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Evaluation of transport ventilators at mild simulated altitude: a bench study in hypobaric chamber

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This study took place in COMEX premices (Marseille, France).

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Authors contribution statement

SB wrote the paper, did the statistics, designed and made the experiment. MC made the experiment and corrected the paper.MG, MF and PM designed and corrected the paper. CM and LN designed and implemented the hypobaric part of the experiment.

Conflict of interest:

Salah Boussen, Mathieu Coulange, Marc Fournier, and Marc Gainnier have no conflict of interest. Pierre Michelet has done consultancies for Air Liquide Medical system in the past without any financial interest. This relation is ended.
Christophe Micoli and Lionel Negrel are employed by COMEX SA, they do not have other conflicts of interest

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Abstract

Introduction: Previous studies on ventilators used for air transport showed significant effects of altitude, in particular in regards to the accuracy of the tidal volume (VT) and respiratory rate. The aim of the study was to evaluate transport ventilators under hypobaric conditions.

Method We conducted a bench study of six transport ventilators in a COMEX hypobaric chamber to simulate mild altitude (1500 and 2500 m (4920 ft and 8200 ft)). The ventilators were connected to a test lung in order to evaluate their accuracy: 1) to deliver a set tidal volume (VT) under normal resistance and compliance conditions at F_{IO2}=0,6 and 1 2) to establish a set PEEP (0, 5,10,15 cmH2O 3) or a set inspiratory pressure in Pressure controlled mode 4) in F_{IO2} setting 5) and in frequency setting.

Results Four ventilators kept an average relative error on VT below 10% without effect of the altitude. The MEDUMAT ventilator was affected by the altitude only at F_{IO2} =1 setting. The Osiris 3 ventilator had more than 40% error even at 1500 m. We found no change in frequency as a function of altitude for any ventilators studied. No clinically significant differences were found between all altitudes with the PEEP or inspiratory pressure settings. While F_{IO2} was affected by altitude, the average error did not exceed 11%, and it is unclear whether this fact is an experimental artifact.

Conclusion We have shown that most of the new transport ventilators tested required no setting adjustment at moderate altitude and are safe at altitude as at sea level under normal respiratory conditions. Older technologies still deliver more volume with altitude in volumetric mode.

Study type: bench study

Keywords: Ventilators, hypobaric chamber, altitude, bench study

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Introduction

Airlifting ventilated patients has become a daily routine for civilian or military emergency mobile services. Two vectors are used: helicopter and airplane. The helicopter is used for the extraction from a dangerous environment, for rapid response and for regional transfers. This vector seems better suited than the road for the unstable patients [1, 2]. The plane is used for transfers over longer distances. These two vectors impact the care of patients, especially critically ill patients. Recently, several teams have become specialized in transporting patients in ARDS or under extracorporeal circulation [3]. The decrease in atmospheric pressure with altitude interferes with mechanical ventilation [4, 5]. Helicopter flights take place at altitudes of less than 3000m and generally around 1500m. During commercial or evacuation flights, the pressure of the aircraft cabin is usually set at a pressure corresponding to altitude of 2500m. Previous studies [6-11] on ventilators used for air transport showed significant effects of altitude, in particular with regards to the accuracy of the tidal volume (VT) and breathing frequency. For some ventilators an increase in VT of over 68% of tidal volume [6] may lead to lung injuries. The next generation of ventilators showed they were better adapted to the hypobaric environment[7] but with adaptations and some residual inaccuracies regarding the VT delivery. While new transport ventilators have emerged[12] with improved performance compared to previous generations, it is unclear how a mild altitude affects performance of new generation ventilators The aim of this bench study was to evaluate the accuracy of six recent transport ventilators to deliver the following adjustable parameters: tidal volume, PEEP, Pressure (in pressure controlled mode), breathing frequency and F_{IO2} in hypobaric conditions corresponding to mild simulated altitudes (1500 and 2500 m (4920 ft and 8200 ft)).

