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Performance of Portable Ventilators at Altitude



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14. ABSTRACT Aeromedical transport of critically ill patients requires continued, accurate performance of equipment at altitude. Changes in barometric pressure can affect the performance of mechanical ventilators calibrated for operation at sea level. Deploying ventilators that can maintain a consistent tidal volume (V_T) delivery at various altitudes is imperative for lung protection when transporting wounded warfighters to each echelon of care. Three ventilators (Impact 731, Hamilton T1, CareFusion ReVel) were tested at pediatric (50 & 100 mL) and adult V_T (250-750 mL) at 0 and 20 cm H_2O positive end expiratory pressure and at inspired oxygen of 0.21 and 1.0. Airway pressure, volume, and flow were measured at sea level, 8,000, 16,000, and 22,000 feet (corresponding to barometric pressures of 760, 564, 412, and 321 mmHg) using a calibrated pneumotachograph connected to a training test lung in an altitude chamber. Set V_T and delivered V_T and changes in V_T at each altitude were compared by t-test. Only the T1 delivered V_T within 10% of set V_T at 8,000 feet. Mean V_T was less than set V_T at sea level as a result of circuit compressible volume with the ReVel and 731. Changes in V_T varied widely among the devices at sea level and at altitude. Increasing altitudes resulted in larger V_T than set for the ReVel and T1. The 731 delivered V_T within 10% at the adult settings at all altitudes. Altitude compensation is an active software algorithm. Only the 731 actively accounts for changes in barometric pressure to maintain the set V_T at all tested altitudes.					
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1.0 SUMMARY

Aeromedical transport of critically ill patients requires continued, accurate performance of equipment at altitude. Changes in barometric pressure can affect the performance of mechanical ventilators calibrated for operation at sea level. Deploying ventilators that can maintain a consistent tidal volume (V_T) delivery at various altitudes is imperative for lung protection when transporting wounded warfighters to each echelon of care. Three ventilators (Impact 731, Hamilton T1, CareFusion ReVel) were tested at pediatric (50 & 100 mL) and adult V_T (250-750 mL) at 0 and 20 cm H_2O positive end expiratory pressure and at inspired oxygen of 0.21 and 1.0. Airway pressure, volume, and flow were measured at sea level, 8,000, 16,000, and 22,000 feet (corresponding to barometric pressures of 760, 564, 412, and 321 mmHg) using a calibrated pneumotachograph connected to a training test lung in an altitude chamber. Set V_T and delivered V_T and changes in V_T at each altitude were compared by t-test. Only the T1 delivered V_T within 10% of set V_T at 8,000 feet. Mean V_T was less than set V_T at sea level as a result of circuit compressible volume with the ReVel and 731. Changes in V_T varied widely among the devices at sea level and at altitude. Increasing altitudes resulted in larger V_T than set for the ReVel and T1. The 731 delivered V_T within 10% at the adult settings at all altitudes. Altitude compensation is an active software algorithm. Only the 731 actively accounts for changes in barometric pressure to maintain the set V_T at all tested altitudes.

2.0 BACKGROUND

Aeromedical transport of critically ill patients requires continued, accurate performance of equipment at altitude. Changes in barometric pressure with increasing altitude are associated with alterations in gas temperature, density, and humidity. These changes can affect the performance of mechanical ventilators calibrated for operation at sea level. The effects of increasing altitude include changes in the movement of gas through fixed orifices, altering accuracy in ventilator settings as well as the measurement of flow and volume. The standard of care for ventilation of patients with acute respiratory distress syndrome (ARDS) dictates the use of lung protection and tidal volumes (V_{TS}) of 6 mL/kg predicted body weight [1]. Since many patients transported by the Air Force Critical Care Air Transport Teams (CCATs) have acute lung injury and ARDS, maintaining appropriate tidal volumes is critical for patient safety. Excess V_T can result in hypocarbia, reduced cerebral blood flow, hypokalemia, cardiac arrhythmias, and a leftward shift of the oxyhemoglobin dissociation curve, which could have a negative effect on outcomes in patients with ARDS and/or head injury. Deploying ventilators that can maintain a consistent V_T delivery at various altitudes is imperative for lung protection when transporting wounded warfighters to each echelon of care. We evaluated the V_T delivered by three portable ventilators either currently in use or being considered for aeromedical transport use in a bench model at sea level and at simulated altitudes.

