MAMBU: A Bolivian Case of Response to Artificial Ventilators Shortage

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***Abstract*—COVID-19 pathology is characterized by a variety of symptoms, from respiratory to cardiac and even neuronal affections. However, from all of these manifestations, lungs' affection remains a focus of attention due to being considered as the main cause of death. Respiratory failure is treated using different strategies, but a very common practice is to provide respiratory support through artificial ventilation to patients. Unfortunately, due to the shortage of devices capable to offer such functionality, many patients are left unattended given that public healthcare systems' resources are not enough - the Bolivian healthcare system was not the exception. This paper reports the approach followed to develop MAMBU which stands for Mechatronic Ambulatory Medical Breathing Unit, an automation system for AMBU-based ventilation designed to face the shortage of ventilation devices in Bolivia. A MAMBU device can be manufactured and assembled in a short amount of time, with a low cost and easy transportation. Furthermore, it includes control schemes to manage the respiratory frequency, I:E ratio, PEEP, and FiO2. The device was validated through instrumental testing and in-vivo procedures following Bolivian current regulations. The results obtained show that the device is safe for human usage as well as relatively reliable (around 7% of error).**

***Keywords*—AMBU automation, Mechanical Ventilation, COVID-19, ambulatory respirator.**

I. Introduction

The first two cases of COVID-19 in Bolivia were officially reported on March 11th, 2020 [1]. In April of the same year, the worst-case scenario predictions according to the Bolivian Ministry of Health pointed to up to 10,000 cases by the end of May [2], which would have meant significant pressure on the healthcare system. Although such predictions were not met given the early lockdown measures [3], the number of cases kept rising steadily and so it did the percentage of patients who required specialized care. The PAHO estimated that, before the pandemic, the country owned 3.43 mechanical ventilators per 100,000 inhabitants [4], however by May 2020, a different study reported that the country owned a total of only 150 mechanical ventilators that could be used to provide respiratory support in severe cases of the disease [5]. In any of both cases, the ratio of mechanical ventilators per 100,000 inhabitants was one of the lowest with respect to other countries in the region [4].

The need for ventilators is based on the required respiratory support for patients whose lungs have been damaged and, therefore, present breathing difficulties [6]. Unfortunately, these devices soon became scarce producing an unprecedented demand which was not able to be covered by manufacturers [7]. In view of such shortage, several alternatives started to get developed, some related to known companies and manufacturers that were not in the area (e.g. General Motors), and even some following the Do-It-Yourself logic [8].

This work shows the design and test results of the MAMBU device, which stands for Mechatronic Ambulatory Breathing Unit. The paper is organized as follows: section II states the related work by briefly reviewing open-source and commercial alternatives; section III introduces the proposed design; section IV explains which experimental procedures and tests were performed to verify the MAMBU device performance; section V presents the conclusions.

II. Related Works

A. Open Source Devices

The development of Open Source ventilators has been an attractive point of attention since the sharing of know-how is critical to overcome the current crisis [6]. Different fast manufacturing techniques, such as 3D printing, were used as the core for these devices [9]. Nevertheless, the general

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manufacturing capability relies on the available supplies and tools that a country may possess, which provides huge opportunities for those countries with an appropriate supply chains, but scarce ones to those without them [10].

The practice of 3D printing has granted opportunities to developing countries in different fields that involve manufacturing [11]–[13]. Furthermore, although it was expected to have issues while resupplying materials, its use became attractive to manufacture diverse products for addressing shortages due to the pandemic [14]. Unfortunately, by the time the lockdown was stated in Bolivia, the supply chain of required materials for 3D printing started to be scarce as imports reduced significantly [15].

There is no doubt that 3D printing is a very useful and popular prototyping technique, and has been a viable option in several respirator projects due to its accessibility, ease of use and open source community. However, these virtues are counter-weighted with defects such as too slow playback speed or even the need of most of the final products to have a finishing process in order to have a clean and uniform surface for air or liquid fluids related to medical devices [16]. Consequently, different techniques are also used for rapid prototyping medical devices, as respirators.

