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AN ALTERNATIVE VENTILATOR PROTOTYPE FOR THE EMERGENCY SITUATION DUE TO COVID-19 PANDEMIC

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Abstract. *The pandemic caused by the SARS-COV-2 virus, called coronavirus disease 2019 (COVID-19), had an unexpected impact around the world, especially in Brazil. People diagnosed with the virus have different levels of respiratory symptoms and may need mechanical ventilation support. In this pandemic scenario, the demand for artificial pulmonary ventilation equipment increased according to the evolution of the disease, becoming a critical factor for the functioning of the intensive care units. A pulmonary mechanical ventilator (PMV) consists of an equipment capable of delivering air and / or oxygen, named fraction of inspired oxygen (FiO_2), in a controlled manner for patients with severe acute respiratory syndrome (SARS). Among the various requirements that this device must meet, the following stand out: monitoring control, alarms for adverse events and adjustments to ventilatory parameters, like FiO_2, respiratory rate, positive end-expiratory pressure (PEEP), inspiration volume and pressure, sensitivity, among others. In this sense, the objective of this study is discussing the development and evaluation of an alternative PMV prototype, inspired on the mandatory functional characteristics indicated by technical notes published by the Brazilian Intensive Care Association (AMIB) and the UK Medicines and Healthcare products Regulatory Agency (MHRA). Due to the lack of clinical material, the prototype development uses accessible and industrially widespread equipment, like pneumatics directional control valves, pressure valves, pipes, and fittings, meshed with available clinical ones. The volume control ventilation mode was performed using programmable logic controller (PLC) and an industrial-kind human machine interface, with lcd touch screen, as interface for the clinical operator. By using a parallel mounting of three inspiration valve, each one calibrated for a specific flow, a set of seven options for inspiration flow adjustment was available. Critical variables like lung pressure were acquired using gauge and differential pressure sensors, and a printed circuit board for signal conditioning providing a standard 0-10V signals for the PLC analog inputs. Inspiratory flow was estimated using an orifice plate method, reaching a discharge coefficient above 0.92. Preliminary tests were performed using an artificial lung under different conditions of complacency and resistance, while the respiratory mechanics data was evaluated by a commercial gas flow analyzer. Finally, for instance, the alternative PMV prototype was evaluated in a pre-clinical test applied to porcine, whose satisfactory results were recently published in another periodical paper.*

Keywords: *mechanical system design, biomedical equipment, fluid power systems, medical, control systems, programmable logic controller*

1. INTRODUCTION

For Coropechi *et al*. (2020), the world is facing an unprecedented situation in which the medical system is placed in a critical situation regarding available intensive care unit equipment, especially mechanical ventilation devices.

According to Hao *et al*. (2021), mechanical ventilation is an effective medical means in the treatment of patients with critically ill, COVID-19 and other pulmonary diseases. Grasselli *et al*. (2020) reports that a large proportion of patients with COVID-19 develop severe respiratory failure requiring admission to the intensive care unit and about 80% of them need mechanical ventilation.

Due to this situation many research teams have designed and developed mechanical ventilation equipment (Oproescu *et al*., 2020, Ramos-Paz *et al*., 2020, Rehm *et al*., 2020, EPUSP, 2021, INESC TEC, 2020, INESC P&D BRASIL, 2020, MIT, 2020). But testing this equipment can be a challenge, some tests can be performed with a simple test lung, with known features like resistance and compliance. However, Coropechi *et al*. (2020) point that ventilator should respond to the various compliances and resistances a patient's lung can pose, but without an adjustable test lung and the ability to simulate patient efforts, it is impossible to tell if the ventilators response is accurate.

The next sections of this paper are organized as follows: initially section 2 presents a review of the literature regarding the development of alternative pulmonary ventilators for the pandemic period. Section 3 presents the materials and methods used for developing and validating the proposed prototype, followed by the implementation results and discussion in section 4. Then, some conclusions are summarized in section 4, followed by acknowledgment and references.

2. REVIEW OF THE LITERATURE

2.1 Medical ventilator systems basics

A pulmonary mechanical ventilator (PMV) consists of an equipment capable of delivering gas in a controlled manner for patients with severe acute respiratory syndrome (Chatburn e Mireles-Cabodevila, 2013). This equipment operates fundamentally as a pneumatic system (Hasan, 2010), and the mixture of gases must be supplied to the patient in adequate conditions of pressure, flow, temperature, and humidity. To ensure minimum patient comfort and safety, the control of these variables must be done rigorously, meeting specific standards (ABNT, 2020).

