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ARTIGO ORIGINAL

# SYSVENT: Proof of Concept Study of a Prototype to Ventilate Critical Care Patients

# SYSVENT: Prova de Conceito de um Protótipo para Ventilar Doentes em Cuidados Intensivos

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## ABSTRACT

**Introduction:** The new coronavirus pandemic has led to scarcity of invasive ventilation resources in hospitals in several countries. In this context, the Portuguese Medical Association invited intensive care physicians who, in collaboration with SYSADVANCE S.A., developed SYSVENT OM1, a ventilator capable of operating in controlled and assisted modes (volume and pressure) and able to treat patients admitted to intensive care units. In this study we do the proof of concept comparing programmed tidal volume, inspiratory pressure and positive end-expiratory pressure with those measured by the ventilator and an external measuring equipment.

**Material and Methods:** We set up the ventilator in tandem with an artificial lung and a flow analyzer. We measured expiratory tidal volume, and inspiratory pressure against three levels of compliance, each with six steps of tidal volume. Positive end-expiratory pressure was measured at 2 $cmH_2O$ incremental along eight steps. For each measurement, we performed three readings.

**Results:** Considering each of the three single variables, the mean value of the highest difference between programmed values and measured values is, for all of them, within what we considered to be acceptable for a prototype model (tidal volume = -28.1 mL, inspiratory pressure = 0.8 $cmH_2O$ and positive end-expiratory pressure = -1.1 $cmH_2O$). This difference is greater when evaluated with the external measuring equipment in comparison with the ventilator.

**Discussion:** The results showed a good monitoring and accuracy performance. Technical limitations related with the artificial lung and the flow analyzer have been documented, which do not compromise the results, but limit their amplitude.

**Conclusion:** For tested parameters, the ventilator has a good operating performance, is in accordance with the initial premises and has potential for clinical use.

**Keywords:** Critical Care; Engineering; Portugal; Respiration, Artificial; Ventilators, Mechanical

## RESUMO

**Introdução:** A pandemia pelo novo coronavírus provocou rotura em hospitais de vários países por falta de recursos para ventilação invasiva. Assim, a Ordem dos Médicos convidou intensivistas que, em colaboração com a SYSADVANCE S.A., desenvolveram o SYSVENT OM1, um ventilador capaz de operar em modos controlados e assistidos (volume e pressão) e apto para tratar doentes em cuidados intensivos. Neste estudo fazemos a prova de conceito, comparando volume-corrente, pressão inspiratória e pressão positiva tele-expiratória programados, com os valores medidos pelo ventilador e por um equipamento de medição externo.

**Material e Métodos:** Montámos o ventilador em série com um pulmão artificial e um analisador de fluxos. Medimos o volume-corrente expiratório e a pressão inspiratória, em três níveis de *compliance* e seis patamares de volume-corrente. A pressão positiva tele-expiratória foi medida com incrementos de 2 $cmH_2O$ ao longo de oito patamares. Para cada medição realizámos três leituras.

**Resultados:** Considerando cada uma das três variáveis isoladamente, a média da diferença máxima entre os valores programados e os valores medidos situa-se, para todas elas, dentro do que considerámos ser aceitável para um modelo protótipo (volume-corrente = -28,1 mL, pressão inspiratória = 0,8 $cmH_2O$ e pressão positiva tele-expiratória = -1,1 $cmH_2O$). Essa diferença é maior quando avalia-da com o equipamento de medição externa comparativamente com o ventilador.

**Discussão:** Os resultados mostraram uma boa capacidade de monitorização e de precisão. Documentaram-se limitações técnicas relacionadas com o pulmão artificial e com o analisador de fluxos que não desvirtuam os resultados, mas limitam a sua amplitude.

**Conclusão:** Para os parâmetros testados, o ventilador apresenta boa *performance* de funcionamento, está de acordo com as premissas iniciais e tem potencial para uso clínico.

**Palavras-chave:** Cuidados Intensivos; Engenharia; Portugal; Respiração Artificial; Ventiladores Mecânicos

## INTRODUCTION

Many countries have been taken by surprise by the current SARS-CoV-2 (COVID-19) pandemic, due to the sudden and overwhelming demand for differentiated resources and interventions to control the spread of the infection. Respiratory failure is the most prevalent form of severe disease manifestation and is the main reason for admission to the intensive care unit (ICU) and mortality. Respiratory failure is predominantly hypoxemic, severe condition, either as a classical acute respiratory distress syndrome (ARDS) or with lung involvement and high compliance in addition to severe hypoxemia associated to an intrapulmonary shunt mechanism. The use of oxygenation and non-invasive ventilation equipment for respiratory support has not been consensual due to the underlying risk of contagion (aerosolisa-

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tion). Therefore, the affected countries have taken on the task of providing their health systems with adequate invasive ventilation equipment to meet the expected needs. This scenario has put enormous pressure on the marketing of these products. Experience has shown that in many countries it has not been possible to meet the increasing need for resources for invasive ventilation in a timely manner. On the other hand, countries that did not have the capacity to produce their own equipment were dependent on liberalised market requirements, which not always allowed to meet the needs in the way that's is desirable and required.

