ALEMBERT EISTEIN LINO ALVARADO

**Continuous mandatory ventilation with pressure-control: a
comparison of airway-pressure waveform patterns**

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Dissertation presented to the Escola Politécnica (POLI) of
the University of São Paulo to obtain the degree of Master of
Science.

Field of Study: Biomedical Engineering.

Supervisor: Prof. Dr. Henrique Takachi Moriya

São Paulo

2021

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Catálogo-na-publicação

Lino Alvarado, Alembert Eistein

Continuous mandatory ventilation with pressure-control: a comparison of airway-pressure waveform patterns / A. E. Lino Alvarado -- São Paulo, 2021.
100 p.

Dissertação (Mestrado) - Escola Politécnica da Universidade de São Paulo. Departamento de Engenharia de Telecomunicações e Controle.

1.Pressão das vias aéreas 2.Modos ventilatório 3.Ventilador pulmonar
4.Ventilação mecânica I.Universidade de São Paulo. Escola Politécnica.
Departamento de Engenharia de Telecomunicações e Controle II.t.

To my mother and father, your
heartfelt support has shaped my
life.

ACKNOWLEDGMENTS

As almost always happens, or as in stories, a journey begins with the idea of mastering or knowing something. My life, like many, and with the exaggeration that words allow, has always been a journey. My reasons have been numerous. However, the longest of those trips have been to learn.

I want to express my deepest gratitude to Prof. Dr. Henrique Takachi Moriya from whom I have been learning more than I expected. Words can only inadequately convey my gratitude to my supervisor for helping me during my studies. This work only was possible due to his willingness to offer his time and expertise. Additionally, I want to thank my supervisor for teaching me that there is still humanity. I am indebted to you.

Additionally, special thanks go to Dr. Maria Aparecida de Oliveira (Cida) for everything she taught me during the experiments at the ICB, the coffees, and those long talks. So far, I do not know anyone else with that patience and respect for life.

Special thanks go to Felipe Fava de Lima, I will never forget the rides, the coffees and the walks, thanks for being my friend.

I am indebted to those at the IPT: Antonio Gentil, Kelvis do Nascimento, Sara Gomes, Erick Barreto, Halon Gurgel, Marcelo Sanches, and Mario Barbosa, for their friendship during this extraordinary COVID era.

Within the University I have also had support from my friends and colleges: Vitor Takeuchi, Renato Vitorasso, Jefferson Santana, and Amanda Barros.

I am grateful to the DEC team at the university: Diego Rosa, Edison Silva, and Miguel Rosa. For those coffees and help.

I would like to thank Milena, Kelly, Isabella, Vanessa, Yeny, Carlos, Persing, Javier, Evelyn, Henry, Luis, and Diana who are part of my life.

Finally, I would like to thank my family to whom I owe unconditional love. To my father Jaime from whom I learned that knowledge is the right path. To my dearest person in life, my mother Mariluz, for all your untold sacrifices. To my brothers, Piero, Al and Güill thank you for the past, the present, and the future. To my sister, Lhia thank you for always being on mother's side.

“It is clear that there is no classification of the Universe that is not arbitrary and full of conjectures. The reason for this is very simple: we do not know what kind of thing the universe is.”

(Jorge Luis Borges)

RESUMO

A ventilação mandatória contínua com pressão controlada (CMV-PC) foi um dos primeiros modos ventilatórios utilizados e continua sendo um dos mais difundidos no manejo de pacientes com insuficiência respiratória aguda. Para fornecer informações sobre o desempenho dos modos ventilatórios, os pesquisadores têm avaliado os parâmetros dos modos ventilatórios. Existem relatos de variabilidade operacional em diferentes modelos de ventiladores pulmonares. Entretanto, geralmente foram empregados diferentes cenários de avaliação nos estudos e as comparações na maioria dos casos foram feitas com modelos de alto custo. Além disso, os critérios empregados na obtenção dos parâmetros não são totalmente detalhados e são baseados em instrumentos de aquisição comerciais. Assim, esta pesquisa visa comparar diferentes padrões de onda de pressão nas vias aéreas de diferentes ventiladores pulmonares em CMV-PC, detalhando os critérios utilizados para as medições dos parâmetros avaliados, como também utilizar modelos normalmente encontrados no mercado brasileiro. Neste estudo foram avaliados 12 ventiladores pulmonares. Nos experimentos, os sinais de fluxo e pressão foram adquiridos a 100Hz . Uma configuração experimental baseada na norma ABNT NBR 80601-2-12: 2014 foi utilizada. Os cenários de teste tiveram 4 diferentes combinações de complacência e resistência: 1 ($50\text{ mL/cmH}_2\text{O}$ - $5\text{ cmH}_2\text{O/L/s}$), 2 ($50\text{ mL/cmH}_2\text{O}$ - $20\text{ cmH}_2\text{O/L/s}$), 3 ($20\text{ mL/cmH}_2\text{O}$ - $5\text{ cmH}_2\text{O/L/s}$) e 4 ($20\text{ mL/cmH}_2\text{O}$ - $20\text{ cmH}_2\text{O/L/s}$). Os parâmetros avaliados foram: *pressão inspiratória*, *pressão positiva de final de expiração (PEEP)*, *tempo inspiratório (T_I)*, *tempo para atingir 90% da pressão inspiratória (T_{90})*, *pico de pressão inspiratória*, *pico de fluxo inspiratório*, *área inspiratória (AI)*, *área expiratória (AE)*, *porcentagem da área inspiratória (I%)* e *porcentagem da área expiratória (E%)*. Para analisar os dados, utilizamos o teste de Kruskal-Wallis e o teste de Dunn's para comparações múltiplas. Além disso, uma avaliação baseada na norma foi realizada para *pressão inspiratória*, *PEEP* e T_I . Embora os ventiladores pulmonares tivessem as mesmas configurações para todos os cenários de teste e obedecessem a mesma norma, diferenças estatísticas foram encontradas para os parâmetros avaliados e entre alguns ventiladores pulmonares ($P < 0,05$). Surpreendentemente, 5 ventiladores pulmonares não conseguiram atingir 90% da pressão ajustada. Além disso, um sobressinal de $2,95\text{ cmH}_2\text{O}$ no cenário de teste 3 foi medido. Em relação à avaliação baseada na norma, os resultados do teste para *pressão inspiratória* mostraram que 4, 8, 2 e 3 ventiladores pulmonares falharam nos cenários de teste 1, 2, 3 e 4, respectivamente. No teste de *PEEP*, tivemos 3 ventiladores pulmonares que foram reprovados nos cenários de teste 1, 2 e 4; e 2 ventiladores pulmonares reprovados no cenário de teste 3. Com relação ao T_I , todos os ventiladores pulmonares estavam conformes. Este estudo evidenciou que as formas de onda da pressão nas vias aéreas no CMV-PC variaram entre os ventiladores pulmonares, principalmente no T_{90} (ou no tempo de subida) e na *pressão inspiratória*. As disparidades foram mais perceptíveis no cenário de teste 3, que possui valores mais altos de complacência e resistência. Um fato intrigante é que a ISO IEC 80601-2-12: 2014 (e sua versão 2020) não possui parâmetros para avaliar o tempo de subida ou sobressinal.

Palavras-Chave: Pressão das vias aéreas. Modo ventilatório. Ventilador pulmonar. Ventilação mecânica.

ABSTRACT

Continuous mandatory ventilation with pressure control (CMV-PC) was one of the first ventilation-modes to be introduced, and continues to be one of the most widespread ventilation-modes to manage patients with acute respiratory failure. In attempt to provide information regarding ventilation-modes performance to help clinicians, researchers have been evaluating ventilation-modes parameters over the years. Previous literature reported an operational variability across different models. These studies, however, have not had the same test scenarios, and they have mostly used top-line lung ventilators. Even more, the criteria used to measure the evaluated parameters were not fully detailed, and its calculation was based on commercial instruments. Thus, this research aims to compare different airway-pressure waveform patterns from different lung ventilators in CMV-PC, detailing the criteria used to measure the parameters and using lung ventilator models that are available on the Brazilian market. In this study, 12 lung ventilators were evaluated. For the experiments, flow and pressure signals were acquired at 100Hz . An experimental setup was chosen from ABNT NBR ISO IEC 80601-2-12: 2014. It comprises four test scenarios with different combinations of compliance and resistance: 1 ($50\text{ mL/cmH}_2\text{O}$ - $5\text{ cmH}_2\text{O/L/s}$), 2 ($50\text{ mL/cmH}_2\text{O}$ - $20\text{ cmH}_2\text{O/L/s}$), 3 ($20\text{ mL/cmH}_2\text{O}$ - $5\text{ cmH}_2\text{O/L/s}$), and 4 ($20\text{ mL/cmH}_2\text{O}$ - $20\text{ cmH}_2\text{O/L/s}$). Evaluated parameters were *inspiratory pressure*, *positive end-expiratory pressure (PEEP)*, *inspiratory time (T_I)*, *time interval to reach 90% of the set pressure (T_{90})*, *peak inspiratory pressure*, *peak inspiratory flow*, *inspiratory area (AI)*, *expiratory area (AE)*, *percentage of inspiratory area (I%)* and *percentage of expiratory area (E%)*. To address statistical differences, we conducted the Kruskal-Wallis test, and the Dunn's test for multiple comparisons. In addition, a standard-based assessment was performed for *inspiratory pressure*, *PEEP* and T_I . Even though the lung ventilators had the same configurations for all the test scenarios and obeyed the same standard, statistical differences were found for all the evaluated parameters, and between some lung ventilators ($P < 0.05$). Surprisingly, there were 5 lung ventilators that could not reach 90% of the set pressure. Further, an overshooting of $2.95\text{ cmH}_2\text{O}$ in test scenario 3 was measured. Relating to the standard-based assessment, *inspiratory pressure* test's results showed that 4, 8, 2 and 3 lung ventilators failed in test scenarios 1, 2, 3, and 4, respectively. For *PEEP* test's results, we had 3 lung ventilators that were reproved in test scenarios 1, 2, and 4; and 2 lung ventilators reproved in test scenario 3. With respect of T_I , all the lung ventilators passed the test. This study evidenced that airway-pressure waveforms in CMV-PC varied among lung ventilators, mainly in T_{90} (or understandably in rise time), and *inspiratory pressure*. Disparities were more noticeable in test scenario 3 that has higher values of compliance and resistance. An intriguing fact is that ISO IEC 80601-2-12: 2014 (and its 2020 version) does not have parameters to evaluate rise time or overshooting.

Keywords: Airway-pressure waveform. Lung ventilator. Mechanical ventilation. Ventilation-modes.

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LIST OF ABBREVIATIONS AND ACRONYMS

ABNT Associação Brasileira de Normas Técnicas.

AI Inspiratory Area.

AE Expiratory Area.

E% Percentage of Expiratory Area.

ANVISA National Agency of Sanitary Vigilance.

A/C-PC Assist Control Ventilation with Pressure Control.

CMV-PC Continuous Mandatory Ventilation with Pressure Control.

CMV-VC Continuous Mandatory Ventilation with Volume Control.

DAQ Data Acquisition.

ECRI Emergency Care Research Institute.

E% Percentage of Expiratory Area.

f_{rc} Respiratory Rate.

FiO₂ Fraction of Inspired Oxygen.

IEC International Electrotechnical Commission.

ISO International Standard Organization.

I% Percentage of Inspiratory Area.

I:E Phase Time Ratio.

IPT Institute of Technological Research.

PEEP Positive End-Expiratory Pressure.

POLI Escola Politécnica.

PPGEE Programa de Pós-Graduação em Engenharia Elétrica.

PS Pressure Support.

SI Start of Inspiration.

SE Start of Expiration.

T_I Inspiratory Time.

TTL Training and Test Lung.

T₉₀ Time to 90% of Set Pressure.

T_E Expiratory Time.

T_{rc} Respiratory Cycle.

USP University of São Paulo.

V_I Inspiratory Volume.

V_T Tidal Volume.

VBS Ventilator Breathing System.

VILI Ventilator-Induced Lung Injury.

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1 INTRODUCTION

Throughout this document, we use the terminology in accordance with the ISO 19223 Lung ventilators and related equipment — Vocabulary and semantics (International Standardization Organization, Switzerland, 2019).

Lung ventilators are also known as mechanical ventilators are life support equipment that feature different ventilation-modes. Among those ventilation-modes, the continuous mandatory ventilation with pressure control (CMV-PC) mode is extensively used in patients with acute respiratory failure; this ventilation-mode intends to deliver a constant pressure at a set level with a fix respiratory rate (set rate). Studies may suggest that CMV-PC improves the gas exchange due to a decelerating flow (ESTEBAN et al., 2000; OĞURLU et al., 2010). Nevertheless, there is not a consensus on whether CMV-PC has better outcomes than other ventilation-modes (e.g., continuous mandatory ventilation with volume control) when leading with patients with acute respiratory failure (DAVIS et al., 1996; GARNERO et al., 2013; RITTAYAMAI et al., 2015).

A challenging problem which arises in this domain is the possibility of lung damage due to unexpected pressure levels in the airways (MAEDA et al., 2004a; HERNANDEZ et al., 1989; PARKER; HERNANDEZ; PEEVY, 1993). A series of studies had indicated that inaccuracy in delivering pressure and volume parameters may derive in ventilator-induced lung injury (VILI) (PINHU et al., 2003; GATTINONI et al., 2003).

Over time, a body of literature has been developed on lung ventilator assessment with the aim of providing information about lung ventilator’s operational variability. For instance, there are studies evaluating home care and anesthesia ventilators’ performance (STAYER et al., 2000; AJNHORN, 2016). Concerning pressure control ventilation, previous studies have emphasized disparities in lung ventilators’ performance in relation to specific parameters (e.g., rise time, inspiration time and peak pressure) (WILLIAMS; MUELVET; KRATOHVIL, 2000; SUNISA; WILLIAMS; DEAN, 2001; CALDERON, 2006; USAQUEN, 2008; MARCHESE et al., 2011; URIBE, 2011; GONZALES et al., 2011; GONZALES et al., 2013).

Although results found in the literature appear to be consistent with performance differences of ventilation-modes in various lung ventilator models, it reveals a number of gaps and questionings. Research studies assessing ventilation-modes did not use same parameters values for lung test and ventilator settings. Test parameters and settings were not standardized, we only found 2 studies (USAQUEN, 2008; URIBE, 2011) that followed ABNT NBR 60601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2004), to date that standard has 2 updates, the first in 2014 and the other in 2020. In addition, there were not many studies evaluating mandatory modes (e.g., CMV-PC) in different lung ventilator models. In the majority, only top-line lung ventilators had been evaluated; despite the fact that there are several ventilator models available on the Brazilian market.

