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Low-cost, rapidly deployable emergency mechanical ventilators during the COVID-19 pandemic in a developing country: Comparing development feasibility between bag-valve and positive airway pressure designs

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***Abstract*— The COVID-19 pandemic disrupted the world by interrupting most supply chains, including that of the medical supply industry. The threat imposed by export restriction measures and the limitation in the availability of mechanical ventilators posed a higher risk for smaller, developing countries, used to importing most of their technologies. To actively respond to the possible device shortage, the initiative "Ventilators for Panama" was established and was able to develop two different, non-competing, open-source hardware mechanical ventilator models for emergency use in case of shortages: one based on a bag-valve design and another based on positive airway pressure. The aim of this article is to compare both devices in terms of feasibility and functionality. Results from the functional testing show that both devices perform within specification, as the error percentage is lower than 5% for the desired pressure values and a standard deviation of less than 0.5 for all cases.**

***Clinical Relevance*— This study shows the feasibility of quickly deploying two different mechanical ventilator designs for emergency use and their effectiveness.**

I. Introduction

SARS-CoV-2 is the most recently discovered coronavirus, responsible for the current COVID-19 pandemic declared by the World Health Organization (WHO) on March 11th, 2020 [1]. Since then, more than 220 countries/regions have been affected, totaling more than 150 million positive cases and over 3 million confirmed deaths around the world [2]. COVID-19 disease can have a wide range of manifestations, ranging from no symptoms to mild common-cold symptoms, all the way to serious respiratory illness and death.

Close to 10% of confirmed COVID-19 patients are hospitalized [3] and probably end up requiring invasive mechanical ventilation (IMV) support to treat the acute respiratory failure caused by the disease [4], [5]. The drastic increase and continuous waves of COVID-19 cases around the world and the subsequent high demand of intensive care unit (ICU) equipment, has led to a shortage of mechanical ventilators (MV) and their components since early in the pandemic [5], [6]. Issues such as export limitations from manufacturing countries to cover their local demand, asymmetries in the power of negotiation and price volatility due to speculation have all heavily affected smaller, developing countries used to importing biomedical technology [7], [8]. At the beginning of May 2020, over 70 countries had taken some sort of export limitation measures [7]. This forced most countries around the world, including developing countries such as Panama, to rely on their local scientific communities to produce MV with the resources readily available to them.

Regulatory agencies such as the Food and Drug Administration (FDA), the Medicine and Healthcare products Regulatory Agency (MHRA) and many others around the world, have to rely on emergency use authorizations (EUA) for MV that loosened or outright eliminated certain manufacturing requirements, considering the known potential benefits of such devices for COVID-19 treatment compared to the any known or potential risks from these devices or from a shortage of supply [7], [9]–[11]. Some regulatory agencies have also published guidelines for local manufacture of minimally viable ventilators by academic laboratories or non-biomedical factories, for use as emergency devices only for the duration of the pandemic [12]–[14]. However, few of these guidelines have come from Latin America and the Caribbean, where less than 4% of medical products are sourced within the region itself, making them highly dependent on exportations [15].

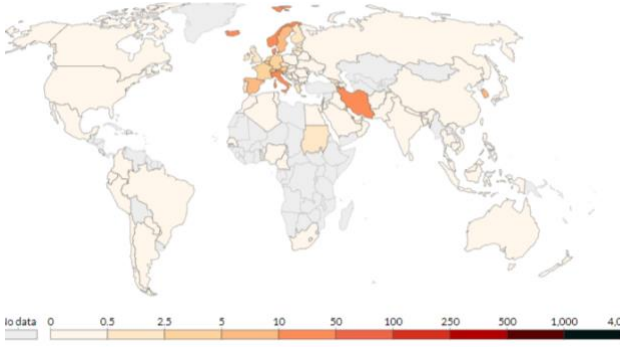

Figure 1. Daily new confirmed COVID-19 cases per million people when COVID-19 was declared as a pandemic by the WHO, March 11, 2020 [18].

Shortly before these regulations were relaxed, a number of initiatives belonging to the field of Open-Source Hardware (OSH) developed low-cost alternatives for MV [16]–[21]. The OSH community claims to be an alternative to the medical device industry [22], which is characterized by high-costs, proprietary systems, and patented technologies. Such high-end medical devices are certainly reliable, but they also exert a heavy burden on low-budget healthcare systems in developing countries and have been inadequate to respond to rapidly escalating emergencies, such as the one posed by COVID-19

Fig. 2. Bag-valve mechanical ventilator during a functional test, with a IMT Analytics, PF-300 gas flow analyzer as measuring reference.

[22]. On the other hand, most OSH devices are not developed with standardized procedures, and their design depends on the resources available to the OSH laboratory.