Materiel & Method

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We tested six portable ventilators Osiris 3 and Monnal T60 (Air Liquide Medical System, Paris, France); Oxylog 3000 and Carina (Dräger Medical, Lübeck, Germany), Elisée 350,(ResMed, San Diego, California), Medumat Transport with CO_2 measure WM 28400, (Weinmann Medical Technology, Hamburg, Germany). The ventilators were provided by the manufacturers or were available in our hospital. Three of the tested ventilators are pneumatic (Oxylog 3000, Medumat, and Osiris 3) while all the others are turbine ventilators. Oxylog 3000, Monnal T60, Elisée 350 and Medumat are certified for operation in altitude by the manufacturers. These ventilators have pressure sensors. We listed below the atmospheric pressure range of use of these devices: Elisée 350: 500-1100 hPa, Monnal T60: 600-1150 hPa, Medumat 540-1100 hPa and Oxylog 570-1200 hPa. Carina does not have a pressure sensor. Carina's manufacturer guarantees a normal functioning between 900 and 1100 hPa, and with restriction of flow and maximal pressure between 700-900 hPa. The Osiris 3 does not have a pressure sensor and the operational atmospheric pressure range is not defined. Osiris 3 was the oldest ventilator of the study.

The experimental set-up was very similar to the one used in previous studies [12-14]. The ventilator to be tested was connected to a dual-chamber test lung (TTL 1600, Michigan Instruments, Grand Rapids, Michigan, USA). The flow, pressure and F_{IO2} measurements were made by the following elements respectively:

- A pneumotachograph attached to a differential pressure transducer (TSD 160)
- A differential pressure transducer (± 2.5 cmH2O – Biopac Systems, Goleta, California) for airflow measurement.
- A side-port connected to a pressure transducer (TSD104 -50 to 300 cmH2O, Biopac Systems, Goleta, California) for pressure measurement
- An oxygen electrochemical sensor COMEX CX0085 (Comex SA, Marseille, France).

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Before the experiment, the pneumotachograph and the pressure transducer were calibrated on ground altitude with an ICU ventilator (PB 840 – Puritan Bennett , Pleasanton, California) operating in ATPD (ambient temperature and pressure dry) conditions. The flow transducer was calibrated with a constant flow in Volume Controlled mode. The calibration of the pneumotachograph was checked by measuring a known volume: we administered 2 l of air through the pneumotachograph via a two-liter super syringe. There was less than 1% discrepancy. The pressure transducer was calibrated with the PB840 in 0 and a 10 cmH_20 PEEP level. During the experiments, the flow and pressure signals were acquired with an analog digital converter (MP100; Biopac Systems, Goleta, California). The volume was obtained by integrating the flow signal. The acquisition frequency of all the signals was set at 200 Hz. All data were stored in a computer for subsequent analysis (Acqknowledge software; Biopac Systems, Goleta, California).

The experiments were conducted in COMEX premises in a COMEX chamber C2400 (35 m^2) (COMEX SA, Marseille, France). For the purpose of safety, the ambient oxygen level was actively maintained below 23% by ventilating the chamber. An electrochemical sensor COMANEX CX0043 (COMANEX SA, Marseille, France) measured the oxygen level continuously. In addition to the ground altitude, we simulated an altitude of 1500 m and 2500 m. In order to simulate altitude, the pressure was lowered in the hypobaric chamber. The pressure was set to 835 and then to 745 hPa. These pressures correspond to respective altitude of 1500 m (4920 ft) and 745 hPa (8200 ft) according to the standard atmosphere defined by the International Civil Aviation Organization (ICAO). 745 hPa is the average cabin pressure of jetliners or medical evacuation planes. That is equivalent to an altitude of 2500 m (8200 ft). This value could slightly change with the type of airplane.

Protocol

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The performances were assessed with the test lung connected to the ventilator tested. The parameters were set to normal respiratory mechanics with a normal airway resistance and lung compliance (R=5 cmH_2O/l/sec and C=100 ml/cmH_2O). The resistance was achieved with a parabolic resistor (PneufloRp5 Michigan Instruments, Grand Rapids, Michigan) and the compliance was set on the test lung. All ventilators were operated according to the manufacturer's instructions taking into account the circuit compliance correction algorithm when it was available.

All experiments listed below were performed at ground and simulated altitude of 1500 m and 2500 m.

