Electric Blower Based Portable Ventilator

Mike Fogarty, Joseph Orr, Dwayne Westenskow, Lara Brewer, Derek Sakata

Abstract: When a patient is unable to breathe or maintain their airway they will most likely be ventilated by a bag-valve-mask. We propose to replace the traditional bag-valve-mask with an electric blower ventilator. This handheld feedback controlled device will automatically compensate for mask leak and enable the clinician to deliver computer controlled respiratory rates and tidal volumes. We have built a working prototype and conducted bench testing verifying that the blower delivers the desired tidal volumes, adapting to changing leak conditions that exist when a mask that is poorly fit to a victim's face. In a volunteer study we will observe how typical clinicians use the blower ventilator so we can develop a product that can be easily and correctly used. We will conduct human trials in the operating room to demonstrate the safety and efficacy of the blower ventilator.

Introduction

The purpose of this research is to develop a replacement device for the bag valve masks by using an electric blower based portable ventilator. The bag valve mask is the most common form of life support

Figure 1: Traditional bag valve mask used to deliver rescue breaths during CPR.

for an unconscious patient before they are intubated and mechanically ventilated. The bag valve mask consists of a flexible air chamber attached to a

facemask via a shutter valve. This manual form of ventilation is a difficult technique to master and requires the full attention of the person performing the ventilation. There is no indicator for the clinician signaling adequate respiratory rate or tidal volume. Clinical studies reveal that trained clinicians give on average 25-35 breaths per minute, not the 10-12 prescribed by guidelines. Hyperventilation results in decreased cardiopulmonary function, which results in decreased absolute survival. Excessive pressures during ventilation have also been shown to cause traumatic brain injury, hemorrhagic shock, gastric insufflation, and lung injury.

Noninvasive ventilation (NIV) refers to the administration of ventilation without the use of an invasive artificial airway tool such as an endotracheal tube. Current methods of NIV require strict conditions that make operating room or emergency ventilation impossible. Current NIV machines require precise and constant leak conditions in the ventilation circuit. To ensure those leak conditions the clinician must perform a time consuming fitting process of the mask to each patient. This process is not possible in an emergency situation. NIV machines also cost upwards of $20,000, which makes their large-scale implementation costly.

This research aims to overcome the limitations of current NIV machines in order to develop a replacement to the bag valve mask. This device will provide constant positive airway pressure (CPAP) to the patient while also delivering increased pressures at intervals to ventilate the patient. This is also known as bi-level positive airway pressure (BPAP). Most importantly, it will eliminate the need for precise mask fitting by constantly adapting to changing leak conditions. It will give the clinician the ability to deliver specific pressures and tidal volumes to their patient at regular intervals. It will provide visual feedback to the clinician assuring proper ventilation. Unlike the expensive current NIV machines, this device will be portable and powered by a rechargeable battery pack.

Significance

The self-inflating manual ventilator or Bag-valve-mask (BVM) is used to ventilate patients during transport, between intubation attempts and at other critical times when the patient is incapable of adequate spontaneous ventilation.

During manual emergency patient ventilation, the victim will most likely be ventilated by a bag-valve-mask like the one shown in figure 1. The bag valve mask consists of a flexible air chamber attached to a facemask via a shutter valve. When the bag is compressed it forces air through the valve and into the patient's airway. When it is released the bag refills with air and the shutter valve closes until the next compression. The bag valve method is a difficult technique to master and requires the full attention and both hands of the person performing the ventilation. [13-17] During manual patient ventilation using a bag valve mask (BVM), the clinician's full attention is needed to hold the mask in place and to give breaths. One hand is needed to hold the mask tightly to the patients face to prevent leak while also holding the airway open to allow breathing during airway collapse. The other hand is used to carefully squeeze the bag to ensure adequate tidal volume while being careful not to over-pressure the lungs and cause harm. Because this task requires the full attention of the person giving ventilation, a second clinician is needed to perform additional patient care tasks such as administer medications and provide other care.