The overall goal of this dissertation is to compare the airway-pressure waveform in CMV-PC across different lung ventilator models, we take into consideration test parameters and settings for pressure-control inflation type prescribed in the Brazilian standard ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b). The standard was chosen based on the fact that lung ventilators must comply the standard for certification, and to normalize the experimental setup. In this manuscript, a testing setup and results obtained for 12 lung ventilators were presented.

1.1 Objectives

In this section the primary and secondary objectives, that motivate the study, are presented.

1.1.1 Primary objective

Compare the airway-pressure waveform patterns of CMV-PC ventilation in different lung ventilators according to a set of parameters partially based on ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b).

1.1.2 Secondary objective

Identify the required parameters to characterize the airway-pressure waveform in CMV-PC.

1.2 Rationale statement

In response to COVID-19, a group of professionals from the Institute for Technological Research (IPT) and the Escola Politécnica (POLI) of University of São Paulo (USP) joined forces to create a node (IPT-POLI) for maintenance and assessment of lung ventilators (LINO-ALVARADO et al., 2020; ALVARADO et al., 2021). Important points were perceived while assessment of lung ventilators had been conducted. First, prototypes under development only implemented CMV-PC and assist control ventilation with pressure control (A/C-PC), because it demands fewer system requirements (hardware) than implementing other ventilation-modes. Second, it was noticed that lung ventilators presented operational variations when evaluated under test scenarios prescribed in ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) for pressure inflation type.

Through these years different studies have been finding differences in lung ventilators performance when assessing ventilation-modes (STAYER et al., 2000; WILLIAMS; MUELVIER; KRATOHVIL, 2000; CALDERON, 2006; SUNISA; WILLIAMS; DEAN, 2001; AJNHORN, 2016; USAQUEN, 2008; MARCHESE et al., 2011; URIBE, 2011; GONZALES et al., 2011; GONZALES et al., 2013). Most of these studies did not use the same protocol for evaluation, which can be led to difficulties to compare these works. Even more, the ISO 80601-2-12 gold standard for critical care ventilator assessment has rarely been used (USAQUEN, 2008; URIBE, 2011).

For this study, it was of interest to investigate in detail airway-pressure waveforms during CMV-PC to understand why there are lung ventilators that despite complying ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b), they presented differences in waveform pattern. Our hypothesis was that the main disparity lies in the lack of parameters in the standard.

To date, the clinical impact of different airway-pressure waveform patterns during CMV-PC still has not been fully addressed. However, experiments involving animals (e.g., rabbits and rats) have brought important information about the connection of mechanical ventilation parameters (volume, peak pressure, peak flow, inspiratory cycle and plateau pressure) and the development of VILI (RICH et al., 2000; SIMONSON et al., 2004; MAEDA et al., 2004b; FUJITA et al., 2007; D'ANGELO et al., 2020).

2 LITERATURE REVIEW

This chapter begins with a brief introduction to the concepts of: lung ventilator, ventilation-modes and CMV-PC. Finally, the existing guidelines for the evaluation of lung ventilators are detailed.

2.1 Lung ventilator

A lung ventilator is a machine designed to carry respirable gas into and out of the lungs (artificial ventilation) in patients who are partially or totally unable to breathe. The lung ventilator is commonly named as mechanical ventilator, positive-pressure ventilator, critical care ventilator and continuous ventilator.

The lung ventilator has 4 requirements to guarantee its operation without any operator intervention. First, it must feature an interface to connect ventilator and patient; the interface secures flow of respirable gas from a ventilator into the lungs, and vice versa. Second, a power source, generally electrical or pneumatic, to operate the lung ventilator. Third, a control system to supervise and regulate ventilation. Finally, it is compulsory to have a monitoring system to check performance; it has to feature a set of alarms along with a safety system to avoid lung damage due to over-pressure (CHATBURN, 2003).

Lung ventilators can be classified according to the amount of the delivered volume. Those which deliver tidal volumes within the physiological range are called conventional ventilators; and those which use smaller tidal volumes and respiratory rates greater than 150 *breaths/min* are named as high frequency ventilators.

In addition, conventional ventilators can be categorized based on the lung ventilator's pressure in reference to the environment: positive-pressure and negative-pressure ventilators.

Positive-pressure ventilators, as its name referred, create a gradient flow to patient by application of a positive pressure; the gas is delivered through a circuit connecting the lung

ventilator to an endotracheal tube or a mask. Negative-pressure ventilators generate a pressure gradient by decreasing a chamber's pressure in which the body is encased without the head; the arrangement drives the air inside the patient's lung (RIMENSBERGER et al., 2015).

Figure 1 depicts a typical positive-pressure ventilator system. The gas supply provides the power to drive the gas into the patient's lungs through the ventilator breathing circuit. Exhalation is released via the exhalation valve.

Figure 1 – Typical positive-pressure ventilator system.

Source: (ECRI, 2012).

2.1.1 Parameters of mechanical ventilation

The mechanical ventilations' controlling is subjected to a set of variables that determines the respiratory function over time.

2.1.1.1 Respiratory cycle (T_{rc})

It refers to the duration of a complete breath which is delimited by the start of the inspiratory phase and the end of the expiratory phase, it is usually expressed in seconds.

The duration of the T_{RC} can be calculated as the summation of the inspiratory time (T_I) and expiratory time (T_E), it is indicated in equation 2.1.

$$T_{rc} = T_I + T_E \quad (2.1)$$

2.1.1.2 I:E ratio

It is also known as phase time ratio and computed as the ratio of T_I and T_E :

$$I : E = 1 \mid \frac{T_I}{T_E} \quad (2.2)$$

2.1.1.3 Respiratory rate (f_{rc})

The f_{rc} is the total number of respiratory cycles in a period; in general, it is expressed as breaths per minute:

$$f_{rc} = \frac{60}{T_{rc}} \left(\frac{breaths}{min} \right) \quad (2.3)$$

2.1.1.4 Tidal volume (V_T)

The V_T is the volume of respirable gas that enters and leaves the patient's lung in every single breath. It is expressed in mL or L .

2.1.1.5 Positive End-Expiratory Pressure (PEEP)

The term is used to designate the pressure at the end of the expiratory phase. It is also a term to specify the baseline airway pressure that encompasses a specific setting for the end-expiratory pressure. It is generally indicated in cmH_2O or $mbar$.

2.1.1.6 Airway pressure

The airway pressure represents the pressure at the patient-connection port (before the endotracheal tube) and can be measured all around the ventilator breathing system (VBS). It is generally indicated in cmH_2O or $mbar$.

2.1.1.7 Fraction of inspired oxygen (FiO_2)

The fraction of inspired oxygen (FiO_2) indicates the percentage of oxygen at the delivered gas. The FiO_2 must be selected between 21% and 100%.

2.1.2 Ventilation control

The control in most of the available lung ventilators on the market is done by a closed-loop control circuit as depicted in Figure 2. In general, the closed-loop control term refers to the use of a feedback signal to maintain consistent output. According to Figure 2, closed-loop control system of mechanical ventilation may be divided into 2 levels of control hierarchy (HOFFMANN, 2016).

In the first level, the parameters are adjusted based upon a reference tracking controller in which the operator sets target values and the ventilator attempts to maintain these values within every single breathing interval (TEHRANI, 2008).

In the second level, the outer control loop adjusts parameters by rule-based control, manually adjusting (physician's decision) or classical feedback control. Rule-base control systems use patient parameters for instance spontaneous V_T , end-tidal partial pressure of carbon dioxide, breathing rate, and airway pressure to adjust lung ventilator's outputs. Physicians commonly adjust ventilatory targets relying on monitoring parameters. Finally, classical feedback control aims to obtain a zero value for error control based on the formulation (mathematical approach) using monitoring and patient parameters during ventilation (HOFFMANN, 2016; CHATBURN; MIRELES-CABODEVILA, 2011).

2.1.3 Ventilation-modes

Ventilation-modes state the procedure by which a lung ventilator carries out its ventilatory function to assist a patient. Nowadays, there exists a large number of names for ventilation-modes due to patent laws and sales strategy. In the course of the years, several methodologies to classify the ventilation modes had been proposed (CARLO; AMBALAVANAN; CHATBURN, 2012; WOUTERS et al., 1999; CHATBURN, 2007); despite, it was not until 2019 that ventilation-modes were standardized by the ISO 19223 Lung ventilators and related equipment — Vocabulary and semantics (International Standardization Organization, Switzerland, 2019). This standard provides a consensus language for describing lung ventilator function.

Figure 2 – Closed-loop control system of mechanical ventilation with 2 levels of hierarchy. The first level of hierarchy is indicated inside the dashed rectangle, it contains a reference tracking controller. Outside the dot-dashed rectangle, there is a outer control loop for setting the reference values that can be configured by the physician, rule-based control or the classical feedback control.

Source: (HOFFMANN, 2016).

2.2 CMV-PC mode

The CMV-PC is a targeted mode in which a set pressure (pressure-control inflation) is generated in the course of a preset T_I . The breath starts at fixed set rate and the patient can not trigger any inflation (continuous mandatory ventilation).

The ventilator settings are $PEEP$, f_{rc} , *inspiratory pressure*, and T_I . Depending on the manufacturer the setting of the *inspiratory pressure* is configured above the $PEEP$, in other words, the *inspiratory pressure* grows as $PEEP$ increases. Otherwise, there is equipment in which the *inspiratory pressure* is independent of the $PEEP$ (NICHOLS; HARANATH, 2007; TOBIN, 2006).

During inspiration, the respirable gas moves into the lungs by the pressure gradient between the airway opening and the alveoli inside the lungS; as a consequence, the airway pressure at the Y-piece rises until it reaches the preset *inspiratory pressure*; then, the pressure is held until the T_I ends; finally, the expiration phase starts, the pressure is released to reach the preset $PEEP$.

Figure 3 illustrates in detail the key features of the airway-pressure and flow waveforms for CMV-PC. The $PEEP$ is the measurement of the airway pressure at the end of the

expiratory phase.

Figure 3 – Airway-pressure and flow waveforms for continuous mandatory ventilation with pressure control (CMV-PC). The key features of the waveforms are indicated. The *Positive End-Expiratory Pressure (PEEP)* is the measurement of the airway pressure at the end of the expiratory phase.

Source: (International Standardization Organization, Switzerland, 2019)

The elapsed time at which the airway pressure attains the preset *inspiratory pressure* is named as rise time, it has been presented as the slope of a ramp in most ventilators. In mechanical ventilation, it is recommended to select a faster rise time with obstructive patients (high-compliance); and a less accelerated rise time with restrictive patients (low-compliance) (BARBAS et al., 2014).

In CMV-PC inflation the V_T varies with the compliance of the respiratory system, the available time for inspiration, the gradient pressure between the airway opening and the alveolar pressure, and the airflow resistance.

2.3 Evaluation of ventilation-modes

Over the years, developers have introduced new ventilation-modes which attempt to improve patient-ventilator synchrony, to enhanced efficacy of weaning, to ease gas exchange and make ventilation safer (ESTEBAN et al., 1994; SINGER; CORBRIDGE, 2011; MARCHESE et al., 2011). However, a number of questions regarding the performance of ventilation-modes in different lung ventilator models need to be addressed. In the literature, there seems to be an indication that lung ventilators have performance differences.

Williams, Muelver & Kratochvil (2000) evaluated assist/control ventilation with pressure control (A/C-PC) and pressure support (PS) in 7 lung ventilators using a bellows-in-a-box lung model (resistance $8.2 \text{ cmH}_2\text{O}/\text{L}/\text{s}$ and compliance $50 \text{ mL}/\text{cmH}_2\text{O}$). The authors chose a set of variables to study lung ventilator trigger, overshooting and peak flow. Results indicated that lung ventilators presented differences in evaluated variables.

Another study by Sunisa, Williams & Dean (2001) assessed A/C-PC in 5 lung ventilators using 3 different rise times with an spontaneous breathing lung model (resistance $8.2 \text{ cmH}_2\text{O}/\text{L}/\text{s}$ and compliance $50 \text{ mL}/\text{cmH}_2\text{O}$). Lung ventilator settings were T_I of 1.0 s , *inspiratory pressure* of $15 \text{ cmH}_2\text{O}$ and *PEEP* of $5 \text{ cmH}_2\text{O}$. They found that varying rise time generated changes in inspiratory variables. Also, rise time and peak flow values were despaired among lung ventilators.

Usaquen (2008) assessed 7 lung ventilators in CMV-VC and CMV-PC according to the ABNT NBR 60601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2004). The study employed 3 test scenarios for CMV-VC and 2 for CMV-PC. In CMV-VC assessment, 3 lung ventilators did not deliver the volumes within the prescribed limits. In the case of CMV-PC assessment, 2 lung ventilators did not comply with prescribed values for CMV-PC.

Marchese et al. (2011) examined 6 lung ventilators in assist/control ventilation with volume control (A/C-VC), A/C-PC and PS. Lung ventilators setting for A/C-PC and PS were *inspiratory pressure* of $15 \text{ cmH}_2\text{O}$, T_I of 0.8 s and *PEEP* of $5 \text{ cmH}_2\text{O}$. In A/C-VC, T_I of 0.8 s and V_T of 500 mL . During the evaluation, a lung model (ASL5000, IngMar Medical, USA) with different combinations of compliance (10 and $60 \text{ mL}/\text{cmH}_2\text{O}$) and resistance (5 , 30 and $10 \text{ cmH}_2\text{O}/\text{L}/\text{s}$) were used. Results in A/C-VC had the highest variability across lung ventilators. In addition, some lung ventilators respond in an unsatisfactory way during test scenarios.

As we emphasize and indicate in previous paragraphs, ventilation-modes have been shown to have performance differences across different models. With respect to CMV-PC assessment, as far as we know, there have been few studies in the literature (CALDERON, 2006; TUNG; DRUM; MORGAN, 2005; USAQUEN, 2008; URIBE, 2011).

CMV-PC in 6 anesthesia machines and 1 lung ventilator were tested to compare the effect of T_I using a lung test (1600i, Michigan Instruments, USA) with a resistance of $5 \text{ cmH}_2\text{O}/\text{L}/\text{s}$ and compliance of 20 and $40 \text{ mL}/\text{cmH}_2\text{O}$. The devices were set to CMV-PC with inspiratory pressure of $40 \text{ cmH}_2\text{O}$, $PEEP$ of $5 \text{ cmH}_2\text{O}$, f_{rc} of 6 *breaths/min* and I:E ratio at 1:2. A set of parameters (V_T , *peak inspiratory flow*, and *peak expiratory flow*) were measured using a pulmonary mechanics monitor (CP-100, Bicore Monitoring Systems, USA); measurements were conducted for nine f_{rc} from 6 to 28 *breaths/min* with increments of 2 *breaths/min*. Authors reported differences in rise time and peak flows between equipment, and reduction in V_T as f_{rc} increases (TUNG; DRUM; MORGAN, 2005).