Tidal volume delivery

For all the ventilators tested, the breathing frequency (f) was set at 12 breaths/min, and the inspiratory time (TI) was 1 second. All ventilators were operated at 5 cmH_2O PEEP. VTs of 300 ml, 500 ml, and 800 ml were set for each ventilator. The measured VT values were averaged over 5 breaths after stabilization. We performed the measurements at F_{IO2} 1 and 0.6 except for the Osiris 3 which does not allow 0.6 but instead uses an undefined air-oxygen mix.

We computed the relative error (RE) for each VT:

$$RE=100 \times (VTm-VT_o)/VT_o$$

VT_O is the set VT, VTm is measured VT. For each altitude and F_{IO2} we averaged the error over VT= 300, 500 and 800 ml.

Breathing frequency and PEEP measurements

For the measures of PEEP and breathing frequency, the setting parameters were the following: VT=500 ml, TI=1 s, f =12 breaths/min, F_{IO2} = 0.6 (air-O_2 mix for Osiris 3).

We averaged the time between 5 consecutives breaths in a steady state and then calculated the frequency. PEEP was set at 0, 5, 10 and 15 cmH_2O except for CARINA that does not allow

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zero PEEP. We computed the relative error for each PEEP level. The error was averaged for the 4 (or 3) PEEP levels.

Pressure accuracy

We tested the pressure accuracy in Pressure Controlled Mode for all ventilators except Osiris 3 that does not have this mode. F_{IO2} was set at 0.6, f=12 breaths/min, TI=1 s and PEEP=5 cmH_2O. The inspiratory pressure was set to 10, 15, 20, and 25 cmH_2O (Inspiratory pressure was defined as the absolute pressure over the PEEP level). Pressures were measured for 5 consecutive breaths after stabilization. We computed the relative error for each pressure and the error was averaged for the 4 levels of pressure.

F_{IO2} accuracy

The ventilators were set as follow: VT=500 ml, f=20 breaths/min, I/E=1:2. The F_{IO2} was varied between 0.21 and 1:

- 0.21-0.4-0.6-1 for Elisée 350, Monnal T60, Carina
- 0.4-0.6-1 for Medumat and Oxylog 3000
- Mix Air/O2 and 1 for Osiris 3

We computed the average error for the 4 or the 3 set F_{IO2}.

Statistical analysis

Each variable value represents the mean of values measured in a steady state. For VT, PEEP, breathing frequency, and pressure accuracy measurements, we considered the mean of 5 consecutive breaths at the steady state. All results were expressed as the mean +/-Standard deviation. For comparative analysis we used a one-way analysis of variance on ranks (Kruskal Wallis test). A p value inferior to 0.05 was considered statistically significant. However, metrology measurements are very precise and lead to situations where differences are always

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significant. Instead, we considered a clinically significant difference to be when the difference between the set and measured parameter exceeds 10%. We did so in order to comply to the standard of "American Society for Testing and Materials" where the tidal volume should be ± 10% of nominal volume [15]. For our statistical analysis, we used SigmaStat software for Windows version 3.5 (SPSS, Chicago, Ill., USA)

Ethical issues

Two volunteer operators conducted the experiments. Both simulated altitudes do not require oxygen in the international regulation of aeronautics. The volunteers health was considered compatible with the relative deprivation of oxygen after medical examination. The oxygen content of the hypobaric chamber was controlled strictly to avoid the risk of explosion in a confined space.

Results

Hypobaric conditions

At a simulated altitude of 2500 m, pressure was 745 +/-5 hPa, temperature was 21 °C and partial pressure of oxygen ($PP0_2$) was actively maintained between 160 and 170 ppm corresponding to a F_{IO2} of 0,215 and 0,22.

At a simulated altitude of 1500 m, pressure was between 835 and 840 hPa with a PPO_2 of 180-190 ppm corresponding to a F_{IO2} of 0.22 to 0.23.

Tidal Volume Delivery

Figure 1 shows the relative errors as a percentage of the VT for three altitude levels for each individual ventilator at two set F_{IO2}, 0.6 and 1. Table 1 lists the VT average error ranges for all the considered F_{IO2}, altitudes, and VT. At a F_{IO2}=0.6, there was no change with respect to the altitude and the errors remain below 10% for all the ventilators excluding the Osiris 3.