3.0 METHODS

We evaluated one device each: 731 (Impact Instrumentation, West Caldwell, NJ), T1 (Hamilton Medical, Reno, NV), and ReVel (Carefusion, San Diego, CA). Pre-use calibration of the ventilators required by the manufacturer was done prior to testing. The performance and physical characteristics of the devices are described in Table 1.

Table 1. Comparison of the Physical and Functional Properties of the Ventilators Included in the Evaluation

Ventilator	Impact 731	Hamilton T1	CareFusion Reveal
Weight (kg)	4.4	6.5	4.5
Dimensions (W x L x D) cm	20.3 x 31.8 x 11.4	31 x 30 x 21	28.7 x 18 x 8.4
Breath types	Volume Pressure	Pressure PRVC	Volume Pressure PRVC
Modes	Assist control SIMV Pressure support CPAP	Assist control SIMV Pressure support CPAP ASV DuoPAP APRV	Assist control SIMV Pressure support CPAP
Tidal volume range (mL)	50-1500	20-2000	50-2000
PEEP range (cm H ₂ O)	0-25	0-35	0-20
Breath rate (breaths/min)	1-60	1-80	1-80
Volume monitoring	Inspired	Inspired and expired	Inspired and expired
FIO ₂ range	0.21-1.0	0.21-1.0	0.21-1.0
Internal air source	Compressor	Blower	Blower
Altitude compensation (ft)	Up to 25,000	Up to 13,120	Up to 10,600

Note: APRV = airway pressure release ventilation; ASV = adaptive support ventilation; CPAP = continuous positive airway pressure; DuoPAP = Duo positive airway pressure; FIO₂ = fraction of inspired oxygen; PRVC = pressure regulated volume control; SIMV = synchronized intermittent mandatory ventilation.

The study was conducted at Wright-Patterson Air Force Base in a man-rated altitude chamber at sea level and altitudes of 8,000, 16,000, and 22,000 feet corresponding to barometric pressures of 760, 565, 412, and 321 mmHg. An altitude of 8,000 feet was chosen to represent a simulated cabin altitude during CCATT flight. An altitude of 22,000 was chosen to represent the upper limit of crew functionality in the case of aircraft decompression and conditions of Special Forces mission requirements.

At sea level and each altitude, ventilators were connected to a two-chamber test lung (TTL, Michigan Instruments, Grand Rapids, MI) via the manufacturer-supplied circuit and evaluated using the combinations of ventilator settings shown in Table 2 using pediatric and adult lung models shown in Table 3. A Fleisch pneumotachograph (Series 4700, Hans Rudolph, Shawnee, KS) was connected between the ventilator circuit and the test lung, and the signals for airway pressure, flow, and volume were collected on a breath-to-breath basis by a research data collection system (RSS 100, Hans Rudolph, Shawnee, KS) and recorded to a PC for later analysis. After a 1-minute stabilization period, a minimum of 1 minute of data was collected at each combination of lung model and ventilator settings. All tests were performed at each altitude a minimum of two times. At sea level and each altitude, barometric pressure was verified and the measurement system was calibrated using a 3-liter super syringe.

Table 2. Pediatric and Adult Ventilator Settings Used in the Evaluation

Lung Model	Respiratory Rate	Tidal Volume (mL)	PEEP (cm H ₂ O)	FIO ₂
Pediatric	30	50 & 100	0 & 10	0.21 & 1.0
Adult	15	500 & 750	0 & 20	0.21 & 1.0

Table 3. Pediatric and Adult Lung Models

Lung Model	Lung Compliance	Airway Resistance
Pediatric	0.01 L/cm H ₂ O	20 cm H ₂ O/L/s
Adult Normal	0.1 L/cm H ₂ O	5 cm H ₂ O/L/s
Adult Restrictive	0.02 L/cm H ₂ O	5 cm H ₂ O/L/s