Many novice clinicians have difficulty maintaining an open airway while giving breaths. It is difficult to grasp the mask in a way that frees two fingers to provide the required chin-lift and the proper head-tilt to keep the airway open with one hand while squeezing the bag with the other hand. If the airway is obstructed, the clinician, who is squeezing the bag, may mistakenly think he is delivering an adequate tidal volume when in fact, the entire tidal volume may be lost through a leak between the mask and the victim's face.

It is difficult for the person operating the bag-valve-mask to adequately ensure that the person they are ventilating is receiving the correct respiratory rate. [13-17] Clinical studies reveal that trained clinicians give on average 25-35 breaths per minute, not the 10-12 prescribed by guidelines.[18] Keeping artificial breath rates low is difficult because the high adrenaline state of the rescuer alters time perception, and the rapidly refilling bag sets up a reflex in which the rescuer is inclined to deliver breaths as soon as the bag inflates.

It is difficult for the person operating the bag-valve-mask to adequately ensure that the person they are ventilating is receiving the correct tidal volume. Excessive pressures can cause a decrease in cardiac preload, traumatic brain injury, hemorrhagic shock, gastric insufflation, and lung injury. Inadequate pressure can lead to the patient not receiving adequate oxygen delivery and carbon dioxide removal.

Methods

The electric blower shown in figure 2 has just recently become available commercially. We are the first research group to use this new technology to enable portable ventilation.

Figure 2: Miniature radial blower, model U51DL-4 Micronel US, LLC.

The Li-ion battery pack (Figure 3) is also a new enabling technology; it delivers sufficient power to turn the blower on and off at the rate required for patient ventilation for 90 minutes. Our group developed the airway flow meter that is shown connected to


Figure 4: Li-ion battery pack.

the blower in figure 2 and will be the first to use it to measure and feedback control the airway pressure and tidal volume delivered by the rapidly responding blower. The software algorithm developed will be unique in the way it uses the measurements of airway pressure and flow to deliver the desired tidal volumes and respiratory rates. The software algorithm will use the airway flow signal to calculate the portion of the inspired tidal volume that is lost through a mask leak and the portion that is delivered to the victim's lungs.

Aim 1: Build a working prototype. An Arduino mega 256 computer controller (Hagerstown, MD) will control the speed of a miniature radial blower

Figure 3: Prototype blower and face mask to deliver rescue breathing during CPR.

(U51DL-4, Micronel US, Carlsbad, CA) to generate the desired pressures using the circuits in figure 5. The circuit takes the pulse-width modulated output of the Arduino board and modifies the signal to a value between 0.5-4.5V, which controls the speed of the
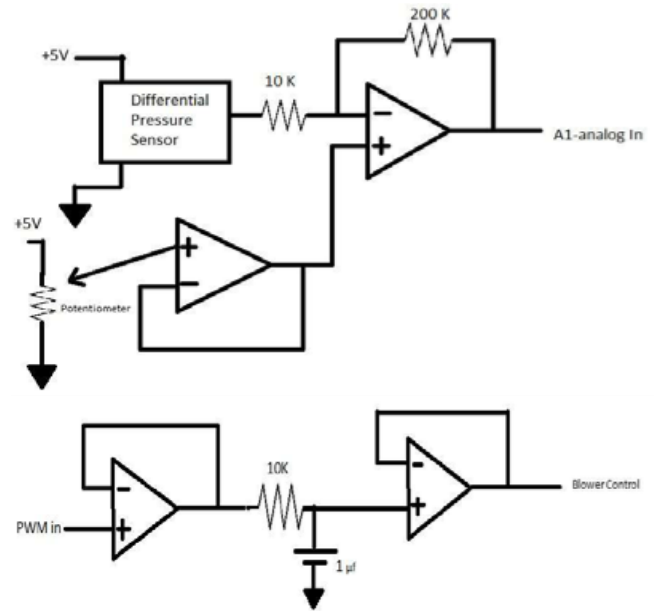

Figure 5: Circuits for feedback control of the electric blower.

blower.

