Metrological Conformity Assessment of Pulmonary Ventilators During the Covid-19 Pandemic in Brazil

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Abstract. In the health area, service rendering regarding maintenance, calibration, verification, and assays is highly demanded to incorporate new technologies and innovations in procedures and clinical treatment. Physiological life support measures aided by equipment play a fundamental role in the daily life of intensive care units (ICU) during the COVID-19 pandemic. Mechanical ventilation, also known as ventilatory support, is essential for maintaining life; it is a method for treating patients with acute or chronic respiratory problems. Its main objective is to maintain gas exchange. However, it can worsen the patient's clinical condition without adequate calibration. This leads to death. Thus, conducting a metrological assessment of medical and hospital equipment is crucial. The goal of the present study is to perform a metrological study following Technical Standards and Technical Manuals, ABNT NBR IEC 60601–2-12 - 2004 and ABNT NBR ISO 80601–2-12 – 2014, to demonstrate the safety and performance of lung ventilators by evaluating the main ventilatory parameters.

Keywords: Metrology · Covid-19 · Pulmonary ventilators · Clinical engineering

1 Introduction

COVID-19, transmitted by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus, began its person-to-person transmission cycle in China around December 2019. Four months after the first report of contagion, the COVID-19 has already reached a global scale [1]. On March 11, 2020, COVID-19 was classified as a pandemic by the World Health Organization [1]. COVID-19 is estimated to have infected about 511 million people, and more than 6.2 million have died [2, 3]. The disease presents different forms of manifestation, from an upper and lower respiratory tract infection to severe pulmonary involvement leading to acute respiratory failure and death. Contact with aerosol particles expelled by infected people is the main form of spread [4]. There is no evidence that early treatments can prevent the disease [5]. Pandemic control occurs by the application of vaccines [6]. Since 2020, different pharmaceutical companies have intensively acted in the technological development of vaccines to combat the coronavirus [6].

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Mechanical ventilation, also known as ventilatory support, is a method for treating patients with acute or chronic respiratory failure. Its main objective is to maintain gas exchange, that is, to correct hypoxemia and respiratory acidosis associated with hypercapnia. Ventilatory support is responsible for relieving the work of the respiratory muscles (in acute situations of high metabolic demand), reversing or preventing respiratory muscle fatigue, reducing oxygen consumption and respiratory discomfort, besides allowing the application of specific therapies [9].

Positive end-expiratory pressure (PEEP), and inspiratory pressure of peak (Pinsp) are critical parameters for the patient's treatment with mechanical ventilation. PEEP, for example, deals with the positive pressure that will remain in the airways at the end of the respiratory cycle (end of expiration) that is greater than the atmospheric pressure in mechanically ventilated patients [18]. Physiologically, PEEP is caused by the closure of the epiglottis and air damming in the respiratory system. Such pressure prevents atelectasis from occurring, and this mechanism is lost when the patient is submitted to ventilatory support [19]. In recent years, professionals in the field and scientists have placed great emphasis on the use of higher PEEP to prevent atelectrauma [11].

The pandemic has drastically affected the logistics and maintenance of healthcare support equipment. Medical centers have faced challenges, such as lack of qualified professionals, lack of ICU beds, and low numbers of ICU beds in public and private hospitals. Since COVID-19 is fundamentally a respiratory disease, the use of mechanical ventilators in patients with extensive pulmonary involvement is essential.

In addition to providing such equipment, it is vital that the ventilators comply with the calibration procedures indicated by the technical standards and manufacturers, mainly in a metrological way.

To ensure safe results and reliable measurements, besides establishing more specific technical criteria, a set of technical standards were prepared by ABNT NBR IEC 60601-2-12 of 2004 and ABNT NBR ISO 80601-2-12 of 2014, Electromedical Equipment, item 2–12: specific requirements for the basic safety and essential performance of critical care ventilators.

One of the major challenges of calibration is the standardization of the manufacturers' permissible tolerance ranges of the measurement parameters; in addition, the uncertainty of measurement in the technical data is not included in their specifications or their tolerances. Each manufacturer defines its test accuracy in its technical manuals [14]. The measured values with dubious results compromised the validation of the process regarding its precision, and, consequently, jeopardized the patient's safety.

In September 2021, twelve low-quality lung ventilators, purchased in March 2021 with exemption from bidding in Brazil, were halted after presenting failures that may have caused the deaths of hospitalized patients with Covid-19. The equipment stopped cycling, compromising the main ventilatory parameters, such as pressure and FiO_2 [22].

There are studies in the literature on the Performance of Mechanical ventilators [23–27]; however, they use different methods for assessing conformity with the International Standard ASTM F1100–90 of 1990. Specifically, they considered the measurement of the parameters; such as, tidal Volume, PEEP, and Pinsp. However, the literature has not presented a comparison of equipment's performance between metrological conditions,

the Technical Manuals, the ABNT NBR IEC 60601-2-12 – 2004 and ABNT NBR ISO 80601-2-12 – 2014.