4.0 RESULTS

Changes in V_T varied widely among the devices at sea level and at altitude. From sea level to 22,000 feet, V_T increase ranged from 2-19% with the pediatric settings and 5-33% at the adult settings with the T1. The largest increase occurred at the 250-mL setting. The majority of the volumes >10% of set V_T with the T1 were at the 250-mL V_T settings. The T1 displayed a critical alarm and delivered V_T from 8-40% lower than set V_T at the 500-mL/20-cm H₂O positive end expiratory pressure (PEEP) setting at 22,000 feet and at the 750-mL/20-cm H₂O PEEP setting at both 16,000 and 22,000 feet. The T1 was the only device that consistently delivered V_T within the American Society for Testing and Materials (ASTM) standard with all settings at sea level. The ReVel V_T increase ranged from 22-32% with the pediatric settings and 30-39% with the adult settings. The increases were consistent across all ventilator settings and lung models. Nearly all V_{TS} delivered by the ReVel at sea level and 8,000 feet were less than the 10% ASTM standard. All V_{TS} with the adult settings at 16,000 feet and the pediatric settings at 22,000 feet were within 10% of set V_T . The lower than ASTM acceptable baseline V_T at sea level coupled with no compensation for altitude allowed the delivered V_T to be within 10% of set V_T at 16,000 feet at the adult settings. All V_{TS} with the adult settings at 22,000 feet were >10% of set V_T . The 731-delivered V_T decreased with increases in altitude. The V_T decrease ranged from 9-21% with the pediatric settings and 1-7% with the adult settings. All but one of the delivered V_{TS} using the pediatric settings with the 731 were less than the 10% ASTM standard at sea level and all altitudes with the exception of the 250-mL V_T setting. With the restrictive lung model, the 731-delivered V_{TS} were within 10% of set V_T using the adult settings. No V_{TS} were >10% of set V_T with this device.

Each of the ventilators delivered some V_{TS} that were outside the ASTM standard of $\pm 10\%$ of the set V_T [2]. The most common occurrences were with the adult settings with the T1, the pediatric settings with the 731, and with both pediatric and adult settings with the ReVel. Figures 1-5 show the measured $V_T \pm$ standard deviation at each V_T setting using 0 cm H₂O PEEP and FIO₂ of 0.21. The addition of PEEP or using an FIO₂ of 1.0 did not demonstrably affect V_T changes at sea level or at altitude with any of the ventilators. Respiratory rate was not affected by increases in altitude.

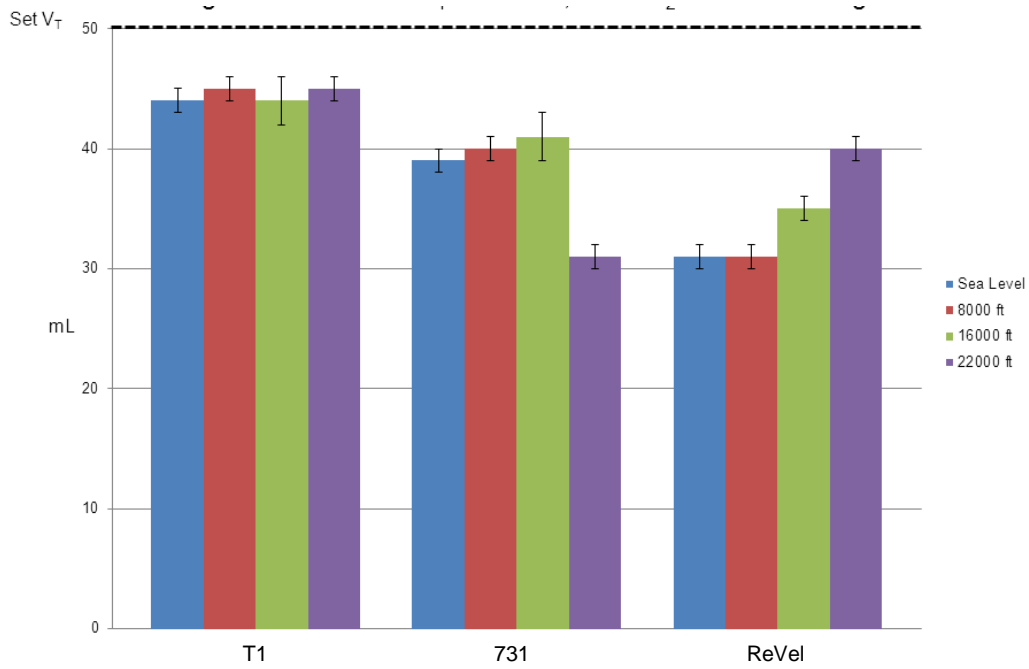


Figure 1. Delivered V_T at 50 mL, 0 cm H_2O PEEP settings.