Software algorithms are written for the Arduino environment to compare the desired pressure with the actual pressure in the facemask, as measured by a pressure transducer mounted in the mask (BLVR-L01D, AllSensors, Morgan Hill, CA). Figure 5 shows the circuit diagram for the differential pressure sensor amplifier that measures the airflow delivered by the blower. The signal of the differential pressure sensor (MPXV5004DP, FreeScale Semiconductor, Austin TX) will be amplified to provide much higher resolution for the pressure drop over the fixed orifice flow meter. The signals from the pressure transducer and the flow meter are displayed to the user via two histogram bars (column of LEDs), which rise and fall with each breath. The user will set the respiratory rate (based on age), the controller will deliver elevated pressure during inspiration and the display will show the delivered tidal volume and airway pressure, alongside target values for each.

The flow and pressure sensors are calibrated using a gas flow analyzer (Bio-Tek VT Plus, Winooski, VT). Figure 6 shows typical data plots of the flow and pressure calibrations. The coefficients of the best-fit linear equations will then be inserted into the Arduino code to provide accurate pressure and flow measurements.
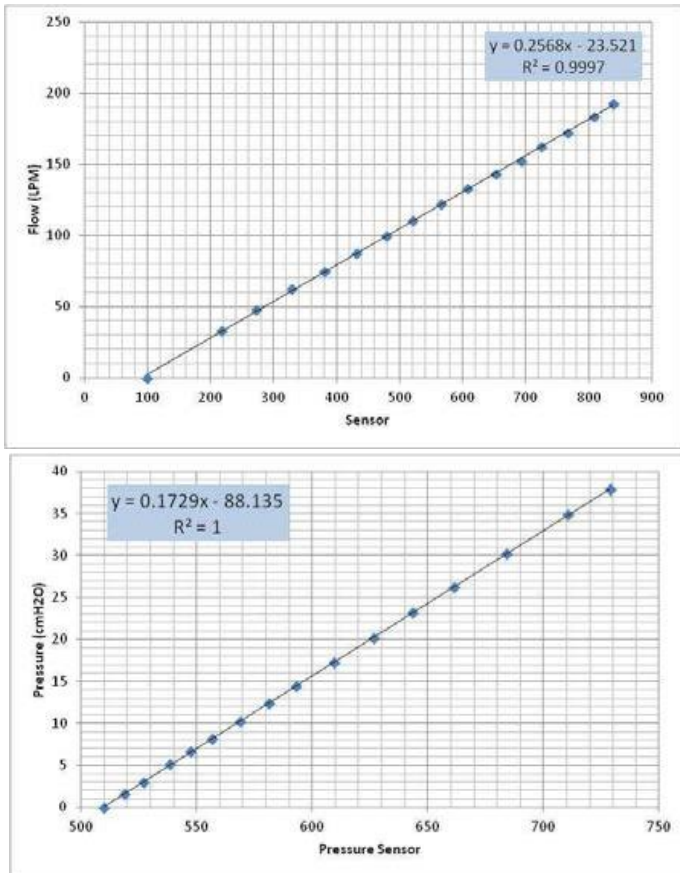

Figure 6: Calibration curves for the pressure transducer and the flow meter.

The coefficients of a proportional, integral, derivative PID controller will be tuned to optimize the blower's response time to reach the desired airway pressure in the mask. We have tuned the PID controller to optimize its response to changing mask leak conditions so that it maintains the desired pressure within the mask independent of the size of the mask leak.

Figure 4 shows the working prototype of the electric blower based portable emergency ventilator. It uses a miniature radial blower (model U51DL-4 from Micronel US, LLC). Figure 7 is a block diagram of the components we assembled to control the blower speed. This feedback control circuit uses the signal from a pressure sensor mounted in the mask to control the blower speed and to generate the desired pressures within the mask. The red line in figure 8 shows the desired airway pressure. The blue line shows the pressure generated by the blower and delivered to the victim, for three breaths. The feedback controller uses the signal from the flow sensor to control the blower speed to deliver the desired tidal volume.