Some requirements that this device must meet, stand out: monitoring control, alarms that signal adverse events of the patient and of the equipment itself or between the patient and the equipment, adjustments of ventilatory parameters; oxygen rate, respiratory rate, positive final expiratory pressure (PEEP), pulmonary volume and pressure, sensitivity, among others, especially descriptors of cleaning and disinfection of the equipment (ABNT, 2020).

A ventilator system, like shown in Figure 1, is typically composed of six essential parts (Lei, 2017):

1. Pressurized O_2 and air supplies;
2. An electrical supply;
3. A ventilator;
4. A breathing circuit;
5. An airway;
6. A patient's lungs or a test lung to mimic the lungs.

In an actual ventilator system, the tube pressure is comparable to opening airway pressure (PAO), while the test lung pressure is comparable to alveolar pressure (PALV). During inspiration, the inspiratory valve opens and the expiratory valve closes. PAO becomes higher than PALV. The pressure gradient generated pushes the gas into lungs, increasing the lung volume. During expiration, the inspiratory valve closes, and the expiratory valve opens. PAO becomes lower than PALV. The opposite pressure gradient pushes gas out of lungs, decreasing the lung volume. It also regulates the expiratory valve to generate the positive end-expiratory pressure (PEEP). If the 'inflation' and 'expiration' alternate, the balloon is 'mechanically ventilated', like lungs. This is how variable PAO is generated (Lei, 2017).

The basic unit of mechanical ventilation is the mechanical breath, which is defined as a breath realized through a ventilator system. Mechanical ventilation can be viewed as a series of mechanical breaths. There are several mechanical breath types. The type of mechanical breath is determined by five essential variables (Lei, 2017):

1. Triggering: defines when inspiration begins;
2. Cycling: defines when inspiration ends;
3. Controlling: defines how delivery of inspiratory gas is controlled;
4. Targeting: defines the size of a mechanical breath;
5. Baseline: defines the baseline pressure at which mechanical breaths occur.

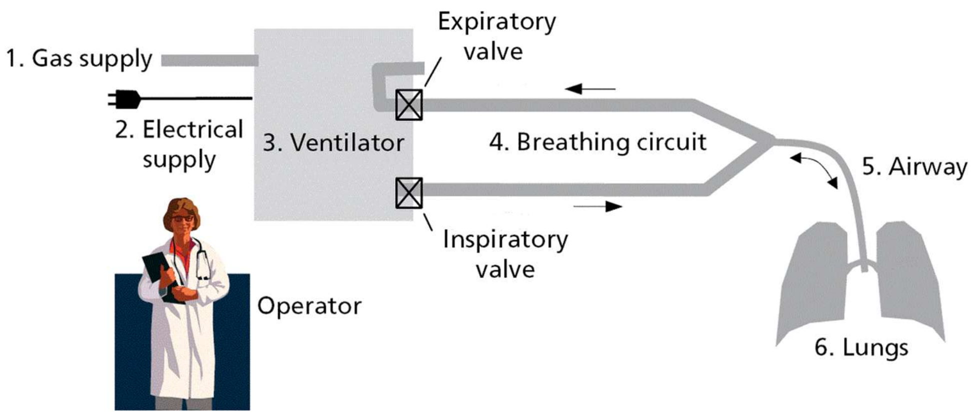

Figure 1. A complete ventilator system and its operator, adapted from Lei (2017).

Table 1. Essential variables and their common mechanisms (Lei, 2017).

Variable	Triggering	Cycling	Controlling	Targeting	Baseline
◆ Common mechanisms	◆ Time triggering ◆ Pressure triggering ◆ Flow triggering ◆ Manual triggering	◆ Time cycling ◆ Flow cycling	◆ Volume controlling ◆ Pressure controlling ◆ Adaptive controlling ◆ Hybrid controlling	◆ Tidal volume ◆ Inspiratory pressure ◆ Target tidal volume	◆ Positive end-expiratory pressure (PEEP)

According to Lei (2017) various mechanisms are associated with these variables, as shown in Table 1, and every type of mechanical breath represents a unique combination of these variables. The major perceived advantage of volume controlling is stable tidal and minute volumes, which makes clinicians more comfortable. In the other hand, in pressure controlling actively breathing patients may influence the inspiratory flow and tidal volume they receive, resulting in better patient-ventilator synchrony. Besides, with pressure controlling, when the system has a leak, causing pressure to drop, the ventilator responds with an increased inspiratory flow, allowing the ventilator effectively to compensate a moderate leak.

