Mechanical Ventilator Prototype for Two Independent Patients, without Risk of Cross-contamination

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Abstract—The emergency measures to limit the damage caused by COVID-19 generated a significant deficit in the trade balance of the health sector in Brazil, mainly with the import of medical equipment. It is proposed the production of a domestically manufactured mechanical ventilator to reduce the costs of importing hospital devices. The system engineering methodology was used to define the best solution, planning and execution of the project. As a result, a ventilator with an adequate level of automation was obtained to assist two patients simultaneously, without cross-contamination risk and with independent operation parameters. Hence, it is concluded that the developed prototype of the device meets the demands mentioned above concerning project cost, likewise meeting the complex medical requirements for the equipment in question.

Keywords—Mechanical ventilator, Project cost, Systems engineering.

I. Introduction

In early 2020, COVID-19 surprised the world with its devastating power. SARS-Cov-2 [1], the virus responsible for the disease, spread so rapidly that it prompted the WHO (World Health Organization) to declare a global pandemic in March.

In Brazil, the situation was not different. Soon the state of community transmission was established [2] and, with the substantial number of patients needing mechanical ventilation, 72% [3], and the country's health system collapsed [4], the race for medical and hospital equipment began especially for mechanical ventilators.

With the international market devoid of medical equipment and the sudden increase in prices due to the law of supply and demand, Brazil found itself with problems acquiring the equipment since 60% of the expenses with health equipment are with imported products [5].

In 2020, spending on imports of this equipment was around US$ 4.33 billion, while exports reached only US$ 697.5 million, generating a trade deficit in the sector of US$ 3.64 billion, influenced by supply and demand, high dollar exchange rate and high logistics costs [5].

Given this context, the motivation arose to develop an investigative work seeking the conception, design and manufacture of a mechanical ventilator prototype that presented as main project requirements the following: a low production cost (compared to conventional ventilators available in the international market); ease and speed of manufacturing and that was portable, aiming to meet the public health system in locations of difficult access in emergencies. It should also include the possibility to use the power to drive the ventilator coming from an outlet inside the ambulances themselves, like cigarette lighters. The last requirement, no less essential, would be the possibility of this ventilator simultaneously serving two patients without risk of cross-contamination.

II. Materials and Methods

A. Systems Engineering Methodology

For the study and design of the mechanical ventilator prototype, a systems engineering approach was used, which according to INCOSE (International Council on Systems Engineering), is an interdisciplinary and integrative approach that enables the successful realization, use and disposal of a designed system, using systems principles and concepts and scientific, technological and management methods [6]. Systems Engineering provides methods, processes, and tools for the analysis, planning, selection, and optimal configuration of systems, in general [7].

According to Pahl [7], the system engineering methodology is defined in seven steps, as shown in Fig. 1. The beginning of

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the process is headed by the phase called "system studies", where a collection of information about the system (i.e., ventilator in the case studied) begins, which can be market analysis, trends research or concrete formulations about the problem that establishes the starting point of the project.

In the second part of the methodology, the "goal program" is established, in which the goals of the projected system are precisely defined, an essential step for the evaluation of the proposed solutions in future steps of the methodology.

Subsequently, there is the "system synthesis", where various solutions are developed to meet the requirements and information gathered earlier.

In the fourth part of the methodology, the "system analysis" is performed, where the solutions proposed in the previous step are confronted with the target program, ensuring that it satisfies the goals in the best possible way.

Subsequently, the "system evaluation" is performed, where the best possible solution for this stage is obtained, and then a "system decision" is made to be adopted. Finally, the "execution planning" of the previously chosen system is performed. It is important to note that this is an iterative procedure, as shown in Fig. 1, where one must go back to previous steps to ensure the best solution.