Several bench studies have been performed for this stage of development. The prototype mask ventilator system was connected to a manikin head via an air cushion mask that was modified to include intentional mask leak. The trachea of the manikin head was connected to a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA). The gas flow analyzer directly measured the volumes entering and leaving the test lung. The results show that the blower continues to deliver the desired ventilation, even with the changing leak conditions that exist when a mask is poorly fitted to a manikin's face.
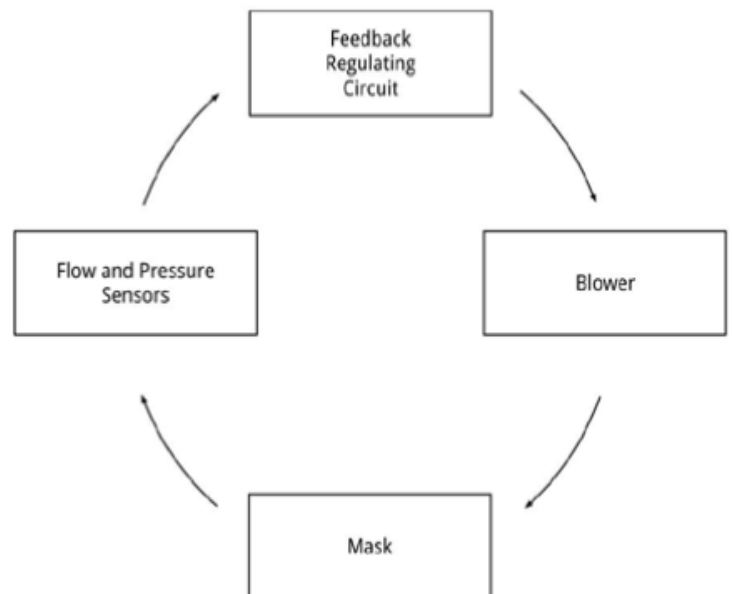
Figure 7: Block diagram of the components that make up the electric blower based portable emergency ventilator.
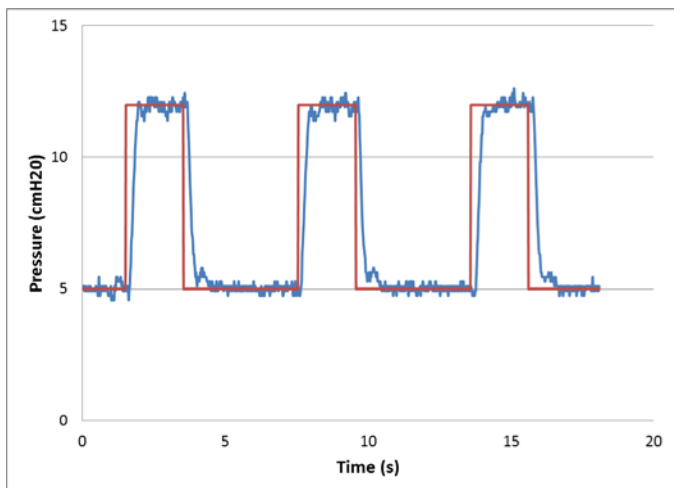
Figure 8: Demonstration of pressure control. Red line shows the desired pressure from the algorithm and the blue line shows the actual pressure within the airway.
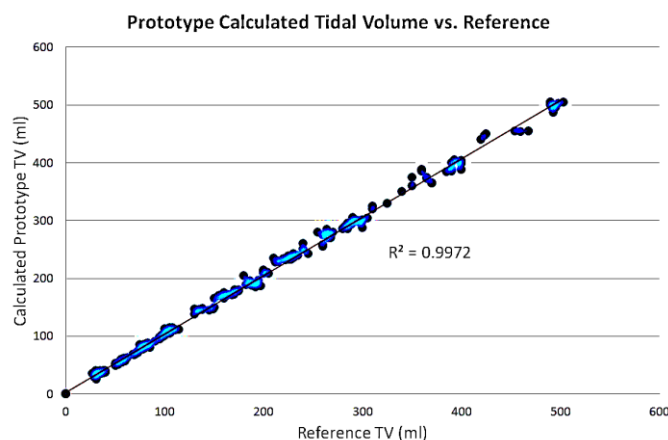
Test #1: The prototype mask ventilator system was connected paced on a manikin head via a modified air cushion mask that was held in place using a common elastomeric strap (H-strap). The trachea of the manikin head was connected to one side of a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA) and the other side of the test lung was mechanically ventilated. The two sides of the test lung were mechanically coupled so that spontaneous breathing was simulated in the side connected to the manikin. CPAP was delivered by the test system and respiratory rates and tidal volumes as measured by the CPAP system and the gas flow analyzer were compared. Data was collected over a range of CPAP settings (4, 6, 8 cm H_2O), respiratory rates (6, 8, 10, 15, 20 breaths/min), supplemental oxygen flows (1, 2, 3, 4, 5 L/min), and tidal volumes (200 and 500 ml).

