



Design and construction of automated mechanical ventilation equipment to assist respiratory failure

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Abstract: This document presents the requirements met for the design, construction and first validation of a mechanical ventilation system to be used in patients with respiratory failure, which in the initial context was due to the COVID-19 pandemic. The design required the use of computer aided drawing software (Computer Aided Design) CAD and the construction required the use of installed capabilities in mechanical, electropneumatic, electronic, biomedical and automation manufacturing of Don Bosco University (El Salvador) institutes and centers. The adjustment, configuration and programming works were in charge of research professors specialized in these disciplines. The elements used for its construction were available in the Salvadoran market, considering the closure of the borders as a government measure in face of the expansion of the pandemic. After the design, manufacture and commissioning stage, measurements of the conditions of the supplied air were made with the help of professionals dedicated to the maintenance of medical equipment and with the approval of internist doctors. The results achieved are those obtained with paramedical equipment and with first aid equipment, for which it has been foreseen that the equipment can be tested in a subsequent instance with the certified medical union.

Key words: mechanical ventilation; assisted respiration; COVID-19, respiratory insufficiency

1 Introduction

The At the beginning of 2020, America becomes the epicenter of the SARS CoV-2 (Severe acute respiratory syndrome coronavirus-2) [1, 2], and in March it is declared a worldwide pandemics due to the ease of propagation because of the globalization phenomenon [3]. The first confirmed case in El Salvador was registered that same month. At that time, different protocols were activated to prevent massive infections in the population. However, hospitals were getting prepared for the attention of future patients.

With the purpose of visualizing the possible impact of the pandemics in the country, different scenarios were considered such as the construction of a specialized hospital for the attention of patients with COVID-19 (Corona Virus Disease - 2019), strengthening the installed capacity of existing hospitals, oxygen supply, possible medication for treating patients, training and hiring of medical staff for attention of patients, among other actions. In the latest case, it is evident that when a patient requires personalized attention with an equipment for manual assistance of respiration, the medical or

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auxiliary staff assisting him/her cannot care other patients, thus becoming a human resource unavailable for assisting people. This impact may be reduced if an automated equipment easy to install and easy to use in emergencies is supplied.

The expectation of a possible shortage of equipment for respiratory assistance motivated researchers to propose alternative systems of mechanical ventilation [4, 5] from auxiliary manual breathing units (AMBU) [6, 7]. This initiative sought the collaboration between the Industrial Design and Manufacturing Innovation Center (CIDIM, Centro de Innovación en Diseño Industrial y Manufactura) and the Research and Innovation Institute in Electronics (IIIE, Instituto de Investigación e Innovación en Electrónica), with the management of special resources of the Energy Research Institute (IIE, Instituto de Investigación en Energía) and the support from the collaboration of the United States Embassy in El Salvador.

To determine the best design of the system, and considering the strengths and capacity of the centers and institutes, it was stated that it fulfilled the following requirements:

- Take advantage of the existence of a manual reviver [8] used by paramedics and internist doctors.
- The reviver should be operated using two systems, one electropneumatic and another electronic.
- Structural accessories should be easy to manufacture in metal-mechanic shops.
- The acquisition of the specialized monitoring sensors would be handled through the American Space UDB of the IIE [9], due to the national quarantine that made the imports by local industries difficult.

2 Materials and methods

The basic fundamental of the designed system is an electropneumatic control system that drives a manual reviving equipment. The operation signals are controlled by a programmable logical controller, which receives electric signals from sensors that monitor the heart rate and the level of oxygen concentration in the air supplied.

The first design stage consisted of meetings between technical researchers and intensive care doctors from the Hospital San Rafael. The control variables that should be monitored in patients were determined in these meetings. These variables include the air volume according to the consistency of the patient, the number of cycles per minute required by patients according to their clinical picture, the ventilation pressure, the positive end-expiratory pressure (PEEP) [4, 10], the air flow, and the inspiratory-to-expiratory (I/E) ratio. Another important requirement is that the system should operate in three types of cycles: volume-cycled, pressure-cycled and combination of both. However, with the approval of the intensive care doctor it was chosen the volume-cycled, since it is a simple and effective operation mode, always taking into account that it is an emergency measure [11].