Computer Numerical Control (CNC) machines comprise another type of popular techniques related to rapid prototyping that have been used in the development of low-cost medical devices. For example, in [17] a CNC was proposed to manufacture implant parts. Nevertheless, through our literature review, we found no current reports of respirators manufactured through this technology around our region (Latin America). Furthermore, laser cutters, which allow to work with another kind of materials and also to reduce manufacturing time, were employed to manufacture a respirator [18].

There have been several regional initiatives that aim at developing support products for COVID response around the globe. In Bulgaria, for example, Air Collective focused on developing 3D printed masks [19]. In the United Kingdom, OxVent proposed a low-cost mechanical ventilator which claims to be ready for mass production [20]. In Spain, the Oxygen respirator took an open hardware approach and used CNC machines [21]. Local interest on developing these devices is well-founded considering the general supply shortage, thus, it was mandatory to develop alternatives considering what was available in the local market. In Bolivia, several devices were proposed in response to the critical situation. Imevent [22] and Barlovento [23], are some of the devices that were presented through media. While both systems were greatly received, none of them have published the corresponding technical details in a public or even academic way. Besides, both systems are non-portable and designed for ICU conditions. Also both systems are still in their validation or certification process.

B. Commercial Alternatives

The development of this type of ventilators has also gone further than academic initiatives. For example, Siemens partnered with GPA innova from Spain and developed "RESPIRA" [24], a commercial option that has different technological qualities: a Siemens PLC, IoT capabilities, among others. Nevertheless, it has also been documented that during the first stages of the pandemic, the demand for these devices increased significantly from different manufacturers [25], which produced the previously mentioned shortage.

Several other manufacturers have ventilator machines available, e.g., Philips EV300, Hamilton T1, GE CARESCAPE R860, for mentioning a few. Nevertheless, each of them is different in practical terms [26], known to be expensive and require highly specialized personnel [27]. In that sense, according to [28] most of them are designed for intrahospital use with the exception of sub-acute ventilators, are expensive and non-affordable for develeping countries.

III. MAMBU

Mechanical ventilation is a therapeutic strategy that consists of mechanically assisted spontaneous pulmonary ventilation when it is non-existent or ineffective for life [29]. The process is commonly performed by a mechanical ventilator or artificial respirator as well as a person pumping the air manually by compressing an AMBU bag.

There are several types of pulmonary ventilation, which go hand in hand with different techniques and technologies [30]. However, mainly 2 different types of mechanical ventilation techniques are used: pressure and volume. Both techniques have a different variety of technologies in order to be viable. Particularly, volume ventilation is presented as a very simple method to control regarding the main variables that a physician must control for the development of safe ventilation. These parameters are:

- **Air volume** - This refers to the air that is programmed to be given at a certain volume (circulating or tidal) to obtain an adequate gas exchange. A tidal volume of 5-10 ml / kg is usually selected in adults.
- **PEEP** - Positive end-expiratory pressure. It is used to recruit or open alveoli that would otherwise remain closed, to increase the mean pressure in the airways and thereby improve oxygenation.
- **Respiratory rate** - It is programmed according to the ventilation mode, tidal volume, physiological dead space, metabolic needs, level of PaCO2 that the patient must have and the degree of spontaneous respiration. In adults it is usually 8-12 / min.
- **I:E ratio** - Is the time ratio between inspiration and expiration of air in the patient.
- **FiO2** - It is the inspiratory fraction of oxygen that we give to the patient. In the air we breathe it is 21% or 0.21. In MV, the lowest possible FIO2 will be selected to achieve an arterial O2 saturation greater than 90%.

While these values may seem easy to control individually, the challenge is to integrate them into a device that effectively performs mechanical ventilation. Unfortunately, volume ventilation techniques are very complex and expensive to perform (parameters that go against the goals of this project), with the