Calderon (2006) evaluated CMV-PC in 10 lung ventilators, evaluation was done with 6 combinations of compliance ($20 \text{ mL}/\text{cmH}_2\text{O}$ and $80 \text{ mL}/\text{cmH}_2\text{O}$) and resistance ($5 \text{ mL}/\text{cmH}_2\text{O}$, $20 \text{ mL}/\text{cmH}_2\text{O}$ and $50 \text{ mL}/\text{cmH}_2\text{O}$) using a test lung (PneuView 3600i, Michigan Instruments, USA). Lung ventilator settings were T_I of 1.42 s, *inspiratory pressure* of $25 \text{ cmH}_2\text{O}$ and 14 *breaths/min*. Pressure values were compared with values prescribed in ABNT NBR 60601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2004). The author sounded a note of caution with regard to the fact that no lung ventilator complied with prescribed values.

Uribe (2011) evaluated CMV-PC in twenty-one lung ventilators in a public hospital using a test lung (Quick Lung-QL, IngMar Medical, USA) according ABNT NBR 60601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2004). The study used 2 different test scenarios. In the first scenario, the test lung was set with compliance of $50 \text{ mL}/\text{cmH}_2\text{O}$ and resistance of $5 \text{ cmH}_2\text{O}/\text{L}/\text{s}$; lung ventilator settings: $PEEP$ of $0 \text{ cmH}_2\text{O}$, *inspiratory pressure* $10 \text{ cmH}_2\text{O}$, I:E ratio at 1:2, f_{rc} of 20 *breaths/min* and T_I of 1.0 s. For the second scenario, the test lung was configured with compliance of $20 \text{ mL}/\text{cmH}_2\text{O}$ and resistance of $20 \text{ cmH}_2\text{O}/\text{L}/\text{s}$; settings for lung ventilator were indicated as follows: $PEEP$ of $0 \text{ cmH}_2\text{O}$, *inspiratory pressure* $25 \text{ cmH}_2\text{O}$, I:E ratio at 1:2, f_{rc} of 20 *breaths/min* and T_I of 1.0 s. The study reported that 79% of the ventilators did not comply with the ABNT standard; also, they showed that only f_{rc} , *peak inspiratory flow* and T_I were in accordance with prescribed values in the standard.

2.4 Standards

This subsection details the guidelines that provide relevant information on the evaluation of mechanical ventilation, as well as the standardization of the vocabulary.

2.4.1 ISO 19223

The ISO 19223 (International Standardization Organization, Switzerland, 2019), published in July 2019, aims to standardized the vocabulary for fields of respiratory care related to mechanical ventilation. The document has applicable terminology for intensive-care ventilation, anesthesia ventilation, transport ventilation, breathing-therapy equipment and home-care ventilation.

The standard defines terminology for artificial-ventilation, breath, lung inflation, time, phase, cycle, rate, pressure, flow, volume, initiation and termination, baseline and *PEEP*, mode, bi-level, safety limits and alarms, and gas ports.

One important characteristic of the standard is the presentation of a mode terminology. The ISO systematizes ventilation-modes based upon 4 groups of classification: ventilation-pattern, inflation-type, selected inflation-type to assist spontaneous breathing in assured inflation and by ventilator's features (e.g., tube compensation and leak compensation). In Table 1 ventilation mode groups are shown.

Table 1 – Groups for mechanical ventilation-modes.

Group	Description
Group 1	One inflation-type can be selected at a time.
Group 1a	No provision for the selected inflation-type to be initiated by a patient-trigger event (e.g., CMV mode).
Group 1b	Selected inflation-type is assured to be initiated at successive intervals determined by the set rate if not initiated within such an interval by a patient-trigger event (e.g., A/C mode).
Group 2	An inflation-type is selected to be initiated at the set rate, with spontaneous breathing possible between assured inflations (either unassisted or supported by a selected inflation-type)
Group 2a	No provision for the assured inflations to be initiated by a patient-trigger event (e.g., IMV mode).
Group 2b	The initiation of each assured inflation is synchronized with any spontaneous breathing while maintaining the set rate (e.g., SIMV mode)
Group 3	Each patient-trigger event initiates a selected inflation-type; where a patient-trigger event does not occur within a set time interval, the ventilator initiates a second selected inflation-type.
Group 4	Ventilation-patterns enable continuous unrestricted breathing or continuous supported breathing, with constant baseline airway pressure at the set BAP level.
Group 4a	Group 4 ventilation-modes with a provision to support each inspiratory activity exceeding a threshold level (e.g., CSV mode).
Group 4b	Group 4 ventilation-modes with no provision to support any inspiratory activity (e.g., CPAP ventilation- mode).

Source: (International Standardization Organization, Switzerland, 2019)

2.4.2 ISO IEC 80601-2-12

The ISO IEC 80601-2-12, which is extensively used, intends to establish the basic safety and essential performance requirements for a lung ventilator and its accessories. The latest version of the standard is the ISO IEC 80601-2-12 Medical electrical equipment — Part 2-12: “Particular requirements for basic safety and essential performance of critical care ventilators” (International Standardization Organization, Switzerland, 2020) released in February 2020; it added performance test for other inflation-types that was not available in the previous versions.

In Brazil, the National Agency of Sanitary Vigilance (ANVISA) adapted the standard and published it, the ABNT NBR 80601-2-12 “Equipamento eletromédico Parte 2-12: Requisitos particulares para a segurança básica e o desempenho essencial de ventiladores para cuidados críticos” (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b).

The Brazilian standard ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) prescribed the tests for volume-control and pressure-control inflation types in items 201.12.1.101 and 201.12.1.102 respectively. Also, the essential alarms for basic safety are listed in item 201.12 (Table 2).

Table 2 – Essential alarms for basic safety.

Test Number	Item	Test
1	201.11.8.101.1	Technical alarm condition for power supply failure
2	201.11.8.101.2	Internal power supply
3	201.12.4.101	Oxygen monitor
4	201.12.4.104	Maximum limited pressure protective device
5	201.12.4.103.1	Ventilators intended to provide a tidal volume >50 mL
6	201.12.4.105	High airway pressure alarm condition and protective device
7	201.12.4.106	PEEP alarm conditions
8	201.12.4.107	Obstruction alarm condition
9	201.12.101	Disconnection alarm condition
10	201.13.102	Failure of one gas supply

Source: (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b)

3 MATERIALS AND METHODS

This chapter describes main components of the setup used in the study. The setup is composed of a lung test and a data acquisition system for flow and pressure signals. Furthermore, procedures developed to assess the functioning of lung test, flow sensor and pressure transducer are described. The chapter concludes with a description of how data analysis was done.

3.1 Lung test

A Training and Test Lung (TTL)(Dual Adult TTL, Michigan Instruments, USA) was used to simulate the human adult lung, allowing to reproduce different lung conditions. It was illustrated in Figure 4 part *a*.

Figure 4 – a) Training and Test Lung (Dual Adult TTL, Michigan Instruments, USA). b) Tension spring for compliance adjustment. c) Flow resistance.

The TTL has 2 elastometer lung chambers acting as adult lungs, in which lung

compliance is simulated by a tension spring (Figure 4 part *b*). An interchangeable flow resistor (Figure 4 part *c*) simulates the airway resistance of the respiratory track; the resistor consists of a tube with a known cross-sectional area. TTL's specifications are shown in Table 3.

Table 3 – Technical specification of the Training and Test Lung (TTL).

Specification	Value
Tidal Volume Capacity	2 <i>L/lung</i>
Residual Lung Volume	1.02 <i>L/lung</i>
Lung Compliance	0.01 to 0.10 <i>L/cmH₂O</i>
Airway Resistance	5, 20 or 50 <i>cmH₂O/L/s</i>
Operating temperature	0° to 40°C
Operating humidity	20 to 90%

Source: (Michigan Instruments, 2020)

In the development of this work, 2 flow resistances of 5 and 20 *cmH₂O/L/s* named as Rp 5 and Rp 20 were used. Figure 5 presents a vertical (part *a*) and frontal view (part *b*) of the resistances. It is possible to identify the difference in the cross-sectional area between the Rp 5 and Rp 20.

Figure 5 – TTL resistances. Frontal (part *a*) and top (part *b*) views are presented.

In Figure 6, the assembly of the TTL is shown. It is conformed by the hose assembly to connect one of elastometer chambers to the airway adaptor, the pickoff pressure adaptor, the flow resistance, and the compliance springs.

Figure 6 – Typical assembly of the Training and Test Lung (TTL).

Source: (Michigan Instruments, 2020)

Lung compliance adjustment was performed by losing the knob of the compliance spring, sliding the compliance spring to the target value, and tightening the knob. The flow resistance was configured by connecting the resistance between the lung inlet port and the pressure pickoff adaptor.

3.1.1 Lung test calibration check

The calibration check procedure verified the elastomer chamber and the compliance spring of the lung test using a pressure monitor system and an one-liter syringe. It consisted in measuring the TTL's pressure response (P) to a specific volume (ΔV) (1 L). The compliance (C) it is calculated by equation 3.1.

$$C = \frac{\Delta V}{P} \quad (3.1)$$

The setup for the calibration check can be seen in Figure 7. In order to conduct the calibration check procedure, the compliance was set at specific value (Table 4). Next, the hose assembly was connected to the pressure pickoff adaptor attached to the pressure sensor. Subsequently, the syringe was connected. Once the connections were made, measured pressure ought to be 0 cmH_2O ; otherwise, trapped air would be release by opening any connection to get 0 cmH_2O . Then, the 1 L volume was pumped by the

syringe generating a pressure rising within the values in Table 4. The procedure was done for each compliance value in Table 4.

Figure 7 – Lung test calibration setup.

Table 4 – Expected pressure values for lung test calibration check.

Compliance L/cmH_2O	Expected pressure cmH_2O
0.1	10.0 ± 0.3
0.05	20.0 ± 0.6
0.01	100.0 ± 3.0

Source: (Michigan Instruments, 2020)

3.1.2 Lung test leakage evaluation

The test used the same setup and procedure of the calibration check part (Figure 7). It consisted in evaluating the leakages (pressure drop) of the lung test while the volume delivered was sustaining for a minute. Pressure drop at the end of the minute must be below 1 cmH_2O .

3.2 Flow and pressure acquisition system

The flow and pressure signals were conditioned using 3 channels of the signal conditioning system (SC-24, SCIREQ, Canada) as illustrated in Figure 8. The signal conditioning system had 4 channels with individual controls for offset and gain. In addition, the signal conditioning system featured an anti-aliasing low pass filter with 4 selectable cutoff frequencies (10, 30, 100, 300 Hz).

Figure 8 – The signal conditioning system (SC-24, SCIREQ, Canada).

The analog signals from the signal conditioning system were converted to a digital signal using a data acquisition (DAQ) device (NI USB-6008, National Instruments, USA). The sampling frequency was 100 Hz for the flow and pressure signals. Digital signals were processed in a virtual instrument (VI) (LabVIEW 2015, National Instruments, USA).

The signal conditioning system used in this study was part of a Forced Oscillation Technique instrument developed in our laboratory (CRUZ, 2016).

3.2.1 Flow measurement

A lilly-type pneumotachometer (3700B, Hans Rudolph, USA) (Figure 9) was applied to measure flow during inspiratory and expiratory phases. It is a bi-directional flow meter that was designed for medical applications. This model features a small dead space, heater control, standard connection port (22 mm) and disinfectable components. Its technical specifications are listed in Table 5.

Table 5 – Technical specification of the pneumotachometer (3700B, Hans Rudolph, USA).

Technical specification	
Calibrated flow range	0 – 160 L/min
Calibration factor	0.10 $mmH_2O/L/min$
Dead space volume	13.674 mL
Operating temperature	5 to 40°C
Operating humidity	0 to 90%

Source: (HANS RUDOLPH, 2020)

Figure 9 – Graphical representation of the pneumotachometer (3700B, Hans Rudolph, USA).

The pneumotachometer created a pressure drop that was non-linear to the flow rate at the nominal range. In Figure 10 the pneumotachometer is presented, the variable flow rate was measured by the differential pressure transducer (HCXM100D6V, SensorTechnics, USA) that recorded the pressure drop (ΔP) related to flow.

Figure 10 – Pneumotachometer and differential pressure transducer.

The sensor's non-linear response could be attributed to the turbulent flow in the respiratory airway during ventilation. A flow's condition could be characterized by the Reynolds number (R_e) defined in Equation 3.2 as

$$R_e = \frac{2\dot{V}\rho}{\pi\mu r} \quad (3.2)$$

with a flow velocity expressed as $\dot{V}$, ρ is gas density, μ is gas viscosity and r is the pipe's radius.

If the Reynolds number is greater than 2000, it indicates the presence of turbulent flow. However, there is another factor named as the Womersley number (α) that brings information about flow's condition. The α is calculated as presented in Equation 3.3:

$$\alpha = r\sqrt{\frac{2\pi\rho f}{\mu}} \quad (3.3)$$

where a respiratory frequency is represent as f .

This number (α) indicates if the streamlines have sufficient time to settle into a steady-state, transition from steady to unsteady flow happens at α values of 1. In mechanical ventilation the flow inside the respiratory system is constantly reversing its direction due to the respiratory cycle, so it is common to have α values that indicates unsteady flow (BATES, 2009).

To deal with the non-linear relation between pressure and flow in the sensor, a calibration was conducted as described in the next section.

3.2.1.1 Flow sensor calibration

The pneumotachograph (3700B, Hans Rudolph, USA) was calibrated before experiments were conducted in order to guarantee the same conditions of gas viscosity related to temperature, humidity and air composition. The flow sensor's calibrations was performed by a polynomial method (TANG et al., 2003) which used a calibrated syringe. The method required mainly the syringe capacity (L), the number of injections (at least 10) and the polynomial degree. In the study, the method employed: 0.5 L syringe; 10 injection strokes having low, medium and high flows as illustrated in Figure 11; and a fourth-degree polynomial.

Figure 11 – Ten injection strokes having low, medium and high flows.

