Effect of Manufacturers Inserted Mask Leaks on Ventilator Performance

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ABSTRACT

Background: Most pressure-support devices use a single circuit with an exhalation port integrated in the mask. The aim was to compare the effects on ventilator performance of masks having different manufacturer inserted leaks.

Methods: We simulated a chronic obstructive pulmonary disease and a restrictive disease. Four ventilators (VENTImotion-WEINMANN; VPAP III STA -RESMED; SYNCHRONY 2-RESPIRONICS; and VIVO 40-BREAS) were tested with the recommended masks and with the masks having the largest and smallest leaks. Tests were done with pressure support levels of 10, 15, and 20 cmH_2O**.** The *in vivo* evaluation compared two ventilators using recommended masks opposed in term of exhaled port resistance. The ventilators were tested with their recommended mask, and after mask exchange.

Results: The mask with the largest leak induced auto-triggering and/or increased inspiratory-trigger sensitivity with VENTImotion under both simulated conditions and with VPAP III STA under the simulated obstructive-disease condition. The mask with the smallest leak increased inspiratory-trigger delay with SYNCHRONY 2 in the simulated obstructive-disease condition and increased rebreathing. The *in vivo* study confirmed the bench results.

Conclusion: When switching to a mask that has a different leak, evaluation is needed to adjust trigger sensitivity and pressurization level and to check the absence of rebreathing.

Keywords: Leaks. Noninvasive ventilation. Interface. Patient-ventilator synchrony. Trigger.

Noninvasive positive-pressure ventilation (NPPV) is recommended as the first-line treatment for acute and chronic respiratory failure.[1] Successful NPPV requires adaptation of the mechanical ventilation to the patient's needs. If ventilation is ineffective or uncomfortable, the patient may have trouble adapting to the device and may even refuse NPPV.[1,2] The broad array of available ventilators and masks should increase the likelihood that a ventilator-mask combination suited to the patient is found. Most ventilators, notably pressure-support (PS) devices, use a single circuit with an exhalation port located as close as possible to the patient's face, often within the mask itself.[3,4] Many manufacturers validate the performances of their ventilators only with their own masks. Using a ventilator with a mask from a different manufacturer is therefore not recommended. However, a patient who is acclimatized to a specific ventilator may be more comfortable with a mask from a different manufacturer. In addition, patients on home ventilation have their ventilator settings determined at the hospital with a given mask but often subsequently switch to another mask at home.

The aims of this study were to compare the leak levels of several masks and to evaluate the effects of masks having different leak levels on the performance of four ventilators.

MATERIALS AND METHODS

Experimental in vitro study

Evaluation of manufacturers inserted mask leaks (MIML) through different masks

The pressure/flow relationship of the mask exhalation port (leak) was evaluated by fitting the mask to a life-size mannequin. Compressed air was used to pressurize the mask to a range of predetermined values between 5 and 20 cm H_2O. A pneumotachograph (Fleisch #1; Gould Electronique, Longjumeau, France) coupled to a differential pressure transducer (Validyne DP45 ± 3.5 cm H_2O, Validyne, Northbridge, CA) served to measure the airflow

delivered to the mask. Another differential pressure transducer (Validyne DP45 ± 35 cm H_2O) with one port connected to the mask and the other open to the atmosphere was used to measure the pressure inside the mask.

Evaluation of the effect MIML on ventilator performance

A two-chamber Michigan test lung (MII Vent Aid TTL; Michigan Instrument, Grand Rapids, MI) was used to evaluate the effect of manufacturers inserted mask leaks on ventilator performance (Figure 1). To simulate a respiratory effort, the second chamber of the Michigan test lung (driving chamber) was connected to a flow-rate generator that could generate various waveforms previously stored in a microcomputer. The two chambers were physically connected to each other by a small metal component that allowed the driving chamber to lift the testing chamber. The flow rate generator, developed by our laboratory as previously described, was built by associating pressurized air, flow-rate measurement, and a servo valve driven by a microcomputer [5]. An adult-sized mannequin head was connected to the lung chamber via a circuit with a dead space of 120 ml. Two adult-sized mannequin head were available according to easily adapt the masks without additional leaks between the mask and the mannequin. Flow ($\dot{V}$) was measured between the mannequin head and the lung chamber using a pneumotachograph (Fleish n°2, Lausanne, Switzerland) connected to a differential pressure transducer (Validyne DP 45 ± 3.5 cm H_2O). Pressure at the level of the mask (Paw) was measured via a differential pressure transducer (Validyne DP 45 ± 56 cm H_2O). A second pneumotachograph was inserted between the mask and the ventilator to measure the leak through the mask exhalation port $\left(\dot{V}_{leak} = \dot{V}_c - \dot{V} \text{ in figure 1}\right)$ and the volume of air that returned into the ventilator circuit during expiration. Signals were digitized at 200 Hz by an analogic/digital system (MP100, Biopac Systems, Goleta, CA) and recorded on a microcomputer for further analysis. Each mask was carefully fitted on the mannequin head

and before each recording we systematically checked that 30 cm H_2O of positive pressure, did not induce leak measurable by the pneumotachograph when the exhalation port and the connection to the lung chamber were closed. To obtain this result mask strips were very tight round the mannequin head, which could not be done in an *in vivo* condition. In addition we retrospectively checked that instantaneous leak $\left(\dot{V}_{leak} = \dot{V}_c - \dot{V}\right)$ corresponded to the expected leak in accordance with Paw.