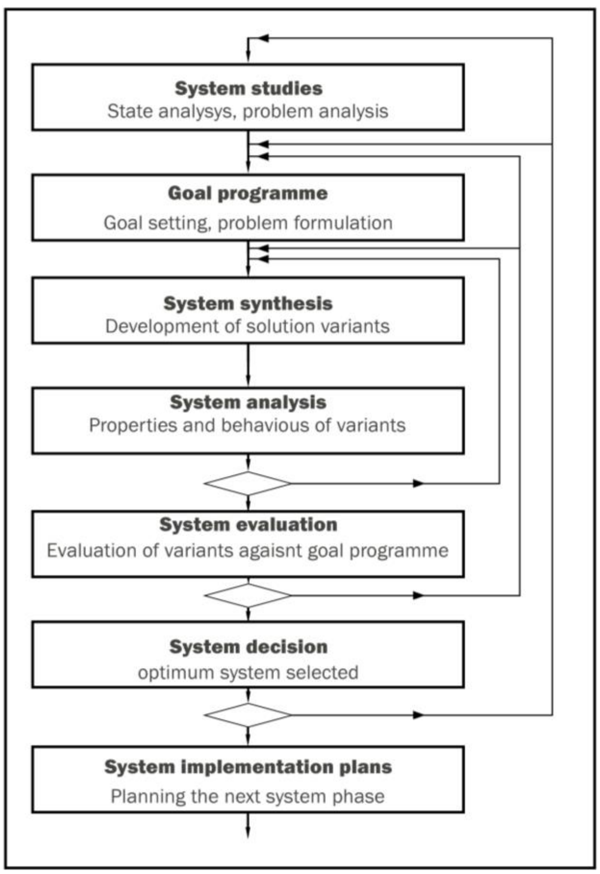

Fig. 1 Systems Engineering Methodology [7].

B. Systems Engineering applied to the ventilator.

Step 1 – Study of the system:

As mentioned in the introduction, one of the primary motivations for this work was the large deficit in the balance of trade of the health sector that the import of medical devices, especially mechanical ventilators, caused in the year 2020. Therefore, in the information-gathering stage, it was sought to obtain data regarding the import values of commercially available devices during the pandemic and arrived at an average value between US$ 13,000 and US$ 15,300, with some purchases reaching the value of US$ 64,500 at the current exchange rate [8] [9].

Based on this initial data survey, the two main correlated problems were defined and emphasized: the shortage of mechanical ventilators on the world stage and exorbitant prices due to this shortage, high demand, and logistical difficulty due to the pandemic.

Step 2 – Goal programme:

After the main problem was defined, the project goals were stipulated, which were subdivided into general and specific objectives, namely:

General Objectives:

- To conceive, design and develop a prototype mechanical ventilator with a simple design capable of being manufactured with parts and materials readily available in the local market, even in times of pandemic (as opposed to imported models), and that would meet the crucial medical requirements for good emergency mechanical ventilation.
- To conceive, design and develop a device that would simultaneously serve two patients without risk of cross-contamination and with the possibility of setting the main medical parameters individually, reducing the need to purchase more devices, thus reducing the cost of purchasing these products.

Specific Objectives:

- The final prototype cost up to 10% of the average value of the imported equipment.
- Functional simplicity.
- Use of parts already approved and certified by ANVISA (National Health Surveillance Agency), the regulatory agency in Brazil, facilitating the production and maintenance of the device.
- Affordable materials and parts, with high availability in the local market, even in times of pandemic.
- Mobility and portability for easy transport and the power to drive the ventilator coming from an outlet inside the ambulances themselves, like cigarette lighter socket.

Step 3 -Synthesis:

This is undoubtedly the most crucial stage but one of the most complicated of the methodology because it discusses the various possible solutions to the same problem. The high degree of complexity occurs because, in developing many ideas related to each element of the system, there is the risk of going beyond what is necessary, creating even some "impossible solutions" in the short and medium-term, delaying the whole process.

So, for better efficiency of the process in the case described here, it was decided to focus on the central element of the

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mechanical ventilator: its way of delivering air to the patient. Some possible solutions were studied, namely:

- Use of compressed air network in conjunction with automatic oxygen blender.
- Use of mechanical actuators in AMBU (Artificial Manual Breathing Unit) type resuscitators in conjunction with the use of the manual oxygen mixer via Venturi valves.
- Use of mechanical actuators in the bellows system in conjunction with the manual oxygen mixer via Venturi valves.

Step 4, 5 and 6 – System analysis, Evaluation and Decision:

In practice, these three steps were performed almost simultaneously because when comparing the possible solutions with the goals pre-established in step 2, the use of a mechanical actuator in the bellows system in conjunction with the use of the manual oxygen mixer through the Venturi valves was found to be the best possible solution for the system.

The option of using compressed air along with the automatic mixer was discarded because it requires a whole system with compressors and specific fixed output points, not meeting the initial requirement of portability, besides the high cost of the automatic blender, which may make it impossible to meet the cost target.

The other option of using the AMBU was also discarded because it is a part not designed to be submitted to a high number of repeated work cycles with great chances of fatigue rupture due to its fragility, reducing the component's useful life. Furthermore, the AMBU does not make it easy to be able to control the tidal volume sent to the patient efficiently. The set of bellows present themselves as adequate components to meet this demand.

Step 7 – Planning the execution of the system:

Finally, in the last step of the process, the first initiative was to seek and acquire some of the parts described in the 3rd specific objective and the necessary raw materials to ratify the real availability and their corresponding costs in the local market. All this happened during the initial months of the 2020 pandemic crisis.