If the zero-flow offset was removed from the sensor data, equation 3.4 represented the flow value ($\dot{V}_i$) as a fourth degree polynomial, where b_1 , b_2 , b_3 and b_4 were unknown constants, and n_i was the digital output of the sensor.

$$\dot{V}_i = b_1 n_i + b_2 n_i^2 + b_3 n_i^3 + b_4 n_i^4 \quad (3.4)$$

The air volume passing through the pneumotachograph could be calculated using equation 3.5 that considers the sampling frequency (f_s).

$$V = \frac{1}{f_s} \sum_i \dot{V}_i = b_1 \frac{1}{f_s} \sum_i n_i + b_2 \frac{1}{f_s} \sum_i n_i^2 + b_3 \frac{1}{f_s} \sum_i n_i^3 + b_4 \frac{1}{f_s} \sum_i n_i^4 \quad (3.5)$$

Finally, multiple linear regression was utilized to calculate the coefficients of the fourth-degree polynomial (b_1 , b_2 , b_3 and b_4) from the 10 injection strokes.

3.2.2 Pressure measurement

Pressure signals were acquired using a piezoresistive strain gauge transducer (FPM-02PG, Fujikura, Japan) (Figure 12) at the TTL's airway opening using a pressure pickoff adaptor as illustrated in Figure 13. The transducer was typically employed for industrial instrumentation, flow measurement, and medical devices.

Figure 12 – A strain gauge pressure transducer (FPM-02PG, Fujikura, Japan).

Source: (FUJIKURA, 2004)

Figure 13 – A strain gauge pressure transducer attached to the pickoff pressure adaptor.

The transducer allowed to measure positive pressure and vacuum in non-corrosive gas environments. Its technical characteristics are listed in Table 6.

Table 6 – Technical specification of the strain gauge pressure transducer (FPM-02PG, Fujikura, Japan).

Technical characteristics	
Pressure Range	$\pm 140 \text{ cmH}_2\text{O}$
Accuracy	5% of the Full Scale Span
Output span voltage	60 to 140 mV
Operating temperature	-20°C to 100°C
Operating humidity	30 to 80%

Source: (FUJIKURA, 2004)

3.2.2.1 Pressure transducer calibration

The transducer's response is shown in Figure 14, in which a linearity response and DC offset value are appreciated. Based on these 2 characteristics, the adjustment of transducer digital response was performed using 2 pressure measurements. The first measurement was done at zero reference (atmospheric pressure) to remove the DC offset. Then, a second measurement at $20 \text{ cmH}_2\text{O}$ was recorded to scale the transducer digital output.

Figure 14 – The strain gauge pressure transducer output (FPM-02PG, Fujikura, Japan).

Source: Modified from (FUJIKURA, 2004)

A U-shaped plastic tube filling with water functions as a manometer, in which a zero reference ($0 \text{ cmH}_2\text{O}$) was set at the difference of height of the liquid in columns whilst the tube was opening to the air. A graduated scale was added to indicate the level of

references. One of the columns was connected to a three-way stopcock to apply pressure to the sensor as shown in Figure 15.

Figure 15 – U-tube manometer.

As a means to measure the zero reference ($0 \text{ cmH}_2\text{O}$), the U-shaped manometer was connected to the sensor through the three-way stopcock as illustrated in part *a* of Figure 16. In order to measure the second point ($20 \text{ cmH}_2\text{O}$), a syringe was connected to the three-way stopcock to create a water displacement of 10 cm that generated the desired pressure in the transducer as exemplified in part *b* of Figure 16.

Figure 16 – Pressure transducer calibration procedure.

3.3 Experimental setup

An experimental setup used for all the ventilators is shown in Figure 17, it was based on item 201.12.1.103 of ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b). The setup allowed to record flow and pressure signals of lung ventilators during CMV-PC.

Figure 17 – Experimental setup to assess lung ventilators in CMV-PC mode.

Ventilator's response in CMV-PC mode was evaluated under different configurations of resistance and compliance. Then, signal post-processing was performed to evaluate the airway-pressure and the flow waveforms employing a set of parameters that were described in the next section.

The pressure transducer and the pneumotachometer were placed between the TTL and the lung ventilator. The pressure transducer was attached to the pressure pickoff adaptor located in between the airway adaptor and the flow resistance. The pneumotachometer was connected to the pressure pickoff adaptor and the patient breathing circuit as shown in Figure 18.

The VBS used in all the experiments was a non-heated circuit consisting of two 22 mm silicone breathing tubes (1.5 m) and one 22 mm Y-piece. No humidifier system was utilized in the trials. The ventilator inspiratory and expiratory port were connected to the TTL through the VBS.

The TTL, the pressure transducer and the flow sensor had been verified before the experiment was conducted.

Figure 18 – Pressure transducer and flow sensor positioning.

Table 7 lists the parameters that were set up in the lung ventilators and TTL, the table had 4 adult test configuration indicated in Table 201.105 of ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b). *Inspiratory pressure* was configured above the *PEEP* value for each configuration scenario. When a ramp option is available, it was configured in the middle option. Also, no tube compensation was selected.

Table 7 – Pressure control inflation-type testing.

Test Number	Test Lung parameter			Ventilator settings			
	Compliance $\text{mL}/\text{cmH}_2\text{O}$ $\pm 10\%$	Linear resistance $\text{cmH}_2\text{O}/\text{L}/\text{s}$ $\pm 10\%$	Set rate $\text{breaths}/\text{min}$	Inspiratory time s	Inspiratory pressure cmH_2O	FiO_2 $\%$	<i>PEEP</i> cmH_2O
1	50	5	20	1	10	30	5
2	50	20	20	1	15	90	10
3	20	5	20	1	25	90	5
4	20	20	20	1	25	30	10

Source: (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b)

After passing the ventilator test, the lung ventilator and the TTL were configured for each of the 4 rows in Table 7. After a period of stabilization (30 initialization breaths), pressure and flow signals were acquired for each test configuration for 60 s using a sampling frequency of 100 Hz and a low-pass 4th order filter with a cutoff frequency of 10 Hz .

3.4 Data analysis

In order to examine collected data, routines were developed to process flow and pressure signals in a programming platform (Matlab R2010a, MathWorks, USA).

3.4.1 Evaluated parameters

Recorded airway-pressure waveforms were analyzed by computing a set of parameters chosen to characterize its performance. For pressure-control inflation type the ABNT NBR 80601-2-12:2014 prescribed in item 201.12.1.102 a group of parameters (*inspiratory pressure*, T_I and *PEEP*) to perform testing, these parameters were used in the study. Even more, *time to 90% of set pressure* (T_{90}), *peak inspiratory pressure*, *peak inspiratory flow*, *inspiratory area* (AI), *expiratory area* (AE), *percentage of inspiratory area* ($I\%$) and *percentage of expiratory area* ($E\%$) were assessed.

Prior to calculate the evaluated variables, the start of inspiration (SI) and start of expiration (SE) were computed using a flow threshold in the recorded flow signal. The SI (Figure 19) was defined as the instant of time at which a positive flow of 0.05 L/s was reached. In the same way, the SE (Figure 19) was established as the instant of time when flow goes to a negative value (reverse direction) of -0.05 L/s . These definitions allow to calculate T_I as the difference between the SE and SI in every breath cycle.

Table 7 indicates the *inspiratory pressure* and *PEEP* values for each of the 4 configuration scenarios. It is important to note that we configure the *inspiratory pressure* over the *PEEP*, as an illustration in line 1 of Table 7 *inspiratory pressure* and *PEEP* are $10\text{ cmH}_2\text{O}$ and $5\text{ cmH}_2\text{O}$ respectively, so the set pressure value in the lung ventilator should be $15\text{ cmH}_2\text{O}$ (*inspiratory pressure* + *PEEP*).

Figure 19 – The start of inspiration and start of expiration are indicated in the airway-pressure and flow waveforms. In the graph, *PEEP* refers to the *Positive End-Expiratory Pressure*

In Figure 20, evaluated variables are represented. The variables were determined for every scenario from Table 7.

3.4.1.1 Inspiratory pressure

Inspiratory pressure was calculated for 5 respiratory cycles and presented as the mean value and standard deviation ($mean \pm SD$). For each respiratory cycle, it was calculated at the end of the inspiratory phase by averaging the airway pressure over the last 50 ms. On account of the sample rate (10 ms), the routine averaged 6 samples before the SE.

Figure 20 – The graph illustrates the evaluated variables in the airway pressure waveform: *Positive End-Expiratory Pressure (PEEP)*, *time to reach the 90% of the set pressure (T_{90})*, *inspiratory pressure*, and *inspiratory time T_I* .

3.4.1.2 Positive End-Expiratory Pressure (PEEP)

It was calculated as the average of airway pressure at the end of the expiratory phase over the last 50 *ms*. Due to sampling period of 10 *ms*, the routine averaged the six last samples before the SI, the procedure was repeated for 5 respiratory cycles to finally compute the mean and standard deviation (*mean* $\pm$ *SD*) as the result.

3.4.1.3 Inspiratory time (T_I)

It was computed as the period of time (in seconds) from the start of inspiratory flow to the start of expiratory flow in each of the 5 cycles and presented as the mean value.

3.4.1.4 Time to 90% of set pressure (T_{90})

It was calculated on the airway pressure waveform as the time required to reach 90% of the set pressure from the SI. The calculation was done for 5 cycles, and T_{90} was determined as the mean and standard deviation (*mean* $\pm$ *SD*) value for the 5 cycles. In

each cycle, the routine looked forward to the instant of time at which the pressure signal was equal to 90% of the set pressure. However, in most of the cases, due to the sampling rate, the exact value of 90% of the set pressure would be between 2 samples.

Figure 21 shows pressure samples (black dots) from a pressure-airway waveform. We observed that the 90% of the set pressure was between these 2 samples. In this case, the routine computed the subtraction between the 90% of the set pressure and each of the 2 samples, the difference was indicated as $d1$ and $d2$. Then the absolute value of the 2 differences were compared to find the minimum value which indicated the sample ($X1$ or $X2$) to calculate T_{90} as the difference $X2 - SI$ or $X1 - SI$ in seconds. If the 2 differences were equal ($d1 = d2$), the routine would choose the first sample ($X1$) to calculate T_{90} .

Figure 21 – An illustration of pressure samples from a pressure-airway waveform. We observed that the 90% of the set pressure was between these 2 samples. In this case, the routine computed the subtraction between the 90% of the set pressure and each of the 2 samples, the difference was indicated as $d1$ and $d2$. Then the absolute value of the 2 differences were compared to find the minimum value which indicated the sample ($X1$ or $X2$) to calculate T_{90} as the difference $X2 - SI$ or $X1 - SI$ in seconds. If the 2 differences were equal ($d1 = d2$), the routine would choose the first sample ($X1$) to calculate T_{90} .

Figure 22 – Graphical representation of the trapezoidal method to approximate the area under a flow waveform (light blue area). The sampling period is represented as Δt .

3.4.1.5 Peak inspiratory pressure

The *peak inspiratory pressure* was the highest airway pressure value during inflation phase, it was recorded at the patient-connection port.

3.4.1.6 Peak inspiratory flow

It was defined as the highest flow of gas delivered to a patient via the patient-connection during the inspiration phase.

3.4.1.7 Inspiratory volume (V_I)

It was computed as the total volume of gas delivered into the lungs through the patient-connection port during the inflation phase.

To calculate the volume, we applied the trapezoidal method to perform an approximation of the area bounded by the flow waveform from the SI to the SE. In Figure 22 the area under the graph of the flow function $f(t)$ was approximated as a summation of trapezoids as indicates in equation 3.6.

$$\int_{SI}^{SE} f(t) dt \approx \frac{\Delta t}{2} \sum_{n=1}^N (f(t_n) + (f(t_{n+1}))) \quad (3.6)$$

3.4.1.8 Inspiratory area (AI)

It was specified as the area under the airway-pressure waveform delimited by the SI and the SE, the area is shown in Figure 23. It represented the product of pressure and time along the inspiratory phase. The integration of the area was done by the trapezoidal method.

Figure 23 – Illustration of the *inspiratory area* (AI)(green area) and *the expiratory area* (AE)(light blue area) in an airway-pressure waveform.

3.4.1.9 Percentage of inspiratory area (I%)

In this document, the $I\%$ was the percentage that the AI represented of an ideal airway-pressure waveform during the inspiratory phase. This ideal area was chosen for practicality, it is depicted in Figure 24 as a blue rectangle; our assumptions for this ideal airway-pressure waveform were mainly two: pressurization happened instantaneously (rise time equals to 0) and the return to the $PEEP$ level occurred immediately. An ideal ventilator's performance would be 100%, however in practice it is impossible. Based on this assumptions, the ideal areas for each of the 4 scenarios from Table 7 can be calculated multiplying the inspiratory time by the sum of the $PEEP$ and the *inspiratory pressure*, for tests scenarios 1, 2, 3 and 4 the values were 15, 25, 30 and 35 $cmH_2O \cdot s$ respectively.

Figure 24 – One cycle of an ideal airway-pressure waveform. The ideal area for the inspiratory and expiratory phases are depicted as a blue and a red rectangle respectively.

3.4.1.10 Expiratory area (AE)

The AE was defined as the area under the airway-pressure waveform from the SE to the start of a new inspiration, Figure 23 exemplifies an airway-pressure waveform in CMV-PC in which the AE was represented as a light blue area. This area brought information about the resistance of the ventilator's expiratory system and the $PEEP$ control.

3.4.1.11 Percentage of expiratory area (E%)

It was calculated as the percentage of the AE in relation to the ideal expiratory area, which was the $PEEP$ value times the duration of the expiratory phase. This ideal area assumed an instantaneous transition from the inspiratory phase to the expiratory phase and a continuous $PEEP$ level as illustrated in Figure 24, it was depicted as a red rectangle. For tests scenarios 1, 2, 3 and 4 the ideal values were 10, 20, 10 and 20 $cmH_2O \cdot s$ respectively.

3.4.2 Assessment of inspiratory pressure, PEEP and T_I based on ABNT NBR 80601-2-12:2014

Item 201.12.1.102 of ABNT NBR 80601-2-12:2014 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) stated that manufacturers should declare in their manuals the maximum error for *inspiratory pressure*, $PEEP$, f_{rc} , T_I , and FiO_2 . In this study, we evaluated only 3 of these parameters: *inspiratory pressure*, $PEEP$ and T_I . The accuracy of control for each parameter were obtained from lung ventilators' manuals, and a summary specifying the upper and lower limits are presented in Table 9.

Regarding *inspiratory pressure* and $PEEP$ assessment, the standard specified the

hectopascal (hPa) as a unit of pressure. In this study, however, we employed the centimeter of water (cmH_2O) as a unit of pressure due to the fact that it is widely employed by clinicians. An important fact is that these 2 units present a slight difference between them.

Parameters' measurements were compared with the limits indicated in Table 9 to determine if the measurements were within the limits.