Results: The average difference between measured and actual respiration rate was 0.093 ± 0.024 (mean $\pm$ one standard deviation) breaths per minute. The prototype system measures supplemental oxygen flow and calculates FiO_2 from the ratio of flow from its compressor to supplemental oxygen flow. The average difference between FiO_2 measured in the test lung and FiO_2 calculated by the system was near zero and was too small evaluate using a clinical monitor (CapnoMAC Ultima, Datex, Helsinki Finland). The plot shows average error in tidal volume measurement when 200 ml breaths were simulated was 2.93 ± 6.83 ml and was -7.4 ± 7.55 ml when 500 ml breaths were simulated.

Test #2: The prototype system was connected to a manikin head via an air cushion mask that was modified to include an intentional leak. The mask was held in place using a head strap. The trachea of the manikin head was connected to a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA) that directly measured tidal volume, respiratory rate and airway pressure. These direct measurements were compared against measurements made by the portable ventilator that was connected distal to the patient through the modified mask. Various levels of simulated lung compliance and pressure support were tested. The system was tested over a range of simulated lung compliance (0.10, .030, 0.50 L/cm H_2O), CPAP (2, 4, 6, 8 cm H_2O) and respiratory rate settings (6, 8, 10, 15, 20 breaths/min).

Results: The plot below shows the tidal volume calculated by the prototype system versus the reference tidal volume as measured by the gas flow analyzer. The average difference in the tidal volume measurement was -4.77 ± 7.02 (mean $\pm$ one standard deviation) ml. The average difference and standard deviation was consistent over all levels of CPAP that were tested.

Figure 9: Tidal volume comparison between the reported values of the prototype system and the values recorded by the gas flow analyzer.

Test #3: The prototype mask ventilator system was connected to a manikin head via an air cushion mask that was modified to include intentional mask leak. The trachea of the manikin head was connected to a test lung through a gas flow analyzer (VT-Plus, Fluke Biomedical, Everett WA). The gas flow analyzer directly measured the volumes entering and leaving the test lung. Eight volunteers were asked to deliver 500 ml tidal volumes at six breaths per minute. The same volunteers were then asked to use the prototype system by holding the modified mask on the manikin face using their non-dominant hand while performing a distracting task on their smart-phones with the other had. The resulting delivered tidal volumes, breath rates and airway pressures were recorded using the gas flow analyzer. If the mask leak was too high to deliver the full volume, the system alerted the user to apply more pressure to the mask and reduce the leak. The accuracy of the delivered ventilation was measured by the gas flow.