The compliance of the test chambers and the resistance (a parabolic airway resistor) (Pneuflo® Airway resistor Rp20 and Rp5; Michigan Instrument, Grand Rapids, MI) were set at 100 ml/cm H_2O and Rp20, respectively, to simulate obstructive disease and at 30 ml/cm H_2O and Rp5, respectively, to simulate restrictive disease. Respiratory rate was set at 10 breaths/minute for the obstructive-disease simulation and 20 breaths/minute for the restrictive-disease simulation. During both simulations, spontaneous tidal volume (V_T) was 300 ml and the ratio of inspiratory time over total respiratory-cycle duration (T_I/T_{TOT}) was 33%. The inspiratory flow contour was rounded to simulate a physiological flow contour.

Positive end-expiratory pressure (PEEP) was 4 cm H_2O. Three levels of PS were evaluated: 10, 15, and 20 cm H_2O, these corresponded to an inspiratory positive airway pressure (IPAP) of respectively 14, 19, and 24 cm H_2O. Whenever possible, the inspiratory trigger was set at the most sensitive level that did not induce auto-triggering, whereas the expiratory trigger was set at the most sensitive level associated with a minimum inspiratory time duration (T_I) of 1 sec.

As previously described,[5] the following parameters were computed from each pressure and/or flow trace: inspiratory trigger sensitivity, based on the trigger time (ΔT), i.e., the time from inspiration onset to achievement of an airway pressure greater than the PEEP level. Pressurization performance (PP) was evaluated as the mean pressure above the PEEP level during the first 0.5 sec of inspiration.[6] This mean pressure was expressed as a

percentage of the PS level delivered by the ventilator. TI was calculated from the flow signal and VT (the volume delivered to the lung chamber) by integrating the flow signal. Rebreathing was evaluated as the percentage of the expired volume remaining in the circuit at the end of expiration.[4,7].

Devices

The relationship between the leak level and airway pressure was measured for six nasal masks and four face masks (Table 1). The choice of the ventilator was based on the ventilator specification which advised to use a specific mask from the same manufacturer. Four ventilators were tested (Table 2) with their recommended masks and with the masks having the largest and the smallest leak levels. Evaluation with non-recommended masks were done without changing the ventilator settings; if auto-triggering occurred, a second evaluation was done after setting the inspiratory trigger at the most sensitive level not associated with auto-triggering and the expiratory trigger at the most sensitive value associated with a minimum TI of 1 sec.

Experimental in vivo study

Devices tested

Two ventilators were tested : The one for which the recommended mask had the most resistive exhaled port and the one for which a recommended mask had the less resistive exhaled port. The aim was to test two the ventilators with their recommended mask, and thereafter to exchange the masks.

Subjects

This study was approved by the local ethic committee and written informed consents were obtained for all subjects. Four healthy subjects aged 36-51 years were included.

Methods

Two pneumotachographs (Fleisch #2, Lausanne, Switzerland), each connected to a differential pressure transducer (Validyne MP 45, Northridge, CA; ±3 cm H_2O), were used (Figure 2). One pneumotachograph was inseted upstream to the mask exhalation port whereas the other was inseted downstream to the mask exhalation port. In fact the first pneumotachograph was before the mask which was fixed to a mannequin face (Figure 2). The air entered through the mannequin nostrils into a short tube (length 20 cm, internal diameter = 0.75 cm, total resistance at 1L/sec 6.8 cm H_2O . L^{-1} . sec) which was connected to the pneumotachograph; and this second pneumotachograph was connected to the subject via a mouth piece while the subject wore a nose clip to be sure that no leak occur between the subject and the interface. This additional circuit induced a dead space increase of 45 ml. Airway pressure (Paw) was measured using a differential pressure transducer (MP 45 model, Validyne ± 100 cm H_2O, Northridge, CA) connected to the mask (Figure 2). All signal outputs were digitized at 200 Hz (MP100, Biopac Systems, Goleta, CA) and recorded.

Experimental protocol

With each device adjustments were performed with the/a recommended mask. Pressure support was adjusted with the study participant sitting comfortably. The backup rate was set at the lowest rate. Positive end-expiratory pressure was set at 4 cm H_2O. The inspiratory positive airway pressure level, the slope of pressure support and the expiratory trigger were adjusted according to the preference of the subject. The inspiratory trigger was set at the most sensitive level that did not induce autotriggering. The study participants were blinded to the condition. This initial condition was maintained to obtain 10 minutes of stabilization followed by 3 minutes of recording. Thereafter, the recommended mask was changed for the non

recommended mask without changing the settings of the ventilator. This new condition was maintained to obtain 10 minutes of stabilization followed by 3 minutes of recording.

Data analysis

The recordings were analysed breath by breath. The parameters analysed were the same as during the experimental in vitro study.

Statistics of the in vitro and the in vivo studies:

Each parameter was averaged for 30 respiratory cycles. Data were given as means ± SDs. For the *in vitro* study the effect of the masks change was evaluated by using a Student's *t* test. The level of significance was set at 5 %. Because the number of subjects tested in the *in vivo* study was too small, the comparison was only qualitative.

RESULTS

Experimental in vitro study

The pressure-flow relationships of the mask ports are shown in Figure 3. The characteristics of the masks were very similar, with the exception of the Weinman SOMNOplus, whose resistance was higher, and the Resmed Ultra Mirage Full Face Medium, whose resistance was lower. These two masks were therefore tested with each of the four ventilators.