3.4.3 Statistical analysis

Data were analyzed using a statistical software (GraphPad Prism 7, GraphPad software Inc, USA). To determine statistical differences for the evaluated parameters among the 12 lung ventilators, we used the Kruskal-Wallis test, and the Dunn's test as post hoc test for multiple comparisons. A non parametric analysis was conducted due to the fact that data from some ventilators did not present a Gaussian distribution.

3.4.4 Evaluated ventilators

In total twelve lung ventilators were evaluated. The ventilators were referred to as lung ventilator *A* (LTV 1200, CareFusion, USA), *B* (LUFT 3, Leistung, Brazil), *C* (FLEXIMAG, MAGNAMED, Brazil), *D* (BIYOVENT, Biosys, Turkey), *E* (WL3, WEG, Brazil), *F* (LTV2 2200, Vyaire Medical, USA), *G* (COMEN AX400, Shenzhen Comen Medical Instruments, China), *H* (ETERNITY SH-300, Beijing eternity electronic technology, China), *I* (CARMEL, KTK, Brazil), *J* (SHANGRILA 510S, AEOMED, China), *K* (MICROTAK TOTAL, KTK, Brazil) and *L* (MONTERREY +3, K. TAKAOKA, Brazil). Table 8 summarizes the models, serial numbers and software versions of all ventilators.

Equipment *J* and *K* are transport ventilators, and equipment *G* is a modified anesthesia machine. We included both in the study, because the equipment was intended to be used as lung ventilators.

Table 8 – Models, serial numbers and software versions of the evaluated lung ventilators.

Lung ventilator	Model	Serial number	Software version
<i>A</i>	LTV-1200	E90322	05.10
<i>B</i>	LUFT 3	E20161	E1555B00CL
<i>C</i>	FLEXIMAG PLUS	5104	*
<i>D</i>	BIYOVENT	600423	2.10.1263
<i>E</i>	WL3	1053999655	E1555B00CL
<i>F</i>	LTV2-2200	L92071	1.06
<i>G</i>	AX400	X4200513046C	V5.0.3/1.4
<i>H</i>	SH300	SH300SLASRCE2006524	E1555B00CL
<i>I</i>	CARMEL	2484	*
<i>J</i>	SHANGRILA 510S	SL510SYRYY085	1.09.0.5
<i>K</i>	MICROTAK TOTAL	762	1.07
<i>L</i>	MONTERREY	1035	*

(*) The software version is not available.

4 RESULTS

This chapter presents the results of the 12 studied lung ventilators. It is divided into 3 sections: standard-based assessment, airway-pressure and flow waveforms, and evaluated parameters. In the first section, the results of the lung ventilators' assessment are presented. In the second section, acquired waveforms are shown. The last section summarizes the results for the four test scenarios from Table 7, and the non-parametric analysis that was conducted. The results for all lung ventilators' parameters are summarized in Tables 10, 11, 12 and 13. Values for the parameters are presented as $mean \pm SD$.

4.1 Standard-based assessment

The limits of the accuracy of control for *inspiratory pressure*, *PEEP*, and T_I were acquired from the manufacturers' manuals as indicated in the standard (item 201.12.1.102); these limits are shown in Table 9. The lung ventilators that complied with the limits prescribed in ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) for *inspiratory pressure*, *PEEP*, and T_I are indicated in Tables 10, 11, 12 and 13.

For *inspiratory pressure* test, a group of lung ventilators were not compliant with the standard. In the test scenario 1, lung ventilators *C*, *H*, *I* and *J* did not reached the acceptable limits. The test scenario 2 had the higher number of lung ventilators (8 out of 12) that reproved the test (lung ventilators *A*, *C*, *D*, *G*, *H*, *I*, *J* and *K*). In the test scenario 3 presented 2 lung ventilators that did not complied with the limits *C* and *I*. In the test scenario 4, lung ventilators *C*, *I* and *K* failed the test.

In regard to *PEEP* test, not all the lung ventilators complied the standard in the four test scenarios. In test scenarios 1 and 2, lung ventilators *A*, *C* and *K* were not within the limits. In the case of test scenario 3, only 2 lung ventilators *A* and *K* were not compliant with the standard. In the test scenario 4, lung ventilators *A*, *B* and *K* failed the test.

All lung ventilators were compliant with T_I limits for all test scenarios.

Table 9 – Ventilators’ acceptable lower and upper limits for *inspiratory pressure*, *PEEP* and T_i according to manufacturers.

Lung Ventilator	Test number	<i>Inspiratory pressure</i> (cmH_2O)		<i>PEEP</i> (cmH_2O)		T_i (s)	
		Lower limit	Upper limit	Lower limit	Upper limit	Lower limit	Upper limit
A	1	14.25	15.75	4.75	5.25	0.95	1.05
	2	23.75	26.25	9.50	10.50	0.95	1.05
	3	28.50	31.50	4.75	5.25	0.95	1.05
	4	33.25	36.75	9.50	10.50	0.95	1.05
B	1	12.40	17.60	2.80	7.20	0.90	1.10
	2	22.00	28.00	7.60	12.40	0.90	1.10
	3	26.80	33.20	2.80	7.20	0.90	1.10
	4	31.60	38.40	7.60	12.40	0.90	1.10
C	1	14.00	16.00	4.00	6.00	0.99	1.01
	2	24.00	26.00	9.00	11.00	0.99	1.01
	3	29.00	31.00	4.00	6.00	0.99	1.01
	4	34.00	36.00	9.00	11.00	0.99	1.01
D	1	13.50	16.50	3.00	7.00	0.85	1.15
	2	22.50	27.50	8.00	12.00	0.85	1.15
	3	27.00	33.00	3.00	7.00	0.85	1.15
	4	31.50	38.50	8.00	12.00	0.85	1.15
E	1	12.40	17.60	2.80	7.20	0.90	1.10
	2	22.00	28.00	7.60	12.40	0.90	1.10
	3	26.80	33.20	2.80	7.20	0.90	1.10
	4	31.60	38.40	7.60	12.40	0.90	1.10
F	1	12.18	17.83	3.75	6.25	0.90	1.10
	2	21.43	28.58	8.50	11.50	0.90	1.10
	3	26.05	33.95	3.75	6.25	0.90	1.10
	4	30.68	39.33	8.50	11.50	0.90	1.10
G	1	12.50	17.50	3.00	7.00	0.80	1.20
	2	22.50	27.50	8.00	12.00	0.80	1.20
	3	27.50	32.50	3.00	7.00	0.80	1.20
	4	32.50	37.50	8.00	12.00	0.80	1.20
H	1	12.50	17.50	3.00	7.00	0.80	1.20
	2	22.50	27.50	8.00	12.00	0.80	1.20
	3	27.50	32.50	3.00	7.00	0.80	1.20
	4	32.50	37.50	8.00	12.00	0.80	1.20
I	1	12.40	17.60	2.80	7.20	0.80	1.20
	2	22.00	28.00	7.60	12.40	0.80	1.20
	3	26.80	33.20	2.80	7.20	0.80	1.20
	4	31.60	38.40	7.60	12.40	0.80	1.20
J	1	13.50	16.50	3.00	7.00	0.85	1.15
	2	22.50	27.50	8.00	12.00	0.85	1.15
	3	27.00	33.00	3.00	7.00	0.85	1.15
	4	31.50	38.50	8.00	12.00	0.85	1.15
K	1	14.25	15.75	4.75	5.25	0.95	1.05
	2	23.75	26.25	9.50	10.50	0.95	1.05
	3	28.50	31.50	4.75	5.25	0.95	1.05
	4	33.25	36.75	9.50	10.50	0.95	1.05
L	1	12.40	17.60	2.80	7.20	0.80	1.20
	2	22.00	28.00	7.60	12.40	0.80	1.20
	3	26.80	33.20	2.80	7.20	0.80	1.20
	4	31.60	38.40	7.60	12.40	0.80	1.20

Table 10 – Overall results from test scenario 1.

Lung Ventilator	<i>Inspiratory pressure</i> (cmH_2O)	<i>PEEP</i> (cmH_2O)	T_I (s)	T_{90} (s)	V_I (L)	<i>Peak inspiratory flow</i> (L/s)	<i>Peak inspiratory pressure</i> (cmH_2O)	AI ($cmH_2O \cdot s$)	$I\%$ (%)	AE ($cmH_2O \cdot s$)	$E\%$ (%)
A	$14.41 \pm 0.05^\checkmark$	$4.04 \pm 0.04^\times$	$1.02 \pm 0.01^\checkmark$	0.51 ± 0.01	0.556 ± 0.002	0.861 ± 0.002	14.59 ± 0.04	12.31 ± 0.01	82.06 ± 0.70	11.78 ± 0.075	117.81 ± 0.75
B	$14.31 \pm 0.03^\checkmark$	$3.78 \pm 0.03^\checkmark$	$1.06^\checkmark^*$	0.74 ± 0.01	0.510 ± 0.001	0.874 ± 0.005	14.04 ± 0.03	12.51 ± 0.05	83.37 ± 0.36	10.79 ± 0.02	107.91 ± 0.21
C	$13.32 \pm 0.04^\times$	$3.39 \pm 0.01^\times$	$1.01 \pm 0.01^\checkmark$	0^Δ	0.513^*	0.840 ± 0.001	13.40 ± 0.01	10.33 ± 0.04	68.88 ± 0.28	9.17 ± 0.04	91.70 ± 0.42
D	$14.05 \pm 0.06^\checkmark$	$4.41 \pm 0.01^\checkmark$	$1.03^\checkmark^*$	0.78 ± 0.01	0.505^*	0.766 ± 0.002	14.26 ± 0.01	11.77 ± 0.03	78.44 ± 0.18	9.96 ± 0.05	99.65 ± 0.46
E	$14.70 \pm 0.05^\checkmark$	$4.70 \pm 0.03^\checkmark$	$1.06^\checkmark^*$	0.55 ± 0.01	0.533 ± 0.001	0.845 ± 0.005	14.81 ± 0.06	13.22 ± 0.05	88.15 ± 0.32	11.66 ± 0.06	116.58 ± 0.62
F	$13.94 \pm 0.07^\checkmark$	$4.54 \pm 0.07^\checkmark$	$1.03^\checkmark^*$	0.69 ± 0.01	0.537 ± 0.003	0.842 ± 0.005	14.09 ± 0.10	12.33 ± 0.05	82.21 ± 0.30	13.24 ± 0.11	132.42 ± 1.14
G	$13.63 \pm 0.02^\checkmark$	$4.64 \pm 0.02^\checkmark$	$1.00^\checkmark^*$	0.86 ± 0.01	0.492 ± 0.001	0.768 ± 0.002	13.92 ± 0.01	10.69 ± 0.01	71.27 ± 0.09	12.72 ± 0.03	127.19 ± 0.31
H	$11.70 \pm 0.03^\times$	$4.69 \pm 0.02^\checkmark$	$0.99^\checkmark^*$	0^Δ	0.338 ± 0.002	0.416 ± 0.001	12.37 ± 0.04	8.63 ± 0.04	57.54 ± 0.26	11.87 ± 0.06	118.72 ± 0.56
I	$12.06 \pm 0.28^\times$	$4.10 \pm 0.02^\checkmark$	$0.98^\checkmark^*$	0^Δ	0.452 ± 0.019	0.680 ± 0.023	12.65 ± 0.34	9.24 ± 0.22	61.59 ± 1.48	9.80 ± 0.14	98.00 ± 1.37
J	$10.14 \pm 0.03^\times$	$6.09 \pm 0.03^\checkmark$	$1.01 \pm 0.01^\checkmark$	0^Δ	0.200 ± 0.002	0.654 ± 0.002	10.26 ± 0.03	9.77 ± 0.05	65.11 ± 0.32	12.49 ± 0.03	124.95 ± 0.31
K	$14.47 \pm 0.01^\checkmark$	$3.74 \pm 0.01^\times$	$1.01 \pm 0.01^\checkmark$	0.72 ± 0.01	0.636^*	0.853 ± 0.001	14.80 ± 0.01	11.39 ± 0.01	75.92 ± 0.03	13.17 ± 0.01	131.72 ± 0.05
L	$13.86 \pm 0.01^\checkmark$	$4.46 \pm 0.01^\checkmark$	$1.01^\checkmark^*$	0.73^*	0.485 ± 0.001	0.830 ± 0.001	14.12 ± 0.04	10.75 ± 0.02	71.68 ± 0.12	13.80 ± 0.04	137.97 ± 0.37

All values are presented as mean $\pm$ standard deviation (SD).

$^\checkmark$ This value complies with ABNT NBR 60601-2-1.

$^\times$ This value does not complies with ABNT NBR 60601-2-1.

* This value does not have a SD.

$^\Delta$ This lung ventilator does not reach the 90% of the *inspiratory pressure*.

PEEP = Positive End-Expiratory Pressure. T_I = *Inspiratory time*.

T_{90} = Time to 90% of set pressure. V_I = *Inspiratory volume*.

AI = *Inspiratory area*. $I\%$ = *Percentage of inspiratory area*.

AE = *Expiratory area*. $E\%$ = *Percentage of expiratory area*.

Table 11 – Overall results from test scenario 2.