At a F_{IO2}=1, excluding Osiris 3 and MEDUMAT, there was no change with respect to the altitude and the errors remain below 7% for all the ventilators. MEDUMAT did not perform well when tested at F_{IO2}=1, all VT were greater than set and the error grew linearly with altitude. This dysfunction began at sea level. Osiris 3 had the same dysfunction at 1500 and 2500 m at both F_{IO2} settings but with normal functioning at sea level (without significant difference between F_{IO2}=1 and air-oxygen mix).

Breathing frequency and PEEP accuracy

We found no change in frequency as a function of altitude for all ventilators studied.

Table 2 lists the average PEEP error in percentage for the different altitudes. No significant differences were found at a relevant clinical level between all the altitudes. The error remains well under 10%. At PEEP of 15 cmH20, an error of 10% represents 1.5 cmH_20. Figure 2 shows the results of the experiments for each individual ventilator.

Pressure accuracy

Figure 3 shows the results of the pressure accuracy experiments. The average errors in percentage ranges are listed in table 2. No significant differences were found at a relevant clinical level between all the altitudes for all ventilators. We did not found any VT changes with altitude although VT values were different across the ventilators.

F_{IO2} accuracy

Figure 4 shows the results of the F_{IO2} experiments. The average errors in percentage ranges are listed in Table 2. None of the ventilators had more than 3% error at 100% so errors are always less than 5% on the F_{IO2} setting. We did find a significant increase in error with respect to the altitude in almost all ventilators. However, the average relative error on the F_{IO2} is still below 11%.

Discussion

There are only a few studies on ventilators under hypobaric conditions due to technical difficulties (availability of hypobaric chambers) or experimental costs (plane or helicopter tests). Early studies showed that older generation pneumatic ventilators did not properly deliver the set tidal volume even at moderate altitudes[6, 10, 16, 17]. These ventilators are still widely used and are the solution in case of pandemic health problems. Studies showed that these devices are inaccurate in delivering volumes even at ground altitude[18-19]. Our study included only one ventilator of this type, the Osiris 3. We found the same type of dysfunction. The Osiris 3 delivers a VT with an error of more than 40% even at mild altitude. This type of ventilator should be avoided for air transport. However, they are less expensive than the new generation of ventilators and are still widely used in air transport.

Studies on more recent ventilators show that they are able to manage altitude without major dysfunction (Impact Eagle 754 and LTV-1000, Oxylog 3000, Elisée 350). The T-bird VS02 must be compensated manually, and LTV-1000 have a drift with increasing altitude greater than 10%[7]. Many of these ventilators are turbine driven. A turbine provides the pressurization and gas flow. Its operation is affected by the reduction of ambient pressure: At altitude, air is less dense and the rotating turbine compresses therefore less air. Recent ventilators have atmospheric pressure sensors in order to compensate this effect (Monnal T60, Oxylog 3000, Elisée 350, Impact Eagle 754, and Medumat). We confirm that new generation ventilators do not have major performances changes at mild altitude even for non-approved ventilators for air transport such as Carina. In our study the Oxylog 3000, Elisee 350, Monnal T60, and

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Carina did not produce any clinically significant differences in VT on the ground or at altitude, and require no adjustment to maintain a constant VT. It seems that taking into account the ambient pressure sensor can properly correct the effects of altitude. Carina does not have pressure sensor and was accurate in volume delivery in the range of pressure we investigated. Maybe, turbine driven ventilators are not very sensitive to mild altitude changes. However, Carina does have a restriction in flow and maximal pressure between 700 and 900 hPa. This limitation was not significant here as we investigated highly compliant lung and normal airway resistance. Previous study found that LTV1000 had 10% increases at 10 000 ft (3300 m) [7]. LTV1000 is a turbine driven ventilator without pressure sensor or altitude compensation like Carina and used by the US Air Force Critical Air Transport Team.

