Pressure and Volume Control in a new Emergency Mechanical Ventilator based on PLC and Industrial Pneumatic Parts in Peru*

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Abstract—This work details a methodology of design and test of a new prototype emergency mechanical ventilator called Fenix for the COVID-19 crisis in Peru. This equipment was manufactured with industrial equipment for the embedded and pneumatic systems, such as a Programmable Logic Controller (PLC), proportional flow valves, sensors, uninterruptible power supply (UPS), industrial panel HMI 15" and other electrical and pneumatic parts from Festo and Schneider Electric. This selection was in accordance with safety requirements based on ISO 80601-2-12: 2020-02. This study included two ventilatory modes, pressure- controlled in continuous mandatory ventilation (PC-CMV) and volume-controlled in continuous mandatory ventilation (VC-CMV), these control algorithms were evaluated analytically and experimentally in a FLUKE VT-650 Gas Flow Analyzer and an Acculung Fluke connected with a computer for comparing 9 ventilatory parameters in 4 different states as µ, simulation of the variation of the pressure control in a patient, and Ѳ, simulation of alveolar recruitment in an intensive care patient, both states to PC-CMV, and also β, simulation of the variation of the flow control in a patient, and α, simulation of alveolar recruitment in an intensive care patient, both last states to VC-CMV. Additionally, we study the pressure, volume, and flow graphs in the Fenix user interface for comparison with data recovered from Fluke Medical VT650 Gas Flow Analyzer. The results demonstrate an error in the flow measurement for the 4 states due to the peaks that are not detected by the low-pass filter of the sensor, however, a similar trend is seen in the control ventilatory graphs of the calibrator. Finally, the ventilator prototype provides ventilatory support, with a maximum tidal volume error of 12.93 % and inspiratory pressure of -20.15 % with respect to the set value; and it allows to monitor the main ventilation parameters with a calculation error between -6 to 25 %.

Clinical Relevance— Established the design of emergency mechanical ventilator using PLC and industrial components.

I. INTRODUCTION

As of 13 July 2020, the WHO through Pan American Health Organization (PAOH) had reported more than 1,326,326 cases and 11,870 deaths for COVID-19 disease in Perú, being the third country of more mortality in America with 3.6% in crude case fatality rate (CFR%) [1]. The Peruvian Ministry of Health before the pandemic had an approximate 5 ventilators per 100,000 people according to PAOH [2]. There was a problem of the Peruvian system care afront this the COVID-19 pandemic. For this reason, the development of this biomedical equipment was important for the country since world demand made it difficult to acquire more.

Based on ISO 80601-2-12: 2020-02: "Medical Electrical Equipment - Part 2-12: Particular Requirements for Safety of Lung Ventilator - Critical Care Ventilators", which describes the basic requirements to operating a mechanical ventilator. The mechanical ventilation theory is very extensive and difficult to study in short term, however, the professionals of the Medicines & Healthcare Product Regulatory Agency developed the Rapidly Manufactured Ventilator System, which describes the basic specification to operating ventilators [3]. For that reason, the components for the manufacture must comply with safety and quality standards.

FESTO company has components for initiatives in mechanical ventilation, such as proportional flow valves, as well as pressure and flow sensors. These components comply with the standard IEC 61010-2-201:2017 for electrical safety [4]. This same company has made a prototype of a mechanical ventilator with a PLC control system and industrial components in the electrical and pneumatic system [5]. We have the hypothesis that by using commercial industrial components, we can accelerate the process of prototyping and validation of medical equipment for regulatory entities in countries that require this emergency equipment, guaranteeing safety and reliability.

For this reason, a new prototype of a mechanical ventilator called "Fenix" is proposed. Based on industrial components, this medical equipment was approved for exclusive emergency use according to the Public Body of the General Directorate of Medicines, Supplies and Drugs of Peru (DIGEMID) [6].

II. METHODS AND MATERIALS

We analyze in the beginning on a basis of continuous mandatory ventilation: Pressure-controlled (PC-CMV) and volume-controlled (VC-CMV). Through the implementation of two channels, one for inhalation and the other for exhalation. A closed-loop control architecture was evaluated with the help of flow sensors in both channels and one of pressure at the proximal level. Finally, the electrical and pneumatic connections are seen in the Fig.1.