A ventilator for invasive ventilation therapy on adult patients - SYSVENT OM1 (SYSVENT) has been developed by the company SYSADVANCE, S.A. in partnership with critical care physicians appointed by the Portuguese Medical Association (*Ordem dos Médicos* - OM) and with the Portuguese Business Association (*Associação Empresarial de Portugali,* AEP). SYSADVANCE, S.A. has started its activity in 2002 as a spin-off from a Research and Development (R&D) university laboratory, aimed at the development and marketing of technology for handling, treating and manufacturing gases and gas purifiers, as well as integrated solutions for compressed air. The SYSADVANCE Quality Management System (QMS) is an ISO 9001 certified standard system for the entire range of industrial and energy sector products. SYSADVANCE QMS is also certified according to ISO 13485 for medical devices, medical oxygen generators and oxygen generation systems, medical air and vacuum systems. These medical devices are certified according to the Medical Devices Directive 93/42/EEC.

The SYSVENT was developed based on assumptions and requirements pre-defined by intensive care physicians appointed by OM for this purpose. As regards this Portuguese-designed ventilator, the premises were defined as the construction of a simple, reliable, robust, financially viable product, able to ensure its clinical application complying with the standards in force.[1-3]

This study was aimed at the development of a proof-of-concept (PoC) by comparing the set tidal volume ($V_T$), total inspiratory pressure (Pinsp) and positive end-expiratory pressure (PEEP) delivered by the SYSVENT ventilator (the first two parameters set in volume-controlled and pressure-controlled modes, respectively) within three pre-defined compliance levels (10, 20 and 50 mL/cm$H_2O$), with those measured by the ventilator itself (monitoring) and by an external measurement equipment.

## MATERIAL AND METHODS

### Equipment

#### SYSVENT OM1

The SYSVENT prototype has been designed for invasive ventilation therapy in adult patients and is operated by compressed $O_2$, with around 22 kg in weight and incorporating an internal (Uninterruptible Power Supply - UPS) battery with up to one hour of autonomy.

The operator-ventilator interface is set through a touch screen, both for setting and monitoring. Remote setting and monitoring are enabled by the technology, reducing the need for any direct contact with the ventilator or the patient's environment. Pressure control (PC) and pressure-assist control (P A/C) modes, volume control (VC) and volume-assist control (V A/C) modes are included, in addition to assist mode (A). The ranges and measurement units for the variable settings are shown in Table 1.

Monitoring is expressed in absolute values of fraction of inspired oxygen (FiO2), respiratory rate (RR), PEEP, Pinsp, VTe (expiratory tidal volume), MV (minute ventilation), inspiration/expiration ratio (I:E ratio) and in F (inspiratory flow), $V_T$ and P (pressure) *versus* time charts. Inspiratory (*Pausainsp*) and expiratory (*Pausaexp*) pauses are also available for the measurement of end-inspiratory plateau pressure (Pplateau) and PEEP, respectively. These special procedures therefore allow the automatic calculation of static compliance (Cst) and airway resistance (R). Alarm hierarchy is set at two alert levels according to the patient risk. The distinctive features for each alarm include light and sound signals. The standard alarm is assigned to RR, $V_T$, $P_{insp}$ and MV. A critical alarm is designed to warn of disconnection, apnoea (with backup ventilation mode) and leak. Unlike the other alarms, disconnection and leak alarms are not programmable. $V_T$ and $P_{insp}$ alarms are active in the sense that the alarm limits defined for these parameters override those that will be set.

#### Artificial lung

An artificial lung (lung ventilator performance analyser - Medishield) allowing R (0, 5, 20, 50, 200 cm$H_2O$/L/s), leak

Table 1 – Measurement units and operation ranges of each parameter

| Parameter | Unit | Range |
|---|---|---|
| $FiO_2$ | % | [0.21; 1] |
| F | L/min | [2; 120] |
| RR | b/min | [0.5; 40] |
| PEEP | cm$H_2O$ | [1; 20] |
| $P_{insp}$ | cm$H_2O$ | [1; 80] |
| PS | cm$H_2O$ | [0; 80] |
| RT | s | [0.1; 2] |
| $Term_{insp}$ | % | [5; 30] |
| $T_i$ | s | [0.3; 10] |
| Trigger | cm$H_2O$ | [1; 10] |
| $V_T$ | mL | [0.1; 1.5] |

$FiO_2$: fraction of inspired oxygen; F: inspiratory flow; RR: respiratory rate; PEEP: positive end-expiratory pressure; $P_{insp}$: total inspiratory pressure; PS: pressure support; RT: rise time; $Term_{insp}$: cycling; $T_i$: inspiratory time; $V_T$: tidal volume