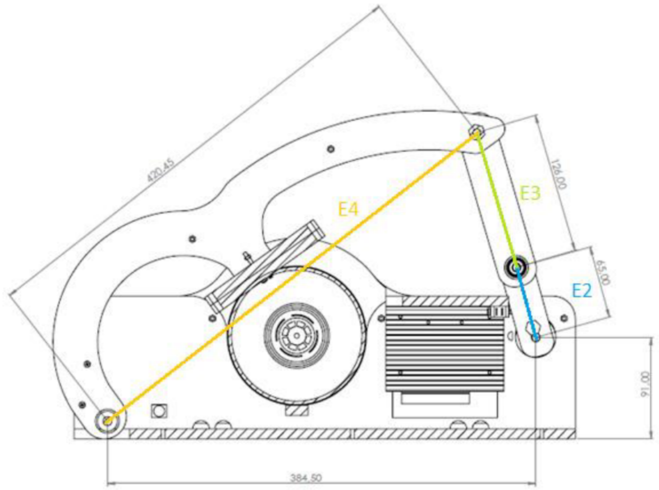

Fig. 1. MAMBU mechanism.

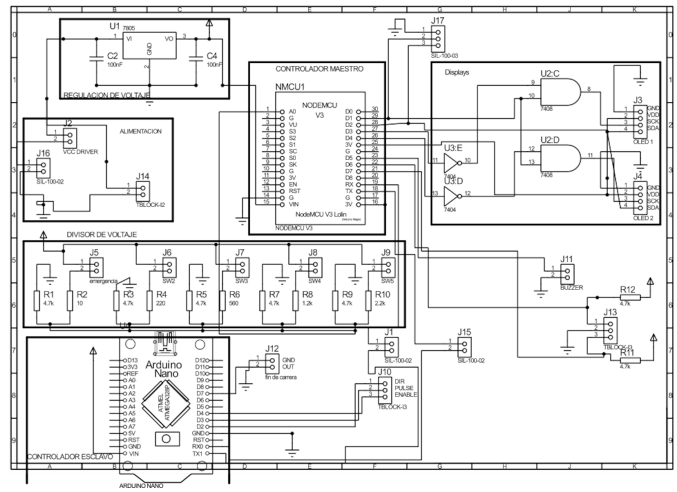

Fig. 2. Electronics schematics.

exception of a medical instrument already introduced on the market and lastly even used in countries such as Spain and Italy. A ventilation resource in patients with COVID-19, is the well-known AMBU bag. Thanks to the AMBU bag (which is a self-inflating bag that provides oxygen in a non-invasive way when manually squeezed by someone from the medical staff), we can apply a set of engineering techniques in order to automate a mechanical arm doing the work of an emergency personnel and even to control different aspects of the design in order to have an air volume output with a certain frequency according to a desired requirement.

A. Mechanical Considerations

There are multiple forms of pressure and versions of mechanisms for the pressure of self-inflating bags, among those that use cams and others that use crushing mechanisms. However, one of the aspects that should prevail in the design is flexibility and reduction of material and energy expenditure, that is, the mechanism must be appropriate to ensure good flexible return and not represent a high load to avoid the consumption of unnecessary energy. This means that, as much as possible, the material that carries out the pressure should be low-weighted and not vertical, since the return to the original position would mean greater energy consumption. Considering these aspects, the use of a simple crank-rod base mechanism was proposed, as seen in Figure 1, which can be modeled as a four-bar mechanism. The pressure towards the self-inflating bag is carried out by means of a dam attached to link E4 of the mechanism, in which the resting situation causes that the links E2 and E3 are practically contiguous, which ensures the self-inflating bag in its position. The whole structure is made up of stacked MDF layers which are manufactured by a laser cutter machine.

It is worth mentioning that within the structure of the device the following is considered:

- Dedicated space to place the AMBU.
- AMBU compressor platform
- Information related to the manufacture, version and model of the device.

B. Electronic Considerations

The device has two sets of parts to manage: the electromechanical actuators and the interface controls. These are the control circuit focused on the NodeMCU controller that uses 5V, and the power circuit following the Arduino Nano using the power controller that requires 12V. In this sense, the control circuit focuses on the management of Displays showing information for the interface with the operator, and receiving the control signals from the available switches as seen in Figure 2. On the other hand, the power circuit regulates the power supply to a stepper motor according to the signals emitted by the Arduino Nano as seen in Figure 3. Furthermore, the device has the following physical commands:

1) Switch On and Off
2) Emergency horn (buzzer)
3) Emergency button
4) Volume information display
5) Respiratory rate information screen
6) Lever (switch) to control the I:E ratio
7) Push-button for air volume control
8) Push-button to control the respiratory rate
9) Push-button to decrease (-)
10) Push-button to increase (+)
11) 12VDC / 3A power input
12) Stepper Motor (main actuator)

C. Control Considerations

The microcontroller follows a simple process that starts with the establishment of the initial memories. Later, errors are read in order to detect possible eventualities that arose previously or at the time of power-up. If they are detected, alarms are issued to alert the operator(s). Next, the screens are switched-on which, in parallel to the reading of the reference variables, allow the start of the motor drive according to a

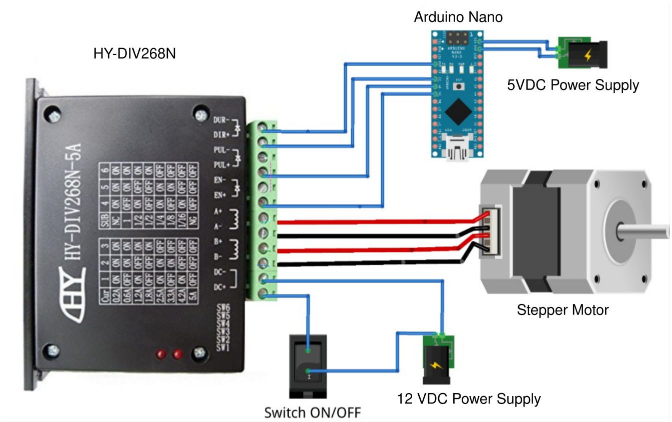

Fig. 3. Power Connections.

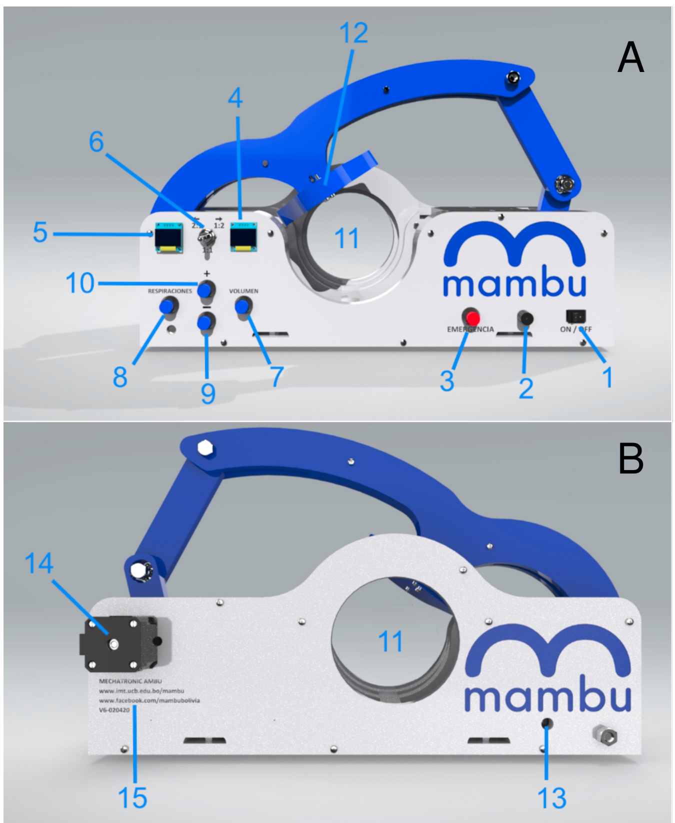

Fig. 4. Front (A) and Back view (B) of MAMBU with the respective physical commands.