Subsequently, in possession of the various data collection and some certified pre-manufactured commercial parts (i.e. those already based on the initial 3D modelling of the conceived prototype in which the various pre-selected parts holding certification by ANVISA were applied), we then proceed to the selection and planning of the manufacturing processes to be adopted in the execution of the various other remaining components for the complete assembly of the proposed ventilator. All Parts were modelled using Creo Parametric 7.0 software.

C. Manufacturing and assembly process

After review and definitive 3D modelling of the system, manufacturing process started from the main structure, in which tubes made from metalon material of various dimensions were chosen because it is a material that is both easily accessible in the market and joined by welding, as shown in Fig. 2.

Then two individual 12V motors were attached, with a torque capacity of 20 N.m, where a pulley system is applied, from the motor to the shaft of a pillow block bearing, providing an increase in motor torque by varying the sizes of the motor pulleys to the driven pulleys. The smaller the ratio

of the diameter 'd' of the motor pulley to the diameter 'D' of the driven pulley, the greater the increase in motor torque, as shown in Fig. 3.

Subsequently, a piston-plate connecting rod assembly was coupled to the pillow block bearing's axis, which when rotating the pillow block bearing's pulley, an upward and downward movement is effected, responsible for activating the bellows coupled to the hood sending air to the patient and pulling air from the atmosphere through the intake valve, where the O_2 mixers are coupled. These mixers use the venturi tube principle and, therefore, are fitted with a narrow tube in which the oxygen supply is coupled, so that the flow through the tube generates a pressure reduction, causing the mixer to pull the ambient air through a side opening that is also part of its structure. Each venturi tube has a specific diameter and a distinctive color, acting as the classic mixers, where for a given venturi tube color, there is a guarantee that a pre-set mixture of oxygen will occur, and thus the system allows the oxygen concentration to vary between 24% and 50%. The usual tube colors used by manufacturers for intermediate oxygen concentrations are blue - 24%, white - 28%, orange - 31%, yellow - 35%, red - 40% and pink - 50%.

The bellows assembly is also outfitted with a height adjustment to the structure, allowing the regulation of the tidal volume of air sent to each patient. Finally, the device includes an inspiratory pressure adjustment valve certified by ANVISA, limiting the pressure sent to the patient's lung (avoiding the risk of barotrauma) and an exhalation valve, also certified, for PEEP (positive end-expiratory pressure) adjustment.

Fig. 2 Structure built with metalon material.

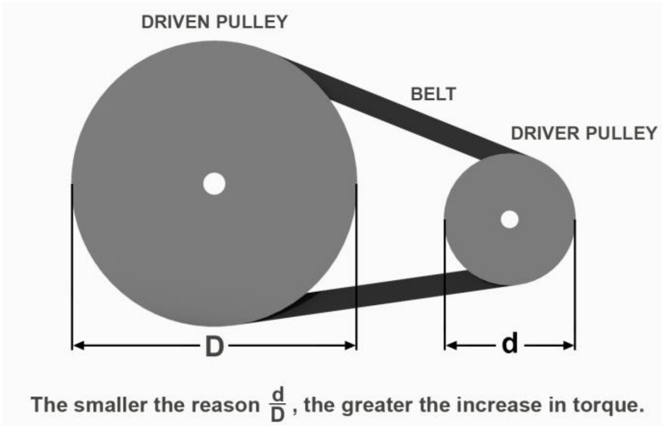

Fig. 3 Torque increase from the use of pulleys.

III. Results

As a result, a final prototype of the mechanical ventilator was obtained as shown in Fig. 4. Table 1 presents most parts described in this paper and their current price in US dollars. To validate the operation of the device, some power supply and continuity tests were performed, where 2 Dräger test lungs were used, with a resistance of 20 mbar/L/s and compliance of 25mL/mbar. In the preliminary power supply tests, the ventilator was connected to a vehicular charger (i.e., cigarette lighter socket) for 3 hours, and in the continuity test, the equipment was connected to a 220V power plug through its 12V source for 720 hours. In both tests, the ventilator was able to supply, in an uninterrupted manner, both lungs simultaneously with independent ventilation parameters and, due to its new design, avoiding any risk of cross-contamination. The automation of the system includes control of pressure, flow, tidal volume of air, respiratory rate control by rotation speed, and basic alarms, such as pressure alarm, tidal volume, frequency, apnea time, and minute ventilation. It is noteworthy that the impossibility of presenting more details of the project is because the mechanical ventilator developed is in the process of patenting by the Technological Innovation Laboratory of UFRN (LAIS).