The design should provide appropriate ventilation for patients prior to releasing a specific ventilator [12], and thus it was considered the tidal volume and the respiratory rate that would maintain patients stable [13]. The tidal volume was determined based on a ratio with the ideal weight of patients and it is calculated with reference to the human weight:

IBW (ideal body weight, kilograms) men [14]:

$$50 + 2.3 * (\text{size in inches} - 60) \text{ or}$$

$$50 + 0.9 * (\text{size in cm} - 152.4)$$

IBW (ideal body weight, kilograms) women:

$$45.5 + 2.3 * (\text{size in inches} - 60) \text{ or}$$

$$45.5 + 0.9 * (\text{size in cm} - 152.4)$$

With respect to respiratory rate, the inspiration and expiration cycle is related to the age of patients, according to the behavior shown in the curve of Figure 1.

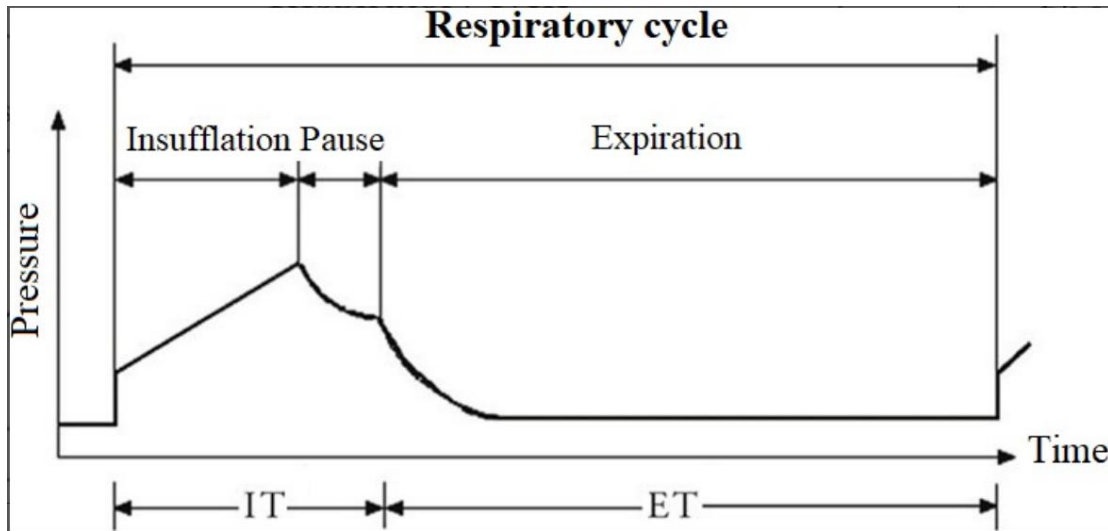


Figure 1. Respiratory cycle

Figure 1 shows the I/E ratio [15], inspiration [16] (insufflation) and expiration (exhalation), which may be adjusted to 1:3. But if the patient condition is preexisting asthma [17] or exacerbation of chronic obstructive pulmonary disease, it may be adjusted to 1:4.

After obtaining the operation requirements, the structural design was carried out with the aid of CAD software [18] and 3D printing light manufacturing [19], with the result presented in Figure 2.

