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PHYSIOLOGICAL AND TECHNICAL NOTES

**Marie Claire Andrieu**
**Cedric Quentin**
**David Orlikowski**
**Gilbert Desmarais**
**Daniel Isabey**
**Bruno Louis**
**Frédéric Lofaso**

# Inductive plethysmography to control volume-targeted ventilation for leak compensation

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**Conflicts of interest**: Marie Claire Andrieu and Cedric Quentin are employed by Saime-ResMed Corporation.

M. C. Andrieu · C. Quentin
Saime-ResMed Corporation,
77176 Savigny le Temple, France

D. Orlikowski · F. Lofaso (✉)
Université Versailles-St Quentin en Yvelines, Physiology–Functional Testing and Technological Innovations Centre, AP-HP, Raymond Poincaré Teaching Hospital,
92380 Garches, France
e-mail: f.lofaso@rpc.ap-hop-paris.fr

G. Desmarais · D. Isabey · B. Louis · F. Lofaso
INSERM, Unit 841,
F94010 Créteil, France

G. Desmarais · D. Isabey · B. Louis
Université Paris 12, Faculté de Médecine,
F94010 Créteil, France

**Abstract** *Objective:* Volume-targeted ventilation is associated with poor compensation for leaks yet is frequently used in neuromuscular patients, many of whom experience mouth leaks. Our objective was to test the feasibility and efficacy of a prototype ventilator designed to achieve leak compensation by feed-back control of the actual tidal volume based on either the volume blown to the expiratory circuit (VTEVC-compensation) or the tidal volume measured by inductive plethysmography (VTplet-compensation). *Design and setting:* Randomized, cross-over, physiological study in a physiological ward of a university teaching hospital. *Participants:* Nine normal individuals. *Intervention:* Subjects tested volume-targeted assist-control ventilation without compensation, with VTEVC-compensation, and with VTplet-compensation. Tests were done with the mouth closed, with mouth leaks during inspiration, and with mouth leaks during expiration. *Measurements and results:* With inspiratory mouth leaks compared to mouth closed, the delivered volume remained unchanged without leak compensation, increased to $143 \pm 30\%$ with VTEVC-compensation, and increased to $132 \pm 17\%$ with VTplet-compensation; the expired tidal volume decreased to $46 \pm 24\%$ without compensation, $66 \pm 20\%$ with VTEVC-compensation, and $68 \pm 23\%$ with VTplet-compensation. With expiratory mouth leaks, the ventilator-delivered volume and expired tidal volume were unchanged with no compensation and with VTplet-compensation; they increased with VTEVC-compensation. *Conclusion:* Leak compensation can be achieved during volume-targeted ventilation. VTEVC-compensation and VTplet-compensation were equally effective in compensating for inspiratory leaks, and VTplet-compensation also performed well when expiratory leaks occurred.

**Keywords** Leaks · Noninvasive ventilation · Inductive plethysmography

## Introduction

Improved gas exchange is the hallmark of successful mechanical ventilation. Gas exchange can be improved by selecting optimal ventilator settings and by avoiding leaks. The interface and mouth are the main sites of leakage [1]. Simple bedside interventions may reduce leakage [1–3] but are often of limited effectiveness. Therefore, ventilators designed to compensate for air leaks are extremely useful [4].

Pressure support partially compensates for air leaks. However, compensation is not adjustable, and adverse effects may occur from excessive Ti prolongation [5, 6].

Leak compensation is poor with volume-targeted ventilation [4], yet this is widely used in patients with neuromuscular diseases, many of whom experience mouth leaks [2, 7] that they are largely unable to prevent or reduce [2].

In this study, we tested the feasibility and efficacy of a ventilator prototype capable of using two feedback control methods of leak compensation during volume-targeted ventilation, based in one method on the volume expired to the ventilator circuit and in the other on the tidal volume measured by inductive plethysmography. Conceivably, the expired-volume method might underestimate the tidal volume if leaks occurred during expiration. Inductive plethysmography is difficult to calibrate. We have developed an automatic calibration system placed in the ventilator that continuously calibrates the system based on leak-free cycles (i. e., cycles with nearly identical inspiratory and expiratory volumes).

The tests were conducted in nine healthy individuals breathing either without volitional leaks, with volitional inspiratory mouth leaks, or with volitional expiratory mouth leaks.

## Materials and method

### Study participants

Volunteers were recruited among hospital staff members. All provided written informed consent. The study was approved by the relevant ethics committee.

