



**AFRL-RH-WP-TR-2023-0016**

**DEVELOPMENT OF A RE-BREATHING SYSTEM FOR  
MECHANICAL VENTILATORS**

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**University of Cincinnati Sponsored Research Services**

**March 2023**  
**Final Report**

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<b>1. REPORT DATE (DD-MM-YY)</b> 08-03-23	<b>2. REPORT TYPE</b> Final Report	<b>3. DATES COVERED (From - To)</b> August 2019 – December 2022
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<b>4. TITLE AND SUBTITLE</b> Development of a Re-breathing System for Mechanical Ventilators	<b>5a. CONTRACT NUMBER</b> FA8650-19-2-6G34
	<b>5b. GRANT NUMBER</b> 846310
	<b>5c. PROGRAM ELEMENT NUMBER</b>

<b>6. AUTHOR(S)</b> Thomas Blakeman*, Richard Branson*	<b>5d. PROJECT NUMBER</b> RHM-19E16
	<b>5e. TASK NUMBER</b> 34G
	<b>5f. WORK UNIT NUMBER</b>

<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> *University of Cincinnati Sponsored Research Services 51 Goodman Drive, Suite 530 Cincinnati, OH 45221-0222	<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>
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<b>9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> **Air Force Materiel Command Air Force Research Laboratory 711 <sup>th</sup> Human Performance Wing Airman Systems Directorate Airman Biosciences Division Product Development Branch Wright-Patterson AFB, OH 45433	<b>10. SPONSORING/MONITORING AGENCY ACRONYM(S)</b> 711 HPW/RHBAM
	<b>11. SPONSORING/MONITORING AGENCY REPORT NUMBER(S)</b> AFRL-RH-WP-TR-2023-0016

**12. DISTRIBUTION/AVAILABILITY STATEMENT**  
Distribution A. Approved for Public Release. Distribution unlimited.

**13. SUPPLEMENTARY NOTES**  
AFRL-2023-2388, cleared 17 May 2023

**14. ABSTRACT**  
Introduction: Maximizing the capabilities of available low flow oxygen is key to providing adequate oxygen to prevent/treat hypoxemia and conserve oxygen. We designed a closed-circuit system which allows rebreathing of gases while scrubbing carbon dioxide (CO<sub>2</sub>) in conjunction with portable mechanical ventilators in a bench model.  
Methods: We evaluated the system using two portable mechanical ventilators currently deployed by the DoD: Zoll 731 and AutoMedx SAVe II over a range of ventilator settings and lung models, using 1 and 3 L/min low flow oxygen into a reservoir bag. We measured peak inspired oxygen concentration (FiO<sub>2</sub>), CO<sub>2</sub> absorbent life, gas temperature and humidity, and the effect of airway suctioning and ventilator disconnection on FiO<sub>2</sub> on ground and at altitude.  
Results: FiO<sub>2</sub> was ≥ 0.9 across all ventilator settings and altitudes using both oxygen flows. CO<sub>2</sub> absorbent life was > 7 hours. Airway humidity range was 87%-97%. Mean airway temperature was 25.4 ± 0.5°C. Ten second suctioning reduced FiO<sub>2</sub> 22-48%. Thirty second ventilator disconnect reduced FiO<sub>2</sub> 29-63% depending on oxygen flow used.  
Conclusion: Use of a rebreathing system with mechanical ventilation has the potential for oxygen conservation but requires diligent monitoring of inspired FiO<sub>2</sub> and CO<sub>2</sub> to avoid untoward consequences.

**15. SUBJECT TERMS:**

<b>16. SECURITY CLASSIFICATION OF:</b>			<b>17. LIMITATION OF ABSTRACT:</b> SAR	<b>18. NO OF PAGES</b> 15	<b>19a. NAME OF RESPONSIBLE PERSON (Monitor)</b> James Lehman
<b>a. REPORT</b> Unclassified	<b>b. ABSTRACT</b> Unclassified	<b>c. THIS PAGE</b> Unclassified			<b>19b. TELEPHONE NUMBER (Include Area Code)</b> N/A

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## 1.0. SUMMARY/DISCLAIMER

### BRIEF SUMMARY OF WHAT THIS STUDY DID.

The University of Cincinnati Institutional Review Board and the United States Air Force Human Research Protection Office approved the clinical trial. The final report will include information covering the methods, results for each research activity.