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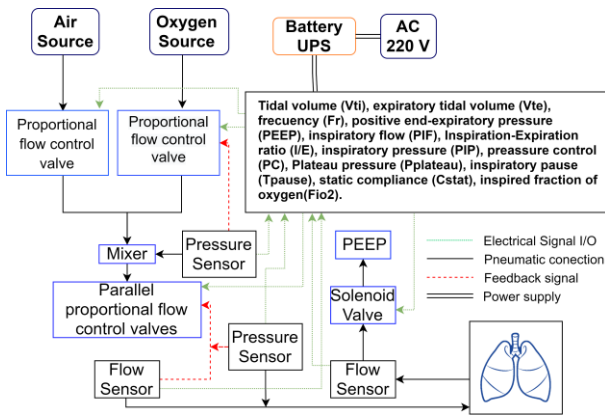L. Parvina is with the Edgardo Rebagliati Martins Hospital ESSALUD, Lima, Perú (e-mail: lsparvinam@unac.edu.pe)

Fig.1. Architecture of proposed in mechanical ventilator Fenix and the nomenclature of the monitoring parameters [7].

A. Modeled

The mechanical ventilator was modeled in SOLIDWORKS, following the relationships and dimensions of several mechanical ventilators found in literature and some commercial models. The equipment has a height of 1.5 m, width 0.35 m by length 0.55 m as seen in Fig. 2.
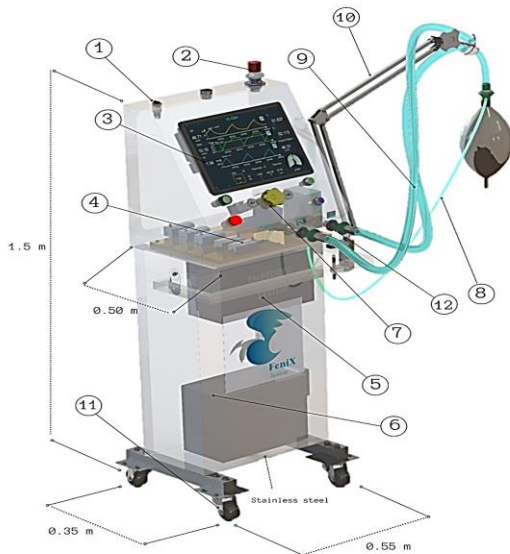

Fig.2. Isometric model of Fenix prototype, 1: On/Off button, 2: Peep Valve, 3: HMI touch panel, 4: Pneumatic system, 5: Embedded System, 6: UPS, 7: Alarms Panel and encoder select, 8: Proximal pressure sensor, 9: Limb-Lung System, 10: Arm support, 11: Wheels, 12: In-Ex HEPA Filter.

III. MANUFACTURING

According to Fig.2, the structure was fabricated from 1.5 mm thick stainless-steel sheets. Using bending and drilling machines to join machined parts, tig welding was used. Finally, 2 sections were established and joined by M6 bolt fixings, the upper section of the pneumatic system and the lower part of the electrical system. Additionally, the electrical part was divided into the pneumatic system and user interface.

A. Pneumatic System

For the pneumatic implementation, we used 2 filter regulators (MS4-RL FESTO 8-2 bar) at the oxygen and air inlet, 5 flow proportional control valves (VMDE FESTO 0-2

bar) for mixer system and control of pressure and flow, pneumatically actuated valve (VLO FESTO 2-8 bar) and solenoid valve (VUVS FESTO 2-8 bar) for exhalation control, also PEEP valve AMBU (5-25 cmH2O). Finally, we have flow sensors SFAB FESTO and pressure sensors SPAN FESTO. See Figure 3.
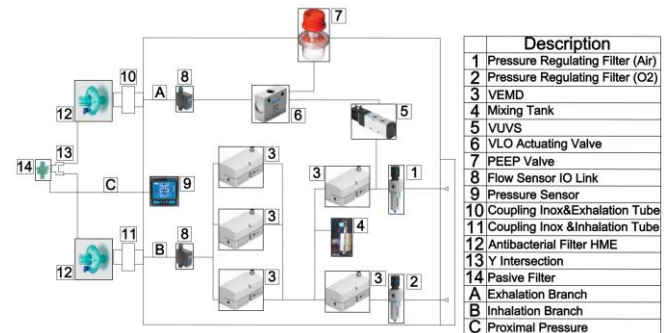

Fig.3. Pneumatic system in the prototype Fenix mechanical ventilator.