For this first study, considering guaranteed of tidal volume, the proposal was the analysis of a commercial pulmonary ventilator performing a volume controlling breath type with time triggering, time cycling, VT targeting, and PEEP baseline.

Volume controlling uses three primary parameters: tidal volume (VT), inspiration time (Ti), and peak flow. Typically, either VT and Ti, or VT and peak flow, are adjusted, and the ventilator calculates the third automatically.

A secondary parameter is the flow pattern, which consists of the inspiratory flow profile of the flow-time waveform. The most common flow pattern is square flow (i.e., constant inspiratory flow). The square flow pattern is the only one available for volume breaths in some ventilators. However, some modern ventilators may also provide other flow patterns, like decelerating, accelerating and sine.

For this first study, considering guaranteed of tidal volume, the proposal was the developing a PMV prototype that can perform a volume controlling breath type with time and pressure triggering, time cycling, VT targeting, and PEEP baseline.

2.2 Similar works

With the growth of SARS-COV-2 infection cases, the world watched the rise of several initiatives associated with simulation models for artificial ventilation applications, and the proposal and development of alternative equipment for use in the situation of emergency.

Al-Hetari *et al*. (2020) presented a mathematical model for the response of a lung under volume-controlled ventilation (VCV), using the proximal pressure signal as an input variable. The authors emphasize that the model facilitates the activities of the clinical staff as a training tool to learn the functionalities of mechanical ventilation in real time. However, it is believed that its application does not go beyond applications in academic laboratories, since artificial ventilation in hospitalized patients depends on equipment capable of presenting all the variables of the lung mechanics of the patient submitted to it.

Coropeţchi *et al*. (2020), in turn, presented the development of a test lung with variable compliance for ventilatory mechanics tests. The device was compared with a mathematical simulation model and calibrated using precision sensors for pressure and displacement variables, furthermore to having been equipped with a manometer and a volume indicator so that it could be used independently of the electronic acquisition system.

Rehm *et al*. (2020) used internet of things (IoT) techniques to access the data available on a commercial pulmonary ventilator, transmit it to a cloud platform and make it available in an android application in order to allow the clinical staff to remote monitoring the main functions of the patient undergoing artificial ventilation.

Ramos-Paz *et al*. (2020) presented the prototype of an automated resuscitator, based on a balloon pumping system and directing air to a mask, also called airway mask bag unit (AMBU). The original system depends on human participation in the balloon pumping process, which hinders the repeatability of variables critical to ventilatory mechanics, such as released volume, inspiratory flow, inspiratory rate, inspiration time, inspiration-expiration ratio (I:E), while the proposed equipment uses a connecting rod-crank set activated by a stepper motor and electronically controlled, in order to guarantee the cadence characteristic of commercial ventilation equipment, even without conditions to be associated with the hospital gas network. The authors highlight the system for being of low cost, which uses 3D printing and an Arduino prototyping platform to build the equipment. The control of the position of the AMBU compression mechanism was presented, but the association of harmonic balloon compression and decompression movement with essential variables for ventilatory mechanics, such as released volume, inspiratory flow and I:E ratio, as well as the possibility of adjustment and monitoring of these variables was not discussed.

Finally, Oproescu *et al*. (2020) present the project of a device for mechanical ventilation intended for use in patients who require sedation and intubation. The equipment is based on a pneumatic system, integrated into the hospital gas network, allowing the delivery of an FiO_2 adjusted by the operator. The authors present several prerequisites that the system must meet, such as different ventilation modes, adjustment intervals for the variables of interest, safety criteria and a graphical monitoring interface. The authors present a block diagram indicating the necessary components and highlight the need to use 3D printing for the construction of pneumatic elements and for prototyping the electronic circuit for conditioning the sensor signals. In addition, a graphical interface with numerical indication of some variables as well as pressure and flow curves is presented, but no prototype validation test is discussed or indicated by the authors, making clear the need for more practical studies and implementations and deeper discussions about the theme.