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## 2.0. BACKGROUND

Under normal hospital conditions oxygen is abundant. Under far forward conditions and other hostile environments, oxygen is a scarce resource. Supplying oxygen in austere/resource constrained environments represents significant logistical challenge. Oxygen can be life-saving in the presence of hypoxemia and is frequently delivered during mechanical ventilation to treat respiratory failure. In military applications, oxygen is a finite resource and methods for conservation include targeted oxygen delivery, closed loop control of inspired oxygen and use of chemical oxygen generation devices and oxygen concentrators.<sup>1,2</sup> In situations where the use of pressurized oxygen cylinders is logistically difficult or are not permitted due to a number of potential hazards including fire and projectile risks, low flow oxygen from alternative sources is the next available option. Maximizing the capabilities of low flow oxygen is key to providing adequate oxygen to prevent/treat hypoxemia and conserve oxygen. We designed a closed-circuit system which allows rebreathing of gases while scrubbing carbon dioxide (CO<sub>2</sub>) in conjunction with mechanical ventilation in a bench model.

## 3.0. METHODS

We used two portable mechanical ventilators currently employed by the DoD (731, Zoll Medical, Chelmsford, MA and SAVe II, AutoMedx, Addison, Tx) for the evaluation. The experiment design is shown in figure 1. We evaluated the system over a range of ventilator settings (table 1) and two lung conditions (table 2). The maximum positive end expiratory pressure (PEEP) setting with the SAVe II was 10 centimeters of water (cm H<sub>2</sub>O), therefore the ventilator settings requiring 20 cm H<sub>2</sub>O PEEP were not possible. Additionally, the inspiratory flow limitations (24 liters per minute (L/min))<sup>3</sup> with the SAVe II prevented testing at the respiratory rates in the testing protocol with the 450 milliliters (mL) and 700 mL ventilator settings. An engineering group (Sparx Engineering, Manvel, TX) designed and 3D printed the

CO<sub>2</sub> absorber canister incorporated into the rebreather system. A soda lime-based CO<sub>2</sub> absorbent (Sodasorb, Molecular Products Inc., Louisville, CO) was used for the evaluation. The canister was placed in the inspiratory limb. We introduced oxygen flows of 1 and 3 L/min into a 3 L reservoir bag attached to the ventilator inlet and made the following measurements.

- Peak fraction of inspired oxygen concentration (FiO<sub>2</sub>) within 30 minutes
- Duration of CO<sub>2</sub> absorbent life based on rise in inspired CO<sub>2</sub> greater than (>) 1 percent (%).
- Peak delivered gas temperature and humidity.
- Volume of condensate in ventilator circuit.
- Effect of 5 and 10 second suctioning with in-line suction catheter on FiO<sub>2</sub>.
- Effect of 15 and 30 second ventilator circuit disconnect on FiO<sub>2</sub>.

Peak FiO<sub>2</sub> was measured with both ventilators and all combinations of ventilator settings but the remaining measurements were only made with the 731 using the respiratory rate (RR)20/ tidal volume (V<sub>T</sub>)450/PEEP5 settings (plus RR30/V<sub>T</sub>250/PEEP5 and RR20/V<sub>T</sub>700/PEEP5 for the duration of CO<sub>2</sub> absorbent life tests). Testing was done in duplicate at ground level, 8,000 feet (ft), and 16,000 ft simulated altitude in an altitude chamber with the exception the absorbent life test, that was completed 5 times due to at ground level. Nitrogen gas was introduced into the test lung during the FiO<sub>2</sub> testing as needed to maintain a 2-3% lower expired than inspired FiO<sub>2</sub> to simulate normal oxygen consumption. CO<sub>2</sub> was introduced into the test lung from a cylinder at 200 mL/min to simulate CO<sub>2</sub> production.

### **Statistical Analysis**

Stratified by device, one-way ANOVA was used to model FiO<sub>2</sub> as a function of ventilator settings and altitude, while unpaired t-tests were used to model the effect of oxygen flow (1 vs 3 L/min.) P-value for significance was set at 0.05.