In the embedded system, we used PLC FESTO CPX-E-CEC-C1-EP with digital and analog input and output modules. Regarding the HMI screen, a 15" screen of Schneider Electric has been used in Profinet communication with the Festo PLC. Codesys 3.15.16 was used to develop the respective programs using Ladder and ST languages. See Fig. 4
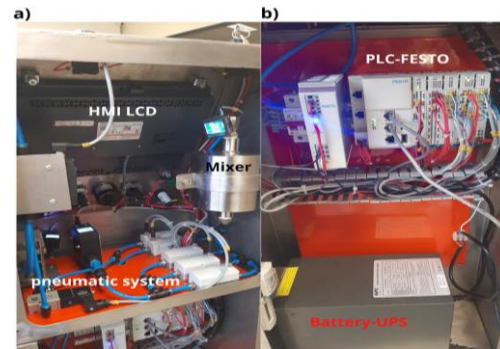

Fig.4. (a) Pneumatic System an interface. (b) PLC panel and power system.

B. User Interface

The interface developed is of the hardware-software interface (HSI) type optimized [8], whose elements are the following: A touch screen (HMI screen), a knob (encoder), four buttons, tow LEDs and a buzzer. The interface communicates the user with the internal processor (PLC) that executes the programmed actions, in addition to providing the data obtained by the sensors.
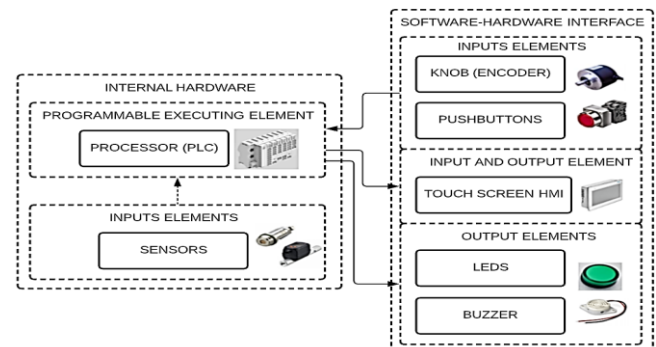

Fig.5. Software-hardware interface components.

IV. VENTILATION CONTROL MODES

A basic ventilation mode has been developed: Pressure and volume controlled continuous mandatory ventilation (PC-CMV and VC-CMV). The input parameters are Fio2 (21-100 %), Fr (10-80 BPM), Tpause (0-2 s), Vt (100-1000 mL), PC in PC-CMV (10-80 cmH2O), Flow (PIF*) in VC-CMV (5-60 L/min) and PEEP (5-25 cmH2O).
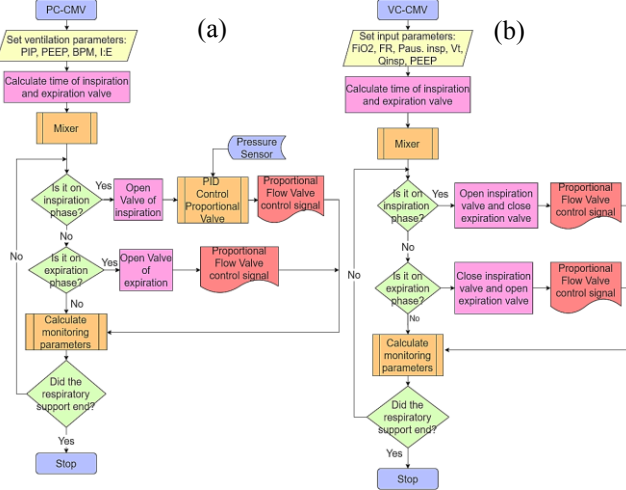

Fig.6 (a) Operating algorithm flow chart of ventilator which describes the continuous pressure control mode ventilation. (b) Operating algorithm flow chart of ventilator which describes the continuous volume control mode ventilation.

A. Pressure Controlled

In the field of industrial automation, the use of PID control is well known in the vast majority of applications, due to its high efficiency and effectiveness. In the mechanical ventilator, the PC-CMV mode is very relevant since it is a very determining parameter in the patient due to the consequences of the condition that could occur in ventilation such as barotrauma [9]. In addition, this ventilatory mode is used in patients who have acute respiratory failure, which does not allow them to breathe on their own [10].

Fig. 6 shows the flow diagram of the ventilation process in PC-CMV with the PID control subprogram for this ventilatory mode, as well as the calculation of the monitoring parameters, which are basically a set of equations that allow obtaining values medical parameters such as compliance, respiratory resistance, plateau pressure, etc. Which helps the specialist doctor to assist patients[11].