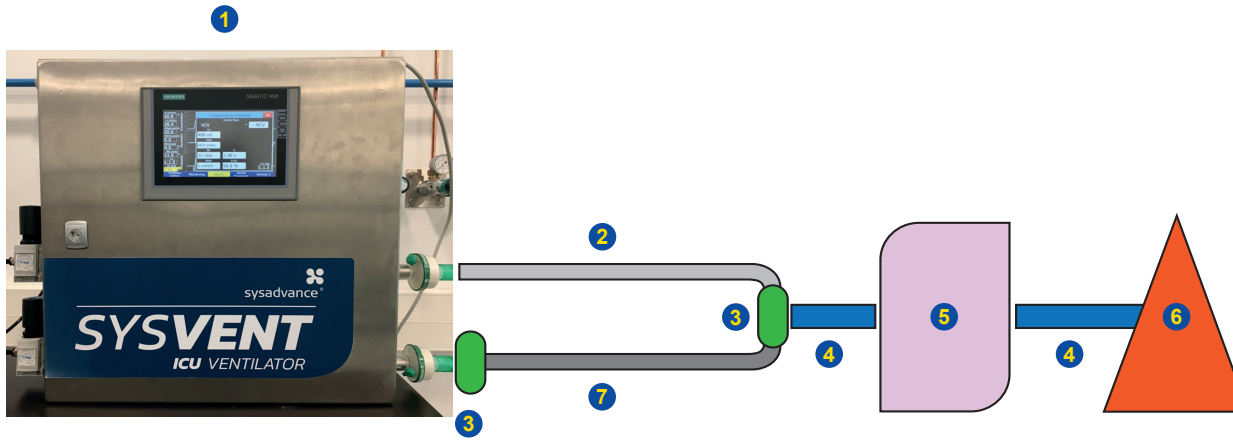


Figure 1 – Assembly of the equipment for bench testing: 1. SYSVENT ventilator; 2. Inspiratory branch; 3. Antibacterial filter + HME (InterThermFilter/Intersrsurgical HME); 4. Tube; 5. Bio-Tek; 6. Artificial lung; 7. Expiratory branch

(variable, although adimensional) and compliance (C) to be selected at three different levels (10, 20 and 50 mL/cm$H_2O$) has been used.

**Gas flow analyser**

As an external measuring instrument, we used the Bio-Tek VT Plus Gas Flow Analyser - Fluke Biomedical (Bio-Tek), allowing real-time and synchronous measurement of different volumetric and pressurometric parameters.

**Assembly of the equipment circuit**

The assembly of the equipment is shown in Fig. 1.

**Measurements**

The ventilator was set at RR = 12 b/min, PEEP = 5 cm$H_2O$, inspiratory flow (F) = 60 L/min (for PC) and 40 L/min (for VC), inspiratory time (Ti) = 1s (for PC) and 1.2s (for VC), R = 0 cm$H_2O$/L/s (apart from the one imposed by the equipment assembly), leak = 0 L/min for $V_T$ and $P_{insp}$ measurement. A 1 mL/kg increment, within a 5 – 10 mL/kg range was set for both ventilatory modes and considering a theoretical 70 kg body weight, therefore including the range of $V_T$ recommended for clinical use with a lung-protective strategy (6 to 8 mL/kg ideal weight). The volumes of 350 mL, 420 mL, 490 mL, 560 mL, 630 mL and 700 mL were tested. Three consecutive measurements for each $V_T$ step were obtained, with expired $V_T$ ($V_{Te}$) recorded at the end of a four-second inspiratory pause. As regards VC mode, $V_T$ was directly set into the ventilator, while at PC mode the pressure that came closest to the predicted $V_T$ was determined for each step, simulating the usual clinical practice. These measurements were obtained at three pre-defined C levels (10, 20 and 50 mL/cm$H_2O$) on the artificial lung. PEEP was evaluated at 2 cm$H_2O$ increments, between 0 and 16cm$H_2O$, based on set $V_T$= 400 mL, RR =12 b/min, F = 40 L/min, Ti = 1s, C = 20 mL/cm$H_2O$, R = 0 cm$H_2O$/L/s (apart from the one imposed by assembly) and leak = 0 L/min. All measurements were taken at ATPS (ambient temperature, ambient pressure and saturated with water vapour) conditions.

The simulation and measurement equipment had two technical limitations that must be clarified:

1. The proper functioning of the assist mode was checked with adequate pressurometric response, whenever an inspiratory demand was simulated. However, this was a subjective analysis, not measurable, since the measuring equipment available at the time did not allow for titrating the pressure of the simulated inspiratory call to the set trigger sensitivity threshold. Therefore, the authors decided to announce only that this ventilatory mode is available in this prototype version, without describing it in detail or obtaining any measurements;

2. Due to a technical defect, the artificial lung did not allow for inflation of the entire set volume, for a 50 mL/cm$H_2O$ lung compliance level and for higher $V_T$ values (8 mL/kg, 9 mL/kg and 10 mL/kg, corresponding to 560, 630 and 700 mL).