Results: Table #1 shows the results for each of the volunteers and the average across all tests. The average delivered tidal volumes ranged from 207 to 723 ml using manual ventilation and from 420 to 524 ml using the prototype ventilator. The average peak inspiratory pressure ranged from 6 to 16.93 cm H_2O with a single breath maximum of 19.3 cm H_2O using manual mask ventilation and from 13.95 to 14.13 with a single breath max of 14.3 cm H_2O using the prototype system. The prototype system maintained CPAP at 4 cm H_2O throughout the test.

| Subject number	Manual Tidal volume avg ± 1 SD	Prototype system TV avg ± 1 SD	Manual rate avg ± 1 SD (breaths/min)	Prototype system rate avg ± 1 SD (breaths/min)	Manual peak insp. pressure (cm H_2O)	Prototype system peak insp. pressure (cm H_2O)
1	207 ± 63.75	513 ± 4.18	4.37 ± 0.21	6.00 ± 0.00	6.00 ± 1.31 (Max = 7.6)	14.03 ± 0.07 (Max = 14.1)
2	723 ± 25.49	507 ± 4.51	7.08 ± 0.56	6.00 ± 0.00	18.1 ± 0.77 (Max = 19.3)	13.95 ± 0.08 (Max = 14.1)
3	415 ± 42.2	519 ± 13.59	5.37 ± 0.28	6.00 ± 0.00	10.83 ± 0.96 (Max = 12.6)	13.82 ± 0.50 (Max = 14.1)
4	462 ± 24.73	524 ± 16.03	5.22 ± 0.29	6.00 ± 0.00	12.07 ± 0.37 (Max = 12.5)	13.97 ± 0.14 (Max = 14.2)
5	623 ± 26.25	495 ± 7.14	5.62 ± 0.43	6.00 ± 0.00	16.93 ± 0.46 (Max = 17.4)	14.02 ± 0.12 (Max = 14.1)
6	607 ± 104.2	505 ± 26.83	5.52 ± 0.78	6.00 ± 0.00	15.93 ± 2.32 (Max = 19.2)	14.05 ± 0.14 (Max = 14.3)
7	451 ± 42.35	420 ± 14.71	5.72 ± 0.88	6.00 ± 0.00	11.75 ± 1.65 (Max = 15.3)	14.13 ± 0.27 (Max = 14.5)
8	502 ± 35.79	486 ± 6.18	7.92 ± 1.19	6.00 ± 0.00	13.77 ± 0.85 (Max = 14.8)	14.05 ± 0.17 (Max = 14.3)
Average across all subjects	499 ± 45.60	496 ± 11.65	5.85 ± 0.58	6.00 ± 0.00	13.18 ± 1.09 (Max = 14.8)	14.00 ± 0.19 (Max = 14.2)

Table 1: Results from the volunteer study comparing the usage of both a conventional BVM and the prototype electronic blower system.

Test #4: The prototype mask ventilator system was connected paced on a manikin head via a modified air cushion mask that was held in place using a common elastomeric strap (H-strap). The trachea of the manikin head was connected to a test lung set to a compliance of 0.5. The first part of the test evaluated the system in automatic ventilation mode. The settings were: CPAP = 4 cmH2O, Pressure Support = 10 cmH2O, and 10 breaths/min. The second part of the test evaluated the system in monitoring mode. The settings were: spontaneously breathing test lung, CPAP = 4 cmH2O, Tidal Volume = 500 ml, and 10 breaths/min. In both tests the batteries were fully charged and the system was run until the blower shut off. Battery levels were recorded by the computer every 5 minutes.