B. Volume Controlled

The VC-CMV ventilation mode uses the open-loop control method in the first version mainly by the limitations of shunt on-off valves that it had in the first month of the health crisis (commercial restriction and lockdown). In the last version, this control method was justified by the implementation of flow control valves, time-cycled ventilation and low probability of use with Covid-19 patients care, according to the opinion of local doctors. However, there are no studies to conclude which ventilation mode is better in the treatment of patients with ARDS [12.] The ventilator operates throughout the inhalation process, but in the exhalation, lets the respiratory system of the patient exhale without a ventilator controlling the process, like Fig. 6 describes, but without a PID controller.

V. TESTING EQUIPMENT

The standard procedure to calibrate a mechanical ventilator is to use a gas flow analyzer, in serial connection with an artificial lung, mechanical ventilator, and computer for taking data in 25°C [13]. We use Fluke Medical VT650 Gas Flow Analyzer and Fluke Acculung. According to Fig. 1 and Fig.7, we obtain in the computer the parameters such as inhalation tidal volume (Vti), expiratory tidal volume (Vte), frequency (Fr), Positive end-expiratory pressure (PEEP), inspiratory Flow (PIF), I/E ratio, inspiratory pressure (PIP), Plateau pressure (Pplateau), static compliance (Cstat)[7].
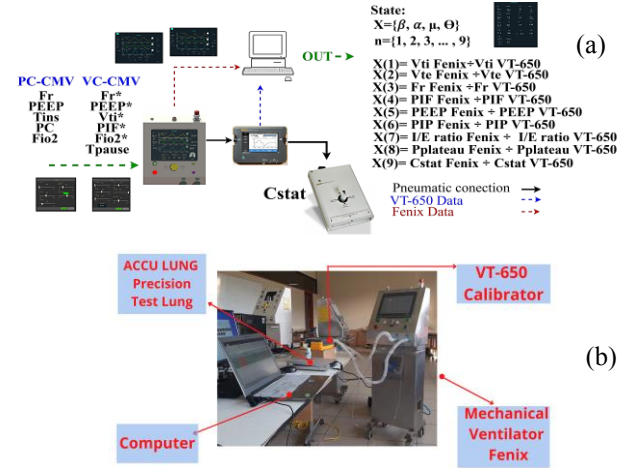

Fig. 7. (a) Diagram of inputs and output values. (b) Test equipment distribution.

In PC-CMV the programmed control pressure PC in cmH2O was evaluated in 13 points (μ ratios) and also perform alveolar recruitment varying in 7 points the PEEP in cmH2O (Θ ratios). In VC-CMV varying the Inspiratory Flow PIF* in lpm in 12 points (β ratios), and also perform alveolar recruitment varying in 7 points the PEEP* in cmH2O (α ratios). Complementarily, a relationship of the interface shape and data measured by the ventilator and the Fluke Medical VT650 Gas Flow Analyzer was established in Fig. 8. and Fig. 10[7].

VI. RESULTS

The experimental results of both PC-CMV and VC-CMV mode, with input parameters Fio2* = 21%, Fr* = 20 BPM, Tpause = 0 s (to VC-CMV), PIF* = 60 L/min (to VC-CMV), PC = 34.5 cmH2O (to PC-CMV), Tins = 1s (to PC-CMV) and PEEP = 10 cmH2O; show the resulting respiratory patterns shown in Fig. 8 and Fig. 10.
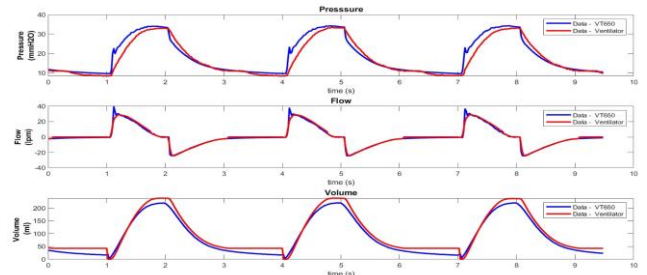

Fig. 8. PC - CMV respiratory patterns of pressure, flow and volume. Input parameters: PC = 34.5 cmH2O, PEEP = 10 cmH2O, Respiration Rate = 20 BPM, I/E Ratio = 1:2.