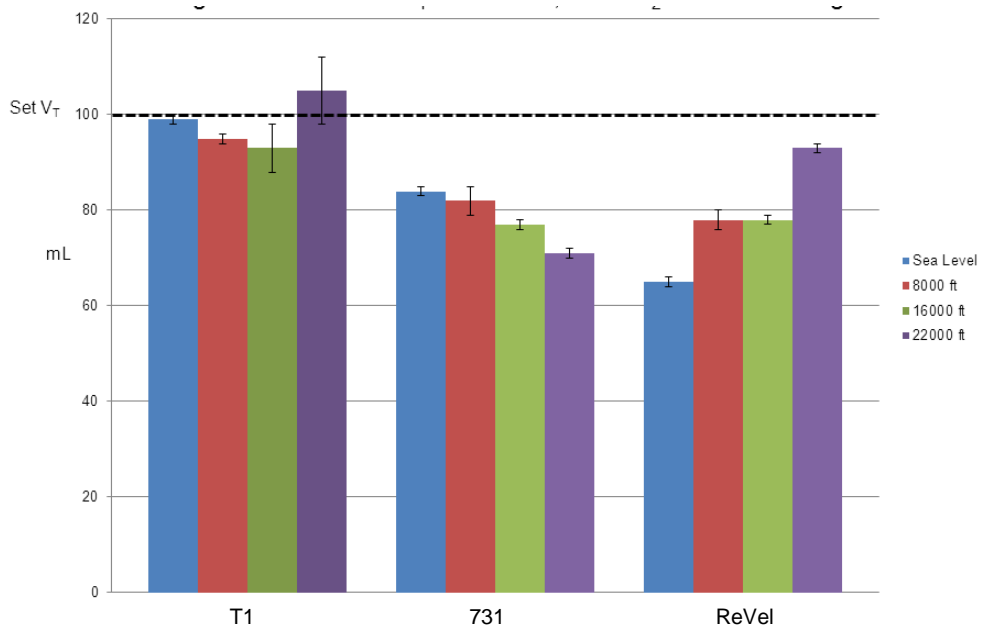


Figure 2. Delivered V_T at 100 mL, 0 cm H_2O PEEP settings.

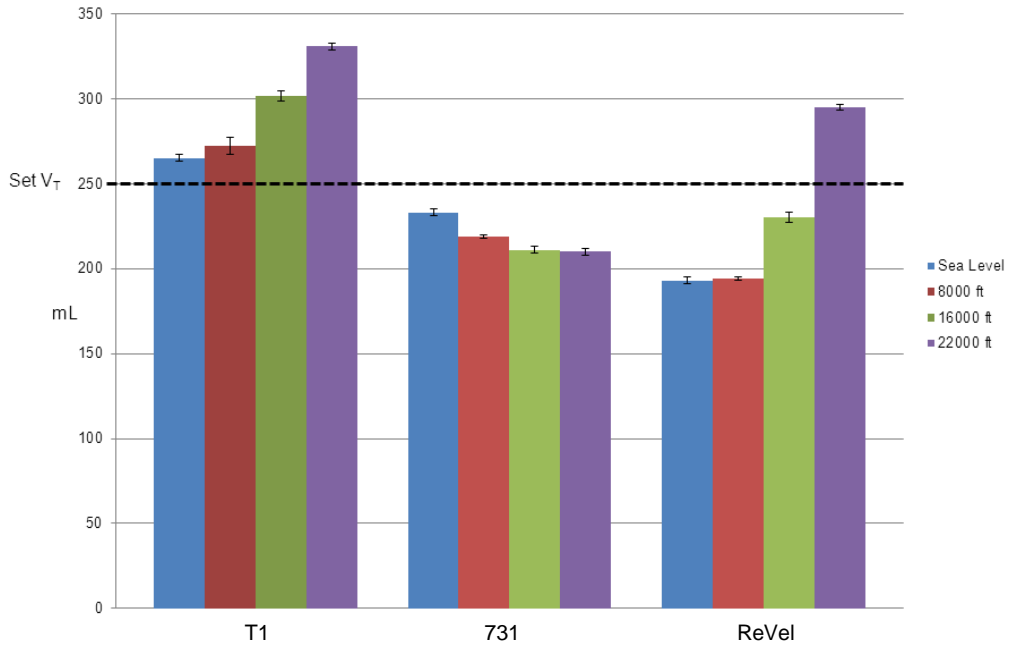


Figure 3. Delivered V_T at 250 mL, 0 cm H₂O PEEP settings.