Five trials were performed for each of three sets of ventilator settings (RR 30/V<sub>T</sub> 250 mL, RR 20/V<sub>T</sub> 450 mL, RR 20/V<sub>T</sub> 700 mL, all with PEEP of 5 cm H<sub>2</sub>O and lung compliance of 80 mL/cm H<sub>2</sub>O and 1 L/min oxygen flow rate) for the CO<sub>2</sub> absorbent life testing. Between-settings differences in temperature, humidity and minutes to inspired CO<sub>2</sub> >1% were assessed using one-way ANOVA. Pairwise comparisons were done using a t-test. Statistical significance was set at p < 0.05.

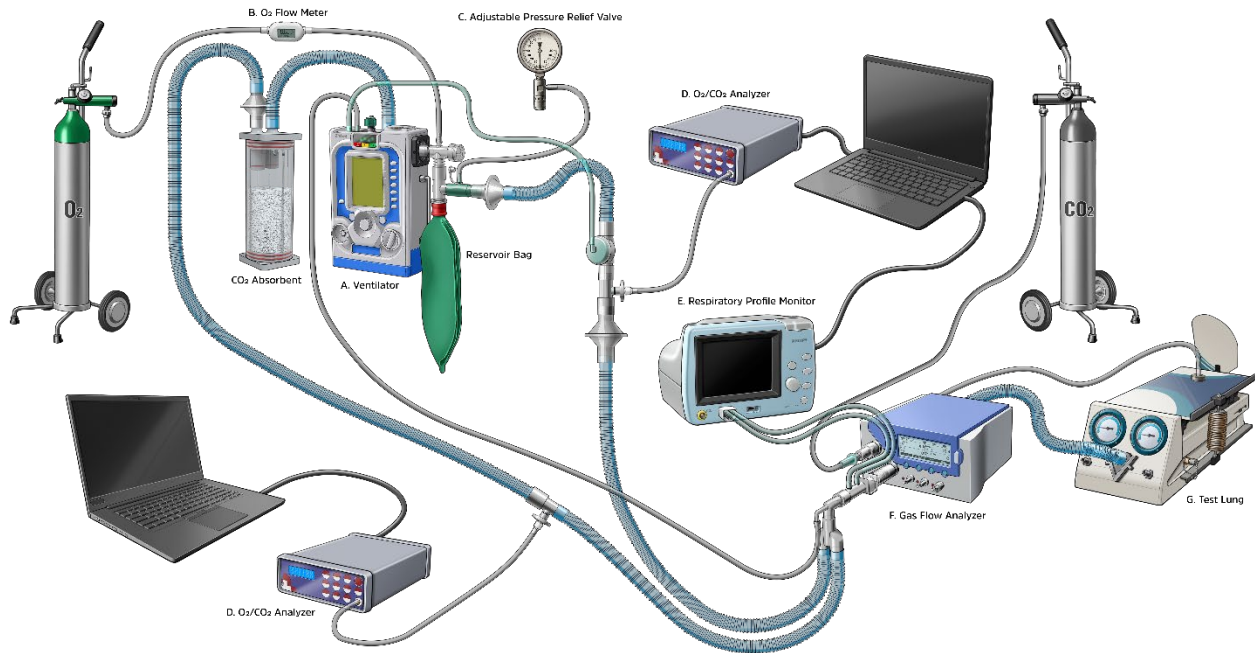


Figure 1 Experiment setup

Table 1. Ventilator settings for the evaluation.