The rapid spread of the SARS-CoV-2 virus around the world materialized the fears of a global pandemic on MV availability and forced OSH engineers and makers to push the boundaries of surge emergency MV design in order to respond to this situation. Developed countries, mainly from the northern hemisphere, were the first hit by the pandemic (Fig. 1) [23]. Engineers in these countries had the challenge of designing the first low-cost, rapid-deployment MV, probably based on previous scientific literature related to past epidemic outbreaks [17], [23]–[25] and causing dwindling inventories of common components used for these devices, such as valves and sensors (e.g., pressure and flow). These components quickly became scarce and, as the coronavirus spread among the developing countries, both commercial and OHS-based MV seemed out of reach for these populations. This has put the spotlight on local scientific communities and has forced them to produce MV with resources readily available to them.

Although the working principle and theory of operation of MVs has been thoroughly explained in literature [26]–[29], it is worth noting that not all mechanical ventilators are meant to work the same way nor under the same conditions; some are better suited for transportation, such as the Bag-Valve Design (BVD) ventilator, while others are better for long term operation, such as the Intermittent Positive Pressure Ventilation (IPPV) ventilator [22]. Few studies, to our knowledge, have directly compared the feasibility of low-cost, rapidly deployable MV to respond to a global pandemic from a developing country perspective. Thus, the purpose of this article is to describe and characterize two different, non-competing, OSH mechanical ventilator models: a BVD based ventilator and a IPPV mechanical ventilator, both designed to respond to the device shortage caused by COVID-19.

The two mechanical ventilators described in this paper were developed simultaneously by two different groups: one in charge of the BVD-based ventilator and another in charge of the IPPV ventilator. Special considerations such as ease of production and modularity were contemplated to provide a solution which consisted of components that were available in the market while complying with the minimum safety and performance requirements needed. Initially, both devices were tested with simulation manikins and, after ensuring correct and robust operation, we proceeded with animal tests under the supervision of both veterinarians and intensive care physicians, with all experimental procedures involving animal models approved by the Institutional Animal Care and Ethics Committee.

II. Bag-valve design

The device based on the bag-valve design (BVD) consists of a lever that, controlled by a mechanical actuator, squeezes the bag at user-defined distances to displace the required air volume. This type of OSH ventilator has the advantage of parts availability, minimal number of components, simple mechanism, and being low-cost and rapidly deployable [21]. An additional benefit of this design is that all components that are in touch with the air flow are already medical-grade and biocompatible, including the bag-valve, PEEP and pressure-release valves and tubing.

A. Electronics - BVD device

The main variable that needs to be measured to ensure the correct functioning of most OSH devices is pressure. For the BVD device, pressure sensing and flow estimation were done with an MPX5010 (NXP, Eindhoven, Netherlands) integrated silicon pressure sensor, connected to a proximal flow sensor (Hamilton Medical, Bonaduz, Switzerland). The MPX5010 sensor was chosen because it has a conditioned output (*i.e.*, amplification and temperature compensation) and the input pressure range (0-100 cm H2O) is within the typical pressure range used for mechanical ventilation [28].

The control algorithm was embedded in a 4PPC70.101G-20B programmable logic controller (PLC) (B&R, Eggelsberg, Austria). An analog input module, model X20AI4622 (B&R) with 13-bit digital converter resolution and 400 µs conversion time, was used to digitize the pressure sensor's output. A X20MM4456 pulse-width modulation (PWM) motor bridge (B&R) was used to drive a 23HS45-420AS stepper motor (OSM, Ningbo, China), which actuated on the lever to squeeze the bag.