TABLE I
Mechanical Ventilator Cost Per Unit In Us$ (Quoted On 14/01/2022)

Denomination	**Quantity**	**Price per unit**
Ventilator body	1,4 m^2	51,66
Admission valve	2 unit	33,98
Inspiratory pressure adjustment valve	2 unit	77,76
Air flow regulator valve	2 unit	1,22
Unidirectional valve with	2 unit	115,73
Respiratory circuits	2 unit	76,84x
Bellows systems	2 unit	126,58
Bellows guide	2,5 m	2,10
Single cardan joint	2 unit	21,18
Linear Bearing	2 unit	2,50
Cylindrical bearing	4 unit	19,87
Pillow block bearings	2 unit	18,48
Driver pulley	2 unit	13,56
Driven pulley	2 unit	13,73
Pulley belt	2 unit	1,43
Electric motor	2 unit	55,88
Casters	4 unit	3,55
Structure and machined parts	5,5 m	23,98
Breaths per minute counter	2 unit	15,85

IV. Discussion

To fully evaluate the project, it is necessary to go back to the goal program in step 2 of the methodology and analyze whether the general and specific objectives were fully met. The general objectives were fully met since the device has a simple design, with mechanically driven devices, and meets the main the medical requirements of ventilation, such as tidal volume control; flow control; RPMI (Respiratory Incursions per Minute) control; inspiration and expiration pressure

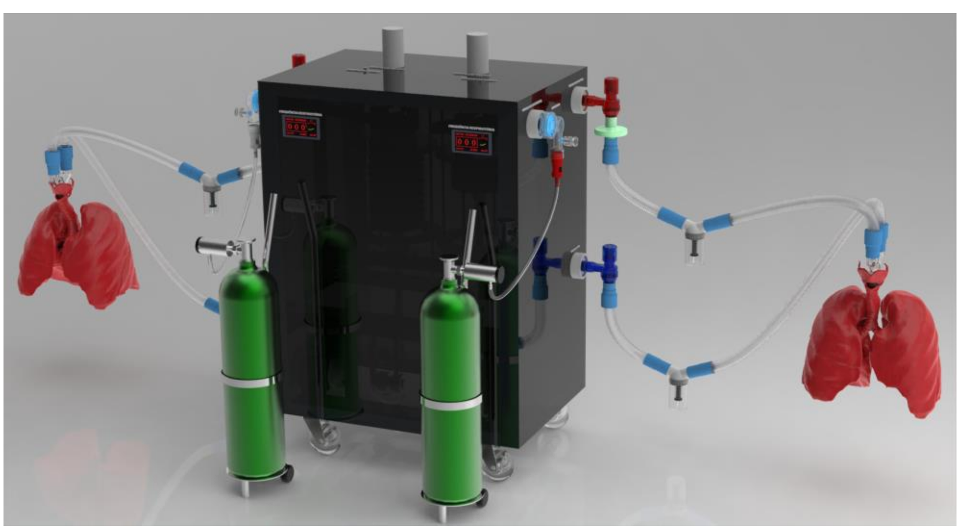

Fig. 4: The proposed mechanical ventilator prototype manufactured and assembled.

control besides providing two individual ventilation systems, serving two patients at the same time, inhibiting the risk of cross-contamination.

The specific objectives were also met since the final project value was 9,5%, as shown in table 2 with the detailed cost per respiratory system. The operation of the device is in its entirety simple, as mentioned previously, all the selected parts that are for medical use are certified by ANVISA, which facilitates the production and future certification of the ventilator, particularly considering the issue of availability of parts on the market. lastly, the portability and mobility requirement were also met, since the device only needs a power source (which can be the ambulance charger socket itself) and oxygen cylinders to serve two patients simultaneously.

TABLE 2
FINAL COST OF THE MECHANICAL VENTILATOR IN US$ (QUOTED ON 14/01/2022)

Denomination	Price per respiratory system	Total price
Mechanical ventilator	726,30	1452,61

V. CONCLUSIONS

Although the worst effects of COVID-19 are attenuated globally, new strains of the virus frequently appear, having the potential to originate new waves of infected people. Thus, a way to prepare for these waves is necessary so that there is no excessive spending of public money and an incessant search for scarce imported devices in the market. That said, the mechanical ventilator presented in this article, through its innovative design, provides the solution to the two issues mentioned above, offering national manufacture of the product at a cost less than 10% of the values of imported products. Moreover, the prototype can serve two patients simultaneously, without the risk of cross-contamination, reducing by half the need for new devices to meet the demand of patients. It was also demonstrated that the equipment has good portability and can even be powered by an ambulance charger socket. Finally, it can be concluded that there are still room and real chances of reducing the manufacturing costs for the proposed ventilator. This could be achieved, if a more significant number of them (i.e., larger lot) are manufactured. The explanation for this lies in the fact that there are some parts that the market refuses to sell only one unit, or even, for example, an ordinary can of paint purchased that may paint more than one ventilator chassis. Certainly, the acquisition price would become diluted.

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