	RR (breaths/min)/V <sub>T</sub> (mL) Combinations	PEEP (cm H <sub>2</sub> O)	I:E	Breath type
SAVE II	30/250 18/450 11/700	5	1:2	Volume
731	30/250 20/450 20/700	5 & 20	1:3	Volume

Table 2. Test lung settings for the evaluation

	Compliance (ml/cm H <sub>2</sub> O)	Resistance (cm H <sub>2</sub> O/L/s)	CO <sub>2</sub> production (ml/min)
Normal	80	5	200
ARDS	20	10	200

## 4.0. RESULTS

### FiO<sub>2</sub>

FiO<sub>2</sub> during use of the 731 was not impacted by ventilator settings ( $p>0.99$ ). Mean FiO<sub>2</sub> was  $0.96 \pm 0.25$  for all settings. FiO<sub>2</sub> was significantly ( $p=0.04$ ) associated with altitude and tended to be lower at higher altitudes although differences were not clinically important. Mean FiO<sub>2</sub> was  $0.97 \pm 0.02$  at ground level,  $0.96 \pm 0.02$  at 8000 ft, and  $0.95 \pm 0.03$  at 16,000 ft (Figure 2). FiO<sub>2</sub> was significantly ( $p<0.0001$ ) higher with 3 L/min oxygen bleed-in, vs 1 L/min. Mean FiO<sub>2</sub> was  $0.94 \pm 0.02$  with 1 L/min oxygen bleed-in and  $0.98 \pm 0.01$  with 3 L/min oxygen bleed-in (Fig 3). Minimum FiO<sub>2</sub> in each group was 0.92 and 0.97 respectively.

FiO<sub>2</sub> during use of the SAVe II was not associated with ventilator settings ( $p=0.73$ ) or altitude ( $p=0.97$ ). There was a minimal decrease in mean FiO<sub>2</sub> with increasing altitude:  $0.95 \pm 0.03$  at ground level,  $0.94 \pm 0.26$  at 8000 feet, and  $0.94 \pm 0.27$  at 16,000 feet. FiO<sub>2</sub> was significantly ( $p<0.0001$ ) higher with 3 L/min oxygen, vs 1 L/min and was less variable (Fig 4). Mean FiO<sub>2</sub> was  $0.92 \pm 0.01$  at 1 L/min oxygen, and  $0.97 \pm 0.01$  at 3 L/min (mean difference 0.05). Minimum FiO<sub>2</sub> in each group was 0.9 and 0.96 respectively. Due to the limited flow capabilities and PEEP limitations of the SAVe II, direct FiO<sub>2</sub> comparisons to the 731 could only be made using the RR30/V<sub>T</sub>250/PEEP 5 settings. Differences in FiO<sub>2</sub> at these settings between the two devices were not significantly different ( $p=0.97$ ).

### Temperature and Humidity

There was no overlap in humidity between the three RR/V<sub>T</sub> ventilator settings. The mean (range) was 89% (87-90%) for RR30/V<sub>T</sub>250 settings, 92% (91-93%) for RR20/V<sub>T</sub>450, and 96% (95-97%) for RR20/V<sub>T</sub>700 (Fig 5). Differences were statistically significant overall ( $p<0.0001$ ) as were all pairwise comparisons. Peak temperature (degrees celsius (°C)) did not differ significantly between the three RR/V<sub>T</sub> ventilator settings ( $p=0.47$ ). Group means were 25.5, 25.2, and 25.6 respectively.

### CO<sub>2</sub> Absorbent Life

Mean time to CO<sub>2</sub> elevation of  $>1\%$  was  $456 \pm 56$  minutes for RR30/V<sub>T</sub>250,  $460 \pm 44$  for RR20/V<sub>T</sub>450, and  $557 \pm 27$  minutes) for RR20/V<sub>T</sub>700 ventilator settings (Fig 6). This difference was statistically significant overall ( $p = 0.005$ ) but not all pairs were significantly different: RR20/V<sub>T</sub>700 was significantly different from the other ventilator settings (both  $p < 0.01$ ), but the RR30/V<sub>T</sub>250 and RR20/V<sub>T</sub>450 settings were not significantly different from each other ( $p=0.89$ .) Condensate from the ventilator circuit was drained and measured after each test (data not shown). The longest the run times produced the largest condensate volume. The condensate volume produced by the RR30/V<sub>T</sub>250 and RR20/V<sub>T</sub>450 ventilator settings run times were not significantly different ( $p=0.55$ , range 25-35 mL) whereas these settings produced condensate volumes that were significantly different than volumes produced using the RR20/V<sub>T</sub>700 ventilator settings (range 45-63 mL,  $p=0.005$  and  $p=0.0003$  respectively).