3. MATERIALS AND METHODS

3.1 Requirements analisys

The system requirements were inspired by the Rapidly Manufactured Ventilator System, issued by the Medicines & Healthcare products Regulatory Agency (MHRA, 2020) and by a technical note on characteristics of artificial ventilator devices in patient support with COVID-19, issued by "Associação de Medicina Intensiva Brasileira" (AMIB, 2020). Bellow there are a list with the minimal specifications of a pulmonary mechanical ventilator that could be used in the treatment of patients with COVID-19, aiming to reduce lung and organ damage (AMIB, 2020):

1. Volume controlled ventilation (VCV) and/or pressure-controlled ventilation (PCV);
2. Delta pressure control (over the peep) in PCV mode (from 5 to 30 cmH_2O) and inspired tidal volume control in VCV mode (from 50 to 700 ml);
3. Control of FiO_2 (21% to 100%);
4. PEEP (0 to 20 cmH_2O);
5. Inspiratory time control (in PCV mode) in seconds (0.3 s - 2.0 s) and inspiratory flow (in VCV mode) - up to 70 L/min;
6. Respiratory frequency control (8 RPM to 40 RPM);
7. Airway pressure measurement (analog or digital pressure gauge);
8. Measurement of expired tidal volume whenever possible;
9. Alarms for the maximum airway pressure, leakage and gas network drop;
10. Possibility of attaching high-capacity hepa filter (n99 or n100) in the expiratory branch;
11. If possible, have a battery with at least 2 hours of capacity.

The list bellow indicates the main requirements pointed by the MHRA (2020) and used for developing the Pneuma PMV prototype:

1. Must have at least 1, optionally 2 modes of ventilation
   a. Must have continuous mandatory ventilation (CMV).
   b. The CMV mode must be either.
      i. (ideally) Pressure Regulated Volume Control, or
      ii. pressure controlled ventilation (PCV) or
      iii. minimally a volume-controlled ventilation (VCV).
   c. Not applicable for VCV
   d. Volume Control Ventilation – the user sets a tidal volume and respiratory rate. The tidal volume is delivered during the inspiratory period. Acceptable only if additional pressure limiting controls are available, see Inspiratory Pressure section.
2. Not applicable for VCV
3. Inspiratory airway pressure, the higher pressure setting that is applied to make the patient breathe in:
   a. Not applicable for VCV
   b. Not applicable for VCV
   c. If volume control ventilation is used, the user must be able to set inspiratory airway pressure limit in the range at least 15 cm H_2O– 40 cmH_2O in at least increments of 5.0 cmH_2O.
   d. There must be a mechanical failsafe valve that opens at 80 cmH_2O.
4. Positive End Expiratory Pressure (PEEP). The pressure maintained in the breathing system during expiration.
   a. The equipment must provide a range 5-20 cmH_2O adjustable in 5.0 cmH_2O increments.
   b. PEEP must be maintained during expiration.
5. Inspiratory:Expiratory ratio (I:E). The proportion of each breathing cycle that is spent breathing in compared to breathing out.
   a. The equipment must provide 1:2 (i.e. expiration lasts twice as long as inspiration) as the default setting.

   b. The equipment could provide adjustable I:E in the range 1:1 – 1:3.
6. Respiratory Rate. The number of breathing cycles every minute.
   a. The equipment must provide a range 10 – 30 breaths per minute in increments of 2 (only in mandatory mode) that can be set by the user.
7. Tidal Volume (VT) setting, if provided. The volume of gas flowing into the lungs during one inspiratory cycle.
   a. Must have at least one setting of 400 mL +/- 10 mL.
   b. Should have 350 mL and 450 mL options.
   c. Could have a range 250 mL – 600 mL in steps of 50 mL.
   d. Could have a range up to 800 mL.

Using these requirements, the alternative PMV prototype was idealized, and it design started taking into account the difficulty in finding clinical components due to the high demand generated by the crisis of the pandemic moment and the possibility of using components easily found in the industrial market.