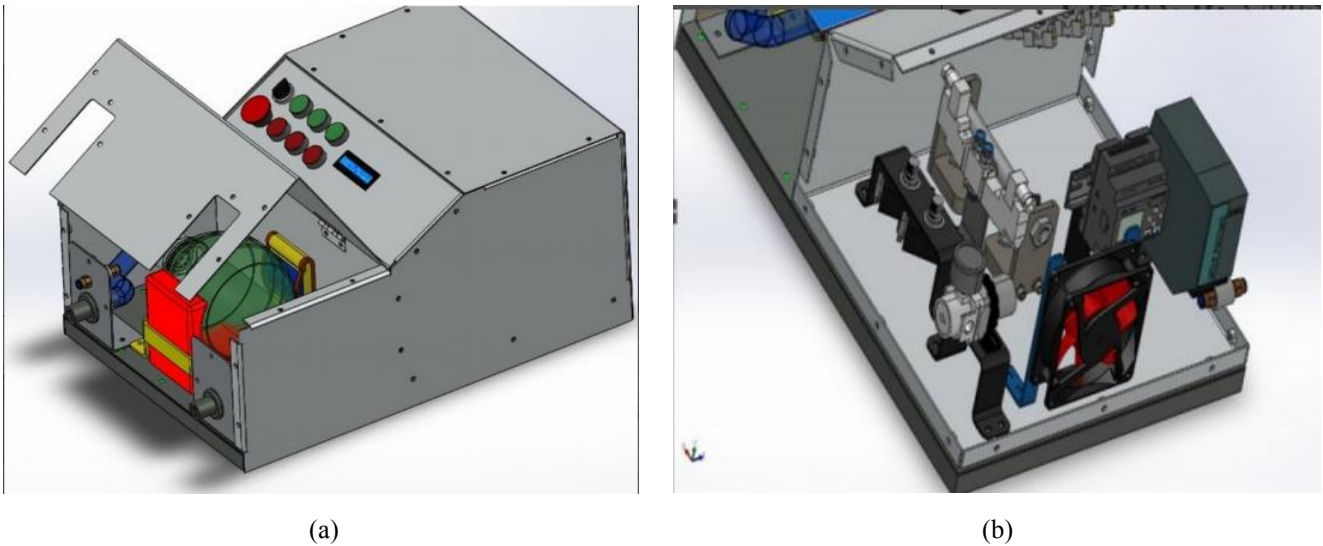


Figure 2. Design of the system with the aid of CAD software

Figure 2 shows the design of the structural system and the electropneumatic system. Figure 2(a) shows the structural distribution to hold the reviver, the location of the access points to the inlet and outlet air connections, together with the valves that regulate the reviver pressure, the mobile door, the cover with the set of buttons and the information display. Figure 2(b) shows the distribution of the electropneumatic control system constituted by the 5/3 bistable electro-pneumatic valve, unidirectional flow regulators, pressure regulator, programmable logic controller (PLC), ventilator, electric and pneumatic adapters, supports and configuration of the structural base.



(a)



(b)

Figure 3. Construction of the electropneumatic system

Figure 3 shows the finalized structural (a) and electropneumatic systems (b), which are ready to carry out tests and measurements. It is important to remark that all control system elements installed were found at the place, since imports to El Salvador were not possible as a consequence of the confinement due to COVID-19 pandemics. This makes it easy to replicate the system when needed.

A SIEMENS LOGO version 8.0 micro-PLC was used to control the process. It can handle 4 digital outputs, better known as output to relays, which are used to govern the valves and electrovalves required by the system. Similarly, the buttons enable to control the number of repetitions per minute demanded by the patient and according to the criterion of the treating physician.

The control system was designed according to the plot of the respiration process shown in Figure 1, where the specialist may determine if the patient requires 12, 14, 16 or more repetitions per minute for his/her treatment. It should be mentioned that the code is versatile enough to be modified at any moment, and configure it in the cadences required by internist doctors.

The PLC has a display where the specialist may see the selected value of repetitions and the buttons are marked to avoid confusions. The electropneumatic system is prepared to receive compressed air from the hospital infrastructure, and thus it has been anticipated that this air is used as pneumatic supply to the control electrovalves.

The system design was prepared to place programmed control processes in the PLC, to enable specialists to be certain about the number of repetitions that they are selecting for the patient. At this moment the system is open-loop, because the sensors required to implement the corresponding control loops are not available. However, appropriate sensors may be installed in a subsequent version to enable the system to self-adjusted based on the information provided by the sensors, thus transforming it into a close-loop system.

Figure 4 shows the connections between the PLC and the different parts of the respirator.

