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Mariana Souza, Matheus H. Lopes, Alembert Alvarado, Renato Vitorasso, Sara Mello, Antonio F. Ferreira Junior, Henrique T. Moriya and Cristina Fais

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EVALUATION OF THE VOLUME-CONTROLLED VENTILATION MODE OF A PULMONARY VENTILATOR SAMPLE IN COVID-19 PANDEMIC

M.C. Souza[1], M.H.G. Lopes[1], A.E.L. Alvarado[1], R.L. Vitorasso[1], S. G. Mello[2], A.F.G.F. Junior[2] and H.T. Moriya[1]

[1] Biomedical Engineering Laboratory, University of Sao Paulo, Brazil
[2] Institute of Technological Research, Brazil

Abstract— **This article refers to the evaluation of a commercial pulmonary ventilator sample according to an excerpt from the ABNT NBR ISO 80601-2-12 standard, about volume controlled ventilation, in the context of the Covid-19 pandemic. To perform the analysis, data collected experimentally by the IPT-Poli union, established in response to the pandemic with the objective of carrying out the maintenance and analysis of pulmonary ventilators in order to alleviate the shortage of these equipment due to high demand, were used. These data were computationally processed in order to allow comparison with the expected values according to the standard. The results obtained demonstrated a consistent behavior of the ventilator in general, since no standard deviation was above 7%. In this context, the analysis presented in this article is important in order to corroborate the understanding of some operating principles of mechanical ventilation, as well as the minimum safety requirements of the equipment.**

Keywords— **Covid-19, lung ventilator, standard.**

I. INTRODUCTION

The pulmonary ventilator is an essential intensive care device for the hematosis supply in cases where physiological respiration is insufficient [1].

The first records of positive pressure mechanical ventilation, as it is used today, date back to the 1952 poliomyelitis epidemic in Denmark, in which the use of pulmonary ventilators was crucial to ensure the survival of a significant number of people [2]. About 70 years later, this scenario is repeated with the Covid-19 pandemic, one of the biggest health crises in history [3].

For the treatment of acute cases of this disease, the use of lung ventilators is essential to maintain respiratory function while fighting the infection. In this context of high demand for mechanical ventilation, it is necessary initiatives, as is the case of the IPT-POLI center, to maintain and analyze this equipment in order to alleviate their scarcity [4].

Therefore, this article intends to present a performance evaluation of the volume-controlled ventilation mode of a commercial ventilator sample from the Brazilian Ministry of Health, which was presented by the initiative IPT-POLI. In this ventilation mode, the ventilator delivers a mixture of medical air and oxygen in the patient's airways until a established tidal volume is reached, which will remain constant throughout the respiratory cycles. Therefore, the interruption of the inspiratory phase is determined by the target volume set in the equipment, hence it is said that cycling is by volume. It is worth mentioning that this type of ventilation does not allow direct control over the pressure in the airways, for this reason it is necessary to incorporate a safety valve in the pressure alarm systems, capable of aborting the inspiratory phase whenever that the pressure exceeds certain levels, in order to prevent trauma to the patient [5].

II. MATERIALS AND METHODS

In order to carry out the analysis of the aforementioned aspects of the equipment (Luft 3, Leistung, Brazil, serial number: E20161), ventilatory data provided by the union of researchers from the Institute of Technological Research (IPT) and the Escola Politécnica of the University of São Paulo, responsible for evaluating and maintain ventilators[4], were used; as well as, for the processing of this data, it was used a software implemented in an integrated development environment (MATLAB R2015a, MathWorks Inc, USA).

The information provided was obtained from the connection of the ventilator under test to a system composed of a test lung (Dual Adult TTL, Michigan Instruments, USA) and a data acquisition system (SC-24, SCIREQ, Canada) for flow and pressure signals. The described configuration can be seen in Figure 1.