3.2 The alternative PMV prototype design

Then, the Pneuma PMV prototype was idealized to work connected to the electrical AC power line as well as to the medicinal gases (air and oxygen). Also, as indicated by Lei (2017), the ventilation system is composed by a breath circuit, an airway, and a test lung, to mimic the patient lung. The operator can interact with the ventilation system by a graphical interface, implemented using a touch screen human machine interface (HMI). Figure 2 illustrates a representative schema for the proposed PMV prototype.

The implemented pneumatic circuit was detailed at Figure 3. The Pneuma PMV prototype composition is dashed in red, while the hospital infrastructure is dashed in blue, and the breath circuit and the test lung were dashed in green. The hospital gases (air and oxygen) were supplied at regular 3.5 kgf/cm^2 pressure and two pressure switches connected to the inlet lines can be used to emit alarms of gases pressure drop. The gases are directed to a blender, who is responsible to adjust the required FiO_2, then, the mixed gas pressure is regulated to 2.0 kgf/cm^2 before being directed to the set of inspiratory valves. These valves are configured to deliver a specific flow of gas each and mounted in parallel in order to allow flow combinations. Therefore, with 3 different flows, and discarding the combination all turned off, it is possible to select up to 7 different inspiratory flows. After the set of inspiratory valves and before outlet to breath circuit, the mixed gas is directed to a diffuser responsible to ensure a laminar flow and facilitate the acquisition of differential pressure for estimation of inspiratory flow and tidal volume. For safety purposes a mechanical relief valve, regulated about 80 cmH_2O was mounted near the diffuser. Furthermore, a derivation of the medicinal air inlet is used to supply the expiratory electro valve, with a regulated pressure about 0.7 kgf/cm^2, required to control the membrane exhalation valve.

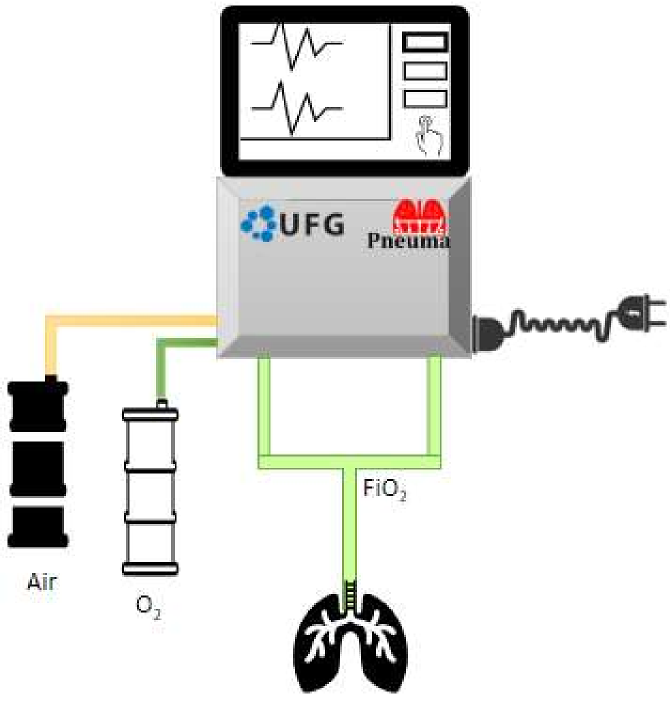

Figure 2. A schematic representation for the proposed PMV prototype.