### Suctioning and Disconnect

FiO<sub>2</sub> at baseline, after 5 and 10 seconds of airway suctioning, and after 15 and 30 seconds of a ventilator disconnect, and recovery times back to baseline FiO<sub>2</sub> are shown in table 3. With the exception of the 15 second ventilator circuit disconnect and the 5 second suction recovery time, the 1 L/min oxygen (O<sub>2</sub>) bleed-in tests resulted in significantly greater decreases in FiO<sub>2</sub> and

significantly longer recovery time than the 3 L/min tests and at baseline ( $p < 0.05$ ). The 15 second ventilator circuit disconnect did not result in significantly different  $FiO_2$  with either the 1 or 3 L/min  $O_2$  tests ( $p > 0.1$ ). Within-group (1 and 3 L/min)  $FiO_2$  and recovery time was significantly different ( $p < 0.05$ ) with the exception of the 15 second ventilator circuit disconnect ( $p > 0.1$ ).

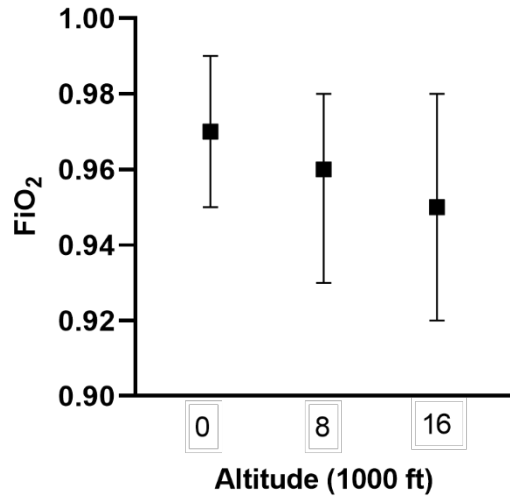


Figure 2 Effect of Altitude on  $FiO_2$  (mean and range) showing combined 1 and 3 L/min oxygen flows at each altitude with the 731 ventilator.

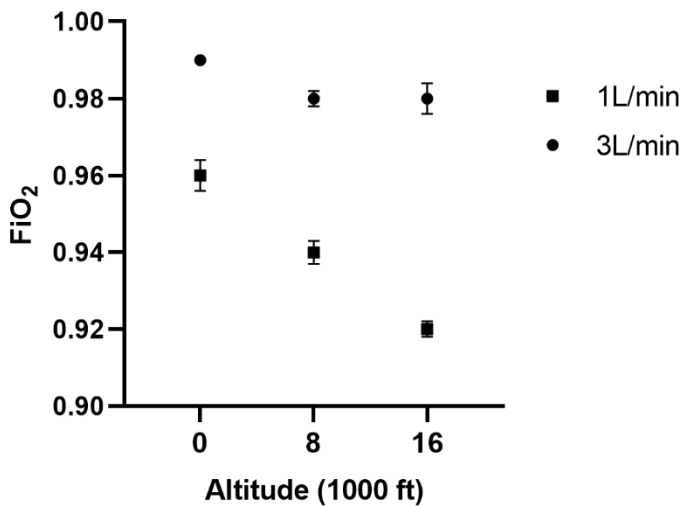


Figure 3 Effect of oxygen flow on  $FiO_2$  (mean and range) with the 731 ventilator.

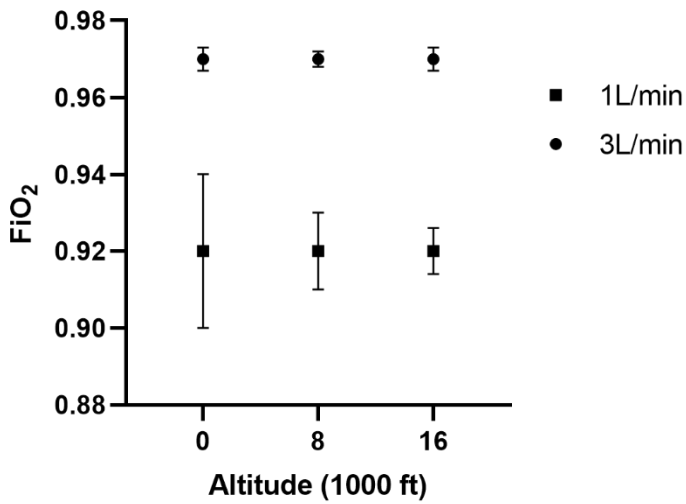


Figure 4 Effect of oxygen flow on FiO2 (mean and range) with the SAVe II ventilator.