Faced with the high demand for ICU equipment during the pandemic and to minimize harmful events associated with mechanical ventilation equipment, the present work aims to develop a comparative metrological study on the performance of pulmonary ventilators following the manufacturers' manuals and the ABNT NBR Standards. IEC 60601-2-12 – 2004 and ABNT NBR ISO 80601-2-12 – 2014 investigate the most important parameters for safe and reliable ventilation: tidal Volume, PEEP and Pinsp.

2 Objective

Comparing the metrological performance of mechanical ventilation equipment following the manufacturers' manuals and the ABNT NBR IEC 60601-2-12 – 2004 and ABNT NBR ISO 80601-2-12 – 2014 Standards.

3 Methodology

The study was carried out in the ICU sectors of several Hospital Units in the states of São Paulo, Rio de Janeiro, and the Federal District from November 2019 to December 2020. Thirty-six lung ventilators from three different brands were selected, between national and imported equipment. Equipment brands were omitted from the article. All the equipment evaluated has been recorded at the National Health Surveillance Agency (ANVISA).

The metrological analysis consists in determining the error (E) and measurement uncertainty (U) of lung ventilators placed for cycling and using connections, sensors, ventilation circuits, and gas network connected to a calibrated lung ventilator analyzer with traceability by the Brazilian Calibration Network (RBC). Four (4) measurements were performed per point on each ventilator for the parameters: Tidal Volume, Positive End Expiratory Pressure (PEEP), and Peak Inspiratory Pressure (Pinsp). The calibrated points were: 700 mL for Volume, 15 cm H_2O for PEEP, and 30 cm H_2O for Pinsp. This number of measuring (4) was considering equipment accessing limitations, yet respecting ISO GUM 2008 and Nit-Dicla-21 – INMETRO ($n > 1$).

The equipment was calibrated against the reference standards according to internal procedures in a controlled environment at a temperature of 22 °C and relative humidity of around 50% RH.

Specific forms were used and transcribed into a spreadsheet with a calculation memorial validated for each measurement parameter for data collection. The methodology used to estimate the measurement uncertainty is the same as described by ISO GUM 2008 [16] and NIT DICLA 021 [17].

The uncertainty of the measurement result is composed of the calculations of several components grouped in two categories: Type A: those that were determined using statistical analysis in a series of observations: repeatability of the standard readings, arithmetic mean, standard deviation, and deviation average standard. Type B: those determined by any other means: the resolution of the reference standard equipment, measurement uncertainty of the reference standard, and resolution of the equipment under test [16].

The Probability Distribution of the uncertainty components is calculated by a random variable probabilistic function, assuming a value within a range of values. The following distributions were used for the calculation memorial: Rectangular, Triangular, Normal, and t-Student [17].

The practical degrees of freedom estimate the standard uncertainty u(y), associated with the output estimate y from the Welch-Satterthwaite equation [16].

The uncertainties reported in the results were combined and expanded by coverage factors k, duly corresponding to the degrees of freedom and a coverage probability of approximately 95% [17]. All the uncertainty calculations were performed following ISO GUM and EA4/02 standards and INMETRO's normative and guidance documents.

The ventilators were separated into three major brands and evaluated by parameters separately. ISO GUM - ISO 14253-2:2011 establishes that, in the absence of another specification (imposed by normative document, regulation, etc.), the following calibration acceptance criterion is used: "The sum of the module of the result of the measurement with the associated uncertainty module shall be less than or equal to the Maximum Permissible Error (MPE) for the equipment". Thus, the MPE acceptance criterion is given by expression [21]:

$$| \text{Error} | + | \text{Uncertainty} | \leq | \text{MPE}|,$$

in which:

Error: Difference between the measured value of a quantity and a reference value.

Uncertainty: It is the expanded uncertainty associated with the corrected result.

MPE: Maximum permissible error.

4 Analysis of Data and Results

In the parameters tidal Volume, measured point: 700 mL of the scale, PEEP (Positive End Expiratory Pressure), measured point: 15 cm H_2O, and PInsp (Peak Inspiratory Pressure), measured point: 30 cm H_2O, we obtained the following results in comparison with the Standards (Fig. 1):

Volume/PEEP/PInsp: **conform**

In the Current Volume parameter, 97% obtained results within the standards established by the NBR ISO 80601-2-12 and NBR IEC 60601-2-12 Standards, and only 3% did not meet the criteria or tolerance of the standards.

For the PEEP parameter, 45% were within the standards established by the NBR ISO 80601-2-12 and NBR IEC 60601-2-12 Standards, and 55% were not.

In the analysis of the PInsp parameter, we found that 56% of the pieces of equipment are within the standards established by the NBR ISO 80601-2-12 and NBR IEC 60601-2-12 Standards, and 44% are not.