Operation is simplified compared to T-Bird VS02 since compensation is automatic and does not require any particular intervention. Oxylog 3000 is a gas-powered ventilator, provides an automatic compensation of altitude and is not affected at mild altitude. The case of the MEDUMAT is different. This ventilator guaranteed for altitude operation by the manufacturer works correctly at F_{IO2} 0,6 and shows no alteration at altitude. But at F_{IO2} 1, it has a major VT error greater than 20% at sea level altitude and this error grows with altitude. Figure 5 shows the flow waveform of the MEDUMAT at F_{IO2} 0.6 and 1. It is clear that the pneumatic valve has a different behavior with F_{IO2} setting. At F_{IO2} 1, the valve lets too much gas entering the early part of the insufflation, and then the algorithm attempts to stabilize the flow. It seems that during the flow overshoot, the amount of gas is not controlled by the ventilator and is not taken in account by the algorithm for the calculation of the VT. This error grows in magnitude with altitude. F_{IO2} effect on VT accuracy had been shown already in pneumatic ventilators but with high airway resistive load[20]: VT was found to be 30% lower than the VT set under 0.6 F_{IO2}. That was not what we observed for Medumat which has an increase in VT greater than 30% in F_{IO2}=1.

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We did not show any change in frequency with altitude as it was observed in older ventilators[6]. All ventilators precisely deliver PEEP and inspiratory pressure in pressure controlled mode when available. It shows that their airway pressure sensors functioned without alteration at moderate altitudes. No adjustment should be made on pressure setting at varying altitude. Maybe, we can propose to use pressure controlled modes instead of volume controlled for pneumatic ventilators without altitude compensation. Unfortunately, this mode is not always available in these ventilators, like Osiris 3. Although we did not observed volume changes with altitude in pressure mode, we did not study the volume measurement accuracy of the ventilators. Since volume monitoring is a important in pressure mode, further explorations are necessary.

We did not show clinically relevant errors in delivering the set F_{IO2}. However, F_{IO2} seems to change with altitude in our measurement. We attribute this phenomenon to the measurement itself. Indeed, the F_{IO2} sensor used measures the partial pressure of oxygen (PPO_2.).In the chamber, this PPO_2 is subject to slight total ambient pressure change and air pollution by the rejected oxygen (1-2 points F_{IO2}) leading to errors at the same level than the one measured. However, the observed variation of F_{IO2} remains weak and is not clinically relevant.

Limitations of this study are similar to those performed on a test bench [12-14]. Concerning the aeronautical environment, we did not reproduce the vibrations that could disrupt turbines of some ventilators. However, tests in real conditions would be more expensive, and these ventilators are already used in harsh environments such as ambulances. We have not tested at simulated higher altitudes because these operations are rare (mountain rescue or exfiltration in a war zone). Additionally, in this study we investigated only a highly compliant lung and a normal airway resistance.

Conclusion

In conclusion, we have shown that most of the new ventilators require no setting adjustments at moderate altitude and they are as safe at altitude as at sea level under normal respiratory conditions. However, we must remain cautious regarding certain new ventilators, such as MEDUMAT under $F_{IO2} = 1$ or the older ventilator like the Osiris 3. On the other hand, we also showed that only the tidal volume is impacted by altitude operation. Clinicians should be aware of the limitations of the ventilator they use as VT plays a very important part in lung protection.

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Figure captions

Figure 1: Mean values of the average error made on VT for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles). The whisker bars represent errors when greater than rectangles. Figure 1-a F_{IO2}=0,6 . Figure 1-b F_{IO2}=1.

Figure 2: Mean values of the average error made on PEEP for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles). The whisker bars represent errors errors when greater than rectangles. Note that the scale is enlarged and that the errors are less than 10% for all ventilators.

Figure 3: Mean values of the average error made on inspiratory pressure for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles). The whisker bars represent errors errors when greater than rectangles.

Figure 4: Mean values of the average error made on F_{IO2} for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles).

figure 5: flow waveform of Medumat at F_{IO2} =0,6 (a) and F_{IO2} =1 (b). Clearly the valve has a malfunction inducing a higher VT at 100 % than set. This pattern was found for all settings. The two waveforms were recorded at 0 altitude, set VT=500 ml.