Performance of the ventilators with their recommended masks

The performance characteristics of the four ventilators tested with the recommended masks are reported in Table 3. We found major differences across ventilators regarding inspiratory-trigger sensitivity, T_I, and V_T. Synchronization between the simulated patient

profile and the ventilator was possible except with the VIVO 40 ventilator under the restrictive-disease condition at IPAP ≥19 cm H_2O.

Effects on ventilator performance of the mask with the largest intentional leak

The performance characteristics of the ventilators with the mask having the largest MIML are shown in Table 4. Auto-triggering occurred with the VENTImotion in both simulated conditions and with the VPAP III STA under the obstructive-disease condition with the highest IPAP level. In addition, inspiratory-trigger sensitivity increased with the VPAP III STA in the obstructive-disease simulation when IPAP was 14 or 19 cm H_2O. This increase in inspiratory-trigger sensitivity was associated with an increase in PP. Performance of the SYNCHRONY was not noticeably changed by using the high-leak mask. In contrast, performance of the VIVO 40 was substantially affected, with differences between the two simulated conditions and across PS levels and with either a decrease or an increase in inspiratory-trigger sensitivity.

Adjustment of the inspiratory trigger corrected the auto-triggering observed with the VPAP III STA and VENTImotion under the obstructive-disease condition. After this adjustment, inspiratory-trigger sensitivity was better than with the recommended mask (Table 5). In contrast, inspiratory-trigger adjustment corrected the auto-triggering observed with the VENTImotion under the restrictive-disease condition only when IPAP was 14 cm H_2O. Ventilator-setting adjustment did not avoid the auto-triggering observed with VIVO 40 under the restrictive-disease condition when IPAP was ≥ 19 cm H_2O.

Effects on ventilator performance of the mask with the smallest intentional leak

Use of the mask with the smallest MIML either increased or decreased inspiratory trigger sensitivity, T_I, V_T, and PP (Table 6). Under the restrictive-disease condition with a

high PS level, this mask was associated with increased rebreathing (Table 6). Auto-triggering occurred with SYNCHRONY 2 and the highest PS level in the obstructive-disease condition. Ventilator-setting adjustment was not possible, since trigger setting was automatic. In contrast, this mask corrected the auto-triggering observed with VIVO 40 in the restrictive-disease condition after ventilator-setting adjustment.

Experimental in vivo study

The ventilators and masks chosen for the *in vivo* study were first, the VENTImotion with its SOMNOplus mask, considering that this mask had the most resistive exhalation port, and second the VPAP III STA because this device can set with the "Resmed Ultra Mirage Full Face" Mask which had the less resistive exhalation port.

The results obtained in the four subjects with these two ventilators and their recommended masks were presented in Table 7. As previously observed in the in vitro study, when the level of pressure support was similar in both conditions, VPAP III STA was associated with a longer T_I, a higher V_T, a shorter ΔT and higher PP than the VENTImotion. In addition, rebreathing was observed in two subjects with the VENTImotion.

The results obtained in the four subjects with these two ventilators but after mask change (which was not recommended by the manufacturers) were presented in Table 8. We observed that, as observed in the *in vitro* study, auto-triggering occurred with VENTImotion when the leak was increased by using the Resmed Ultra Mirage Full Face mask and rebreathing occurred in 3 subjects with the VPAP III STA when the leak was decreased by using the SOMNOplus mask.

DISCUSSION

This bench study showed substantial differences in manufacturer inserted leaks levels across masks that are widely used in clinical practice and established that leak level affected ventilator performance. The mask with the largest leak was associated with auto-triggering and/or decreased inspiratory-trigger sensitivity with three of the four ventilators. The mask with the smallest intentional leak was associated with increased rebreathing. An *in vivo* evaluation confirmed these results.

Although it was not the aim of the study, striking differences were observed between the ventilator devices. For some ventilator and in certain conditions the inspiratory trigger delay was inacceptable. It was previously considered that an acceptable inspiratory trigger needs to have a ΔT of less than 150 msec. None of the ventilators reached this value when simulating an obstructive disease and only two ventilators reached this value when simulating a restrictive disease. The systematic higher ΔT when simulating an obstructive disease than when simulating a restrictive disease was mainly explained by the fact that for the same negative pressure inside the testing chamber, produced by the driving chamber, at the beginning of the inspiration, the depression at the mask level was less when simulating the obstructive disease than when simulating the restrictive disease. This may be explained by the presence of a higher resistance (RP20 *vs* RP5) between the testing chamber and the mask which impedes the transmission of the negative pressure to the mask.

The other important difference between ventilators is the large difference in VT despite a similar level of pressure support. This was explained by differences in the TI which was mainly influenced by the difference in expiratory trigger sensitivity between ventilators. For these reasons it is not recommended to change a pressure support device for another device without a new complete adjustment of the ventilator settings to the patient.

Importantly, the effect of the MIML level on the inspiratory trigger is variable and unpredictable. In one study, increasing the leak either induced auto-triggering or had no effect

on the inspiratory trigger, depending on the type of ventilator.[8] Similarly, a leak greater than 10 L/min was associated with auto-triggering in seven of eight ventilators and with effects on inspiratory-trigger time consisting in an increase (four ventilators) a decrease (one ventilator), or no change (two ventilators).[9] We also found that the inspiratory trigger was not consistently affected by the leak level. Some of these discrepancies may be ascribable to the experimental conditions. For example, one study found no effect of leakage on the inspiratory trigger,[10] whereas another, conducted on the same ventilators, showed that a large leak induced auto-triggering when the inspiratory trigger was excessively sensitive [11]. From a mechanical point of view, the effect of a leak on the inspiratory trigger cannot be predicted without detailed information on the algorithm used to drive ventilator behaviour, and particularly the ventilator whose aim is to maintain a constant PEEP as long as it detects no new patient effort. This behaviour is different if we assume that the ventilator acts as a perfect flow generator ($\dot{V}_c = Cst$) or a perfect pressure generator ($P_v = Cst$). In the first case, a decrease in the leak level facilitates the detection of the inspiratory effort by the ventilator, while this is not true in the second case (for more explanation see the online depository).