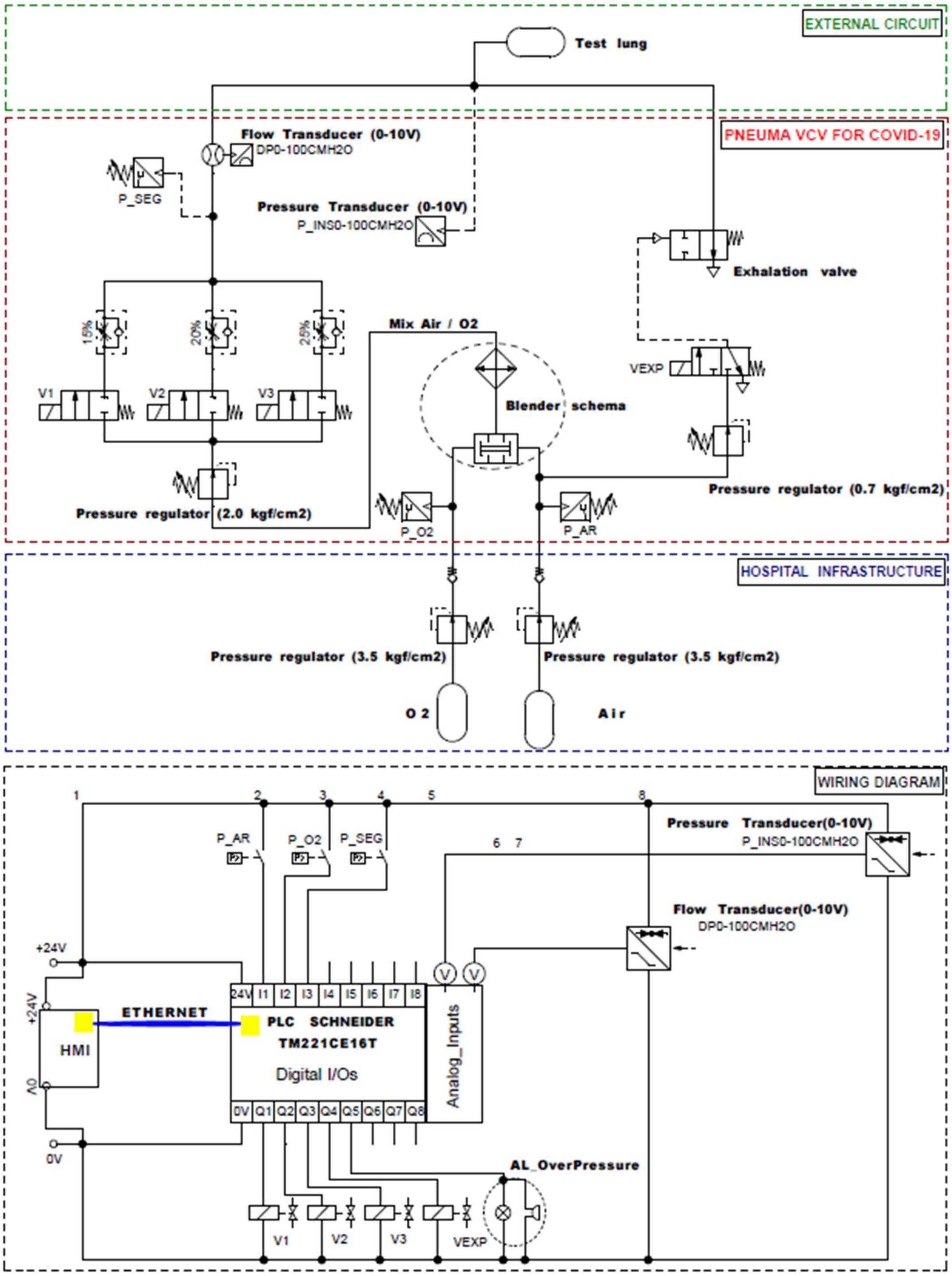

Figure 3. The pneumatic schema for the proposed PMV prototype.

The wiring diagram in Figure 3 shows the electronics and logic control, implemented using an industrial programmable logic controller (PLC) while an industrial HMI is used as graphical user interface. All pressure switches are addressed as digital inputs, while the PLC digital outputs are connected to the solenoid valves and to a buzzer-led for light and audible alarm signals. An analog input module is used to acquire 0-10V standard signals from the pressure and flow transducers. The transducers are responsible for the precision sensors signal conditioning, allowing a full-scale 35 mV signal to be read by a standard 0-10V analog input. Inspiratory flow was estimated using a differential pressure sensor applied to an orifice plate method, reaching a discharge coefficient above 0.92. All communication between PLC and HMI is performed over Modbus TCP/IP protocol.