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Table 1. V_T Measurements

		Error Range* %	Median* %
F_{IO2} = 0.6			
Altitude m	VT (ml)		
0 m	300	-7.5 - 9.5	-5.5
	500	-7 - -4	-5
	800	-4.5 - 2	-2
1500 m	300	-5.5 - 62	1
	500	-12.5 - 36	-12.5
	800	-4.5 - 23.5	2
3000 m	300	-12.5 - 68	-7.5
	500	-5.5 - 35	-1
	800	-3 - 30	0
F_{IO2} = 1			
Altitude m	VT (ml)		
0 m	300	-13.5 - 26.5	0.5
	500	-13 - 24	4
	800	-13 - 19.5	5.5
1500 m	300	0 - 38.5	7.5
	500	-3 - 29	6.5
	800	-4.5 - 28.5	4
3000 m	300	-6.5 - 60.5	-0.5
	500	-5.5 - 99	4
	800	2 - 37.5	5

* Relative to target volume.

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Table 2. PEEP, Pressure accuracy, and FIO2 Measurements

	Error Range*	Median*
	%	%
PEEP		
Altitude m		
0 m	–3,3 to 5,8	0,1
1500 m	–5 to 3,5	-1,1
2500 m	–2,7 to 4,1	-1,1
Pressure accuracy		
Altitude m		
0 m	–2,1 to 3,9	1,0
1500 m	–2,2 to 6,9	4,4
2500 m	–1,3 to 6,0	4,4
F_{IO2} accuracy		
Altitude m		
0 m	0,5 to 10,9	2,1
1500 m	3,8 to 10,8	7,2
2500 m	2,7 to 11,2	7,4

* Relative to target volume.

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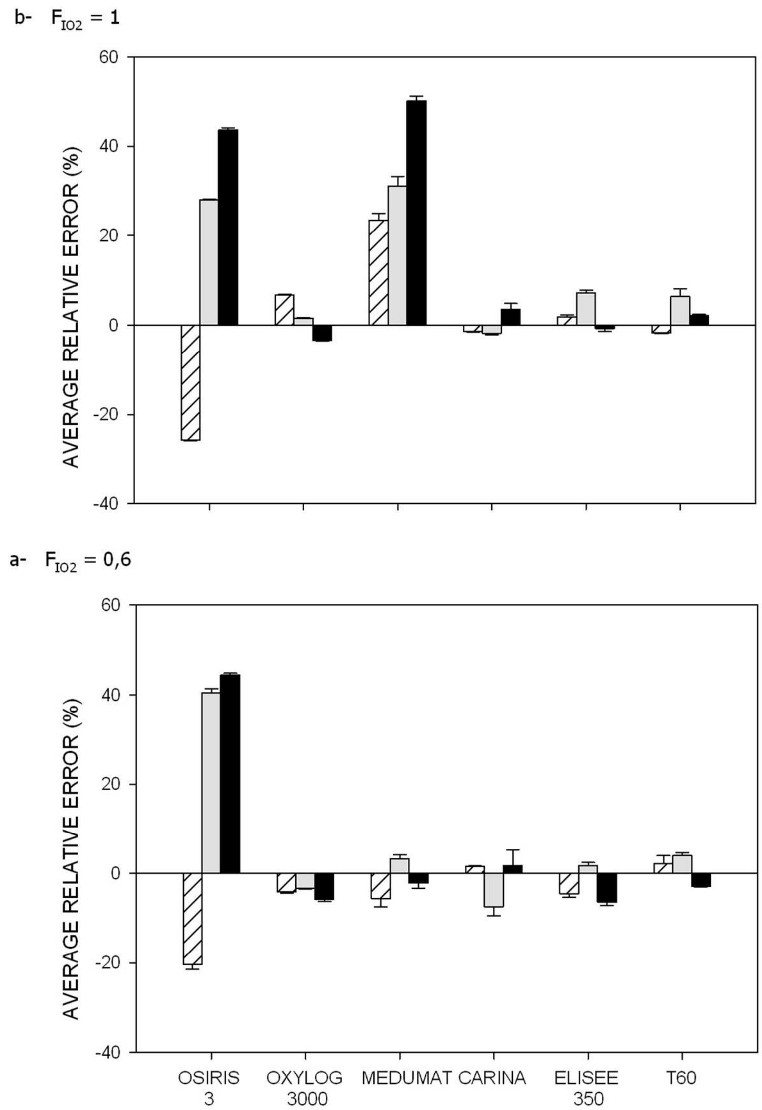