### Experimental device

The Elisee® home ventilator (Saime, Savigny le Temple, France) is able to operate in volume- and pressure-targeted modes (Fig. 1). The ventilator monitored the study participant's tidal volume cycle by cycle, and an algorithm ensured automatic adjustment of the inspiratory flow in the following cycle to produce a tidal volume as close as possible to the set value. Briefly, when leaks led to a tidal volume smaller than the set value, the servo-system increased the next delivered volume by increasing the inspiratory flow, without changing flow contour, by an amount equal to the difference between the set tidal volume and the observed tidal volume. However, leak compensation was limited to 80 l/min since leak compensation was not relevant to severe leaks. The study participant's tidal volume was estimated either by measuring the volume blown into the ventilator expiratory circuit (VTEVC-compensation) or by inductive plethysmography (VTplet-compensation). Each participant wore a vest (Visuresp jacket®, RBI, Meylan, France) made of a material whose texture allowed horizontal wiring only. The vest contained two inductance plethysmograph coils [8]. The jacket was plugged into the ventilator microcomputer. The tidal volume delivered by the ventilator was distributed between the thorax (Vtho) and the abdomen (Vabd), and could be denoted as (gain factor) $\times$ [$\alpha$ Vtho + $(1-\alpha)$ Vabd], where $0 \leq \alpha \leq 1$. The coefficients of the linear combination of the rib-cage and abdomen signals that best fit the integrated flow signal of the ventilator expiratory limb were determined using the recursive least squares method. Calibration was performed automatically based on cycles with less than 20% inspiratory leakage, i. e., with a volume blown to the expiratory limb greater than 80% of the volume delivered by the ventilator. Calibration was continuously adjusted by the ventilator, using a moving time average of 10 selected cycles.

### Measurements

Three pneumotachographs (Fleisch #2, Lausanne, Switzerland), each connected to a differential pressure transducer (Validyne MP 45, Northridge, CA; $\pm 3\,cmH_2O$), were used (Fig. 1). Airway pressure (Paw) was measured

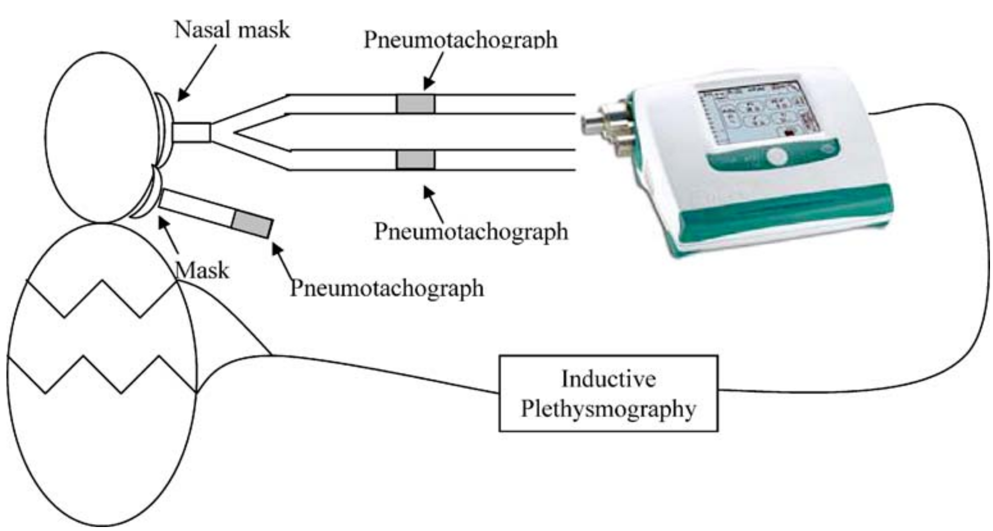


**Fig. 1** Diagram of the experimental setup

using a differential pressure transducer (Validyne MP 45; $\pm$ 100 cm$H_2O$) (Fig. 1). All signal outputs were digitized at 128 Hz (MP100, Biopac Systems, Goleta, CA) and recorded.

### Experimental protocol

Volume-targeted assist-control ventilation was adjusted with the study participant sitting comfortably. The backup rate was set at 15 cycles/min, VT at 12 ml/kg, and Ti at 1.2 s. We chose a decreasing inspiratory flow shape. Thereafter, the settings were modified to maximize comfort to the study participant rather than to eradicate unintentional leaks, considering that this was also the case in clinical conditions and particularly in patients with neuromuscular diseases, for whom leaks were quasi systematically observed during wakefulness [2].