In the analysis of the same parameters, we obtained the following results in comparison with the manufacturers' manuals (Fig. 2):

Volume/PEEP/PInsp: **conform**

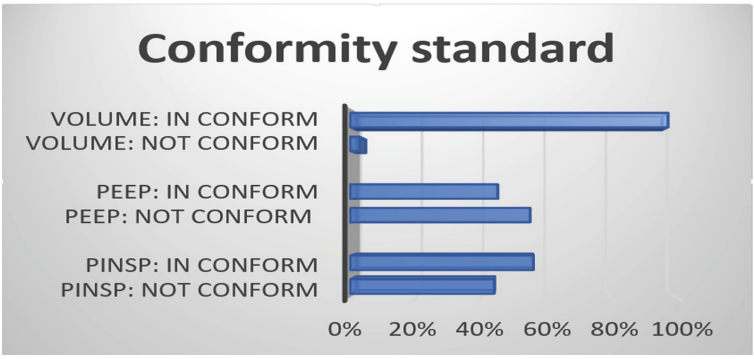

Fig. 1. Conformity standard (*source* personal archive).

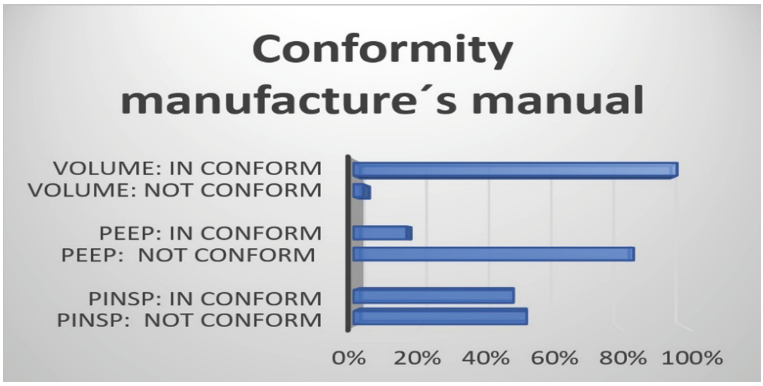

Fig. 2. Conformity manufacture's manual (*source* personal archive).

In the Current Volume parameter, we found the same results of compliance with the standards; that is, 97% obtained results within the standards established by the manufacturers' manuals, and only 3% did not meet the criteria or tolerance of the manuals.

From the analysis of these same parameters, we obtained the following results compared to the manufacturers' manuals.

In evaluating the PEEP parameter, only 16% were within the standards established by the manufacturers' manuals, and 84% were outside the metrological standards established by these manuals.

As for the PInsp parameter, from a sample of thirty-six pieces of equipment evaluated, 48% were within the tolerance standards of the manuals, and 52% did not reach the results established by these documents.

5 Discussion and Conclusion

Our study demonstrated the safety and performance of lung ventilators by metrological reliability. The metrological characteristics, measurement error, and uncertainty found in the equipment evaluated were determined for analysis purposes. These characteristics

point to significant concern and care that we have to have with life support equipment, especially with pulmonary ventilators (PV).

Among the three parameters investigated, the one involving pressure, Positive End Expiratory Pressure (PEEP) and Peak Inspiratory Pressure (PInsp), did not presented satisfactory results. This is due to the restricted tolerance range established by the NBR ISO 80601-2-12, NBR IEC 60601-2-12 Standards, and the manufacturers' technical manuals.

Observing the tests of the Tidal Volume parameter in general, we observed satisfactory results, approximately 97% of the MV within acceptable safety limits.

One of the significant problems that we found in the study is related to the standardization of the permissible tolerance ranges of the measurement parameters; in addition to not including in their specifications their high accuracy of measurement uncertainty in the technical data, each manufacturer defines its precision of test in their technical manuals [14]. Regarding the Standards, they only thoroughly provide for pressure and volume specifications, treating the other parameters superficially, thus leaving parameters such as Respiratory Rate, Inspiratory Fraction of O_2 (FiO_2), and Inspiratory Flow outside our study.

Another critical point to note would be improving the current technology for parameter records, which we call analyzers or reference standards. These measuring instruments deserve to have high precision in their measurements, representing a higher resolution than the test equipment.

It would be of great importance to improve methods and results, also that manuals and standards add measurement uncertainty to their evaluation methods; results would therefore be more satisfactory.

Other factors that we observed and that led to unsatisfactory results were the equipment evaluation with a large number of accumulated working hours. Devices have been used on a large scale in the ICU sectors due to the high demand during the pandemic. Most of the time, equipment is overloaded and made available to the patient without replacing its respective preventive maintenance kits, as recommended by the manufacturers, somehow compromising the results and, consequently, the proper performance of the equipment. According to authors such as Blanch (2001), after a VP accumulates 40,000 h of work, its reliability and performance decrease drastically [20].

In mid-September 2021, in Americana, in the interior of the state of São Paulo, twelve low-quality pulmonary ventilators, purchased with exemption from a March 2021 bidding process, were cast aside after presenting failures that may have caused the deaths of hospitalized patients with Covid-19. The equipment stopped cycling, compromising the main ventilatory parameters, such as pressure and FiO_2 [22].

There has notedly been greater involvement and consensus among manufacturers of medical-hospital equipment, analyzers and simulators, the Technical Standards Committee from Anvisa, and also from the most significant metrological authority in the country, Inmetro. There is greater concern about minimizing problems and risks leading to legal suits regarding patients' safety and health.

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