The calculated ventilation monitoring parameters and their errors, resulting from comparison with the calibrator and varying the inhalation flow and PEEP; are shown in Fig. 9 and Fig. 11 where according to the experimental test, the ratios of each parameter are established as results.
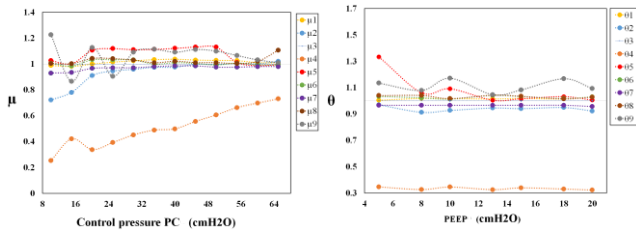

Fig. 9. Ventilation monitoring parameters calculated in PC-CMV test varying set pressure (left figure) and set PEEP (right figure) with input parameters Fio2=21%, Fr=20 BPM, Tpause= 0 s, PEEP=10 cmH2O. The parameters measured by the ventilator over measured by the calibrator (μ and Θ) to Vti, Vte, Fr, PIF. PEEP, PIP, I/E, Pplateau, CMPL, in ascending order of variables μ and Θ.
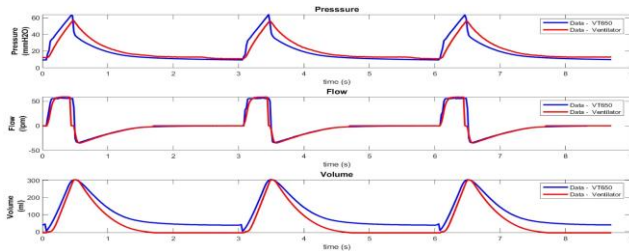

Fig. 10. VC-CMV respiratory patterns of pressure, flow and volume. Input parameters: Fio2*=21%, Fr*=20 BPM, Tpause = 0s, Vti*=410mL, flow=60 L/min, PEEP*=10 cmH2O.
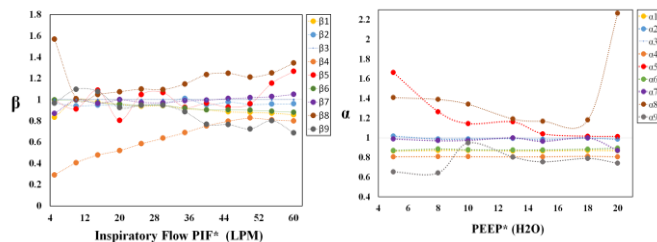

Fig. 11. Ventilation monitoring parameters calculated in VC-CMV test varying set flow (left figure) and set PEEP* (right figure) with input parameters Fio2=21%, Fr=10 BPM, Tpause= 0 s, Vt=410mL, PEEP*=10 cmH2O. The parameters measured by the ventilator over-measured by the calibrator (α and β) to Vti, Vte, Fr, PIF. PEEP, PIP, I/E, Pplateau, CMPL, in ascending order of variables α and β.

TABLE I. RMSE COMPARISON BETWEEN THE RESULTS OF CALIBRATOR AND THE VENTILATOR IN PRESSURE, FLOW AND VOLUME SIGNAL.

RMSE	PC – CMV	VC - CMV
Pressure	2.660	6.055
Flow	1.958	7.618
Volume	16.819	47.099

Table 1 shows the comparison between the results of PC-CMV and VC-CMV of the mechanical ventilator with the respective measurements obtained in the Fluke VT 650 calibrator in Fig. 8 and Fig. 10.

VII. CONCLUSION

Between the ventilation mode developed, the PC-CMV is much more efficient than VC-CMV, due to the continuous control, it has on maximum pressure (inspiratory phase) and positive end-expiratory pressure (PEEP). Furthermore, a considerable error is observed in the PIF flow measurements in the μ states of PC-CMV and β in VC-CMV. This is due to the pneumatic distribution at the moment of inhalation, due to an instantaneous peak at the beginning of the sequence as can be seen in Fig. 3. This ventilator provides ventilatory support, with a maximum tidal volume error of 12.93 % and -20.15 % with respect to set and measured value, respectively, in CM-CMV; and PIP of -13.38 % and 3.15 % respect to the set and measured value, respectively, in PC-CMV. This prototype allows to monitor the main ventilation parameters with a calculation error between -6 % and 25 %. Finally, the next step will be the implementation of an electronic PEEP valve.

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