A test lung was used, which is able to simulate adult lung resistance and compliance from an exchangeable flow resistor and tension spring, respectively. The values adopted for resistance were 5 and 20 cmH_2O/L/s and for compliance, 50 mL/cmH_2O, according to the scenarios provided by the standard[5]. The corresponding parameters of each scenario can be seen in Table 1.

As for the data acquisition system, a pneumotachograph

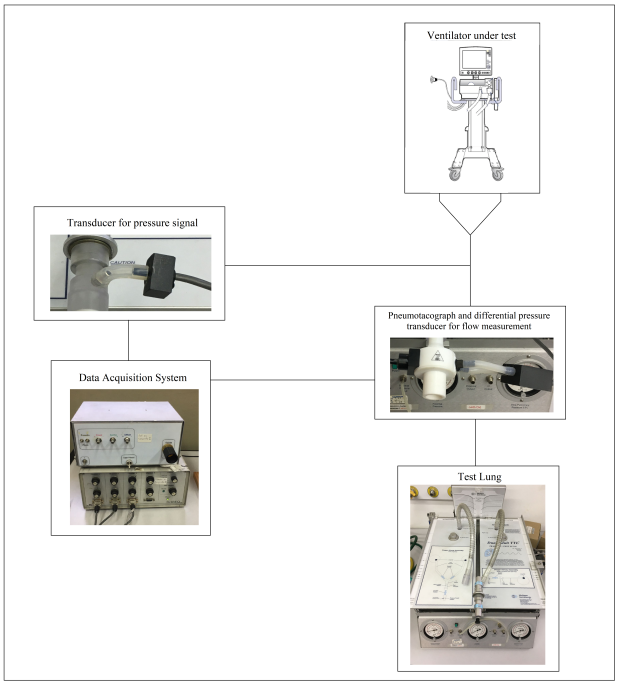

Fig. 1: Configuration for data acquisition system of the ventilator under test

Table 1: Test parameters according to each scenario provided by the standard.

Scenario	Resistance (cmH_2O/L/s)	Compliance (mL/cmH_2O)
1	5	50
2	20	50
3	5	20
4	20	20

(3700B, Hans Rudolph, USA) attached to a differential pressure sensor (HCXM100D6V, SensorTechnics, USA) was used for flow signal and a pressure transducer (FPM 02PG, Fujikura, Japan) together with pressure capture adapter for pressure signal. The measured analog signals were conditioned using two channels of the data acquisition system and were converted into digital signals through a data acquisition (DAQ) hardware (NI USB-6008, National Instruments, USA). The signals were captured at a sampling frequency of 100 Hz.

It is worth mentioning that, for the calibration of the flow sensor, the method proposed by [6] was used: a fourth degree calibration polynomial was chosen and 10 injections were performed (4 of low flow, 3 of medium flow and 3 of high flow), which allowed the determination of the coefficients of the polynomial, thus finishing the calibration.

Regarding the pressure sensor calibration, it was performed by removing the transducer offset using atmospheric pressure as the first reference and, as the second reference, performing a measurement (the value used was 30 cmH_2O) in order to verify the sensor output. To carry out this measurement, a U-shaped manometer and a syringe, which caused a displacement of the water column inside the tube, were used.

The designed software receives an ASCII file, containing the aforementioned collected pressure and flow signals and, from these, isolates a single respiratory cycle and defines the start and end points of inspiration and expiration. Later, removes the offset from the flow signal, this is an unwanted signal that shifts the baseline of the flow wave. Then the program measures the inspiratory time (*Tins*) and positive end-expiratory pressure (*PEEP*), through the arithmetic average of the pressures of the 50 ms before the end of expiration, according to ABNT NBR ISO 80601-2-12 [7], as well as determines the volume released via flow signal integration. In addition, the curves of flow, pressure and volume were acquired. This procedure is repeated for ten cycles, then it is calculated the average and standard deviation of the obtained values and, finally, compare the results to the standard.

III. Results

Examples of the flow, pressure and volume curves for each scenario are shown in Figure 2.

Tables 2 and 3 show the results obtained for inspiratory time, volume and positive end expiratory pressure.