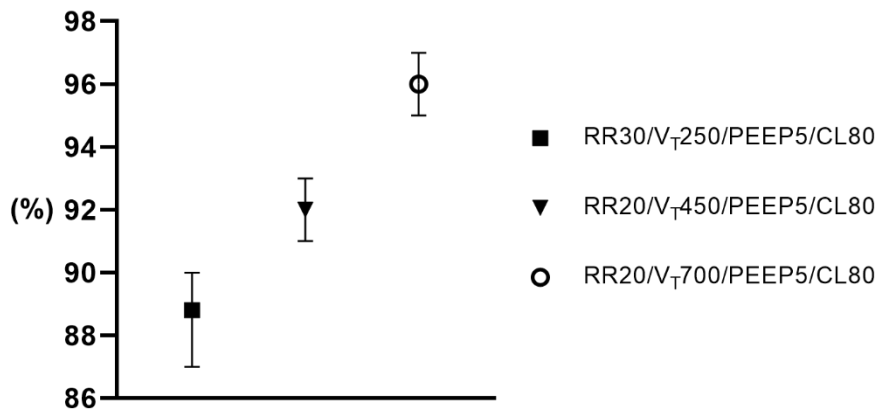


Figure 5 Effect of ventilator settings on humidity (mean and range).

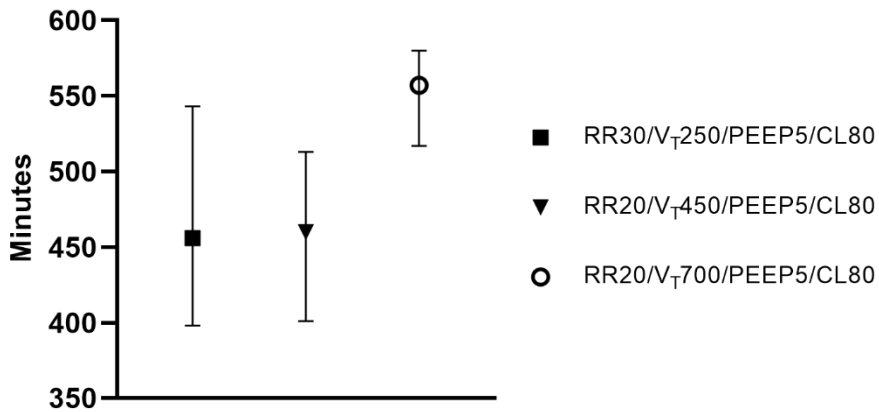


Figure 6 Effect of ventilator settings on time to CO2 > 1% (mean and range).

*Table 3. FiO<sub>2</sub> and recovery time after 5 and 10 second suctioning and 15 and 30 second ventilator circuit disconnect using 1 and 3 L/min oxygen.*

	1L/min	3L/min
Baseline FiO <sub>2</sub>	0.96 ± 0.003	0.99 ± 0.01
5 second suction FiO <sub>2</sub>	0.9 ± 0.01	0.93 ± 0.001
Recovery time (sec)	5.3 ± 0.4	4.0 ± 1.4
10 second suction FiO <sub>2</sub>	0.47 ± 0.09	0.77 ± 0.04
Recovery time (sec)	1125.5 ± 140.7	334.5 ± 14.8
15 second disconnect FiO <sub>2</sub>	0.96 ± 0.001	0.99 ± 0.01
Recovery time (sec)	0	0
30 second disconnect FiO <sub>2</sub>	0.32 ± 0.05	0.69 ± 0.02
Recovery time (sec)	1446 ± 178	443 ± 5.7