Three conditions were tested in random order: no compensation, VTEVC-compensation, and VTplet-compensation. The study participants were blinded to the condition. Testing under each condition involved two periods, each comprising 10 min of stabilization followed by 3 min of recording. One recording period consisted of 1 min with the mouth closed (no volitional leaks), 1 min with inspiratory mouth leaks, and 1 min with mouth closed, in that order. The other period consisted of 1 min with the mouth closed followed by 1 min with expiratory mouth leaks followed by 1 min with the mouth closed. The two periods were performed in random order.

### Data analysis

The recordings were analyzed breath by breath. The three flow signals were integrated to obtain the delivered volume (integrated inspiratory flow signal through the inspiratory limb), inspiratory leak volume through the mouth, expiratory leak volume through the mouth, and expiratory tidal volume (integrated expiratory flow signal through the expiratory limb + integrated expiratory flow signal through the mouth). Mean values were obtained during each compensation condition (none, VTEVC, and VTplet) and each mouth-leak condition (none, inspiratory, and expiratory).

### Statistical analysis

Data were expressed as mean $\pm$ SD. The result during mouth leaks was expressed as the percentage of the mean during the two 1-min recordings with the mouth closed. These percentages were compared using analysis of variance for repeated measurements. Where appropriate, pairwise comparisons were performed using Fisher least statistical difference tests. $p$-values smaller than 5% were considered significant.

## Results

Nine healthy volunteers participated in the study (Table 1).

The inspiratory mouth leak during each compensation condition (none, VTEVC, and VTplet) was respectively $422 \pm 260$ ml/cycle, $675 \pm 363$ ml/cycle, and $579 \pm 362$ ml/cycle. The expiratory mouth leak during each compensation condition (none, VTEVC, and VTplet) was respectively $509 \pm 190$ ml/cycle, $708 \pm 567$ ml/cycle, and $567 \pm 235$ ml/cycle.

### Delivered volume

With no compensation, mouth leakage did not change the delivered volume (Fig. 2, Table 2). In contrast, the delivered volume increased with both compensation methods during inspiratory mouth leakage, the magnitude of the increase being similar with the two methods (Fig. 2, Table 2). During expiratory mouth leakage, the delivered volume increased with VTEVC-compensation but not with VTplet-compensation (Fig. 2, Table 2).

**Table 1** Characteristics of the nine healthy volunteers and ventilator settings

| Patient | Sex | Age (years) | Height (cm) | Weight (kg) | Set tidal volume (ml) | Backup rate (cycles/min) | Set Ti (s) |
|---|---|---|---|---|---|---|---|
| 1 | M | 48 | 185 | 88 | 1.100 | 15 | 1.3 |
| 2 | M | 38 | 173 | 97 | 1.100 | 15 | 1.3 |
| 3 | F | 23 | 165 | 50 | 800 | 17 | 1.2 |
| 4 | F | 53 | 160 | 66 | 840 | 13 | 1.0 |
| 5 | F | 22 | 164 | 55 | 800 | 15 | 1.1 |
| 6 | M | 28 | 174 | 75 | 960 | 17 | 1.2 |
| 7 | M | 56 | 170 | 80 | 960 | 17 | 1.5 |
| 8 | M | 53 | 168 | 68 | 810 | 16 | 1.3 |
| 9 | F | 22 | 170 | 65 | 780 | 15 | 1.2 |
| Mean | | 38 | 170 | 72 | 906 | 15.6 | 1.23 |
| SD | | 15 | 7 | 15 | 129 | 1.3 | 0.14 |