Similarly, the effect of the leak on the expiratory trigger is unpredictable without detailed information on the ventilator software. Usually, the expiratory trigger is based on detection of the time when the flow rate reaches a given percentage of the peak inspiratory flow. The presence of a leak ($\dot{V}_{leak}$) may partly mask the fall in the patient's inspiratory flow ($x\%\dot{V} \neq x\%\left(\dot{V} + \dot{V}_{leak}\right)$). Underestimation of $\dot{V}_{leak}$ should theoretically delay the expiratory trigger time, whereas overestimation should shorten the expiratory trigger time. Therefore, underestimation of the leak should increase T_I and V_T, whereas overestimation should decrease both parameters. Thus, although the level of the leak is determined by the mask, estimation of this leak and therefore of the variations in T_I and V_T is determined by the ventilator.

Our findings may apparently differ from a recent study of the effects of various masks on the performance of a range of ventilators [12]. However, these apparent discrepancies may be ascribable to differences in the study ventilators. Indeed, in the other study, the ventilator whose performance was the most affected by the mask with the largest leak in our study was not tested.[12] The experimental conditions were also different. Respiratory system compliance was equal to or lower than 30 ml/cm H_2O in the other study [12] and equal to or greater than 30 ml/cm H_2O in our study. In our study, the effects of mask changes were greatest under the obstructive-disease condition with a high respiratory-system compliance (100 ml/cm H_2O). In addition, at a similar level of PS, VT measured in the other study [12] was higher than in our study, although respiratory compliance was lower, suggesting that the simulated patient effort was higher. Nevertheless, increasing the leak affected VT in both studies. We also showed that inspiratory-trigger performance was affected by the mask having the largest leak and that rebreathing was affected by the mask having the smallest intentional leak.

Our index of rebreathing [4,7] did not measure exactly measure the rebreathing volume. In fact, by inserting a pneumotachograph between the mask with its exhalation port and the ventilator, we were able to measure the expiratory gas which returned and remained upstream the exhalation port just before the next inspiration. Obviously this value overestimated the rebreathing, since a part of this volume is washed through the exhalation port and toward the atmosphere during inspiration. Nevertheless ideally, the totality of expiratory gas should be washed through the exhalation port at the end of expiration. This means that VT/TE should be lower than the leak during expiration. When regarding the breathing pattern of patients under pressure support in the literature, the mean VT/TE was equal to 243 ml/sec (14.5 L/min) during sleep in stable neuromuscular patients [13], equal to 333 ml/sec (20 L/min) during wakefulness in both neuromuscular patients and chronic

obstructive pulmonary disease patients [14], and equal to 370 ml/sec (22 L/min) in intubated patients, having an acute respiratory failure, who could not breathe spontaneously during more than 15 min [7]. These data suggest that the leak should exceed 20 L/min when treating chronic respiratory failure and 22 L/min in case of acute respiratory failure if the clinician want to be sure that no expired gas is forced back to the circuit upstream to the exhalation port, ready to be in part rebreathed at the next inspiration. In our study, this was not the case for all the masks when a minimal PEEP of 4 cmH_2O was applied (see the Figure 3). Notably the SOMNOplus mask would induce an additional rebreathing in almost any clinical condition considering that its leak was equal to 12.6 L/min for a 4 cmH_2O pressure (Figure 3).

The size of the mask may also affect the rebreathing by modifying the apparatus dead space and one can suggest that facial masks markedly increased this value. However, Saatci et al. [15] demonstrated that the exhalation port in the nasal bridge of face masks generates a beneficial flow path that decreases the apparatus dead space, but only if leak during the expiratory phase is sufficient (see above). In this condition, they observed that the dynamic apparatus dead space of the different masks varied only from 35 ml to 60 ml while their static volume varied between 100 ml and 400 ml [15]. This reduction of apparatus dead space induced by accurately positioning the exhalation port to the mask could therefore be considered as a beneficial effect of using a single circuit system if, obviously, the leak during the expiratory phase is sufficient.

The change of the leakage was not the unique factor which may influence the result when the mask change and our experimental conditions did not cover all the hazards and difficulties observed during non-invasive ventilation. A mask and a mouth leakage may greatly disturb the ventilator performances. In addition, interaction of mask with the face may impact the geometry of the airflow route and therefore the interaction between the nasal mask and the face and the connecting tube influence the total circuit resistance [16]. In addition, we

did not evaluate the influence of the airway route breathing between the nose and the mouth; but it is clear that a facial mask allows a reduction of the upper airway resistance by breathing through the mouth and bypassing the nasal resistances which may represent 50% of the total airway resistances. This mouth route is generally preferred during acute respiratory failure [17]. To limit our evaluation to the MIML effects we used the same connecting tubes in each condition and according to Windisch et al. [16], we assumed a minor effect of the size of the mask on the total circuit resistance with the respect of its own resistance.

Our study had other limitations : TI/Ttot is generally shortened in a COPD population in order to prolong TE and avoid intrinsic PEEP due to the expiratory flow limitation induced by the dynamic airway collapse. Because, unfortunately, our model did not simulate this phenomenon we did not observe intrinsic PEEP and we did not need to prolong TE. Nevertheless, it was interesting to observe that a similar pattern of breathing without mechanical ventilation during the simulation of both obstructive disease and obstructive disease did not induce a similar inspiratory trigger when adding the assisted mechanical ventilation.

