes a crescent-shaped cam to compress the BVM, which allows smooth, repeatable deformation to ensure constant air delivery (Figure 3). As it rotates, the cam makes a rolling contact along the surface of the bag and unlike the roller-chain, achieving low-noise of
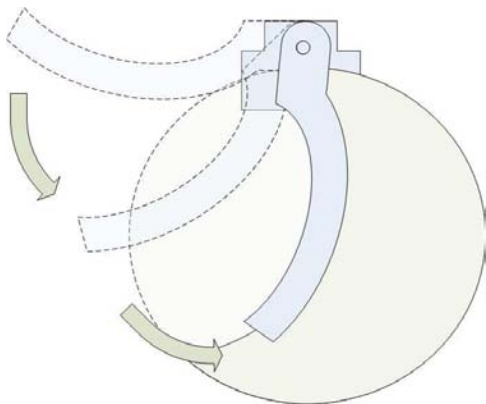
Figure 3: Sketch of cam based device

operation. By controlling the angle of the cam's shaft, the amount of air volume delivered can be accurately controlled. The cam mechanism was found to be more space efficient and have a lower power requirement than the roller chain concept, and was therefore the method of choice.

3. Prototype Design

### 3.1. First Prototype Design
With the cam concept selected as the best method for BVM compression, an initial prototype was built to measure force and power requirements. The enclosure's frame consists of four vertically mounted sections of ½" (12.5 mm) clear acrylic, each mounted on the bottom section of the frame with interlocking mates. The material is easily laser cut and allows for visibility of the internal components. The two inner sections (ribs) have U-shaped slots made to conform to BVM's surface contour, while the end sections feature openings to accommodate the BVM's valve neck and oxygen reservoir. The pivoting cam assembly was mounted on top of the hinged aluminum lid, and consisted of two 2.5" (63.5 mm) radius crescent-shaped pieces attached to a 5/16" (8 mm) aluminum shaft mounted with nylon bushings.

3.2. First Prototype Experiment
A bench 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. The test apparatus included a spirometer to measure flow-rate (and volume, by integrating over time), a hand dynamometer to measure force exerted on the cam, a rotary motion sensor to measure cam angular displacement, and a pressure sensor to measure internal air pressure. The experimental setup is depicted in Figure 4 and 5.
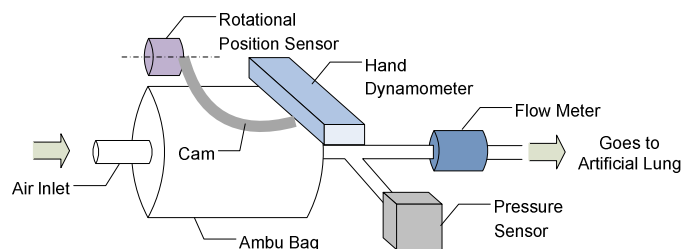

Figure 4: Sketch of experiment setup
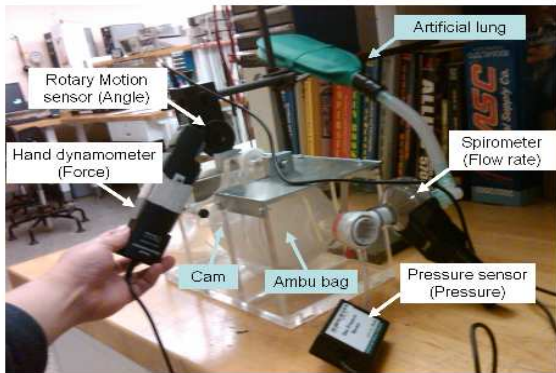
Figure 5: Actual experiment setup

The air volume delivered was measured as a function of cam angle by integrating the flow rate over time. Results indicated that the volume delivered versus cam angle relation is approximately linear (Figure 6). Data analysis showed that the peak power required was 30 W, and maximum torque was 1.5 Nm. The maximum volume delivered per stroke was approximately 750 mL. The target tidal volume is 6-8 ml/kg for adult human use, so this is adequate for most clinical situations.
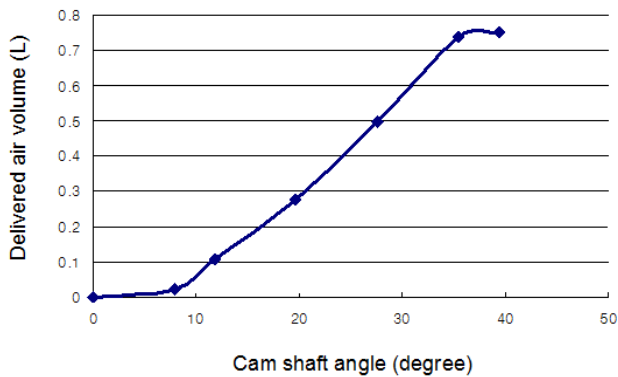