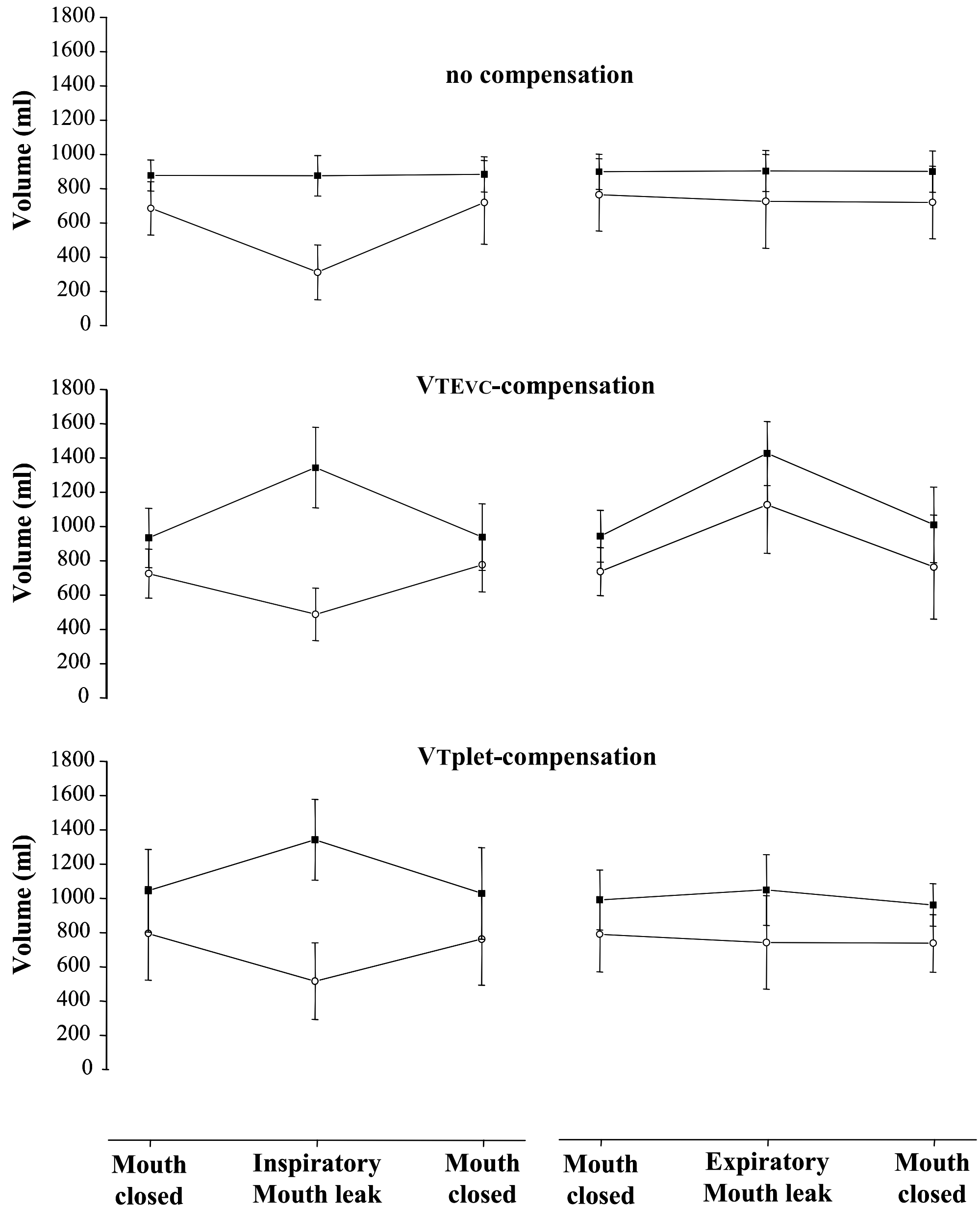


**Fig. 2** Delivered volumes (*filled squares*) and expiratory tidal volumes (*open circles*) under each compensation condition (none, VTEVC-compensation, and VTplet-compensation) and each mouth-leak condition (mouth closed, inspiratory leak, and expiratory leak). *VTEVC-compensation*, compensation based on volume blown into expiratory circuit; *VTplet-compensation*, compensation based on actual tidal volume measured by inductive plethysmography

**Table 2** Expiratory tidal volume changes during mouth leaks

| | No compensation | VTEVC-compensation | VTplet-compensation |
|---|---|---|---|
| Inspiratory mouth leaks | 46 ± 24 | 66 ± 20 * | 68 ± 23 * |
| Expiratory mouth leaks | 97 ± 22 | 160 ± 58 * | 103 ± 8 § |

Values are mean ± SD expressed as the percentage of the mean of two mouth-closed periods before and after a mouth-leak period; * Statistically significant versus no compensation (Fisher test); § statistically significant difference between VTEVC-compensation and VTplet-compensation (Fisher test); VTEVC-compensation, compensation based on volume blown into expiratory circuit; VTplet-compensation, compensation based on actual tidal volume measured by inductive plethysmography

Expiratory tidal volume

During inspiratory mouth leakage, the decrease in expiratory tidal volume was smaller with the two compensation methods than without compensation (Fig. 2, Table 2).