The reason for which the VIVO 40 ventilator presented auto-triggering with the recommended mask when simulating restrictive disease and when pressure support was above 10 cmH_2O is unclear. One explanation could be the presence of the pressure signal noise induced by both the low compliance of the simulated patient and the high pressure variation between inspiration and expiration which both facilitated auto-triggering.

The correction of the trigger sensitivity after mask change was made only in case of auto-triggering considering that if auto-triggering does not occur, the clinician would not be able to clinically detect the change of the trigger sensitivity and therefore would have no reason to change it.

In conclusion, changes in manufacturers' inserted leak through the mask exhalation port may modify patient-ventilator synchronization and ventilator performance. Therefore, we recommend a routine clinical evaluation at every mask change in order to check inspiratory-trigger sensitivity and pressurization, which should be adjusted if needed, and to check the absence of rebreathing. In addition our results and the pattern of breathing of patients under pressure support in the literature suggest that the leak of the mask should exceed 22 L/min, which was not observed with all the masks when the PEEP level was at its lowest value.

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Table 1. The ten masks tested

BRAND	MODEL
NASAL MASKS	
WEINMANN (Hamburg, Germany)	SOMNO*plus*
RESMED (Saint Priest, France; North Ryde, Australia)	Ultra Mirage
RESMED (Saint Priest, France; North Ryde, Australia)	Mirage Activa Large
RESPIRONICS (Nantes, France; Murrysville, PA)	Profile Lite
FISHER & PAYKEL (Villebon-s/Yvette, France)	Flexifit 407
BREAS (Saint Priest, France; Mölnlycke, Sweden)	IQ 50293
FACE MASKS	
RESMED (Saint Priest, France; North Ryde, Australia)	Ultra Mirage Full Face Medium
RESPIRONICS (Nantes, France; Murrysville, PA)	Comfort Full
FISHER & PAYKEL (Villebon-s/Yvette, France)	Flexifit 432
WEINMANN (Hamburg, Germany)	JOYCE Full Face

Table 2. The four ventilators tested

BRAND	MODEL	"Recommended" Mask
WEINMANN (Hamburg, Germany)	VENTImotion	SOMNO*plus*
RESMED (Saint Priest, France; North Ryde, Australia)	VPAP III STA UM Cfg	Ultra Mirage
RESPIRONICS (Nantes, France; Murrysville, PA)	SYNCHRONY 2	Profile lite
BREAS (Saint Priest, France; Mölnlycke, Sweden)	VIVO 40	IQ 50293

Table 3: Performance of the ventilators with the recommended masks

Conditions			Measured parameters						
Ventilator	Patient profile	PS (cmH_2O)	PEEP (cmH_2O)	IPAP (cmH_2O)	ΔT (msec)	TI (sec)	VT (ml)	Rebreating (% of VT)	PP (%)
VENTImotion	Obstructive disease	10	4.0 ± 0.02	14.9 ± 0.04	629 ± 106	1.6 ± 0.03	330 ± 7	0 ± 0	0.0 ± 0.1
		15	4.0 ± 0.01	19.7 ± 0.04	618 ± 42	1.6 ± 0.04	375 ± 6	0 ± 0	0.0 ± 0.1
		20	4.0 ± 0.02	25.3 ± 0.07	618 ± 135	1.7 ± 0.07	450 ± 24	0 ± 0	0.0 ± 0.1
	Restrictive disease	10	4.0 ± 0.02	15.6 ± 0.04	224 ± 5	1.0 ± 0.00	406 ± 1	0 ± 0	31.6 ± 1
		15	4.0 ± 0.02	20.3 ± 0.08	218 ± 7	1.1 ± 0.01	471 ± 1	17.2 ± 0.3	26.2 ± 1.4
		20	4.0 ± 0.02	25.5 ± 0.11	218 ± 7	1.0 ± 0.59	575 ± 117	22.5 ± 5	20.3 ± 1
VPAP III STA UM Cfg	Obstructive disease	10	3.7 ± 0.01	13.5 ± 0.02	230 ± 16	2.3 ± 0.02	478 ± 2	0 ± 0	31.1 ± 3.2
		15	3.7 ± 0.01	18.3 ± 0.02	214 ± 19	2.3 ± 0.02	617 ± 2	0 ± 0	32.1 ± 3.7
		20	3.7 ± 0.01	23.0 ± 0.04	248 ± 12	2.4 ± 0.01	754 ± 2	0 ± 0	24.0 ± 2.5
	Restrictive disease	10	3.6 ± 0.02	13.8 ± 0.36	112 ± 5	1.0 ± 0.02	392 ± 6	0 ± 0	52.2 ± 2.6
		15	3.6 ± 0.01	18.2 ± 0.03	111 ± 5	0.8 ± 0.01	366 ± 5	0 ± 0	53.1 ± 1
		20	3.6 ± 0.01	22.9 ± 0.04	111 ± 5	0.7 ± 0.03	398 ± 11	0 ± 0	52.6 ± 1.1
SYNCHRONY 2	Obstructive disease	10	3.8 ± 0.01	13.7 ± 0.02	299 ± 21	2.4 ± 0.07	500 ± 13	0 ± 0	23.1 ± 4.3
		15	3.8 ± 0.13	18.7 ± 0.08	274 ± 82	2.4 ± 0.44	659 ± 122	0 ± 0	27.4 ± 13.7
		20	3.7 ± 0.02	23.6 ± 0.10	248 ± 25	2.7 ± 0.20	828 ± 63	0 ± 0	28.6 ± 8.1
	Restrictive disease	10	3.8 ± 0.01	15.9 ± 0.05	136 ± 3	1.0 ± 0.01	402 ± 1	0 ± 0	46.0 ± 0.7
		15	3.8 ± 0.03	20.6 ± 0.06	139 ± 30	1.0 ± 0.01	450 ± 1	0 ± 0	48.8 ± 0.7
		20	3.9 ± 0.01	25.4 ± 0.09	139 ± 35	1.0 ± 0.01	497 ± 1	0 ± 0	48.7 ± 1
VIVO 40	Obstructive disease	10	3.7 ± 0.02	12.2 ± 0.17	402 ± 46	1.9 ± 0.08	386 ± 13	0 ± 0	1.9 ± 2.6
		15	3.7 ± 0.02	16.6 ± 0.10	342 ± 69	2.4 ± 0.06	558 ± 15	0 ± 0	4.4 ± 2.1
		20	3.7 ± 0.07	20.8 ± 0.19	381 ± 88	2.5 ± 0.17	658 ± 47	0 ± 0	2.7 ± 2.4
	Restrictive disease	10	3.7 ± 0.03	14.6 ± 0.14	217 ± 24	1.0 ± 0.01	389 ± 2	0 ± 0	19.2 ± 4.5
		15	AT	AT	AT	AT	AT	AT	AT
		20	AT	AT	AT	AT	AT	AT	AT