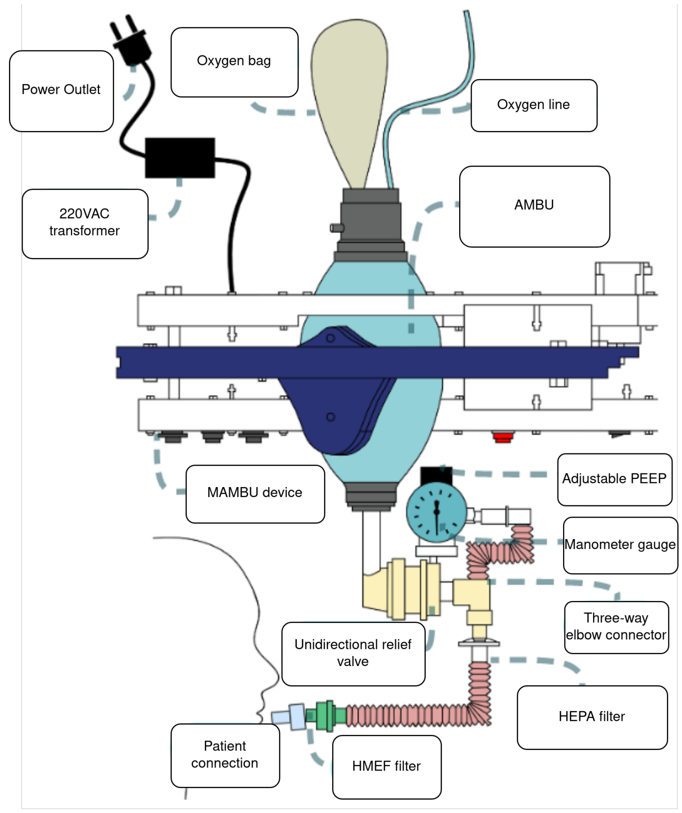

Fig. 5. Complete MAMBU system.

defined compensation scheme identified in the validation and technical verification stage with the motor tuning.

It should also be mentioned that an emergency button was included in the device, in case the patient needs assistance and is unable to inform the caring staff. This alarm is immediate and proceeds accordingly to interrupt the microcontroller and to sound the audible horn.

D. Employed Materials

The materials used by MAMBU are diverse, but they can be classified into 3 important groups: electronic, mechanical and others. The electronic materials are those that control the motor that drives the AMBU bag, the most noteworthy materials in this section are the stepper motor that gives the mechanical movement in order to pressure the AMBU bag, the Arduino microcontroller and the NodeMCU controller, which, together with the push-buttons and screens, form the control scheme necessary to control all ventilation variables. On the other hand, the mechanical materials are all those components that make up the very structure of the MAMBU, the MDF sheets, shafts and screws, 3D printed accessories or soft tooling and the bearings of the arms. Regarding miscellaneous materials we have those such as paint or even medical supplies like filters or connectors that are part of the complete medical devices system shown in Figure 5.

Before assembling the device, the MDF layers must be manufactured in the laser cutter machine. For this, three frontal parts and three rear parts are combined. The same procedure must be followed for the compressing arm. Then, all combined MDF parts are painted to later assembly the electronic parts. For this latter process, components must be soldered to the PCB to then include the microcontrollers. Next, buttons, wires, buzzer, motor and connectors must be placed. Afterwards, screws are inserted to fix the board to the device, wires are held by T-blocks. Finally, the MAMBU structure is closed

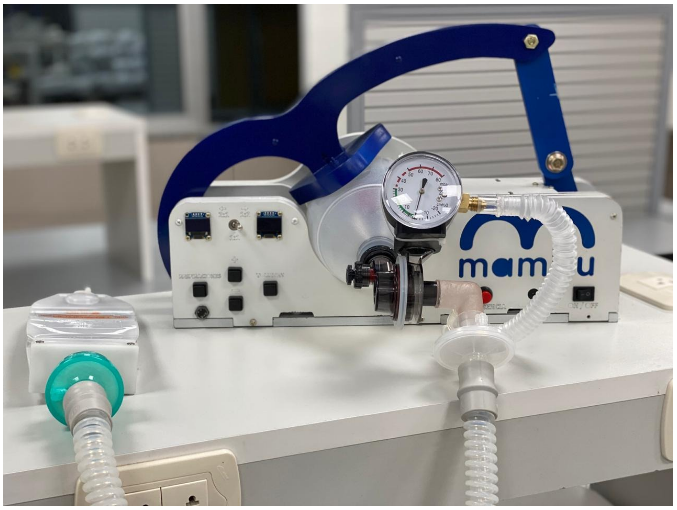

Fig. 6. Final aspect of the MAMBU device once it is assembled.

by inserting the compressing arm, joining the require pieces for the motor and setting up the displays. Once the device is assembled, its aspect is similar to the one depicted in Figure 6, while the parts that are available to the user are the following (see Figure 4 for reference):

1) On-off switch
2) Emergency buzzer
3) Emergency button
4) Volume information screen display
5) Respiratory frequency screen display
6) I:E control switch
7) Volume control button
8) Respiratory frequency control button
9) Decrease button (-)
10) Increase button (+)
11) AMBU-reserved space
12) AMBU compressing platform
13) Power supply input (12 VDC at 3A)
14) Stepper motor
15) Manufacturing, version, model information.