Figure 6: Volume vs. Cam angle

3.3.   Second Prototype Design

A second prototype was built in which all the moving components were moved inside the enclosure. Enclosure dimensions were increased to accommodate the cam arm's range of motion, and to make space for the motor, microcontroller and battery pack. The enclosure's lid was made

of acrylic, and hinges from the side of the unit to better constrain the top of the bag. The support ribs inside the enclosure also serve as mounting blocks for camshaft bushings. A potentiometer was coupled to the end of the shaft for use as a position feedback sensor. An isometric view of the second prototype's CAD model is shown in Figure 7, and the built device in Figure 8.
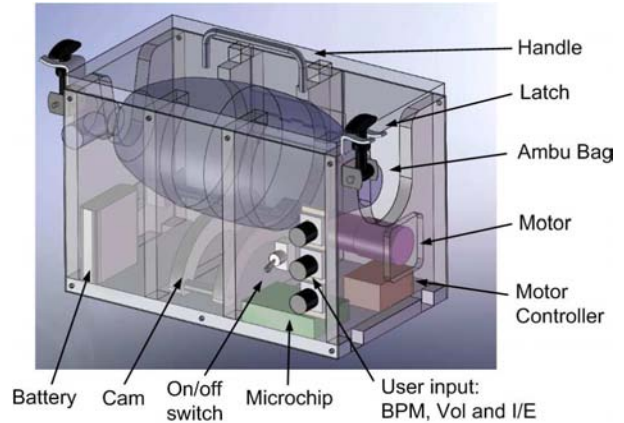
Figure 7: Second prototype CAD model
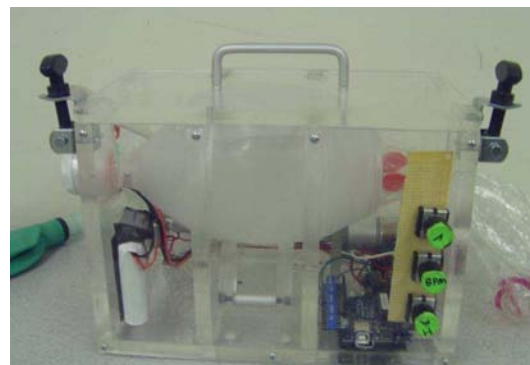
Figure 8: Second prototype

4.   Control Implementation

4.1.   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 a minimum assured minute ventilation (V_e). If the patient is breathing above the set

rate, negative inspiratory pressure that exceeds 2 cmH20 vacuum triggers the ventilator to deliver the set tidal volume.

The advantage of AC mode is that the patient has an assured minute ventilation to 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 continous positive airway pressure (CPAP).

4.2. 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 a 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.

4.3. 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 9.
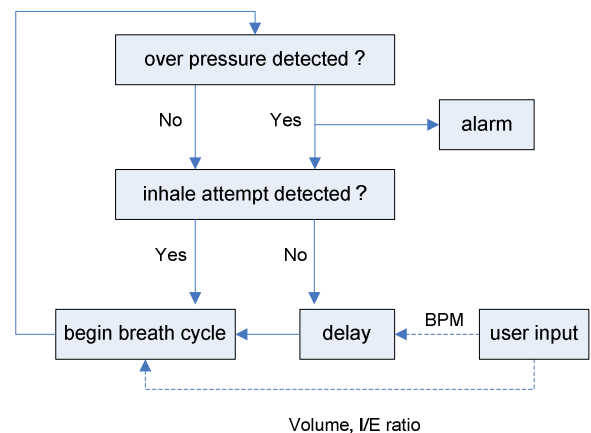

Figure 9: Ventilator control loop

4.4. Motor

According to initial experiments, a maximum torque of 1.5 Nm was required for maximum volume delivery. A PK51 DC gearmotor 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.

4.5. 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 Solarbotics® 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.

4.6. 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.

4.7. 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.

4.8. 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.

5. Analysis and Testing

5.1. Battery-life Test

The battery life for the second prototype was tested by running the ventilator on the test lung until the battery voltage dropped to a level insufficient for operation. The device was set at maximum volume and BPM rate (30 breaths/minute). The overall duration of the test was three hours and thirty-five minutes at which point the battery was depleted. Based on the battery capacity and voltage, the electrical power consumption during this test averages to only 9 Watts (this includes the inactive time between breaths).

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-ons, these components can be easily purchased and incorporated. Ways to minimize deadspace will be explored, including the option of using a *Laerdal®* brand BVM whose valves can be placed at the patient end of the tubing. In later iterations we hope to be independent from *Laerdal®* 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 $200 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 product.

7. Acknowledgements

8. References

[1]   Aït-Khaled N, Enarson D, Bousquet J (2001) Chronic respiratory diseases in developing countries: the burden and strategies for prevention and management, Bulletin of the World Health Organization, 79 (10)

[2]   Chan-Yeung M, Aït-Khaled N, White N, Ip MS, Tan WC (2004) The burden and impact of COPD in Asia & Africa. Int J Tuberc Lung Dis.

[3]   *Webster's New World™ Medical Dictionary* First, Second and Third Editions (May, 2008) John Wiley & Sons, Inc.

[4]   McNeil, DG (2006) Hospitals short of ventilators if bird flu hits, NYT, May 12

[5]   Klein KR, Nagel NE (2007) Mass medical evacuation: Hurricane Katrina and nursing experiences at the New Orleans airport. Disaster Manag Response. 2007 Apr-Jun;5(2):56-61

[6]   deBoisblanc, B.P. (2005) Black Hawk, please come down: reflections on a hospital's struggle to survive in the wake of Hurricane Katrina. Am J Respir Crit Care Med. Nov 15;172(10):1239-40

[7]   http://www.news-medical.net/news/2009 1020/CDC-stockpiles-ventilators-for-use-during-public-health-emergency.aspx

[8]   Kerechanin CW, Cytcgusm PN, Vincent JA, Smith DG, Wenstrand DS (2004) Development of Field Portable Ventilator Systems for Domestic and Military Emergency Medical Response, John Hopkins Apl. Tech. Digest Vol 25, Number 3

[9]   ASTM F920-93(1999)