Abbreviations: PS, pressure support; PEEP, positive end-expiratory pressure ; IPAP, inspiratory positive airway pressure measured; TI, inspiratory time; VT, tidal volume; rebreathing, percentage of expired volume remaining in the device circuit at the end of expiration; ΔT, time

from inspiration onset to airway pressure above PEEP; PP, pressurization performance (see methods section for the definition); AT, auto-triggering.

Table 4: Performance of the ventilators with the mask having the largest leak (Resmed Ultra Mirage Full Face Medium) while the ventilator settings remained those adapted with the recommended masks.

Conditions		Measured parameters						
Ventilator	Patient profile	PS (cmH_2O)	IPAP (%)*	ΔT (%)*	TI (%)*	VT (%)*	Rebreathing (% of VT)*	PP (%)*
VENTImotion	Obstructive disease	10	AT	AT	AT	AT	AT	AT
		15	AT	AT	AT	AT	AT	AT
		20	AT	AT	AT	AT	AT	AT
	Restrictive disease	10	AT	AT	AT	AT	AT	AT
		15	AT	AT	AT	AT	AT	AT
		20	AT	AT	AT	AT	AT	AT
VPAP III STA UM Cfg	Obstructive disease	10	99 ± 0.2	49 ± 9	91 ± 4	92 ± 3	0 ± 0$	22 ± 8
		15	99 ± 0.2	45 ± 7	83 ± 3	85 ± 3	0 ± 0$	23 ± 3
		20	AT	AT	AT	AT	AT	AT
	Restrictive disease	10	97 ± 0.2	100 ± 6$	81 ± 5	83 ± 4	0 ± 0$	2 ± 2
		15	99 ± 0.2	97 ± 4	91 ± 1	92 ± 1	0 ± 0$	0 ± 1
		20	99 ± 0.4	95 ± 4	89 ± 1	90 ± 1	0 ± 0$	1 ± 1
SYNCHRONY 2	Obstructive disease	10	99 ± 0.2	88 ± 2	97 ± 4	97 ± 3	0 ± 0$	6 ± 0
		15	100 ± 0.4	96 ± 12$	101 ± 13$	100 ± 12$	0 ± 0$	2 ± 5
		20	99 ± 0.5	108 ± 23$	102 ± 0	102 ± 3	0 ± 0$	-4 ± 11
	Restrictive disease	10	100 ± 0.3	103 ± 2	100 ± 0$	100 ± 0	0 ± 0$	-2 ± 1
		15	100 ± 0.3$	103 ± 11$	100 ± 1	100 ± 0	0 ± 0$	-2 ± 1
		20	100 ± 0.3	103 ± 18$	100 ± 1	100 ± 0	0 ± 0$	-2 ± 1
VIVO 40	Obstructive disease	10	108 ± 0.6	113 ± 29	112 ± 3	112 ± 3	0 ± 0$	-1 ± 1
		15	106 ± 0.7	144 ± 42	105 ± 6	112 ± 3	0 ± 0$	-4 ± 1
		20	106 ± 0.8	79 ± 17	96 ± 2	103 ± 2	0 ± 0$	3 ± 3
	Restrictive disease	10	98 ± 0.6	81 ± 13	100 ± 1	100 ± 0	0 ± 0$	2 ± 3
		15	AT	AT	AT	AT	AT	AT
		20	AT	AT	AT	AT	AT	AT

Note that the Resmed Ultra Mirage Full Face Medium is recommended for VPAP III STA, but this ventilator remained configured with the Ultra Mirage, which is therefore not recommended.

*Values are percentage of baseline value with the recommended mask (Table 3), except for rebreathing, which is the percentage of V_T; and PP, which is the percentage change versus baseline.

All the results were statistically different from the baseline values except results marked with $

Abbreviations: see Table 3

Table 5: Performance of the ventilators with the mask having the largest leak (Resmed Ultra Mirage Full Face Medium) once the ventilator settings were adjusted with this mask in order to reverse auto-triggering which occurred when ventilator settings were those adapted with the recommended masks.