Mean values of the average error made on VT for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles). The whisker bars represent errors when greater than rectangles. Figure 1-a FIO2=0,6 . Figure 1-b FIO2=1.
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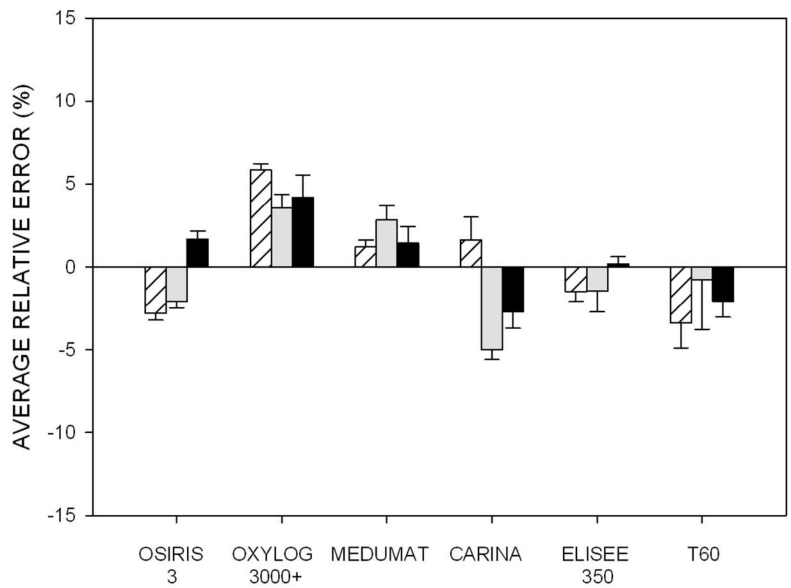

Mean values of the average error made on PEEP for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles). The whisker bars represent errors errors when greater than rectangles. Note that the scale is enlarged and that the errors are less than 10% for all ventilators.

226x180mm (150 x 150 DPI)

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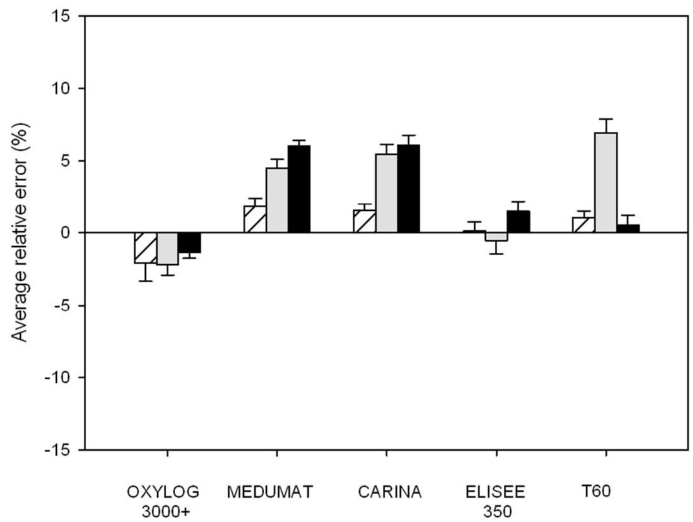

Mean values of the average error made on inspiratory pressure for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles). The whisker bars represent errors errors when greater than rectangles.
206x153mm (150 x 150 DPI)