Results: Figure 10 shows that the system lasted just over 8 hours in automatic ventilation mode. Figure 11 shows that the system lasted almost 18 hours in monitor mode. These numbers are preliminary and do not include the use of a display that will ultimately be incorporated into the final design. These figures do show the portability of this system and the viability of providing portable ventilation and monitoring to patients for an extended amount of time.
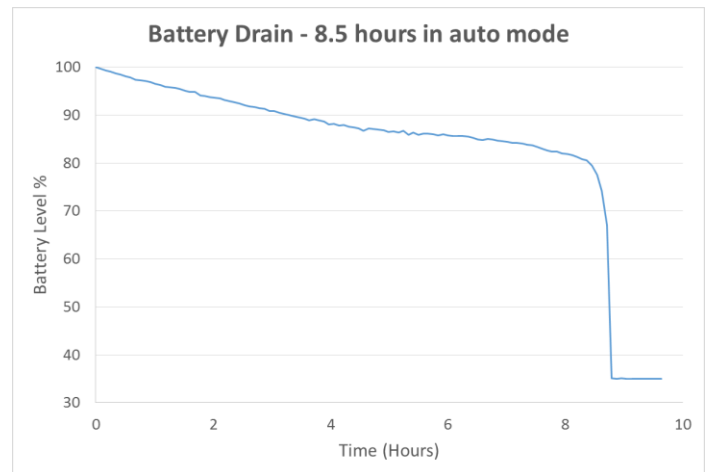
Figure 10: Results from the battery drain test in automatic ventilation mode.
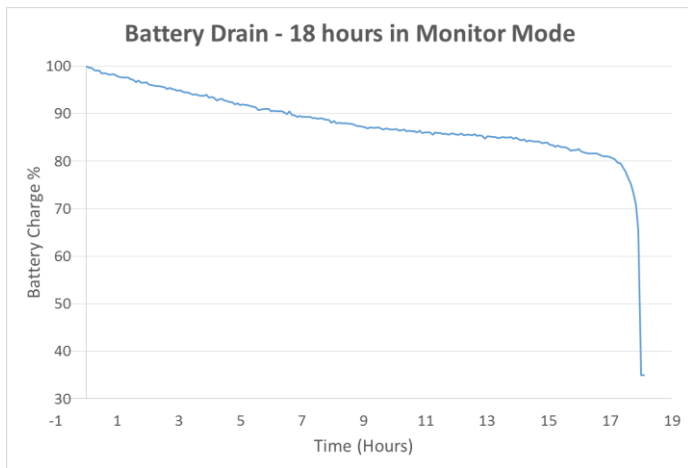
Figure 11: Results from the battery drain test in monitoring ventilation mode.

The remainder of the verification testing is currently under way and will be concluded summer 2014. The plan for the rest of the bench verification is outlined below:

1. Breath rate and tidal volume verification without oxygen in auto mode.
2. Tidal volume verification with oxygen in auto mode.
3. Breath rate and tidal volume verification without oxygen in monitor mode.
4. Tidal volume verification with oxygen in monitor mode.
5. Tidal volume and breath rate verification with manual mask holder in auto and monitor mode.
6. CO2 removal tests.
7. Alarm verification tests.
8. Leak factor limit testing.
9. Decibel level testing comparing to V-60 ventilator.

Aim 2: Create an ergonomic and simple user interface for the prototype.   Clinicians will not adopt the use of a device that is not easy to use. A comparison study of clinicians using the prototype and the bag valve mask on a test lung will be conducted. Clinician feedback will be implemented into the final design of the prototype. Also, initial equivalency will be shown between the prototype and the bag valve mask.

Aim 3: Demonstrate safety and efficacy of the device in a clinical setting. Non-invasive ventilation with leak adaptable tidal volume measurements has never been done, especially with a portable device. A clinical trial of this kind will require extensive cooperation and coordination with clinicians as well as the IRB. Through these trials, safety and efficacy will be established so that the device can be FDA approved.

Conclusion

The portable mask ventilator system could help maintain adequate ventilation by maintaining positive airway pressure to hold the airway open in overly sedated patients and those susceptible to sleep apnea. Patient monitoring capability in this system is useful for selecting CPAP levels and ensuring adequate patient ventilation during sedation. The system includes a battery powered blower to generate a high gas flow under feedback control to maintain a fixed pressure even when mask leak is high. Our system uses an integrated flow sensor along with a leak-compensation algorithm to accurately measure breathing rate, tidal volume, airway pressure, and inspired oxygen (FiO_2). The system will also alert the clinician of sudden changes in airway resistance. If apnea is detected the system can automatically engage in BPAP (Bi-level positive airway pressure), which will ventilate the patient during central apnea. This allows the patient to receive automatic mask ventilation until respiratory drive is restored.

The electric blower based portable emergency ventilator will increase the positive outcomes for patients by reducing the risk of injury that comes from bag valve mask ventilation. It will be the first portable positive pressure ventilation device to have leak adaptable tidal volume measurements. The device will reduce operator error, comply with guidelines for ventilation, and improve a clinician's ability to perform other critical tasks. The reduction of injury to the patient and the increase in convenience for the clinician will reduce the financial burden on hospitals and medical providers.