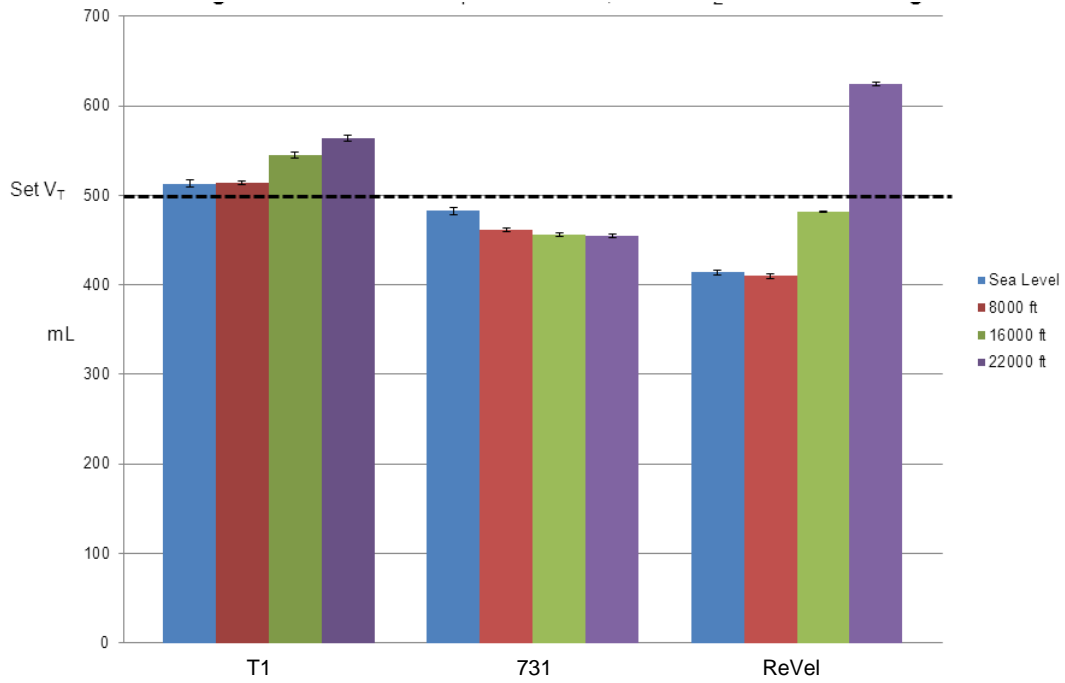


Figure 4. Delivered V_T at 500 mL, 0 cm H₂O PEEP settings.

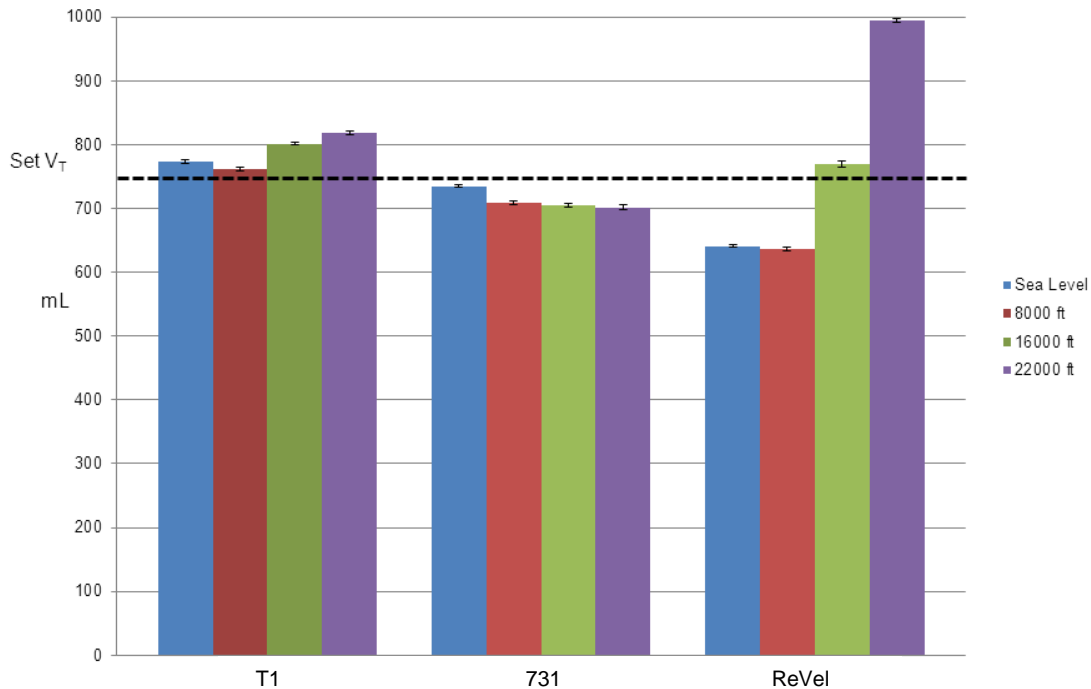


Figure 5. Delivered V_T at 750 mL, 0 cm H₂O PEEP settings.