**Statistics**

A descriptive analysis of variations between measured and set $V_T$, $P_{insp}$ and PEEP was carried out. The Kolmogorov-Smirnov non-parametric test was applied for each of these variables and no arguments to reject a normal distribution were found. Therefore, mean was used as the measure of central tendency and standard deviation as measure of dispersion. For this purpose, we used IBM SPSS Statistics Version 26 software.

## RESULTS

**Volume-controlled**

The overall mean variation between set and measured $V_T$ was - 28.1 mL for Bio-Tek and 6.2 mL for SYSVENT. In percentage terms, mean variations corresponded to -5.3%

Table 2 – Variations between set $V_T$ and measured $V_{Te}$

| | | Set C (mL/cm$H_2O$) | | | | | |
|---|---|---|---|---|---|---|---|
| | | 10 | | 20 | | 50 | |
| | | SYSVENT | Bio-TEK | SYSVENT | Bio-TEK | SYSVENT | Bio-TEK |
| Set $V_T$ (mL) | **350** | 9.0 (3.0) | -19.7 (2.5) | -4.7 (7.5) | -14.7 (8.6) | 5.0 (6.1) | -8.7 (1.2) |
| | **420** | 7.3 (5.5) | -29.3 (3.2) | 3.0 (10.1) | -18.3 (3.8) | 7.3 (1.2) | -11.3 (3.2) |
| | **490** | 14.7 (2.1) | -2.7 (52.6) | 8.0 (2.0) | -24.0 (3.0) | 6.3 (4.0) | -16.0 (1.7) |
| | **560** | 8.3 (2.5) | -46.3 (7.6) | 2.3 (3.8) | -34.3 (2.5) | N/A | N/A |
| | **630** | 10.3 (10.7) | -48.7 (0.6) | 7.3 (1.2) | -37.3 (1.5) | N/A | N/A |
| | **700** | 3.3 (2.1) | -61.0 (4.4) | 5.7 (10.3) | -48.7 (7.5) | N/A | N/A |
| | **Global** | 8.8 (5.7) | -34.6 (27.3) | 3.6 (7.3) | -29.6 (12.9) | 6.2 (3.8) | -14.9 (3.7) |

Mean and standard deviation of the variations between set $V_T$ and measured $V_{Te}$ by the SYSVENT and Bio-Tek, expressed in mL, for each step of set $V_T$ and for each level of C. All data are aggregated into a global measure in the bottom row, reflecting the partial measurements.

for Bio-Tek and 1.3% for SYSVENT. When comparing the variations for each step and for each level of C between SYSVENT and Bio-Tek (Table 2), we found that the former are closer to set values (average of the largest variation = 14.7 mL) and with a positive sign. Bio-Tek measured values are usually lower than set values and showing more significant variations (average of the largest variation = - 61 mL). Furthermore, unlike SYSVENT (which maintains a stable variation throughout the different $V_T$ steps and C levels, with average variations ranging from -4.7 mL to 14.7 mL), an increasing variation from set values has been found with the Bio-Tek, with an increment in set $V_T$ at all C levels, from -2.0 mL to -61.0 mL (Table 2).

The graphical expression of these variations (Fig. 2) showed that, in contrast to what happens with SYSVENT, an increasing variation in the measurements has been