References

1. American Heart Association. (2007). Heart Disease and Stroke Statistics — 2007 Update. Dallas, Tex.: American Heart Association; available at http://www.americanheart.org/presenter.jhtml?identifier=1200026 ; accessed July 2007.

2. Zheng ZJ, Croft JB, Giles WH, Mensah GA. Sudden cardiac death in the United States, 1989 to 1998. *Circulation.* 2001; 104: 2158–2163.

3. Chugh SS, Jui J, Gunson K, Stecker EC, John BT, Thompson B, Ilias N, Vickers C, Dogra V, Daya M, Kron J, Zheng ZJ, Mensah G, McAnulty J. Current burden of sudden cardiac death: multiple source surveillance versus retrospective death certificate–based review in a large US community. *J Am Coll Cardiol.* 2004; 44: 1268–1275.

4. Vaillancourt C, Stiell IG. Cardiac arrest care and emergency medical services in Canada. *Can J Cardiol.* 2004; 20: 1081–1090.

5. Rea TD, Eisenberg MS, Sinibaldi G, White RD. Incidence of EMS-treated out-of-hospital cardiac arrest in the United States. *Resuscitation.* 2004; 63: 17–24.

6. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of- hospital ventricular fibrillation, 1980–2000. *JAMA.* 2002; 288: 3008–3013.

7. Bayes de Luna A, Coumel P, Leclercq JF. Ambulatory sudden cardiac death: mechanisms of production of fatal arrhythmia on the basis of data from 157 cases. *Am Heart J.* 1989; 117: 151–159.

8. Cummins RO. CPR and ventricular fibrillation: lasts longer, ends better. *Ann Emerg Med.* 1995; 25: 833–836.

9. Valenzuela TD, Roe DJ, Cretin S, Spaite DW, Larsen MP. Estimating effectiveness of cardiac arrest interventions: a logistic regression survival model. *Circulation.* 1997 Nov 18; 96(10):3308-13.

10. Larsen MP, Eisenberg MS, Cummins RO, Hallstrom AP. Predicting survival from out-of-hospital cardiac arrest: a graphic model. *Ann Emerg Med.* 1993; 22: 1652–1658.

11. Wik L, Hansen TB, Fylling F, Steen T, Vaagenes P, Auestad BH, Steen PA. Delaying defibrillation to give basic cardiopulmonary resuscitation to patients with out-of-hospital ventricular fibrillation: a randomized trial. *JAMA.* 2003; 289: 1389–1395.

12. Cobb LA, Fahrenbruch CE, Walsh TR, Copass MK, Olsufka M, Breskin M, Hallstrom AP. Influence of cardiopulmonary resuscitation prior to defibrillation in patients with out-of- hospital ventricular fibrillation. *JAMA.* 1999; 281: 1182–1188.

13. Liberman M, Lavoie A, Mulder D, Sampalis J. Cardiopulmonary resuscitation: errors made by pre-hospital emergency medical personnel. *Resuscitation.* 1999;42:47–55.

14. Kaye W, Mancini ME. Retention of cardiopulmonary skills by physicians, registered nurses, and the general public. *Crit Care Med.* 1986;14:620–622.

15. Mandel LP, Cobb LA. Initial and long term competency of citizens trained in CPR. *Emerg Health Serv Q.* 1982;1:49–63.

16. Weaver FJ, Ramirez AG, Dorfman SB, et al. Trainees' retention of cardiopulmonary resuscitation: how quickly they forget. *JAMA.* 1979; 241: 901–903.

17. Wynne G, Marteau TM, Johnston M, et al. Inability of trained nurses to perform basic life support. *Br Med J (Clin Res Ed).* 1987; 294: 1198–1199.

18. William P Wiesmann, M., *Dangers of Bag Valve Masks.* Respiratory and Airway Management, 2011.