IV. Discussion

Covid-19 can be defined as a highly transmissible acute respiratory infection, and it was responsible for a deep health crisis: the pandemic. [8]. Faced with this scenario, health systems collapsed, mainly due to a huge demand for equipment whose supply was limited, especially lung ventilators, since their use is indispensable in the treatment of the most severe cases of the disease. In this way, the industry saw the need to invest in ventilators and improve them.

So that an electromedical equipment can be registered with the National Agency of Sanitary Vigilance (ANVISA) and thus enter the Brazilian market, it is necessary that it obeys criteria defined by regulatory standards. In the case of pulmonary ventilators, ABNT NBR ISO 80601-2-12 stands out, which aims to assess the safety of these equipment, as well as their performance in different physiological scenarios.

In this article, a performance analysis was performed according to an excerpt from the aforementioned standard for a

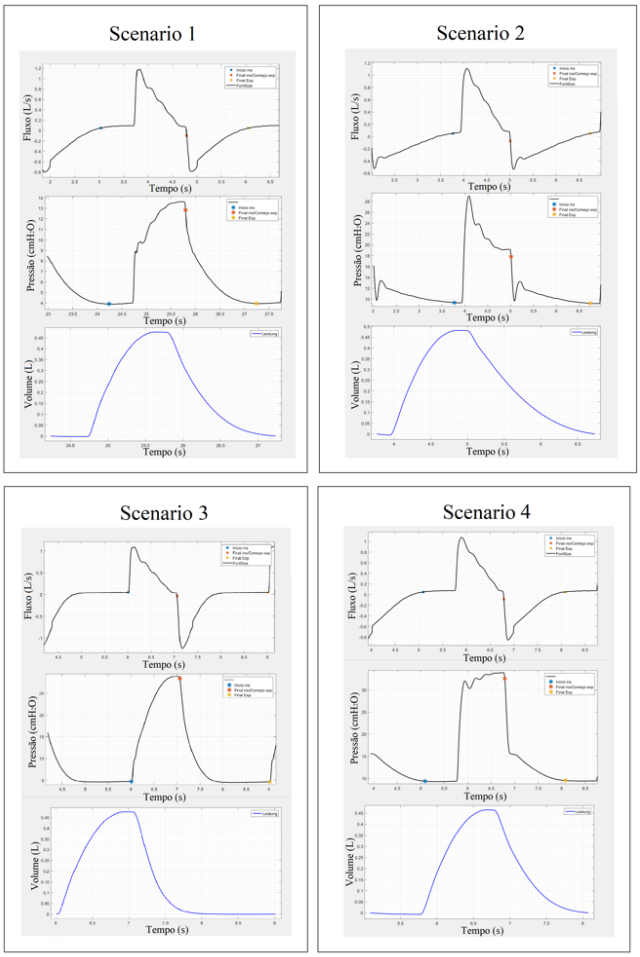

Fig. 2: Flow, pressure and volume curves for each scenario.

Table 2: Results obtained under the conditions of scenarios 1 and 2.

Scenario	1			2		
Cycle	Volume (L)	*PEEP* (cmH_2O)	*Tins* (s)	Volume (L)	*PEEP* (cmH_2O)	*Tins* (s)
1	0.486	4.096	1.55	0.482	9.228	1.24
2	0.491	4.022	1.60	0.483	9.248	1.30
3	0.492	3.974	1.52	0.485	9.155	1.24
4	0.479	4.039	1.56	0.460	9.197	1.26
5	0.488	3.932	1.60	0.479	9.104	1.25
6	0.489	3.935	1.61	0.481	9.127	1.30
7	0.493	3.890	1.38	0.483	9.087	1.31
8	0.478	3.943	1.51	0.465	9.141	1.30
9	0.488	3.898	1.41	0.483	9.011	1.23
10	0.490	3.895	1.48	0.480	9.093	1.31
Average	0.487	3.962	1.52	0.478	9.139	1.27
Deviation	0.005	0.070	0.08	0.005	0.070	0.08
Expected Value	0.500	5.000	1.00	0.500	10.000	1.00

Table 3: Results obtained under the conditions of scenarios 3 and 4.