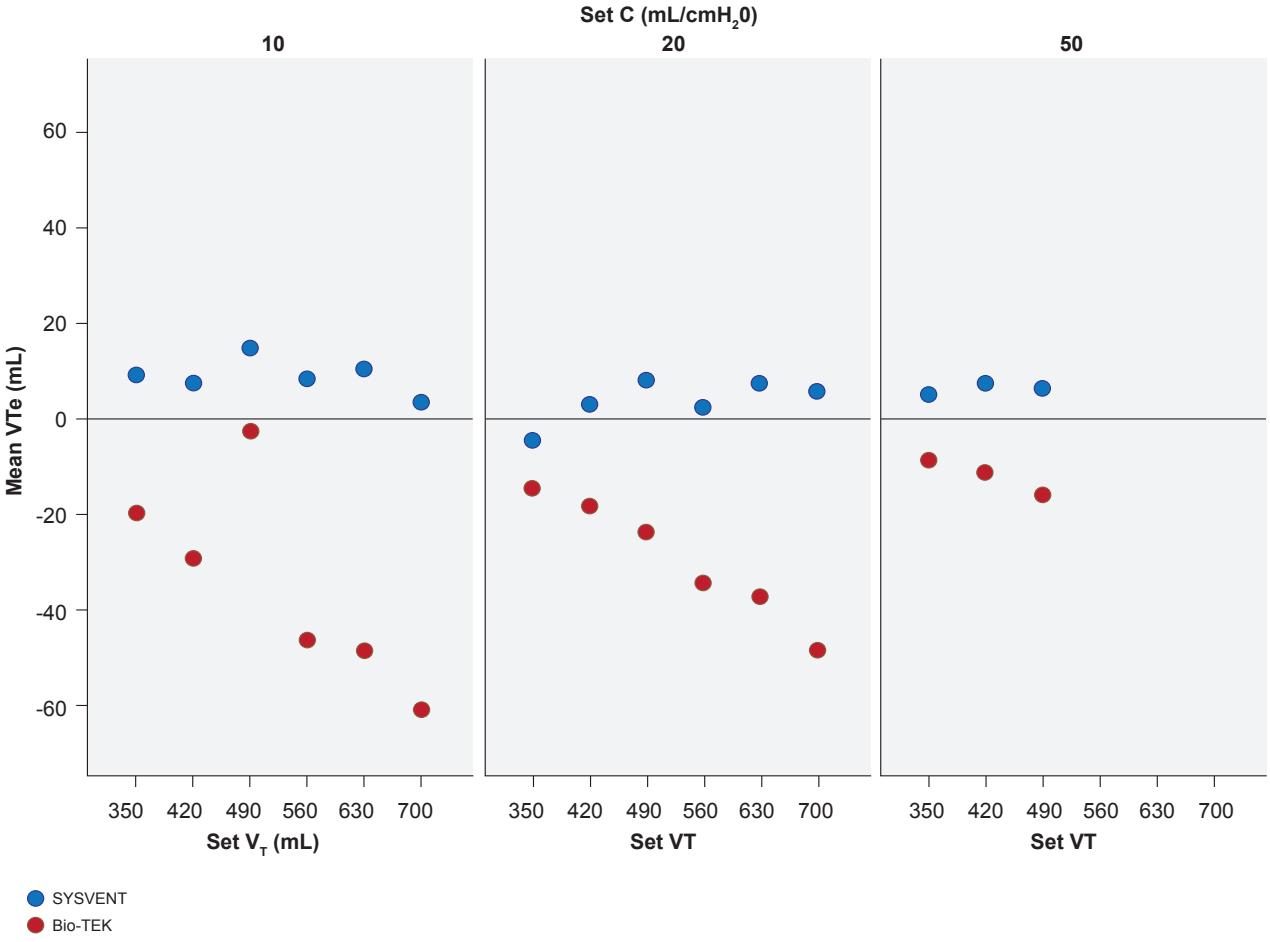


Figure 2 – Distribution of mean variations between SYSVENT and Bio-Tek-measured $V_{Te}$ for each threshold of set $V_T$ and for each level of C, expressed in mL

found along the set $V_T$ thresholds and at all levels of C with Bio-Tek, particularly for the levels of C = 10 mL/cm$H_2O$ and C = 20 mL/cm$H_2O$. A smaller variation seems to exist for the level of C = 50 mL/cm$H_2O$, although this interpretation is limited by the fact that not all $V_T$ steps were tested (see above).

### Pressure-controlled

An overall mean variation of 0.8 cm$H_2O$ was found for both SYSVENT and Bio-Tek (Table 3). The distribution of these variations with set Pinsp and stratified by C (Fig. 3) showed overlapping measurements taken with the SYSVENT and Bio-Tek and that the magnitude of the variation from the set values is not clinically relevant. For a level of C = 10 mL/cm$H_2O$, increasing variations tend to exist for higher pressures, with a maximum value of around 4 cm$H_2O$. However, the increase is still not clinically relevant as it occurs at a level of set Pinsp which is neither used nor recommended in clinical practice.

Table 3 – Variations between set and measured $P_{insp}$

| | | $P_{insp}$ variation (cm$H_2O$) | |
|---|---|---|---|
| | | SYSVENT Mean (SD) | Bio-Tek Mean (SD) |
| Set C (mL/cm $H_2O$) | 10 | 1.5 (1.1) | 1.5 (1.0) |
| | 20 | 0.3 (0.2) | 0.3 (0.1) |
| | 50 | 0.6 (0) | 0.3 (0) |
| | Global | 0.8 (0.9) | 0.8 (0.9) |

Mean and standard deviation of the variations between set and measured $P_{insp}$ by the SYSVENT and Bio-Tek, expressed in cmH2O (both globally and for each level of C)

### PEEP

The mean variation between set and measured PEEP was -1.1 cm$H_2$0 and -0.6 cm$H_2O$ for Bio-Tek and SYSVENT, respectively (Table 4). The average variation, when distributed throughout set PEEP (Fig. 4), remained at a lower value for Bio-Tek when compared with SYSVENT. On the other hand, with increasing set PEEP, it is worth mentioning that mean variations have increased for both the SYSVENT and the Bio-Tek, even though with no clinical significance.