All differences in V_T from baseline to each altitude were statistically significant ($p < 0.01$) but not necessarily clinically significant. Clinical significance is defined as those V_{T_S} that were outside the $\pm 10\%$ ASTM threshold for accuracy.

5.0 DISCUSSION

The findings of this study show that differences remain among ventilators with respect to V_T delivery at altitude and at sea level at selected settings. The evaluation of changes in V_T in our current project is twofold: (1) measuring the percentage change in delivered V_T with increases in altitude and (2) determining if the delivered V_{T_S} are within the 10% ASTM standard.

Several laboratory evaluations of portable ventilator performance at sea level have been performed in the past decade. The two most recent were by Chipman et al. [3] and our group [4]. Chipman et al.'s study evaluated the performance of 15 portable ventilators at different combinations of airway resistance and lung compliance and found that a number of the devices delivered V_{T_S} that were outside the $\pm 10\%$ of the set V_T . Our group evaluated the performance of four of the newest portable ventilators, including the T1 and 731, and found that as in our current evaluation, with a few exceptions, the devices delivered V_{T_S} that were within the $\pm 10\%$ threshold for accuracy at sea level.

Published works evaluating the performance of mechanical ventilators at altitude date back to the 1960s. Kirby et al. evaluated the Bird Mark VIII respirator at various altitudes from sea level to 34,000 feet in an altitude chamber [5]. Device settings were set at sea level and kept constant through testing at each altitude. Baseline V_T was 705 mL at sea level and increased by 38% at 34,000 feet to a V_T of 1144 mL. Interestingly, the device's respiratory rate steadily decreased at each altitude with increased V_T , keeping minute ventilation relatively constant. Although inspiratory time shortened with decreasing barometric pressure, V_T increased due to

increased gas flow as a result of the lower gas density at altitude. Devices such as the Bird Mark VIII that utilize pressure-controlled breath delivery keep inspiratory pressure constant and lower density gas at altitude flows through a fixed orifice, resulting in larger V_T .

Similarly, Thomas and Brimacombe evaluated the Drager Oxylog ventilator in an altitude chamber at sea level and altitudes of 6,700 and 30,000 feet utilizing normal and restrictive lung models [6]. With the normal lung model, V_T increased by 106% from sea level to 30,000 feet. The restrictive lung model produced similar increases in V_T but to a slightly lesser degree. As with the Kirby study, respiratory rate decreased in response to increasing altitude, but the increase in V_T was so large that minute volume increased progressively from sea level to 30,000 feet. Roeggla and associates found similar percentage increases in minute ventilation with the same ventilator from sea level to an altitude of 9,800 feet [7].

In more recent studies, Flynn and Singh evaluated the Oxylog 1000, 2000, and 3000 ventilators using normal, restrictive, and obstructive lung models over a range of altitudes from sea level to 10,000 feet [8]. The authors found the evaluation results were similar to previous evaluations of the Oxylog 1000 with increases in V_T of 68% and decreases in respiratory rate of 28% at 10,000 feet. The Oxylog 2000 experienced a 29% increase in V_T at the same altitude but with no decrease in respiratory rate. The Oxylog 3000 experienced no change in V_T at any altitude up to 10,000 feet due to the incorporation of an internal pressure sensor that measures barometric pressure and corrects gas flow accordingly. The device did not have any change in respiratory rate during the evaluation.

Rodriguez et al. evaluated two ventilators, Impact 754 and Pulmonetics LTV-1000, used by the U.S. Air Force CCATTS at a range of altitudes from sea level to 15,000 feet in an altitude chamber [9]. Study results showed that the 754-delivered V_T remained within 10% of set V_T at all altitudes. The delivered V_T increased 30% at 15,000 feet with the LTV-1000. At 8,000 feet, the V_T increase with the LTV-1000 was less than 10% of set V_T . The 754 is compressor driven and contains an internal pressure sensor to monitor barometric pressure and adjust V_T accordingly. The LTV-1000 is constant speed turbine driven and has a flow control valve to deliver gas flow. Decreases in gas density at altitude cause the turbine speed to increase to maintain a constant pressure across the control valve, which increases delivered volume.