Scenario	3			4		
Cycle	Volume (L)	*PEEP* (cmH_2O)	*Tins* (s)	Volume (L)	*PEEP* (cmH_2O)	*Tins* (s)
1	0.456	4.902	0.89	0.467	9.548	0.90
2	0.471	4.801	0.88	0.471	9.600	0.93
3	0.478	4.771	0.89	0.461	9.642	0.89
4	0.479	4.794	0.91	0.469	9.561	0.89
5	0.459	4.842	0.89	0.472	9.526	0.90
6	0.474	4.743	0.89	0.472	9.550	0.89
7	0.477	4.718	0.87	0.457	9.509	0.90
8	0.479	4.687	0.88	0.468	9.473	0.89
9	0.463	4.750	0.88	0.471	9.470	0.92
10	0.475	4.519	0.90	0.472	9.431	0.89
Average	0.471	4.753	0.89	0.468	9.531	0.90
Deviation	0.009	0.010	0.01	0.005	0.063	0.01
Expected Value	0.500	5.000	1.00	0.500	10.000	1.00

sample of a commercial lung ventilator in volume-controlled ventilation mode. Each scenario evaluated is characterized by a combination of different values of lung resistance and compliance. The parameters are configured on the ventilator under test and the values of delivered volume, *Tins* and *PEEP* acquired are compared to the theoretical expectation (500 ml, 1 second and 5 cmH_2O for scenarios 1 and 3 and 10 cmH_2O for scenarios 2 and 4, respectively).

Analyzing the results shown in tables 2 and 3, it can be seen that scenario 1 was the one in which the ventilator presented the best performance in terms of volume, although, in all scenarios considered, the relative error (the relative error was calculated by taking the difference between the expected value and the calculated average divided by the expected value) for this parameter remained below of 6.4%. This observation is related to the fact that the scenario 1 presents the lowest resistance to the flow in the airways, which allows more accurate values of volume. In terms of *PEEP*, the worst performance was verified in scenario 1 (relative error of 20.76%) and the best performance was verified in scenario 3 (relative error of 4.94%). It is worth mentioning that in none of the scenarios, the *PEEP* value exceeded the expected, which is important in terms of avoiding lung injuries caused by high pressure. Since lung compliance is defined as lung volume for each unit of change in pulmonary pressure, then scenarios characterized by lower compliance values requires minor pulmonary volume variations to reach the established *PEEP*. Finally, in terms of *Tins*, the best performance was seen in scenario 4 (relative error of 10%) and the worst performance was observed in scenario 1 (relative error of 52%). Possibly this happens because higher values of compliance require more time to expand the lung chamber to reach the set parameters, then the higher compliance scenarios presented greater *Tins*.

Observing the standard deviations obtained, it can be seen that all values are below 7%, which demonstrates a consistent behavior of the ventilator in general.

V. Conclusion

The Covid-19 pandemic has promoted a race for lung ventilators to provide support to seriously ill patients, including initiatives to produce alternative ventilators[9].

However, even if it is an altruistic collaboration, the technical and regulatory knowledge about lung ventilators, together with the experience in this niche, are crucial for the manufacture of safe equipment, which minimize the risks associated with them, as is the case of the Ventilator Induced Lung Injury (*VILI*).

In this context, the analysis presented in this article is important in order to corroborate the understanding of some operating principles of mechanical ventilation, as well as the minimum safety requirements of the equipment.

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Author: Mariana Carvalho de Souza
Institute: Biomedical Engineering Laboratory, University of Sao Paulo, Brazil
Street: Av. Prof. Luciano Gualberto, 380 - Butantã, São Paulo - SP, 05508-010
City: São Paulo
Country: Brazil
Email: carvalho.souzamariana@usp.br