## DISCUSSION

In general, SYSVENT OM1 ventilator bench test results showed good monitoring capacity (measured values are

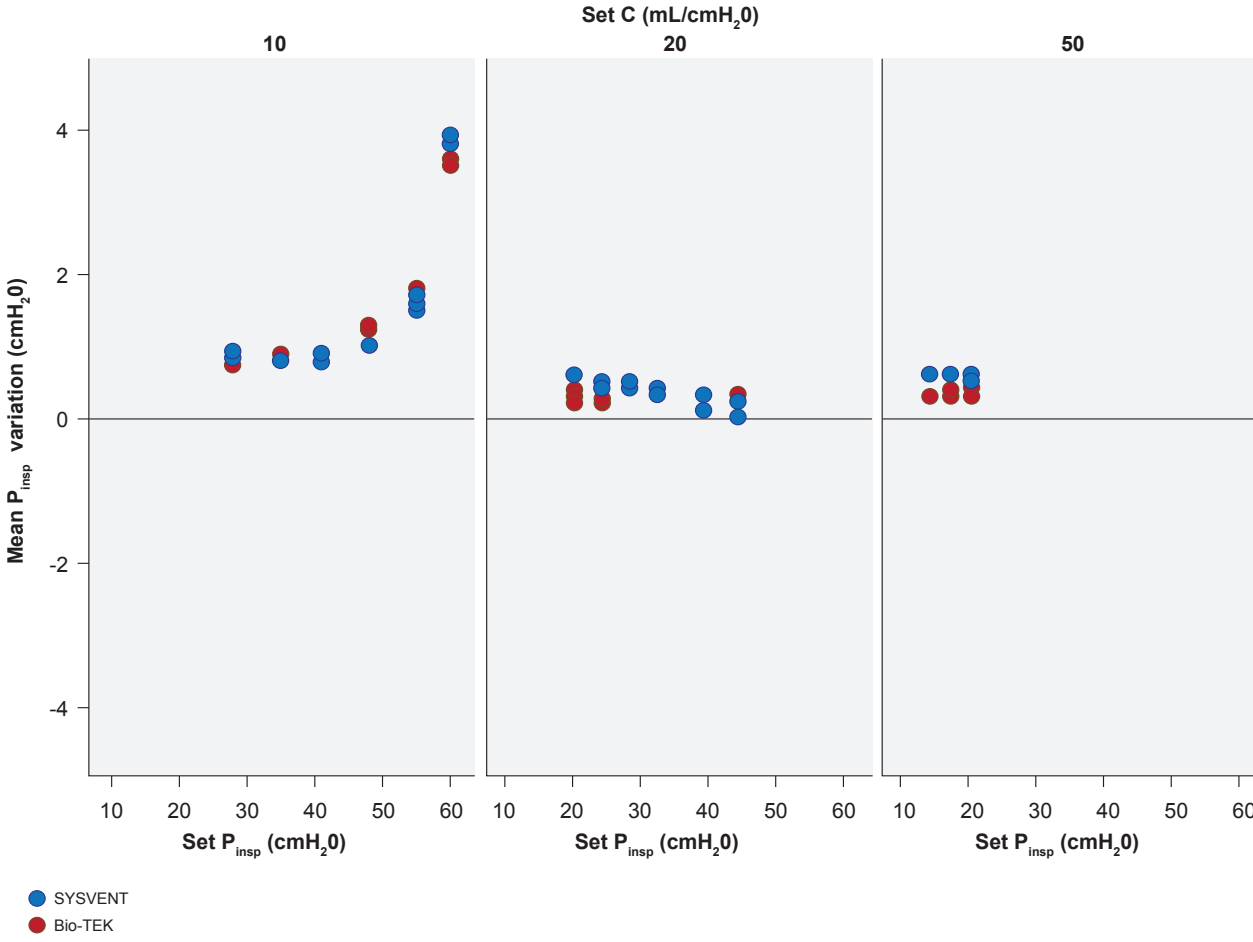


Figure 3 – Distribution of variations between SYSVENT and Bio-Tek measured $P_{insp}$ for each set $P_{insp}$ and for each level of C, expressed in cm$H_2O$

Table 4 – Variations between set and measured PEEP

| | | PEEP variation ($cmH_2O$) | |
|---|---|---|---|
| | | SYSVENT Mean (SD) | Bio-Tek Mean (SD) |
| Set PEEP ($cm H_2O$) | 0 | 0.5 (0) | 0 (0) |
| | 2 | 0.1(0) | -0.6 (0) |
| | 4 | -0.6 (0) | -1.3 (0.2) |
| | 6 | -0.8 (0.1) | -1.3 (0.2) |
| | 8 | -0.9 (0.1) | -1.5 (0.3) |
| | 10 | -0.8 (0.1) | -1.2 (0.2) |
| | 12 | -1.0 (0.1) | -1.3 (0.2) |
| | 14 | -1.1 (0.1) | -1.4 (0.1) |
| | 16 | -1.1 (0.1) | -1.4 (0.2) |
| | Global | -0.6 (0.5) | -1.1 (0.5) |

Mean and standard deviation of the variations between set and measured PEEP by the SYSVENT and Bio-Tek, expressed in cmH2O (both globally and for each level of PEEP)

similar to set values) and accuracy (clinically acceptable variations between set and Bio-Tek measured values).