## 5.0. DISCUSSION

Rebreathing systems are used in the majority of anesthetic procedures around the world. These systems use an anesthesia workstation that includes a complete suite of monitoring equipment (oximeter, capnograph, blood pressure, electrocardiogram), ventilator, manual delivery system, oxygen source, anesthetic vaporizers, circuit and CO<sub>2</sub> absorber. These workstations cost over \$150,000 and typically do not have advanced ventilator modes and monitoring. These systems have been used for over 100 years and the operation is well understood. Key aspects of the system integral to operating room systems include a scavenging system (which prevents exposure of the caregivers to exhaled anesthetic agents) and monitoring of inspired oxygen and inspired carbon dioxide. Failure to recognize both low inspired oxygen concentrations and excessive carbon dioxide concentrations have lethal consequences. Any rebreathing system deployed would require continuous monitoring of FiO<sub>2</sub> and CO<sub>2</sub>.

Rebreathing systems utilize three gas sources: exhaled alveolar gas, system dead space gas, and fresh gas. Many early rebreathing system configurations are attributed to designs by Mapelson.<sup>4</sup> <sup>5</sup> These systems were simple to operate but were inefficient and required fresh gas flows of 1-3 times the patient's minute ventilation in order to prevent rebreathing of CO<sub>2</sub>. Modifications of these early systems to mitigate the dangers CO<sub>2</sub> rebreathing and excessive fresh gas use lead to the advent of circle or closed systems.<sup>6</sup> These closed systems forced the exhaled gas through CO<sub>2</sub> absorbent before re-entering the inspiratory limb for delivery to the patient during the next breath cycle. This innovation allowed for much lower fresh gas flows while producing a higher FiO<sub>2</sub>. In anesthesia, lower fresh gas flows allow conservation of expensive anesthetic agents.

Full size rebreathing anesthesia machines are too cumbersome and weight and cube prohibitive for use in transport and/or austere environments. Oswald and DeBoer in the early 1990's described a closed-circuit anesthesia device developed for transport use with off the shelf components.<sup>7</sup> The potent agent portable apparatus (PAPA) was intended to be used for anesthesia gas delivery but could also be used without anesthesia, potentially extending the life of an oxygen cylinder. The device was much smaller and lighter (30 pounds (lbs)) than a typical anesthesia machine and could be mounted to a hospital bed, but it required fresh gas flows up to 6 L/min, albeit an improvement over its predecessors. Pollock and Natoli conducted a pilot study with 6 normal subjects, evaluating the performance of a closed-circuit emergency medical oxygen (REMO<sub>2</sub>) system designed for field use in a laboratory setting. Subjects breathed spontaneously on the device via oronasal mask for eight hours. The device provided 0.93 – 0.98 peak FiO<sub>2</sub> using 1.0 ± 0.17 L/min oxygen flow. However, this device did not provide positive pressure ventilation, instead relying on users to generate their own minute ventilation.<sup>8</sup>

In the hospital setting, oxygen is generally abundant and inexpensive but is often not the case in combat and aeromedical evacuation settings. Oxygen containing and/or generating equipment occupy 15-30% of the available footprint for a given setting<sup>9, 10</sup> and represent substantial weight.<sup>10</sup> Due to these logistical constraints, efforts have been made to reduce oxygen usage primarily by the automatic titration of oxygen delivery to a target oxygen saturation (SpO<sub>2</sub>).<sup>9-11</sup> Barnes et al found in an observational study that 68% of mechanically ventilated, aeromedical transport combat casualties required < 3 L/min oxygen.<sup>12</sup> Although this was a small observation study with important findings, a substantial number of casualties required higher FiO<sub>2</sub>, prompting a search for a potential solution to providing higher FiO<sub>2</sub> while using ≤ 3 L/min oxygen; the maximum flow provided by portable oxygen concentrators (POC) deployed by the DoD (Saros, Caire Inc, Ball Ground, GA).