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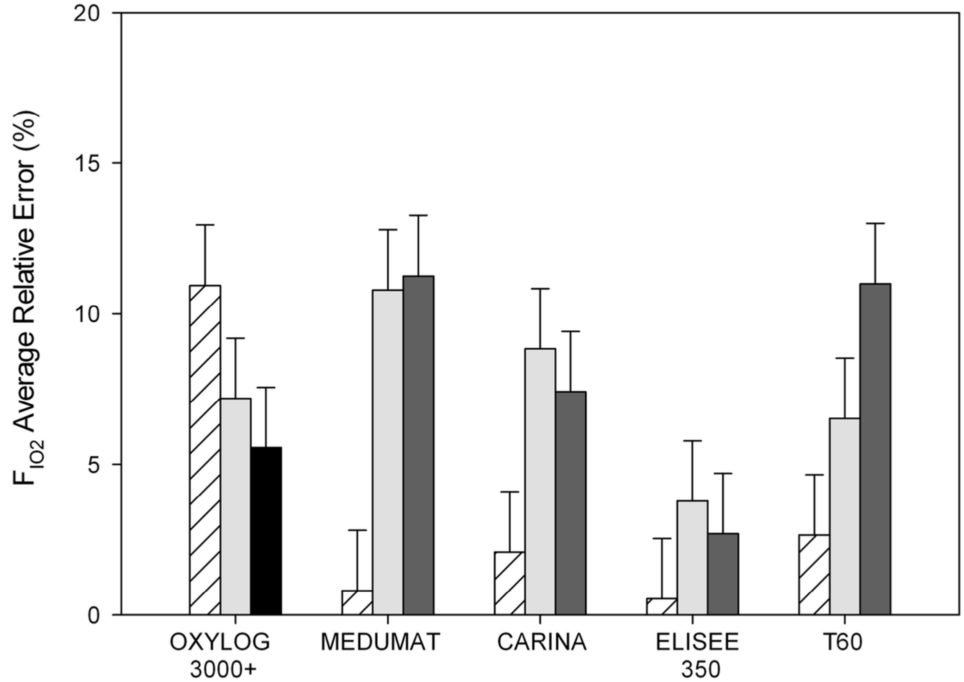

Mean values of the average error made on FIO2 for the three altitudes: Altitude 0 (hatched rectangles), altitude 1500 m (white rectangles) and 2500 m (black rectangles).
113x86mm (300 x 300 DPI)

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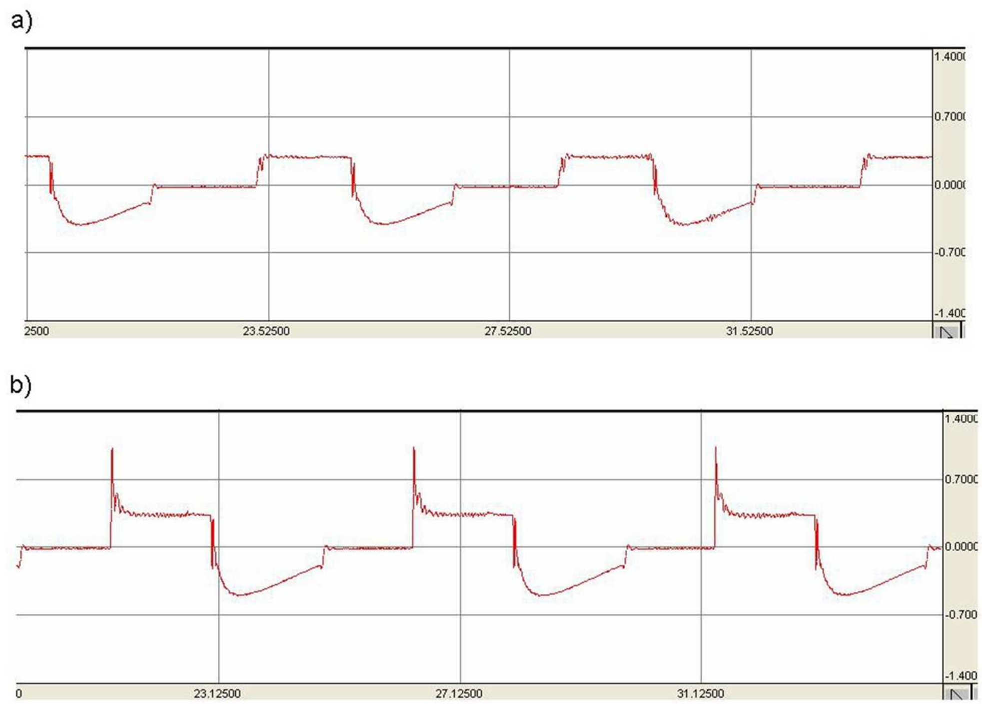

flow waveform of Medumat at FIO2 =0,6 (a) and FIO2 =1 (b). Clearly the valve has a malfunction inducing a higher VT at 100 % than set. This pattern was found for all settings. The two waveforms were recorded at 0 altitude, set VT=500 ml.
254x190mm (96 x 96 DPI)