Lung Ventilator	<i>Inspiratory pressure</i> (cmH_2O)	<i>PEEP</i> (cmH_2O)	T_I (s)	T_{90} (s)	V_I (L)	<i>Peak inspiratory flow</i> (L/s)	<i>Peak inspiratory pressure</i> (cmH_2O)	AI ($cmH_2O \cdot s$)	$I\%$ (%)	AE ($cmH_2O \cdot s$)	$E\%$ (%)
A	$22.51 \pm 0.10^\times$	$9.22 \pm 0.06^\times$	$1.04 \pm 0.01^\checkmark$	0.41 ± 0.01	0.606 ± 0.002	0.725 ± 0.003	24.24 ± 0.11	22.19 ± 0.09	88.75 ± 0.35	21.39 ± 0.11	106.95 ± 0.54
B	$22.36 \pm 0.19^\checkmark$	$8.71 \pm 0.04^\checkmark$	$1.07^\checkmark^*$	0.79 ± 0.02	0.626^*	0.772 ± 0.001	22.91 ± 0.04	22.87 ± 0.04	91.47 ± 0.15	19.40 ± 0.06	97.02 ± 0.30
C	$21.63 \pm 0.17^\times$	$8.16 \pm 0.01^\times$	$1.01^\checkmark^*$	0^Δ	0.616^*	0.795 ± 0.001	22.13 ± 0.02	20.23 ± 0.04	80.91 ± 0.14	18.78 ± 0.08	93.88 ± 0.40
D	$22.26 \pm 0.30^\times$	$9.05 \pm 0.01^\checkmark$	$1.04 \pm 0.01^\checkmark$	0.74 ± 0.01	0.595 ± 0.002	0.738 ± 0.004	23.35 ± 0.04	21.55 ± 0.07	86.20 ± 0.27	19.08 ± 0.07	95.39 ± 0.35
E	$23.10 \pm 0.06^\checkmark$	$9.47 \pm 0.09^\checkmark$	$1.06 \pm 0.01^\checkmark$	0.33 ± 0.02	0.649 ± 0.001	0.791 ± 0.001	23.76 ± 0.04	23.45 ± 0.06	93.80 ± 0.25	21.46 ± 0.11	107.28 ± 0.55
F	$21.90 \pm 0.11^\checkmark$	$9.67 \pm 0.04^\checkmark$	$1.04^\checkmark^*$	0.50^*	0.615 ± 0.002	0.721 ± 0.001	23.22 ± 0.05	21.88 ± 0.04	87.51 ± 0.15	22.96 ± 0.07	114.82 ± 0.36
G	$22.00 \pm 0.03^\times$	$9.41 \pm 0.01^\checkmark$	$1.01^\checkmark^*$	0.86 ± 0.01	0.552^*	0.743 ± 0.001	22.85 ± 0.02	20.16 ± 0.01	80.65 ± 0.02	21.64 ± 0.02	108.21 ± 0.09
H	$19.54 \pm 0.11^\times$	$9.80 \pm 0.05^\checkmark$	$0.98^\checkmark^*$	0^Δ	0.428 ± 0.004	0.534 ± 0.003	21.59 ± 0.12	17.02 ± 0.08	68.07 ± 0.32	21.94 ± 0.08	109.72 ± 0.42
I	$17.53 \pm 0.44^\times$	$8.59 \pm 0.06^\checkmark$	$1.05 \pm 0.01^\checkmark$	0^Δ	0.500 ± 0.022	0.688 ± 0.024	20.15 ± 0.64	18.23 ± 0.74	72.93 ± 2.95	18.59 ± 0.14	92.94 ± 0.70
J	$20.67 \pm 0.10^\times$	$10.54 \pm 0.03^\checkmark$	$1.04 \pm 0.01^\checkmark$	0^Δ	0.476 ± 0.001	0.649 ± 0.002	21.13 ± 0.03	20.07 ± 0.09	80.29 ± 0.35	23.14 ± 0.01	115.69 ± 0.06
K	$20.80 \pm 0.03^\times$	$6.63 \pm 0.03^\times$	$1.02^\checkmark^*$	0^Δ	0.661 ± 0.001	0.780 ± 0.001	21.77 ± 0.02	19.62 ± 0.01	78.46 ± 0.06	16.99 ± 0.05	84.94 ± 0.25
L	$22.18 \pm 0.48^\checkmark$	$10.25 \pm 0.01^\checkmark$	$1.03 \pm 0.01^\checkmark$	0.19 ± 0.01	0.576 ± 0.006	0.774 ± 0.001	24.03 ± 0.11	23.23 ± 0.17	92.91 ± 0.70	24.91 ± 0.10	124.57 ± 0.48

All values are presented as mean $\pm$ standard deviation (SD).

$^\checkmark$ This value complies with ABNT NBR 60601-2-1.

$^\times$ This value does not complies with ABNT NBR 60601-2-1.

* This value does not have a SD.

$^\Delta$ This lung ventilator do not reach the 90% of the *inspiratory pressure*.

PEEP = Positive End-Expiratory Pressure. T_I = *Inspiratory time*.

T_{90} = Time to 90% of set pressure. V_I = *Inspiratory volume*.

AI = *Inspiratory area*. $I\%$ = *Percentage of inspiratory area*.

AE = *Expiratory area*. $E\%$ = *Percentage of expiratory area*.

Table 12 – Overall results from test scenario 3.

Lung Ventilator	<i>Inspiratory pressure</i> (cmH_2O)	<i>PEEP</i> (cmH_2O)	T_I (s)	T_{90} (s)	V_I (L)	<i>Peak inspiratory flow</i> (L/s)	<i>Peak inspiratory pressure</i> (cmH_2O)	AI ($cmH_2O \cdot s$)	I% (%)	AE ($cmH_2O \cdot s$)	E% (%)
A	$29.22 \pm 0.08^\checkmark$	$4.22 \pm 0.05^\times$	$1.02^\checkmark^*$	0.42 ± 0.01	0.558 ± 0.002	1.193 ± 0.009	29.40 ± 0.07	24.39 ± 0.06	81.30 ± 0.20	13.68 ± 0.05	136.84 ± 0.49
B	$28.16 \pm 0.12^\checkmark$	$4.46 \pm 0.02^\checkmark$	$1.03^\checkmark^*$	0.49 ± 0.01	0.493 ± 0.001	1.219 ± 0.003	28.31 ± 0.08	24.62 ± 0.07	82.06 ± 0.24	13.08 ± 0.04	130.80 ± 0.39
C	$28.50 \pm 0.02^\times$	$4.02 \pm 0.02^\checkmark$	$0.99 \pm 0.01^\checkmark$	0.49 ± 0.01	0.538 ± 0.001	1.391 ± 0.001	28.58 ± 0.01	23.61 ± 0.09	78.69 ± 0.30	10.86 ± 0.09	108.60 ± 0.87
D	$29.31 \pm 0.03^\checkmark$	$4.51 \pm 0.01^\checkmark$	$1.01^\checkmark^*$	0.58 ± 0.01	0.556 ± 0.001	1.183 ± 0.003	29.35 ± 0.03	22.63 ± 0.10	75.42 ± 0.33	11.53 ± 0.11	115.32 ± 1.10
E	$29.69 \pm 0.04^\checkmark$	$4.62 \pm 0.02^\checkmark$	$1.01 \pm 0.01^\checkmark$	0.42^*	0.573 ± 0.001	1.290 ± 0.003	29.81 ± 0.05	25.64 ± 0.08	85.46 ± 0.25	16.02 ± 0.06	160.17 ± 0.56
F	$28.93 \pm 0.03^\checkmark$	$4.22 \pm 0.03^\checkmark$	$1.02^\checkmark^*$	0.38^*	0.564 ± 0.001	1.262 ± 0.014	29.17 ± 0.03	25.15 ± 0.02	83.85 ± 0.07	15.29 ± 0.05	152.86 ± 0.53
G	$28.89 \pm 0.06^\checkmark$	$5.04 \pm 0.10^\checkmark$	$0.98^\checkmark^*$	0.59 ± 0.01	0.499 ± 0.002	1.116 ± 0.007	28.94 ± 0.05	21.89 ± 0.06	72.98 ± 0.20	15.75 ± 0.21	157.52 ± 2.08
H	$32.68 \pm 0.03^\checkmark$	$4.56 \pm 0.03^\checkmark$	$1.01^\checkmark^*$	0.66	0.613 ± 0.001	0.827 ± 0.001	32.95 ± 0.03	20.65 ± 0.03	68.85 ± 0.19	13.78 ± 0.05	137.75 ± 0.47
I	$25.29 \pm 0.45^\times$	$4.16 \pm 0.03^\checkmark$	$0.98^\checkmark^*$	0^Δ	0.456 ± 0.010	1.074 ± 0.018	25.38 ± 0.44	19.15 ± 0.33	63.83 ± 1.10	11.88 ± 0.15	118.80 ± 1.54
J	$27.67 \pm 0.02^\checkmark$	$4.38 \pm 0.02^\checkmark$	$1.01 \pm 0.01^\checkmark$	0.77 ± 0.01	0.462^*	0.821 ± 0.002	27.70 ± 0.03	20.52 ± 0.08	68.39 ± 0.26	13.65 ± 0.05	136.53 ± 0.53
K	$28.59 \pm 0.11^\checkmark$	$3.65 \pm 0.01^\times$	$1.00^\checkmark^*$	0.72 ± 0.01	0.561 ± 0.003	0.834 ± 0.001	28.62 ± 0.12	20.05 ± 0.04	66.82 ± 0.13	13.32 ± 0.03	133.22 ± 0.29
L	$29.66 \pm 0.03^\checkmark$	$4.65 \pm 0.01^\checkmark$	$0.85 \pm 0.01^\checkmark$	0.51 ± 0.01	0.487^*	1.210 ± 0.002	29.73 ± 0.02	19.59 ± 0.10	65.30 ± 0.33	18.77 ± 0.12	187.66 ± 1.22

All values are presented as mean $\pm$ standard deviation (SD).

$^\checkmark$ This value complies with ABNT NBR 60601-2-1.

$^\times$ This value does not complies with ABNT NBR 60601-2-1.

* This value does not have a SD.

$^\Delta$ This lung ventilator does not reach the 90% of the *inspiratory pressure*.

PEEP = Positive End-Expiratory Pressure. T_I = *Inspiratory time*.

T_{90} = Time to 90% of set pressure. V_I = *Inspiratory volume*.

AI = *Inspiratory area*. I% = *Percentage of inspiratory area*.

AE = *Expiratory area*. E% = *Percentage of expiratory area*.

Table 13 – Overall results from test scenario 4.

Lung Ventilator	<i>Inspiratory pressure</i> (<i>cmH₂O</i>)	<i>PEEP</i> (<i>cmH₂O</i>)	<i>T_I</i> (s)	<i>T₉₀</i> (s)	<i>V_I</i> (L)	<i>Peak inspiratory flow</i> (L/s)	<i>Peak inspiratory pressure</i> (<i>cmH₂O</i>)	AI (<i>cmH₂O</i> · s)	<i>I</i> % (%)	AE (<i>cmH₂O</i> · s)	<i>E</i> % (%)
<i>A</i>	35.50 ± 0.35✓	9.56 ± 0.06×	1.02✓*	0.50 ± 0.07	0.534 ± 0.005	0.716 ± 0.025	36.27 ± 0.10	30.02 ± 0.54	85.76 ± 1.54	23.87 ± 0.13	119.37 ± 0.66
<i>B</i>	32.94 ± 0.03✓	9.02 ± 0.03×	1.03✓*	0.41 ± 0.01	0.491*	0.853 ± 0.001	32.97 ± 0.03	31.19 ± 0.05	89.12 ± 0.15	21.92 ± 0.06	109.58 ± 0.28
<i>C</i>	32.91 ± 0.02×	8.48 ± 0.04✓	0.99 ± 0.01✓	0.59 ± 0.01	0.480 ± 0.001	0.920 ± 0.002	32.97 ± 0.01	29.23 ± 0.10	83.51 ± 0.28	19.38 ± 0.10	96.90 ± 0.52
<i>D</i>	33.91 ± 0.10✓	9.18 ± 0.01✓	1.02 ± 0.01✓	0.62 ± 0.01	0.498 ± 0.001	0.817 ± 0.002	34.20 ± 0.02	29.22 ± 0.12	83.50 ± 0.34	19.52 ± 0.04	97.59 ± 0.18
<i>E</i>	34.55 ± 0.08✓	9.56 ± 0.02✓	1.02✓*	0.26 ± 0.01	0.513 ± 0.001	0.884 ± 0.004	34.58 ± 0.08	32.36 ± 0.07	92.46 ± 0.19	25.91 ± 0.07	129.53 ± 0.36
<i>F</i>	33.82 ± 0.03✓	9.09 ± 0.09✓	1.02✓*	0.39 ± 0.01	0.519 ± 0.002	0.815 ± 0.005	34.93 ± 0.03	30.75 ± 0.10	87.86 ± 0.29	24.45 ± 0.10	122.24 ± 0.48
<i>G</i>	33.48 ± 0.02✓	9.37 ± 0.01✓	0.99✓*	0.59 ± 0.01	0.500*	0.879 ± 0.002	33.59 ± 0.02	28.20 ± 0.02	80.58 ± 0.04	23.70 ± 0.02	118.49 ± 0.11
<i>H</i>	35.00 ± 0.07✓	9.53 ± 0.03✓	1.01 ± 0.01✓	0.53*	0.490 ± 0.001	0.674 ± 0.002	35.50 ± 0.07	27.36 ± 0.10	78.16 ± 0.29	20.26 ± 0.07	101.32 ± 0.34
<i>I</i>	29.89 ± 0.39×	8.62 ± 0.05✓	0.98 ± 0.01✓	0 [△]	0.457 ± 0.008	0.816 ± 0.009	30.22 ± 0.41	24.82 ± 0.44	70.93 ± 1.24	20.48 ± 0.08	102.41 ± 0.41
<i>J</i>	32.06 ± 0.03✓	10.96 ± 0.02✓	1.04 ± 0.01✓	0.89*	0.410*	0.585 ± 0.002	32.33 ± 0.01	26.86 ± 0.13	76.73 ± 0.36	24.95 ± 0.09	124.73 ± 0.43
<i>K</i>	32.37 ± 0.01×	7.53 ± 0.10×	1.01 ± 0.01✓	0.78 ± 0.01	0.542 ± 0.001	0.750 ± 0.001	32.49 ± 0.02	26.89 ± 0.04	76.83 ± 0.13	18.70 ± 0.17	93.52 ± 0.88
<i>L</i>	34.36 ± 0.07✓	9.54 ± 0.01✓	0.94✓*	0.37 ± 0.01	0.500 ± 0.001	0.882 ± 0.002	34.86 ± 0.11	29.10 ± 0.06	83.14 ± 0.18	27.19 ± 0.18	135.93 ± 0.90

All values are presented as mean ± standard deviation (SD).

✓ This value complies with ABNT NBR 60601-2-1.

×

 This value does not complies with ABNT NBR 60601-2-1.

* This value does not have a SD.

△ This lung ventilator does not reach the 90% of the *inspiratory pressure*.

PEEP = *Positive End-Expiratory Pressure*. *T_I* = *Inspiratory time*.

T₉₀ = Time to 90% of set pressure. *V_I* = *Inspiratory volume*.

AI = *Inspiratory area*. *I*% = *Percentage of inspiratory area*.

AE = *Expiratory area*. *E*% = *Percentage of expiratory area*.

4.2 Airway-pressure and flow waveforms

In Figure 25, we exemplify how the airway-pressure and flow waveforms are presented for a lung ventilator in the four test scenarios. The start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

One cycle of airway-pressure and flow waveforms of all lung ventilators for the four test scenarios are presented in Figures A.1, A.2, A.3, A.4, A.5, A.6, A.7 and A.8.

Figure 25 – One cycle of airway-pressure and flow waveforms of lung ventilator A for the four test scenarios. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

4.3 Evaluated parameters

4.3.1 Inspiratory pressure

Figure 26 presents the results of *inspiratory pressure* for the four test scenarios. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 14.

Figure 26 – Results of *inspiratory pressure* for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Lung ventilator *E* had the nearest values to the target pressure within test scenarios 1, 2 and 3. In the test scenario 4, lung ventilator *H* had the best performance for *inspiratory pressure*. These lung ventilators (*E* vs. *H*) were significantly different in test scenarios 1 and 2.