Conditions			Measured parameters					
Ventilator	Patient profile	PS (cmH_2O)	IPAP (%)*	ΔT (%)*	TI (%)*	VT (%)*	Rebreathing (% of VT)*	PP (%)*
VENTImotion	Obstructive disease	10	87 ± 0.5	37 ± 3	88 ± 7	96 ± 10	0 ± 0$	35 ± 3
		15	88 ± 0.2	37 ± 3	96 ± 7	115 ± 11	0 ± 0$	27 ± 4
		20	88 ± 0.3	38 ± 5	89 ± 8	107 ± 12	0 ± 0$	21 ± 4
	Restrictive disease	10	85 ± 0.3	121 ± 4	93 ± 7	43 ± 5	0 ± 0$	-8 ± 4
		15	AT	AT	AT	AT	AT	AT
		20	AT	AT	AT	AT	AT	AT
VPAP III STA UM Cfg	Obstructive disease	20	93 ± 0.3	84 ± 8	78 ± 3	79 ± 1	0 ± 0	14 ± 3

*Values are percentage of baseline value with the recommended mask (Table 3), except for rebreathing, which is the percentage of VT; and PP, which is the percentage change versus baseline.

All the results were statistically different from the baseline values except results marked with $

Abbreviations: see Table 3

Table 6: Performance of the ventilators with the mask having the smallest leak (SOMNOplus) while the ventilator settings remained those adapted with the recommended masks.

Conditions			Measured parameters					
Ventilator	Patient profile	PS (cmH_2O)	IPAP (%)*	ΔT (%)*	TI (%)*	VT (%)*	Rebreathing (% of VT)*	PP (%)*
VPAP III STA UM Cfg	Obstructive disease	10	100 ± 0.2	86 ± 9	98 ± 1	99 ± 1	0 ± 0$	6 ± 4
		15	100 ± 0.2	93 ± 8	99 ± 1	100 ± 0.4	0 ± 0$	3 ± 4
		20	101 ± 0.1	78 ± 8	98 ± 1	100 ± 0.3	10 ± 0.3	11 ± 4
	Restrictive disease	10	100 ± 2.1$	106 ± 3	100 ± 2$	100 ± 2$	8 ± 1	-1 ± 2$
		15	101 ± 0.4	106 ± 3	107 ± 8	106 ± 6	0 ± 0$	-1 ± 1
		20	101 ± 0.3	101 ± 4$	99 ± 4$	101 ± 3$	0 ± 0$	1 ± 1
SYNCHRONY 2	Obstructive disease	10	101 ± 0.2	140 ± 8	109 ± 3	107 ± 2	0 ± 0$	-19 ± 2
		15	100 ± 0.3	125 ± 2	114 ± 3	109 ± 2	14. ± 2.	-14 ± 4
		20	AT	AT	AT	AT	AT	AT
	Restrictive disease	10	100 ± 0.4	99 ± 2$	100 ± 0.5	101 ± 0.3	1 ± 0.2	0 ± 1
		15	100 ± 0.3	100 ± 2$	100 ± 0.5	100 ± 0.2	7 ± 0.3	0 ± 1
		20	100 ± 0.4	101 ± 11$	100 ± 1	100 ± 0.3	12 ± 0.3	-1 ± 1
VIVO 40	Obstructive disease	10	114 ± 1.3	97 ± 14$	95 ± 6	96 ± 6	0 ± 0$	2 ± 2
		15	113 ± 1.1	109 ± 14$	105 ± 2	111 ± 2	0 ± 0$	-2 ± 0
		20	116 ± 1.5	52 ± 8	98 ± 1	115 ± 1	10 ± 1	9 ± 0
	Restrictive disease	10	AT	AT	AT	AT	AT	AT
		15	AT	AT	AT	AT	AT	AT
		20	AT	AT	AT	AT	AT	AT

*Values are the percentage of baseline conditions with the recommended mask (Table 3), except for rebreathing, which is the percentage of VT, and PP, which is the percentage change versus baseline.

All the results were statistically different from the baseline values except results marked with $

Abbreviations: see Table 3

Table 7: *In vivo* performance of the ventilators with the recommended masks condition

Conditions		**Measurements**							
ventilator	**Recommended Mask**	**Subject**	**PEEP** (cmH_2O)	**Peak P** (cmH_2O)	**ΔT** (msec)	**Ti** (sec)	**VT** (ml)	**Rebreathing** (% of VT)	PP (%)
VENTImotion	**SOMNOplus**	**1**	3.7	18.1	265	1.2	865	0	18
		2	3.7	18.4	120	1.1	919	0	46
		3	3.5	21.0	169	1.2	1213	30	34
		4	3.5	18.8	185	1.4	1083	5	32
		Mean ± SD	**3.6 ± 0.1**	**19.1 ± 1.3**	**185 ± 60**	**1.2 ± 0.1**	**1020 ± 159**	**9 ± 15**	**33 ± 12**
VPAPIIISTA	**Ultra Mirage Face medium**	**1**	2.9	18.6	75	1.8	1522	0	63
		2	3.1	16.8	168	1.8	1164	0	44
		3	2.7	17.3	77	1.3	1160	0	62
		4	2.9	18.5	77	1.8	1517	0	63
		Mean ± SD	**2.9 ± 0.2**	**17.8 ± 0.9**	**99 ± 46**	**1.7 ± 0.3**	**1341 ± 206**	**0**	**58 ± 9**