During expiratory mouth leakage, expiratory tidal volume was unchanged when no compensation or VTplet-compensation was used but increased with VTEVC-compensation (Fig. 2, Table 2).

## Discussion

We did not try to eliminate non-volitional leaks in mouth-closed conditions, given that, in our experience, absence of leaks was rarely observed in the neuromuscular population [2]. We were accustomed to adjusting the ventilator settings in this clinical condition. The problem is that leaks increase when mechanical ventilation is maintained for long periods and particularly when sleep occurs. Therefore a system designated to compensate these leak increases should be useful.

Mehta et al. [4] used a lung model and tested different amounts of leak to show that increasing the delivered volume increased the actual tidal volume. Our study extends this finding to the in vivo situation. In addition, our leak-compensation system automatically adjusted the delivered volume based on the actual tidal volume. However, this added volume was also exposed to leaks, theoretically precluding the achievement of the set tidal volume.

Mehta et al. [4] suggested that compensation of large leaks might require a high and sustained maximal flow capacity greater than 180 l/min. We voluntarily limited leak compensation to 80 l/min, because leak compensation is not relevant to severe leaks, since these compromise sleep quality [7, 9], patient–ventilator synchrony [10], and gas humidity [10]. Another limitation is that calibration of inductive plethysmography is not obtained when cycles with less than 20% inspiratory leakage never occur. In this possible clinical condition, the leak compensation is inactivated and therefore the ventilator delivers the set volume without any leak compensation until occurrence of the inductive plethysmography calibration. However, one cycle with less than 20% inspiratory leakage is sufficient to obtain a calibration which can be progressively improved until obtaining 10 cycles with less than 20% inspiratory leakage. Thereafter, the calibration is regularly updated by replacing the oldest retained cycle as and when a new cycle with less than 20% inspiratory leakage occurs. Finally our device is designed not to run when severe and constant leakage occurs. The objective was mainly to reduce the short periods of hypoventilation induced by intermittent mouth leaking, frequently observed during sleep [3, 4, 11].

As we can observe in Table 2, when the subjects opened the mouth during inspiration without leak compensation the effective tidal volume fell to a value below 50% of the closed-mouth condition. This level of tidal volume decrease was concordant with our experience in neuromuscular patients during sleep [12]. When these leaking episodes during sleep were intermittent and reduced the tidal volume to less than 50%, we considered them as hypopnea episodes [12]. Meyer et al. (see Fig. 2) [7] observed a similar phenomenon in neuromuscular patients during sleep. This important leakage during sleep was also observed by Stoore et al. [13] in patients with the obesity hypoventilation syndrome and Teschler et al. [3] (see Fig. 3) and Windisch et al. [14] in heterogeneous populations. As suggested by Table 2, during inspiratory mouth leakage these modes of leak compensation permitted maintenance of the expiratory tidal volume at around two-thirds of the tidal volume observed during the mouth-closed period, whereas it was below half of the baseline condition without leak compensation. These results obtained in wakeful subjects with normal respiratory system mechanics have to be confirmed in patients and during sleep.

Leakage is less marked during expiration than during inspiration, because upper-airway pressure decreases markedly when mechanical insufflation switches off to permit expiration. However, positive end-expiratory pressure may promote expiratory leakage.

We found that the VTEVC-compensation method underestimated the tidal volume during volume-expiratory mouth leaks, leading to inadvertent severe hyperventilation (see Fig. 2). This harmful effect of VTEVC-compensation explains why this system is not commercialized in this present form, and is one of the reasons that led us to develop the VTplet-compensation method.

More sophisticated modes may be improved by leak compensation when using our inductive plethysmography method. These sophisticated modes include proportional-assist ventilation [15]. With this assist ventilation driven by flow or volume, a runaway may occur when leaks cause a mismatch between delivered flow or volume and patient inspiratory flow or volume. Inductive plethysmography-driven ventilation is theoretically not altered by air leaks.

In conclusion, leak compensation can be achieved during volume-targeted ventilation using a servo-control system based either on the volume blown to the expiratory circuit or on the tidal volume measured by inductive plethysmography continuously calibrated by the ventilator. These two methods were equally efficient during inspiratory leakage, and the inductive plethysmography method also performed well when expiratory leaks occurred.

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