Lowes and Sharley evaluated the Modified Circle System (MCS), an adaptation of the closed-circuit anesthesia system, in a bench model.<sup>2</sup> The evaluation used two tidal volume/respiratory rate combinations, two PEEP settings, and normal and stiff lung settings. The majority of the testing was accomplished with a LP 10 ventilator (Puritan Bennett, Medtronic, Minneapolis, MN). Across all settings, the authors found that the oxygen flow required to maintain a stable FiO<sub>2</sub> > 0.93 was 0.75-1.5 L/min. The findings were similar to the results of a portion of our study, although the goal of our testing was to determine the highest FiO<sub>2</sub> using two oxygen flows over a range of ventilator/lung compliance settings and three altitudes. The setup configurations were similar with the MCS and our system with two exceptions. The CO<sub>2</sub> absorber in the MCS model was placed on the ventilator air intake side vs the ventilator output side with our configuration. Additionally, the LP 10 has an external PEEP valve vs PEEP controlled internally with the ventilators we used for testing. We initially attempted to place the CO<sub>2</sub> absorber on the ventilator air intake but this configuration interfered with ventilator PEEP controls and resulting in alarms, necessitating placement of the CO<sub>2</sub> absorber in the inspiratory limb. Using the external PEEP valve likely allowed for the CO<sub>2</sub> absorber attachment to the LP 10 without an impact on PEEP.

One of the most important aspects when discussing these closed-circuit systems is the effect of breaking the system, potentially resulting in decreased FiO<sub>2</sub> and patient hypoxia. Mechanically ventilated patients often require suctioning via in-line suction catheters or disconnection from the

ventilator for open suctioning. Our study showed that utilizing in-line suction for 10 seconds or disconnection from the ventilator for 30 seconds can result in low  $\text{FiO}_2$  and recovery times back to baseline from 5 – 24 minutes, depending on oxygen flow used. These results suggest that with patients requiring high  $\text{FiO}_2$  to maintain oxygenation these practices should be limited due to possible hypoxemia and resulting sequelae.

### **Limitations**

There are several limitations with this study. This was a bench study conducted under controlled settings including room temperature, close control of  $\text{CO}_2$  production, oxygen delivery and simulated oxygen consumption. We cannot be certain the rebreathing system would perform the same if used with patients with differing  $\text{CO}_2$  production and/or oxygen consumption, with and without spontaneous breathing. We only studied two portable ventilators and only one of each model. The system may perform differently with other ventilators. The rebreather system was studied at simulated altitudes in an altitude chamber. The system may perform differently in real world conditions at altitudes encountered during aeromedical transport. We did not evaluate long term use on ventilator function (moisture in the ventilator inlet) nor did we evaluate the potential for contamination of the ventilator and need for cleaning between patients. Although we used several filters within the system, perhaps these should be HEPA filters to reduce bacterial/viral contamination.

## **6.0. CONCLUSION**

The results of this study show that using low oxygen flow  $\leq 3$  L/min with a rebreathing system attached to a portable ventilator can provide  $\text{FiO}_2 \geq 90\%$  across a range of ventilator settings and lung models, at ground level and at altitude. In its current form, this system is not compatible with some portable ventilators due to inability to attach to ventilator air intake in order to complete the closed system. Suctioning and disconnection from the ventilator should be used sparingly due to hypoxemia risk. In our models,  $\text{CO}_2$  absorbent life was at least 7 hours at all conditions which would be adequate for most aeromedical and ground transports and anywhere oxygen is scarce. Use of a rebreathing system has the potential for oxygen conservation but requires diligent monitoring of inspired  $\text{FiO}_2$  and  $\text{CO}_2$  to avoid untoward consequences.

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## LIST OF SYMBOLS, ABBREVIATIONS AND ACRONYMS

%	Percent
<	Less Than
>	Greater Than
±	Plus Minus
≥	Greater Than Equal To
cm H <sub>2</sub> O	Centimeters of Water
CO <sub>2</sub>	Carbon Dioxide
FiO <sub>2</sub>	Fraction of Inspired Oxygen
ft	Feet
I:E	Inspiratory Expiratory Ratio
L	Liters
L/min	Liters per Minute
lbs	Pounds
MCS	Modified Circle System
mL	Milliliters
mL/cm H <sub>2</sub> O	Milliliters per Centimeter
mL/min	Milliliters per Minute
O <sub>2</sub>	Oxygen
°C	Degrees Celsius
p	Statistical Probability Value
PEEP	Positive End Expiratory Pressure
RR	Respiratory Rate
V <sub>T</sub>	Tidal Volume