Abbreviations: see Table 3

Table 8: *In vivo* performance of the ventilators with the unrecommended masks

Conditions			Measurements						
ventilator	**unrecommended Mask**	**Subject**	**PEEP** (%)*	**Peak P** (%)*	**ΔT** (%)*	**Ti** (%)*	**VT** (% of VT)*	**Rebreathing** (%)*	PP (%)*
VENTImotion	**SOMNOplus**	**1**	AT	AT	AT	AT	AT	AT	AT
		2	AT	AT	AT	AT	AT	AT	AT
		3	AT	AT	AT	AT	AT	AT	AT
		4	AT	AT	AT	AT	AT	AT	AT
		Mean ± SD	**AT**	**AT**	**AT**	**AT**	**AT**	**AT**	**AT**
VPAPIIISTA	**Ultra Mirage Full Face medium**	**1**	105	107	107	83	86	39	63
		2	112	109	108	104	102	0	44
		3	121	117	114	113	123	39	62
		4	110	98	148	85	77	30	63
		Mean ± SD	**112 ± 6**	**108 ± 8**	**119 ± 20**	**96 ± 14**	**97 ± 20**	**27 ± 19**	**-3 ± 3**

*Values are the percentage of baseline conditions with the recommended mask, except for rebreathing, which is the percentage of VT, and PP, which is the percentage change versus baseline

Abbreviations: see Table 3

Figure legends

Figure 1: Lung bench test

Abbreviations: $\dot{V}$, flow into the lung chamber; $\dot{V}_c$, flow delivered by the ventilator; Paw, airway pressure

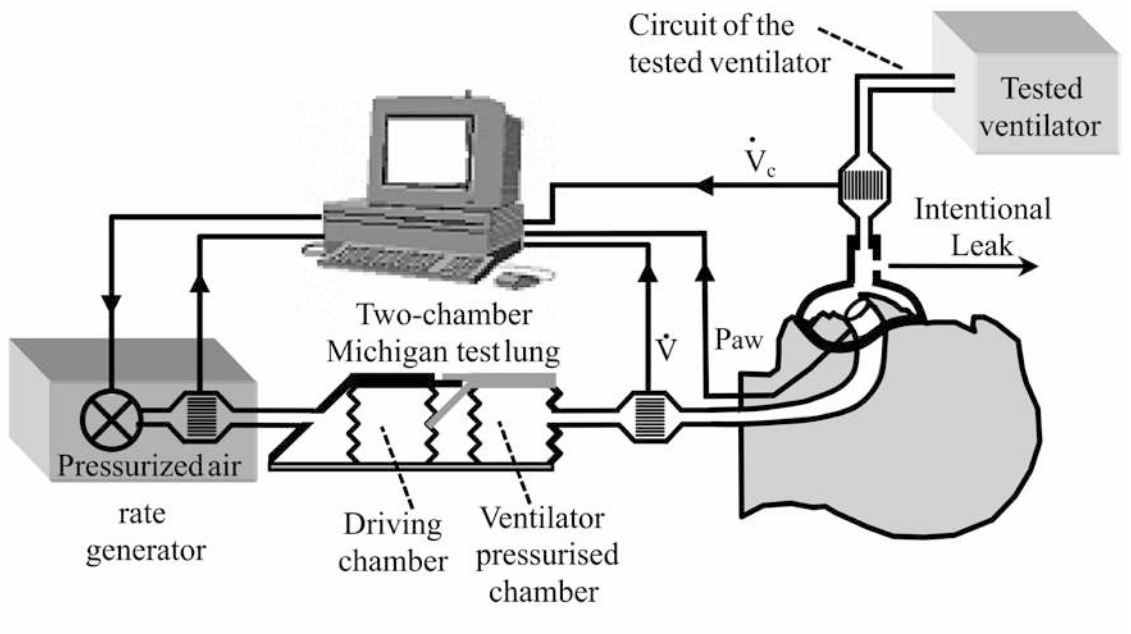


Figure 2 : The in vivo experimental set up.

Abbreviations: $\dot{V}$, airway flow; $\dot{V}_c$, flow delivered by the ventilator; Paw, airway

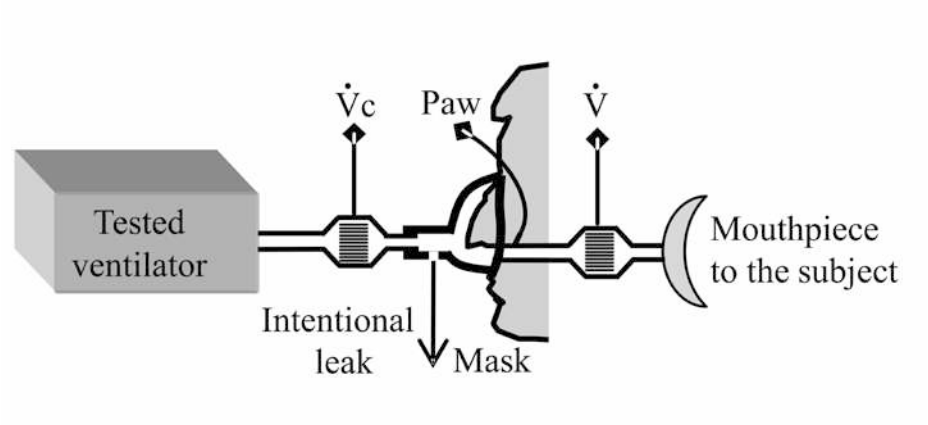


Figure 3: Pressure-flow relationships of the exhalation ports of the ten masks