As regards $V_T$, the literature showed variations between measured and set $V_{Te}$ ranging from -5% to 20%.[4-7] An overall mean variation ranging from -5.3% to 1.2% has been found in our study, depending on whether the $V_{Te}$ was measured by the SYSVENT or by Bio-Tek. These results compare with those described in literature, supporting the good accuracy of the ventilator. Small and uniform variations have been found between SYSVENT measured and set values, in favour of a good monitoring capacity. As regards Bio-Tek measured values, a higher variation from set values has been found, as opposed to what has been found with the SYSVENT and as set $V_T$ thresholds increase. This has been found regardless of the value of C, in a magnitude that does not seem to have a clinical impact - all the more so as it corresponds, at most, to a -8.7% mean variation. This pattern associated to Bio-Tek measurements is less noticeable at PEEP and does not occur at Pinsp (see below).

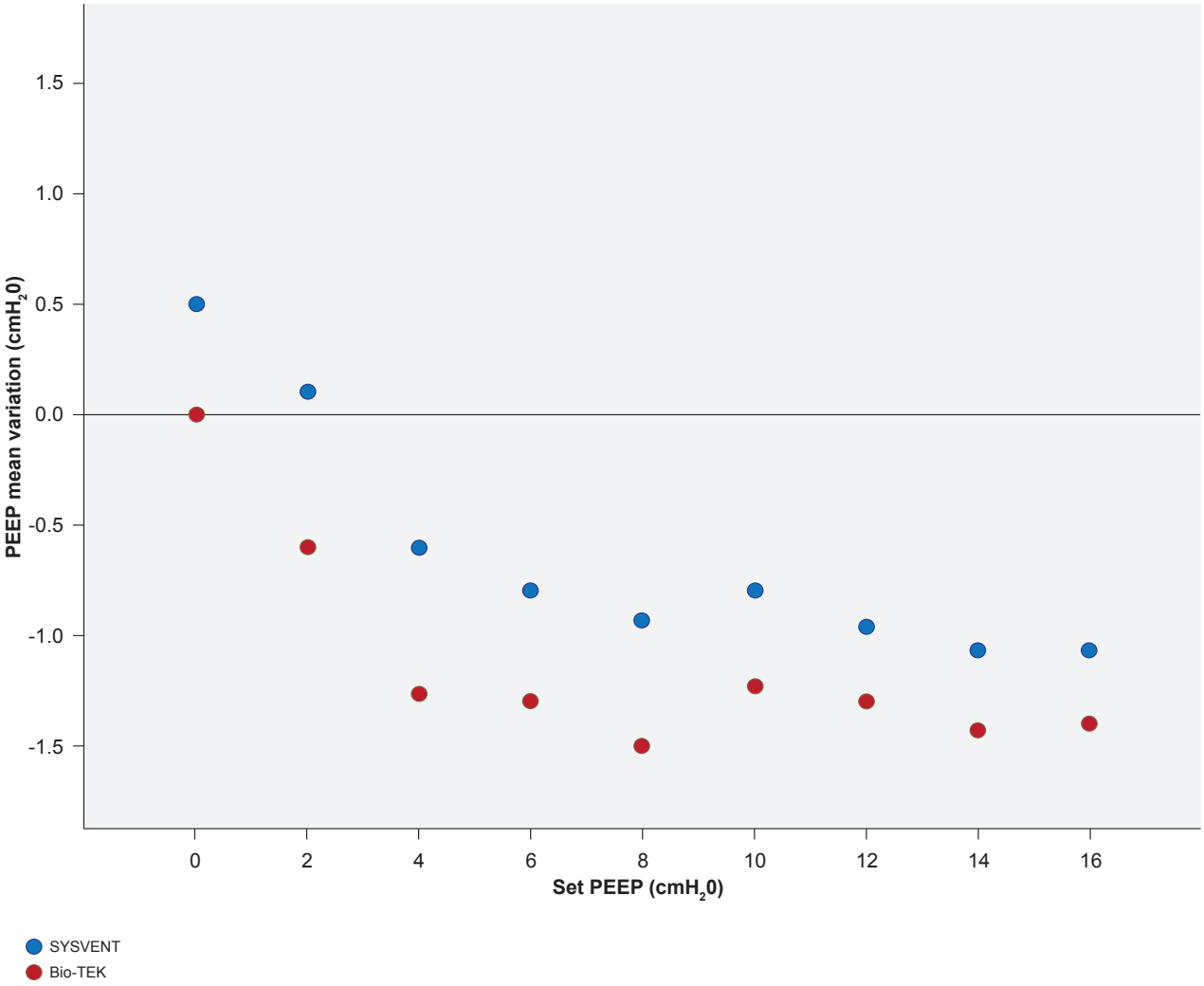


Figure 4 – Distribution of mean variations between SYSVENT and Bio-Tek measured and set PEEP, expressed in $cmH_2O$