3.3 Basic operation of the alternative PMV prototype

The Pneuma user interface was designed to be intuitive and easy to operate. The operator must set some parameters in the HMI bottom horizontal row, like tidal volume (ml), inspiration flow (L/min), PEEP (cmH_2O), limit for peak inspiratory pressure (cmH_2O), respiratory rate (min^{-1}), trigger sensitivity (cmH_2O), and inspiratory pause (s). In the HMI right side, the operator can check some indirect variables, given from those adjusted ones, such as inspiration time (s), expiration time (s), and I:E ratio (dimensionless), and the respiratory mechanics response variables, such as the measured peak inspiratory pressure (cmH_2O), PEEP (cmH_2O), tidal volume (mL), peak inspiration flow (L/min), and minute ventilation (mL/min). A vertical bar graph for the current pulmonary pressure is approximately centralized in the HMI. Furthermore, line charts over time for the main respiratory mechanics variables - pressure, flow, and tidal volume - give conditions to the operator making a better analyze of the patient response. An HMI screen snapshot for the proposed PMV prototype is show in Figure 4.

Before starting the equipment, the operator must check the breathing circuit connections, as well as the medical gases inlet. Once the equipment is turned on, the operator set the parameters based on the clinical staff recommendations and touch the ON button. If the mechanical ventilatory variables response is adequate, the ventilation keeps ongoing until a clinical staff update or until the operator choose to turn off the ventilator.

Figure 4. An HMI screen snapshot for the proposed PMV prototype.

4. RESULTS AND DISCUSSIONS

4.1 The alternative PMV basics specifications

Based on the literature review and the minimal requirements indicated in the material and methods section, a list with the specifications for the Pneuma PMV prototype are presented below:

1. Continuous mandatory ventilation with Assist/Control volume cycled ventilation (A/C VCV);
2. Assisted mode with pressure trigger-sensitivity threshold;
3. Inspired tidal volume control in (300 mL to 800 mL);
4. FiO_2 adjustment (21% to 100%), with a commercial blender;
5. PEEP adjustment (0 to 20 cmH_2O);
6. Inspiratory flow (square waveform) - up to 70 L/min;
7. Respiratory frequency control (8 RPM to 40 RPM);
8. Inspiratory airway pressure limit (15 cmH_2O to 45 cmH_2O);
9. Pressure trigger-sensitivity threshold (0 (off) to 5 cmH_2O);
10. Inspiratory pause resource (0 to 2 s);
11. Compliance and plateau pressure estimation when executing inspiratory pause;
12. Airway pressure measurement;
13. Measurement of inspired tidal volume; this version does not measure expired tidal volume;
14. HMI with numerical and line chart over time response for the main mechanical respiratory variables;
15. There be a mechanical failsafe valve that opens at 80 cmH_2O;
16. Alarms for the maximum airway pressure, leakage and gas network drop;
17. Possibility of attaching high-capacity hepa filter (n99 or n100) in the expiratory branch;
18. This version does not have alternative battery power.

A photography evidencing the electronics is detailed in Figure 5. A 24VDC/3A power source is referenced as (1), while the PLC and the PCB used for sensor signal conditioning are respectively referenced as (2) and (3). The sensors S1/S2 read pressure down and upstream of the orifice plate, these signals are used to estimate the inspiratory flow. The sensor S3 read the proximity pressure, associated with the pulmonary current pressure, and used to register PEEP and PIP. S4 is a sensor available to monitor the gas mixture pressure, pick up after the blender output.

A photography with A test setup implemented in laboratory can be viewed in Figure 6. The Pneuma PMV Prototype (1) was configured to deliver 300 mL of tidal volume, with 18 L/min of inspiratory flow, combined with a PEEP of 5 cmH_2O, a peak inspiratory pressure of 35 cmH_2O, a respiratory rate of 20 min^{-1}, with no sensitivity (no assist mode) and without inspiratory pause. With the adjusted tidal volume, inspiratory flow and respiratory rate, the ventilator estimates an inspiration time of 1.0 s, an expiration time of 2.0 s, and a I:E ratio of 1:2. In Figure 8 the HMI there are for important elements: the ins/ex and proximity connections, and a blender knob used for FiO_2 adjustment. The breathing circuit is attached to the ventilator over its ins/ex connections and pass through a mechanical ventilation analyzer (2) before reaching a test lung (3).