In two recent studies, Tourtier and associates [10,11] published the results of performance evaluations of the T-BirdVSO2 and LTV-1000 at ranges of altitudes from sea level to 9,800 feet using lung models of ARDS and severe asthma. The T-BirdVSO2 showed >10% decreases in V_T and the LTV-1000 showed increases up to 20% regardless of the lung model.

Our study is the first to evaluate the effect of altitude on V_T delivery of three of the newest portable ventilators. Each device has different mechanisms for monitoring and delivering V_T . The Impact 731 is compressor driven, employs both volume-controlled and pressure-controlled breath types, and measures the volume exiting the ventilator via a single limb circuit to determine delivered V_T . The device has an internal pressure sensor that monitors ambient pressure and adjusts delivered volume in response to barometric pressure changes.

The Hamilton T1 is blower driven and measures both inspired and expired V_T as gas exits and reenters the device via a dual limb or coaxial circuit. The T1 does not allow for traditional volume control ventilation; all breaths are pressure controlled. This explains the V_T overshoot at the 250-mL setting in the normal lung model. With pressure-controlled/volume-targeted breaths, the device is targeting 250 mL, but at a lung compliance of 100 mL/cm H_2O and a minimum delivery pressure of 5 cm H_2O , delivering that volume could not be achieved. Delivered V_T is determined by comparing measured inspired and expired V_{T_S} and using those volumes to adjust

the pressure to deliver the set target V_T . The operator's manual states the device will operate as intended up to an altitude of 13,123 feet. The pressure deviations at a range of ventilator pressures up to this altitude were listed in the manual, but accuracy of the delivered V_T was not noted.

The CareFusion ReVel is blower driven and, like the LTV-1000, uses a flow control valve to deliver gas flow. Pressure and flow are monitored by a pressure differential transducer across a fixed orifice flow transducer at the patient wye. Pressure and flow are transmitted to the ventilator where delivered volume is determined and adjusted to deliver set V_T . With increases in altitude and associated decreases in gas density, the blower speed must increase to maintain the constant pressure drop across the flow control valve, which increases gas flow, resulting in a larger delivered than set V_T . The operator's manual states the device will operate up to 10,600 feet, but V_T accuracy at altitude is not specified.

6.0 CONCLUSIONS

The Impact 731 ventilator delivered V_{TS} that were within the ASTM standards at the adult settings at all altitudes. Neither the ReVel nor T1 have mechanisms for V_T compensation with increases in altitude. Many of the pediatric V_{TS} delivered by the 731 were not within the $\pm 10\%$ standard but were always less than the set V_T . The 731 tended to overcompensate and deliver progressively lower V_T at all settings with increases in altitude. Interestingly, the ReVel delivered V_{TS} that were less than the ASTM standard at both sea level and 8,000 feet, which can partly be attributed to compressible volume lost in the ventilator circuit. Compressible volume is created during inspiration when the pressure required to deliver the set V_T expands the ventilator circuit, resulting in part of the delivered V_T being trapped in the circuit and not reaching the patient's lungs.

The T1 delivered V_{TS} that were much greater than set V_T at the highest altitude. The T1 performed well at the lower altitudes with the exception of the 250-mL settings due to the way pressure-controlled, volume-targeted mode delivers volume, as detailed in the Discussion section. The device had more V_{TS} that were progressively greater than the ASTM standard at 16,000 and 22,000 feet. Aeromedical evacuation crews must be aware of the capabilities and limitations of the ventilators they are using to care for patients at sea level and especially at higher altitudes with Special Forces unpressurized aircraft and in the case of pressurized aircraft decompression.

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LIST OF ABBREVIATIONS AND ACRONYMS

APRV	airway pressure release ventilation
ARDS	acute respiratory distress syndrome
ASTM	American Society for Testing and Materials
ASV	adaptive support ventilation
CCATT	Critical Care Air Transport Team
CPAP	continuous positive airway pressure
DuoPAP	Duo positive airway pressure
FIO₂	fraction of inspired oxygen
PEEP	positive end expiratory pressure
PRVC	pressure regulated volume control
SIMV	synchronized intermittent mandatory ventilation
V_T	tidal volume