The expected range of variations between set and measured Pinsp has not been clarified. However, when pressures were compared in this study, variations < 3.9 $cmH_2O$ have been found, which is clinically irrelevant, as already described. Regardless of the variation from the set values, overlapping variations have been found by both devices. This means that the ventilator has a good monitoring capacity, i.e., that set values displayed on the ventilator screen correspond to those that are actually delivered.

The ventilator behaviour regarding PEEP also showed a clinically acceptable variation between measured and set values. In general, lower measured PEEP values have been found when compared to set values especially by Bio-Tek and this variation seems to worsen as set PEEP increases. However, no clinical impact is anticipated by the magnitude of the variation.

These results correspond to a good mechanical behaviour of the ventilator, as well as good monitoring, with a variability within an acceptable range, from a clinical point of view. The measurement variations between SYSVENT and Bio-Tek, which may be caused by intrinsic variations in the measurement performance of both devices, does not exceed the limits of clinical acceptability. Nevertheless, the possibility of using new simulation and measurement equipment in subsequent tests (already planned) will enable a better understanding the variations that were found.

The methodology used in these bench tests tried to simulate the usual clinical practice, which we believe represents a relevant methodological concept. The ventilator parameter setting was indexed (whether in VC or PC) to a $V_T$ range covering the most frequently used volumes, based on a 70 kg body weight and a therapeutic $V_T$ range within a lung protective strategy (6 - 8 mL/kg). The ventilatory mechanic conditions were only varied within the compliance dimension, aiming to introduce the least number of variables into the analysis of results. On the contrary, similar studies have chosen to vary ventilatory mechanic conditions (compliance and resistance), trying to simulate normal, low compliance (ARDS) and high resistance (obstructive diseases) clinical contexts.[4,8] We acknowledge that the advantage of maintaining homeostasis during measurements by only varying compliance limits the range of ventilator testing, a fact which may be overcome in future bench studies.

This study has three limitations:

1) Equipment-related: the technical limitations of the artificial lung have already been described. These limitations restrict the area of experimentation, but do not question the results, nor the concept that was intended to be proven. Additional bench tests with different equipment are being planned to overcome this .

2) Number of readings: reading sampling is not consensual in literature. Some studies use automated systems that allow the recording of the measurement[2-4] while others take manual readings (three to five readings), as in our study.[1] It is expected that a larger number of readings for each step of the variable will increase the significance of the results. This methodological adjustment is planned with the new bench tests, for which test and measurement equipment with capacity to record the measurements will be made available.

3) Parameters: apart from $V_{Te}$ and Pinsp, there is a wider range of parameters that should be evaluated within the development of a ventilator and flow is probably the most relevant. The absence of simulation in scenarios where not only C but also R and leakage can be varied was a limitation that's was already described and explained. In this study, mainly aimed at proving the concept of the SYSVENT OM1 ventilator, the authors have chosen to restrict the analysis to fundamental ventilation parameters (volume and pressure), which is a limitation. However, it is unanimously acknowledged by all authors that, in the iterative process to which this ventilator is subject to, new bench tests using measurement equipment with greater capacity and functionalities should contemplate a broader evaluation panel.

## CONCLUSION

This study proves the concept that the SYSVENT OM1 has an operational performance for the tested parameters in accordance with the premises that were initially defined. Therefore, the authors consider that the conditions for further studies aimed at the clinical use of the SYSVENT OM1 have been met, including further bench testing whenever required. Therefore, new bench tests, in vivo tests (in a veterinary laboratory) and electrical and electromagnetic safety tests have been planned to evaluate the operation of SYSVENT in a controlled adult intensive care environment, prior to the submission of the project to the scientific committee and the ethics committee.

## HUMAN AND ANIMAL PROTECTION

The authors declare that this project complied with the regulations that were established by the Ethics and Clinical Research Committee, according to the 2013 update of the Helsinki Declaration of the World Medical Association.

## DATA CONFIDENTIALITY

The authors declare that they have followed the protocols of their work centre on the publication of patient data.

## CONFLICTS OF INTEREST

The authors declare that there were no conflicts of interest in writing this manuscript.

## FINANCIAL SUPPORT

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