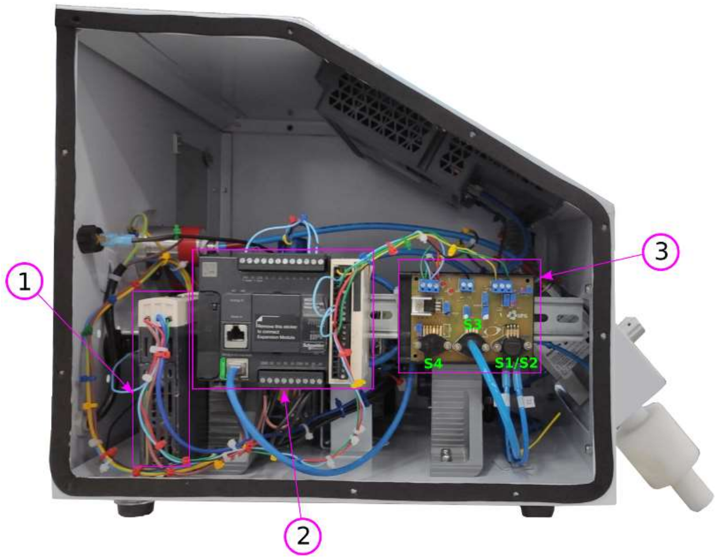

Figure 5. An internal photography for the proposed PMV prototype revealing the 24VDC/3A power source (1), the Schneider PLC (2) and a developed signal conditioner PCB (3).

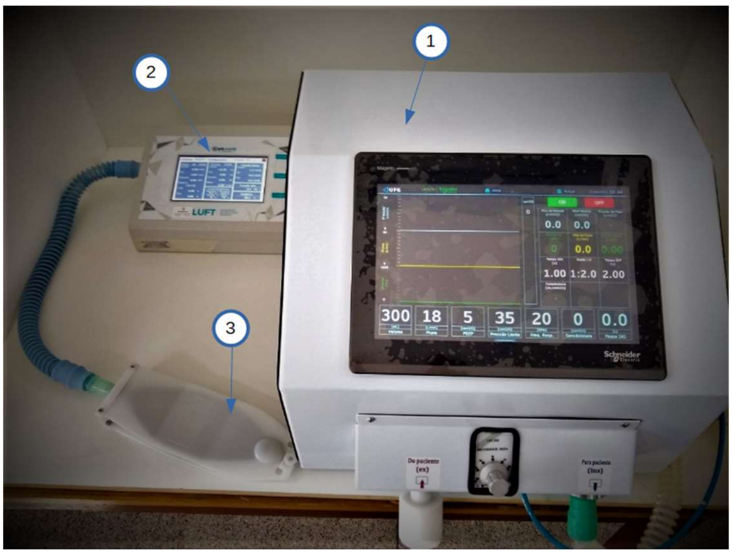

Figure 6. A test setup with the Pneuma PMV prototype (1), a mechanical ventilation analyzer (2), and a test lung (3).

Ultimately Pneuma PMV Prototype (UFG, 2020), was evaluated at the EVZ/UFG veterinary Hospital with an in-vivo experimental protocol and it worked properly, obtaining satisfactory statistical results when compared with a gold standard PMV, as shown by Alcântara *et al.* (2021).

5. CONCLUSION

In the present paper, the development and operation of the Pneuma alternative PMV prototype were briefly presented. Due to the lack of available clinical equipment and components caused by the COVID-19 pandemics, their key characteristics are the manufacture with materials and instrumentation equipment found in Brazil. Furthermore, the proposed equipment was designed with the requirement analysis based on national and international agencies recommendations and currently it can perform invasive ventilation in adults using the assist/control volume-controlled ventilation (A/C VCV) and allow the operator to set several important parameters with graphically monitoring the patient's response.

As discussed in Alcântara *et al.* (2021), some improvements are needed, especially in the exhalation period and the PEEP control. Validation at regulatory agencies depends on improvement, mainly in the scalability of the own manufacture components, such as the membrane expiratory valve and the diffuser to ensure laminar flow. Special attention must be given to tests to define the accuracy of controls and instruments, according to ABNT NBR 60601-2 (ABNT, 2014). Some necessary points, such as electromagnetic compatibility, usability, alarm systems, identification and labeling, software life cycle, and protection against mechanical equipment hazards were not completed evaluated in this project, being indicated as proposals for future work.

Finally, in future version of the Pneuma PMV prototype, it is intended to improve other ventilation modes, performing pressure-controlled ventilation (PCV), pressure support ventilation (PSV) and assisted ventilation with flow trigger.

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8. RESPONSIBILITY NOTICE

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