Table 14 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *inspiratory pressure* among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	A	B	C	D	E	F	G	H	I	J	K	L
A	Ø	-	4	-	-	-	-	1	4	1,4	4	-
B	-	Ø	-	-	3	-	-	2,3	2	-	-	-
C	4	-	Ø	-	1	-	-	3	-	-	-	-
D	-	-	-	Ø	-	-	-	2	2,3	1	-	-
E	-	3	1	-	Ø	-	-	1,2	1,2,3,4	1,2,3,4	2	-
F	-	-	-	-	-	Ø	-	-	-	-	-	-
G	-	-	-	-	-	-	Ø	-	2	-	-	-
H	1	2,3	3	2	1,2	-	-	Ø	3,4	3,4	1,4	-
I	4	2	-	2,3	1,2,3,4	-	2	3,4	Ø	-	1,3	4
J	1,4	-	-	1	1,2,3,4	-	-	3,4	-	Ø	1,3	-
K	4	-	-	-	2	-	-	1,4	1,3	1,3	Ø	-
L	-	-	-	-	-	-	-	-	4	-	-	Ø

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.2 PEEP

Figure 27 illustrates the results of *PEEP* for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 15.

Figure 27 – Results of *Positive End-Expiratory Pressure (PEEP)* for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

In test scenarios 1, 2 and 3, lung ventilators *E*, *H* and *G* had the closest values to the target *PEEP*, respectively. In the test scenario 4, lung ventilators *A* and *E* were the closest to the target *PEEP*, and also both were approximately equals.

Table 15 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *Positive End-Expiratory Pressure (PEEP)* among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>	<i>I</i>	<i>J</i>	<i>K</i>	<i>L</i>
<i>A</i>	Ø	-	4	-	-	-	-	-	-	1	4	-
<i>B</i>	-	Ø	-	-	-	-	-	-	-	2,4	-	-
<i>C</i>	4	-	Ø	-	1,3,4	-	1,3	1,2	-	1,2,4	-	2,3
<i>D</i>	-	-	-	Ø	-	-	-	-	-	-	-	-
<i>E</i>	-	-	1,3,4	-	Ø	-	-	-	-	-	1,3,4	-
<i>F</i>	-	-	-	-	-	Ø	3	-	-	-	2	-
<i>G</i>	-	-	1,3	-	-	3	Ø	-	3	-	3	-
<i>H</i>	-	-	1,2	-	-	-	-	Ø	-	-	1,2,3,4	-
<i>I</i>	-	-	-	-	-	-	3	-	Ø	1,2,4	-	23
<i>J</i>	1	2,4	1,2,4	-	-	-	-	-	-	Ø	1,2,4	2
<i>K</i>	4	-	-	-	1,3,4	2	3	1,2,3,4	1,2,4	-	Ø	3,4
<i>L</i>	-	-	2,3	-	-	-	-	-	2	3,4	-	Ø

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.3 T_{90}

Figure 28 illustrates the results of T_{90} for the four test scenarios from Table 7. In test scenario 1, as depicted in the graph, lung ventilators C , H , I and J did not reach the 90% of the target pressure. In the case of test scenario 2, lung ventilators C , H , I , J and K failed to reach the target value. In test scenarios 3 and 4, only the lung ventilator I did not reach the target value.

Figure 28 – Results of *time to 90% of set pressure* (T_{90}) for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

(*) This lung ventilator do not reach the 90% of the target pressure.

Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 16 which lists the results of the statistical analysis conducted for T_{90} among all the lung ventilators.

Table 16 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *time to 90% of set pressure* (T_{90}) among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>	<i>I</i>	<i>J</i>	<i>K</i>	<i>L</i>
<i>A</i>	Ø	-	-	1	-	-	1,2	-	-	3	3	-
<i>B</i>	-	Ø	-	-	2	-	-	-	-	3,4	-	2
<i>C</i>	-	-	Ø	-	-	-	2	-	-	-	-	-
<i>D</i>	1	-	-	Ø	14	-	-	-	-	-	-	2,4
<i>E</i>	-	2	-	14	Ø	-	1,2	-	-	3,4	3,4	-
<i>F</i>	-	-	-	-	-	Ø	1,3	3	-	3,4	3,4	-
<i>G</i>	1,2	-	2	-	1,2	1,3	Ø	-	-	-	-	2
<i>H</i>	-	-	-	-	-	3	-	Ø	-	-	-	-
<i>I</i>	-	-	-	-	-	-	-	-	Ø	-	-	-
<i>J</i>	3	3,4	-	-	3,4	3,4	-	-	-	Ø	-	4
<i>K</i>	3	-	-	-	3,4	3,4	-	-	-	-	Ø	4
<i>L</i>	-	2	-	2,4	-	-	-	-	-	4	4	Ø

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.4 T_I

Figure 29 illustrates the results of T_I for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 17.

Figure 29 – Results of *inspiratory time* (T_I) for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Table 17 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *inspiratory time* T_I among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>	<i>I</i>	<i>J</i>	<i>K</i>	<i>L</i>
<i>A</i>	∅	-	2	-	-	-	3	2	3,4	-	-	1,3,4
<i>B</i>	-	∅	1,2,3,4	-	-	-	2,3,4	1,2	1,3,4	-	2	1,3,4
<i>C</i>	2	1,2,3,4	∅	-	1,2	-	-	-	-	4	-	-
<i>D</i>	-	-	-	∅	-	-	-	-	-	-	-	1,4
<i>E</i>	-	-	1,2	-	∅	-	2	1,2	1	-	-	1,3
<i>F</i>	-	-	-	-	-	∅	3		3	-	-	1,3
<i>G</i>	3	2,3,4	-	-	2	3	∅	-	-	4	-	-
<i>H</i>	2	1,2	-	-	1,2		-	∅	2	-	-	-
<i>I</i>	3,4	1,3,4	-	-	1	3	-	2	∅	4	-	-
<i>J</i>	-	-	4	-	-	-	4	-	4	∅	-	4
<i>K</i>	-	2	-	-	-	-	-	-	-	-	∅	-
<i>L</i>	1,3,4	1,3,4	-	-	1,3	1,3	-	-	-	4	-	∅

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.5 Peak inspiratory pressure

Figure 30 illustrates the results of *peak inspiratory pressure* for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 18.

Figure 30 – Results of *peak inspiratory pressure* for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Table 18 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *peak inspiratory pressure* among lung ventilators’. An intersection between a column and a row indicates a comparison (column vs row). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators (column vs row) is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>	<i>I</i>	<i>J</i>	<i>K</i>	<i>L</i>
<i>A</i>	Ø	4	4	-	-	-	-	1,2	2,3,4	1,2,4	2,4	-
<i>B</i>	4	Ø	-	-	3	-	-	3	-	-	-	-
<i>C</i>	4	-	Ø	-	1	-	-	3	-	-	-	-
<i>D</i>	-	-	-	Ø	-	-	-	-	2	1	-	-
<i>E</i>	-	3	1	-	Ø	-	-	1	1,2,3	1,2,3	-	-
<i>F</i>	-	-	-	-	-	Ø	-	-	4	4	-	-
<i>G</i>	-	-	-	-	-	-	Ø	-	-	-	-	-
<i>H</i>	1,2	3	3	-	1	-	-	Ø	34	34	1,3,4	2
<i>I</i>	2,3,4	-	-	2	1,2,3	4	-	34	Ø	-	1	2,3,4
<i>J</i>	1,2,4	-	-	1	1,2,3	4	-	34	-	Ø	1	2,3
<i>K</i>	2,4	-	-	-	-	-	-	1,3,4	1	1	Ø	-
<i>L</i>	-	-	-	-	-	-	-	2	2,3,4	2,3	-	Ø

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.6 Peak inspiratory flow

Figure 31 illustrates the results of *peak inspiratory flow* for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 19.

Figure 31 – Results of *peak inspiratory flow* for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Table 19 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *peak inspiratory flow* among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	<i>A</i>	<i>B</i>	<i>C</i>	<i>D</i>	<i>E</i>	<i>F</i>	<i>G</i>	<i>H</i>	<i>I</i>	<i>J</i>	<i>K</i>	<i>L</i>
<i>A</i>	∅	-	4	-	-	-	-	1	1	1	-	-
<i>B</i>	-	∅	-	1	-	-	-	1	1	1,3	-	-
<i>C</i>	4	-	∅	-	-	2	-	2,3,4	2,3	2,3,4	3,4	-
<i>D</i>	-	1	-	∅	-	-	-	-	-	-	-	-
<i>E</i>	-	-	-	-	∅	-	-	1,2,3,4	2,3	2,3,4	-	-
<i>F</i>	-	-	2	-	-	∅	-	3	-	3	-	-
<i>G</i>	-	-	-	-	-	-	∅	-	-	4	-	-
<i>H</i>	1	1	2,3,4	-	1,2,3,4	3	-	∅	-	-	1,2	2,4
<i>I</i>	1	1	2,3	-	2,3	-	-	-	∅	-	-	-
<i>J</i>	1	1,3	2,3,4	-	2,3,4	3	4	-	-	∅	1,2	4
<i>K</i>	-	-	3,4	-	-	-	-	1,2	-	1,2	∅	-
<i>L</i>	-	-	-	-	-	-	-	2,4	-	4	-	∅

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.7 V_I

Figure 32 illustrates the results of V_I for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 20.

Figure 32 – Results of *inspiratory volume* (V_I) for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Table 20 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *inspiratory volume* (V_I) among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	A	B	C	D	E	F	G	H	I	J	K	L
A	Ø	-	-	-	-	-	-	1,2,4	1,4	1,2,4	-	-
B	-	Ø	-	-	-	-	-	3	-	-	-	-
C	-	-	Ø	-	-	-	-	2	-	-	-	-
D	-	-	-	Ø	-	-	-	-	-	-	-	-
E	-	-	-	-	Ø	-	-	2	2,3	1,2,3,4	-	3
F	-	-	-	-	-	Ø	-	1,4	3	1,3,4	-	-
G	-	-	-	-	-	-	Ø	-	-	-	2	-
H	1,2,4	3	2	-	2	1,4	-	Ø	3	3	1,2,4	3
I	1,4	-	-	-	2,3	3	-	3	Ø	-	1,2,3,4	-
J	1,2,4	-	-	-	1,2,3,4	1,3,4	-	3	-	Ø	1,2,3,4	-
K	-	-	-	-	-	-	2	1,2,4	1,2,3,4	1,2,3,4	Ø	1,4
L	-	-	-	-	3	-	-	3	-	-	1,4	Ø

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.8 AI

Figure 33 illustrates the results of *AI* for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 21.

Figure 33 – Results of *inspiratory area* (*AI*) for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Table 21 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for *inspiratory area* (AI) among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	A	B	C	D	E	F	G	H	I	J	K	L
A	$\emptyset$	-	-	-	-	3	-	12	34	-	-	-
B	-	$\emptyset$	-	-	-	3	-	12	1234	14	4	3
C	-	-	$\emptyset$	-	1	3	-	-	-	-	-	-
D	-	-	-	$\emptyset$	-	-	-	-	-	-	-	-
E	-	-	1	-	$\emptyset$	3		12	1234	124	234	3
F	3	3	3	-	3	$\emptyset$	-	1	1	-	-	-
G	-	-	-	-		-	$\emptyset$	-	-	-	-	
H	12	12	-	-	12	1	-	$\emptyset$	-	-	-	2
I	34	1234	-	-	1234	1	-	-	$\emptyset$	-	-	2
J	-	14	-	-	124	-	-	-	-	$\emptyset$	-	-
K	-	4	-	-	234	-	-	-	-	-	$\emptyset$	2
L	-	3	-	-	3	-	-	2	2	-	2	$\emptyset$

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.9 I%

Figure 34 illustrates the results of $I\%$ for the four test scenarios from Table 7. The statistical analysis of $I\%$ was not conducted due to the fact that this parameter was derived from AI .

Figure 34 – Results of *percentage of inspiratory area ($I\%$)* for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

4.3.10 AE

Figure 35 illustrates the results of *AE* for the four test scenarios from Table 7. Statistical differences were found across the 12 lung ventilators by the Kruskal-Wallis test in each of the four test scenarios. Results of the multiple comparison test are shown in Table 22.

Figure 35 – Results of *expiratory area* (*AE*) for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

Table 22 – Results of the non-parametric multiple comparisons (Kruskal-Wallis and Dunn’s tests) for expiratory area (AE) among lung ventilators. An intersection between a column and a row indicates a comparison (column vs row) or vice-versa (row vs column). Numbers 1, 2, 3 and 4 specify that a comparison between 2 lung ventilators is statistically significant ($P < 0.05$) for tests scenarios 1, 2, 3 and 4 respectively.

Lung ventilators	A	B	C	D	E	F	G	H	I	J	K	L
A	Ø	-	-	-	-	-	-	-	-	-	-	-
B	-	Ø	-	-	-	-	-	-	-	-	-	1,3
C	-	-	Ø	-	3,4	1,3	1,3	-	-	2,4	1	1,2,3,4
D	-	-	-	Ø	3,4	1	3	-	-	-	-	1,2,3,4
E	-	-	3,4	3,4	Ø	-	-	-	-	3	4	-
F	-	-	1,3	1	-	Ø	-	-	1	-	2,4	-
G	-	-	1,3	3	-	-	Ø	-	-	-	-	-
H	-	-	-	-	-	-	-	Ø	-	-	2	4
I	-	-	-	-	-	-	-	-	Ø	2	1	1,2,3
J	-	-	2,4	-	3	-	-	-	2	Ø	2,4	-
K	-	-	1	-	4	-	-	2	1	2,4	Ø	2,4
L	-	1,3	1,2,3,4	1,2,3,4	-	-	-	4	1,2,3	-	2,4	Ø

- Not statistically significant.

1 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 1.

2 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 2.

3 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 3.

4 These lung ventilators are statistically significant ($P < 0.05$) for test scenario 4.

4.3.11 E%

Figure 36 illustrates the results of $E\%$ for the four test scenarios from Table 7. The statistical analysis of $E\%$ was not conducted due to the fact that this parameter was derived from AE .

Figure 36 – Results of *percentage of expiratory area* ($E\%$) for the four test scenarios during continuous mandatory ventilation with pressure control (CMV-PC).