IV. Verification and Testing

In Bolivia, medical affairs are regulated by the Government Medical and Health Technology Agency (AGEMED). The agency provides the framework for ensuring the applicability of both national and international rules as well as standards related to testing, validation and approval of medical devices. In the case of our device (MAMBU), we followed AGEMED's protocols and proceeded to test the performance of the device in Metrology Bolivian Institute (IBMETRO) ($k = 2$ as coverage factor and 95% of confidence) and the Regulations and Quality Bolivian Institute (IBNORCA). The methodology depended on the parameter. The measurements for volume and its resolution were based on the determination of air volume by water displacement; for respiratory frequency on oscilloscope calibration; for pressure-related parameters on a pressure transducer at 0.05% variability and a pressure gauge. The obtained results can be seen in Table I

TABLE I
Testing and Validation results

Ventilation Parameters	**Range**	**Resolution**	**Error**
Tidal Volume	420-620 ml	20 ml	± 7%
Respiratory Frequency	12 - 22 bpm	1 bpm	± 4%
I:E	2:1/1:1/1:2	1	± 5%
PEEP	5 - 20 cmH2O	5 cmH2O	± 3%
FiO2	21 - 100 %	10%	± 7%
Peak Inspiratory Pressure	35 cmH2O		
Volume per minute	Min: 5.04 L/min.; Max: 13.64 L/min.		

Through the tests, we were able to test and verify the main output variables of our device showing acceptable error rates on all of them. This was the first approach of the project in order to receive the approval certification from the AGEMED [31]. On the other hand, due to political instability and the lack of equipment in rural locations for transportation of infected people, AGEMED as the Government allowed us to validate the calibrated MAMBU device directly with patients that have no other possibility than using our device in order to have respiratory assistance. While procedures for validation on humans require extensive and long procedures that must be strictly followed, the critical situation made the authorities to provide an exemption. Furthermore, with the support of the results that IBMETRO provided, a bio-ethical committee, and the help and supervision of many physicians and local government hospitals, we performed three human medical tests using our device for giving respiratory support. Due to confidentiality agreements, no more data can be shown in this paper, but after three different tests in three different hospitals for three patients (trying to remain as much as possible with the same biological conditions as age, weight and respiratory support parameters) both physicians and government authorities did agree that the MAMBU device performed as expected and the recommendation for approval was sent in order to use it as fast as possible for ambulatory or emergency purposes.

V. Conclusions

The COVID-19 pandemic has produced a significant crisis in the response capabilities of health care systems. Considering that respiratory problems are thought to be the main cause of death, the demand for respiratory-supporting machines increased substantially. In this paper we presented MAMBU, a device capable of providing basic respiratory support and that has been designed for tackling the lack of resources while addressing the COVID-19 crisis in Bolivia. We focused on developing a device that can be manufactured using laser cutters and also low-cost hardware.

As seen in previous sections, the MAMBU device is capable of controlling different parameters that are required for mechanical ventilation. However, its capabilities are not sufficient to be considered as replacement of an ICU ventilator. Despite that, the design answers to the immediate needs of the country by using low-cost materials (MDF and low-cost hardware) and relatively-low acceptable error rates. Furthermore, its design and results were validated by the local regulatory institutions.

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Any other validation information such as used , tools, procedure, patients and hospitalization characteristics are confidential and part of the Full Document of Validation for the MAMBU Medical device submitted to AGEMED. Nevertheless, this device was calibrated by the corresponding agency, validated and approved by medical authorities and physicians through the appropriate institutions to face the emergency and provide a helpful tool to save as many lives possible.

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