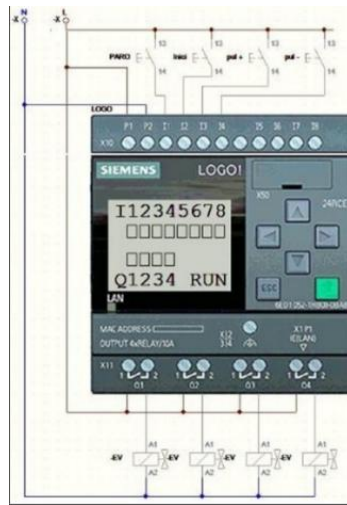


Figure 4. Configuration of the PLC

3 Results and discussion

Due to the agreement between the diagrams and the final equipment, it is considered that the conceptual prototype may be easily reproduced, both its structural and electropneumatic components.

Measurements were carried out by the INFRA personnel in El Salvador, to conduct operation tests and verify that it complies with the parameters indicated by the internist doctor. They are responsible of performing maintenance of assisted mechanical ventilation equipment, with the use of specialized equipment.



(a) (b)
Figure 5. Equipment for measuring operational parameters

Figure 5 presents the measurement equipment: (a) it verifies that it is a Certifier FA TSI High Flow Module [20] and (b) it presents the detected value of 0.301 liters of air and 15.2 blows per minute (BPM). The values shown are in agreement with the ones indicated by internist doctors for patients with ages between 25 and 40 years, with 15 to 19 inspirations per minute. The values adjusted by the flow regulator can be programmed and changed by PLC to create predefined buttons for these parameters and the patient's medical condition. In addition, measurements were carried out with the NI ELVIS [21] equipment of the University Biomedical Laboratory, which was used to build a plot from the

signals detected by sensors, that coincides with the data obtained by the INFRASAL specialists.

Table 1 shows the data measured with the TSI equipment, indicating the respirations per minute (RPM), the minimum and maximum air volume given in milliliters, the minimum and maximum air flow in liters per second, the minimum and maximum air pressure in cm H₂O. The equipment was configured for 15 and 19 RPM, as requested by specialists. When configured for 15 RPM, the volume transfer obtained was between 290 and 330 ml, the flow varied from 2.5 to 3 l/s and the pressure reached a value of 42 cm H₂O. On the other hand, when the equipment was configured for 19 RPM, a volume transfer between 270 and 320 ml was obtained, the flow varied from 2.5 to 3 l/s and the pressure reached a value of 40 cm H₂O [22, 23]. In both cases, the values obtained are considered appropriate.

Table 1. Measurements carried out with TSI equipment

	RPM	Volume (ml)		Flow (l/s)		Pressure (cm H ₂ O)	
		Min.	Max.	Min.	Max.	Min.	Max.
1	15	290	330	2.5	3	-	42
2	19	320	320	2.5	3	-	40

4 Conclusion

Some of the strong proficiencies of the Don Bosco University are in the areas of electronics, automation and manufacturing, and thus this work proposes the design of a mechanical ventilation system assisted by automatic control systems.

The support provided by the American Space UDB was key to obtain electronic elements that were not available at the moment due to the closure of borders as a consequence of the pandemics, but that are necessary for developing automatic and medical equipment, which enables to give a fast response to face worldwide challenges.

Improvements may be implemented in the design and the prototype which makes it more complex, efficient and precise, and then allow it to be applied to a larger number of cases that arise at the medical level.

The systems designed and constructed are versatile, because they may be configured according to the requirements of doctors and patients in short time, both face-to-face and remotely. Different programs may be simultaneously loaded in the PLC, therefore, pressing different buttons or changing the position of a knob can call different programs for the operation of the pneumatic cylinder (cycles, stroke length) according to the requirement of each patient.

Another advantage of the PLC is that different clinical sensors may be connected to it, and with the interpretation of such signals changes in the operating conditions of the pneumatic control system are automatically activated.

The system constructed may be used for studies in medicine, manufacturing, electronics, automation, both in continuous training of specialists, and in graduate and undergraduate studies. The objective is always to provide humanitarian aid.

The constructed physical model may be a reference for future development of mathematical and simulation models, in the medical and engineering areas, among others.

Conflicts of interest

The author declares no conflicts of interest regarding the publication of this paper.

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