5 DISCUSSION

The clinical course of COVID-19 brought serious challenges to the Brazilian health system. Since February 2020, there has been an increasing demand for lung ventilators hampered by the worldwide shortage of lifesaving equipment. For this reason, the Brazilian industry and community-based initiatives have started the development of new lung ventilators. In this context, the National Agency of Sanitary Vigilance (ANVISA) published the RDC 349/2020 (National Agency of Sanitary Vigilance, São Paulo, 2020a), 356/2020 (National Agency of Sanitary Vigilance, São Paulo, 2020b), and 386/2020 (National Agency of Sanitary Vigilance, São Paulo, 2020c); in which, the temporary criteria to approve lung ventilators and obtain the medical device registration are established.

According to the ANVISA, the manufacturers have to present clinical and laboratory trials (SUZUMURA et al., 2020). The laboratory trials consist in perform items of the NBR ISO IEC 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) or the Specification for Rapidly Manufactured Ventilator System by the Medicines and Healthcare Products Regulatory Agency of the United Kingdom (Medical and Healthcare Products Regulatory Agency, UK, 2020). However, the ANVISA documents only specify tests for CMV-VC and CMV-PC modes leaving many technical gaps such as trigger requirements, and testing for other ventilation modes.

The global shortage of ventilators has come along with the shortage of electronic components (flow sensors, pressure transducers, etc.) that restrict the capabilities of ventilators in development; hence, developers have prioritized the development of ventilators with only CMV-PC mode.

This study has begun due to the unexpected findings in CMV-PC pressure signals from commercial and prototype lung ventilators that were recorded for maintenance and assessment at the node IPT-POLI. These findings highlighted gaps in the standard that allow different waveform shapes to comply with standard requirements. A new approach is therefore needed for characterizing CMV-PC mode.

The assessment of pressure-control inflation type is specified in item 201.12.1.102 of ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b). According to the standard, to perform testing in pressure-control inflation type, it is necessary to measure: *inspiratory pressure* (cmH_2O), T_I (s), *PEEP* (cmH_2O), f_{rc} (breaths/min) and FiO_2 (%). Nevertheless, this approach does not fully cover the required parameters to characterize a pressure waveform in CMV-PC; in particular, the overshooting and the rise time.

Previous studies have emphasized the variability in the delivered volume on account of differences in rise time. These studies evaluate the time elapsed to reach 90% of the respiratory pressure from the SI (GONZALES et al., 2011; GONZALES et al., 2013; MARCHESE et al., 2011). The rise time is related to the peak flow generating during inspiration; in addition, it helps to indicate the time remaining to hold the plateau. Studies highlighted the importance of control the set pressure to avoid lung damage.

There are not many works assessing CMV-PC mode in different ventilator models (CALDERON, 2006; TUNG; DRUM; MORGAN, 2005; USAQUEN, 2008; URIBE, 2011). Moreover, although research has revealed important facts as the importance in the rise time, no study to date has examined the ventilators based on the values of resistance and compliance stipulated in ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b).

In order to address CMV-PC pressure waveform, we selected parameter from ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b), and the literature (MARCHESE et al., 2011; GONZALES et al., 2011; GONZALES et al., 2013; SUNISA; WILLIAMS; DEAN, 2001). Parameters from the literature such as AI , AE , $I\%$ and $E\%$ were employed mostly to assess PS with a slight modification. In previous literature, researchers calculate these parameters without considering the area under *PEEP* level. For this study, we considered this area due to the fact that measured *PEEP* levels varied across lung ventilators.

With the aim of discriminating where inspiratory and expiratory phases start during the evaluation of mechanical ventilation parameters, the choice of a certain type of threshold is required. The most frequent types of threshold are pressure, flow, or volume (Néos Indústria de Tecnologia, 2018; Fluke Biomedical, 2018). For instance, the widely used breathing simulator (ASL 5000, Ingmar Medical, USA) uses a volume threshold of 5 mL for adult configuration.

In this study, a flow threshold of 0.05 L/s was selected to determine the inspiratory and

expiratory time stamps. The value allowed to overcome mistaken detection of inspiratory or expiratory phases happened by noise in the flow signal.

The differences in T_{90} (understandably in rise time) cause variability in the shape of the pressure curves, which can be translated into differences in plateau time, V_I and *peak inspiratory flow*. Another important point is that lung ventilators do not present a standard pattern to indicate the rise time options, it is common to see graphic scales or percentages of the T_I as indicatives. The standard ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) did not indicate any parameter related to the rise time, which allows different types of curves being accepted during the evaluation of the lung ventilators. To date, the 2020 version of the ISO IEC 80601-2-12 (International Standardization Organization, Switzerland, 2020) also did not prescribe an item regarded to this point.

Even though lung ventilators' rise times were configured at medium values, the results demonstrate that T_{90} varies ($P < 0.05$) across the lung ventilators in the four test scenarios. We did not expect such variations for all the lung ventilators.

Comparing lung ventilators that did not fail in one of the test scenarios (A , B , D , E , F , G and L). We found that all the lung ventilators except A and L had greater T_{90} values for the first 2 test scenarios, it can be attributed to the fact that higher values of compliance require more time to expand the lung chamber to reach the set pressure.

Test scenarios 1 and 2 had a greater number of failing lung ventilators in T_{90} , this result could reflect that these lung ventilators do not properly work for higher compliance scenarios at the medium rise time configuration. Lung ventilator I did not reach the 90% of the intended pressure in the four test scenarios, and the reasons for this result are not yet completely understood.

It is important to highlight the fact that AE or $E\%$, in conjunction with $PEEP$ can bring information about airway-pressure patterns during the expiratory phase. With an $E\%$ value closer to 100% and a $PEEP$ value closer to the target, it is expected to have a rapid fall and almost flat pattern with few oscillations.

From Figure 30 we note that in test scenario 3 lung ventilator H presented a *peak pressure* of $32.95 \pm 0.03 \text{ cmH}_2\text{O}$, which can be referred as an overshooting of approximately $2.95 \text{ cmH}_2\text{O}$. Whereas in test scenario 4, lung ventilators A ($36.27 \pm 0.1 \text{ cmH}_2\text{O}$) and H ($35.50 \pm 0.07 \text{ cmH}_2\text{O}$) had overshooting of $1.27 \text{ cmH}_2\text{O}$ and $0.50 \text{ cmH}_2\text{O}$ respectively.

Whether what level of pressure overshooting may have a clinical impact on patients

remains unanswered. However, to our knowledge, there is only 1 guideline that states a maximum value for overshooting. The Medicine and Healthcare Products Regulatory Agency published a document for Rapidly Manufactured Ventilator System in 2020 (Medical and Healthcare Products Regulatory Agency, UK, 2020), in which it specified a maximum overshooting value of $2.00 \text{ cmH}_2\text{O}$. Based on this limit, the lung ventilator H is out of the recommended limit in test scenario 3.

Regarding test scenarios (1 and 2) that had greater values of compliance, lung ventilators (H , I , J and K) which had lower values of *peak inspiratory flow* did not reach 90% of the set pressure. It would be attributed to the fact that at the medium rise time configuration for target pressure, these lung ventilators were not able to deliver the required flow levels to pressurize the lung test within the set T_I .

In test scenarios 1, 2, and 3, the shortest value of T_{90} was related to the highest value of AI and in consequence $I\%$. In test scenario 3, lung ventilator E presented the highest AI and *inspiratory pressure* values, and was the lung ventilator with the second shortest value of T_{90} . This result can be justified by the fact that AI depends on how rapidly the lung ventilator increases airway pressure to the target level.

Lower values of AI and $I\%$ are expected when lung ventilators do not reach the 90% of the intended pressure, or $PEEP$ values are under the set level. For instance, the lung ventilator H did not get to the 90% of the intended pressure in test scenarios 1 and 2, and had the lowest AI value. Further, the lung ventilator I had the same outcomes for test scenarios 3 and 4.

V_I in CMV-PC will depend on different factors that vary from lung ventilator settings to lung mechanics. It is somewhat related to $PEEP$ that is a reference to the baseline pressure level at which the inflation starts. At lower $PEEP$ values, the lung ventilator will require more flow to pressurized the lung, and to reach the intended pressure than at higher $PEEP$ values. In this study, there existed significant V_I differences among almost all the lung ventilators, especially with lung ventilators H , I , J and K . Concerning lung ventilator K , we noticed that in 3 test scenarios (1, 2, and 4) it had the highest V_I and was significantly different from lung ventilators G , H , I , J and L . Because of that fact we expected greater values of *inspiratory pressure*; nonetheless, it did not get to the 90 % of the intended pressure in test scenario 2. This problem could be related to its low values of $PEEP$ in all the four test scenarios.

Lung ventilators B and E are similar devices with respect to hardware and software design, the only difference is their chassis. The reason for this is a product technology

transfer strategy between manufacturers. Based on this fact, we would expect similar results for these lung ventilators. However, There were statistical differences ($P < 0.05$) in *inspiratory pressure* (test scenario 3), T_{90} (test scenario 2) and *peak inspiratory pressure* (test scenario 3).

Lung ventilators *A* and *F* belong to the same series, and lung ventilator *F* is the most recent available model. Both lung ventilators only presented a significant difference ($P < 0.05$) in *AI* (test scenario 3). A relevant fact is that the manufacturer changed the accuracy of control for the lung ventilator *F* to be more permissive. As a consequence, this lung ventilator comply with all tests (*inspiratory pressure*, *PEEP* and T_{90}).

Interestingly, there were several statistical differences ($P < 0.05$) between transport lung ventilators *J* and *K*: *inspiratory pressure* (test scenario 1 and 3), *PEEP* (test scenario 1, 2 and 4), *peak inspiratory pressure* (test scenario 1), *peak inspiratory flow* (test scenario 1 and 2), V_I (test scenario 4) and *AE* (test scenarios 2 and 4). It seems reasonable to assume that the findings were related to its design. These lung ventilators were probably developed employing standards for transport ventilators. In Brazil, the standard ABNT NBR ISO 10651-3:2014 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014a) is currently used for transport lung ventilators. This standard, however, do not present test scenarios for CMV-PC with different combinations of compliance and resistance.

As can be seen in Figures A.1, A.2, A.3, A.4, A.5, A.6, A.7 and A.8, lung ventilators *C* and *H* had a pattern during the expiratory phase that may suggest a problem with the expiratory valve. Nevertheless, only lung ventilator *H* had a reporting of leakage at its expiratory valve during the expiratory phase.

It is important to notice that ABNT NBR ISO IEC 80601-2-12: 2014 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) only prescribes a fixed value of T_I for testing. Nevertheless, this parameter varies across the patients according to their requirements. Further work needs to be carried out to evaluate the impact of T_I variations.

In this study, all the lung ventilators complied with the inspiratory time test in the four test scenarios, this result is consistent with Uribe (2011).

Inspiratory pressure's evaluation under the standard (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) had the maximum number of failing lung ventilators in test scenario 2 (8 out of 12). It would indicate that lung ventilators in this study do not properly control pressure when being testing with higher values of resistance and compliance. This inference is also supported by the T_{90} results in test scenario 2.

It is important to highlight the fact that accuracy of control (upper and lower limits) for *inspiratory pressure*, *PEEP* and T_I varied among the lung ventilators' disclosures (Table 9). Reason is that item 212.12.1.102 of ABNT NBR 80601-2-12 (ASSOCIAÇÃO BRASILEIRA DE NORMAS TÉCNICAS, São Paulo, 2014b) leaves the choice of it up to the manufacturer without any suggestion or restriction. This fact will bring conflicting cases when lung ventilators are assessed under the standard. For instance, in the case of *PEEP* assessment in test scenario 4, lung ventilator *A* ($9.56 \pm 0.06 \text{ cmH}_2\text{O}$) did not pass the test and lung ventilator *C* ($8.48 \pm 0.04 \text{ cmH}_2\text{O}$) passed the test. In spite of the fact that *A* vs *C* were statistical different ($P < 0.05$), and lung ventilator *C* likely had problem with its exhalation valve as we commented previously.

One concern about the findings of this study was that only 1 lung ventilator per model was evaluated, thus it is not possible to generalize lung ventilators' outputs of a model, probably they will have different responses. However, the samples used in this study were part of lots that were or would be distributed to cope with the COVID-19 pandemic.

6 CONCLUSION

In the course of this dissertation, the comparison of airway-pressure waveforms from 12 lung ventilators during CMV-PC has been presented. To achieve this task, we came up with a set of parameters that allowed us to highlight differences among waveforms, and employed test scenarios prescribed in ABNT NBR 80601-2-12: 2014 to standardized our experiments. Taken together, our results suggest that despite being compared in almost equal conditions, lung ventilators' waveforms do have disparities among different lung ventilator models. Interestingly, we found differences in T_{90} and *peak inspiratory pressure* which are parameters that the standard does not contemplate. An implication of the results is the possibility that additional parameters are required, not only the standard's parameters, to evaluate CMV-PC.

As we had been conducting the study, some relevant matters arose. Nevertheless, we could not address it due to the fact that signal acquisition for this dissertation was performed in parallel with others tasks, and was subjected to hectic schedules due to its link with an initiative to cope with the COVID-19 pandemic. Thus, future work would concentrate on comparing different rise time configurations in a given lung ventilator, and evaluate more lung ventilators per model.

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APPENDIX A

One cycle of airway-pressure and flow waveforms of all lung ventilators during CMV-PC are presented here. The lung ventilator and the lung test are configured based on test scenarios from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.1 – One cycle of airway-pressure and flow waveforms of lung ventilators *A*, *B*, *C*, *D*, *E*, and *F* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 1 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.2 – One cycle of airway-pressure and flow waveforms of lung ventilators *G*, *H*, *I*, *J*, *K*, and *L* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 1 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.3 – One cycle of airway-pressure and flow waveforms of lung ventilators *A*, *B*, *C*, *D*, *E*, and *F* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 2 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.4 – One cycle of airway-pressure and flow waveforms of lung ventilators *G*, *H*, *I*, *J*, *K*, and *L* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 2 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.5 – One cycle of airway-pressure and flow waveforms of lung ventilators *A*, *B*, *C*, *D*, *E*, and *F* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 3 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.6 – One cycle of airway-pressure and flow waveforms of lung ventilators *G*, *H*, *I*, *J*, *K*, and *L* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 3 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated. In the case of ventilator C, it does not reach the 90% of the set pressure.

Figure A.7 – One cycle of airway-pressure and flow waveforms of lung ventilators *A*, *B*, *C*, *D*, *E*, and *F* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 4 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated.

Figure A.8 – One cycle of airway-pressure and flow waveforms of lung ventilators *G*, *H*, *I*, *J*, *K*, and *L* during continuous mandatory ventilation with pressure control (CMV-PC). The lung ventilator and the lung test are configured based on test scenario 4 from Table 7. In each figure, the start of inspiration (SI), start of expiration (SE), and the interval of time to reach 90% of the set pressure are indicated. In the case of ventilator C, it does not reach the 90% of the set pressure.