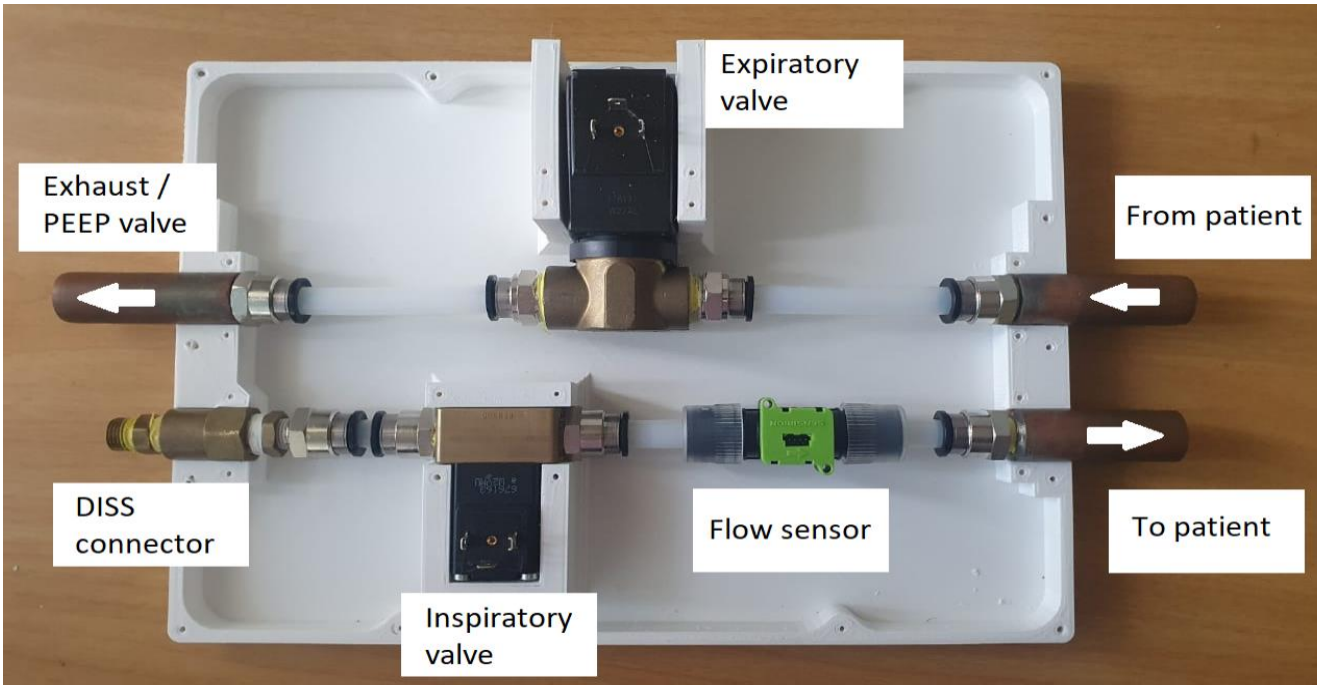

Fig. 3. Pneumatic system configuration for the CPAP MV. Above from right to left: diss connector containing air/oxygen blend, proportional valve, flow sensor, outlet port towards patient (inspiration). Below: from left to right, inlet containing exhalation gas, solenoid valve, outlet port for PEEP valve.

B. *Algorithm - BVD device*

The control scheme of the BVD device is that of an open loop control system, where the controlled variable is the travel distance of the lever. The pressure and flow curve profiles for this device correspond to volume-control ventilation (Fig. 2B). The BVD MV operator manually tuned the system to deliver the tidal volume within the inspiration time asked by the physician.The variables set by the user comprised the percent of lever compression of the bag (10 to 100%, which directly controlled the tidal volume) and the respiratory rate (10 to 30 bpm) through the PLC, electronically; and the positive end-expiratory pressure (PEEP, 5 to 20 cmH2O), manually. The ventilation process consisted mainly of three stages: inspiration (bag squeezing), hold (plateau) and exhalation (bag release). Additionally, an assisted control mode was included, which allows the patient to set the pace of breathing by triggering an inspiration event if the pressure sensor detects any negative pressure during exhalation. Specifically, if the pressure fell below a user-specified threshold after the PEEP pressure was reached, and 50% of the exhalation time had passed, this would trigger an inspiration event. This was implemented to have the option of weaning the patient from mechanical ventilation.

It is worth noting that a key benefit of the BVD is that it is a standardized device used for ventilation [30]. No further analysis regarding its composition, mechanical properties, biocompatibility or oxygen compatibility is needed, paving the way for rapid deployment for clinical applications.

III. Intermittent Positive Pressure Ventilation Device

An Intermittent Positive Pressure Ventilation device is a generic term used for a mandatory ventilation mode, with fixed volume and frequency. The role of the ventilator machine is to control the air/oxygen volume (Volume Control) being delivered to the patient. These ventilators can be safely connected directly to the medical gas supply system for oxygen and medical air inputs, normally available in all hospitals using pressure regulators at 15 psi (or a pressure that allows a maximum desired airflow, normally of 60 LPM) and using safety valves (80 cmH2O) at the airway hoses. Gas cylinders can be used in case of lack of centralized gas supply. The IPPV device consists mainly of a pneumatic system and an electronic system.

A. *Pneumatic System*

The pneumatic system involves the tubing and the electro-valves to be operated by the control circuit. The pneumatic layout of the system can be seen in Fig. 3.

The inspiratory valve used was a direct-acting standard solenoid control, proportional valve Type 2873 (Burkert, Huntersville, NC, USA). A proportional valve is needed in the inspiration to modulate flow and respiratory frequency, as patients' need for air flow and inspiratory times vary. The expiratory valve is an on/off, oxygen solenoid valve type 6027 (Burkert). Because exhalation is a passive process, air flow needs to be unrestricted, which we empirically determined can be achieved by valves with a 10 mm bore or higher. Because there were no direct-acting, proportional valves with 10 mm bore or more available, the expiratory valve was chosen as an on/off.

B. *Material compatibility*

To our best knowledge, few other OHS initiatives established worldwide to produce and test mechanical ventilators [20] have shared any information to verify the oxygen compatibility with components in contact with air flow. Considering that oxygen systems have many inherent hazards, a risk assessment was carried out to evaluate the

pneumatic components that were in direct contact with the fluid, using the worst-case design parameters.

A list of materials used for this device (directly in contact with oxygen) is described in Table 1.

TABLE I. MATERIAL COMPATIBILITY CHART

Device	*Material/seal*	*Oxygen Compatibility*	*Brand, Model*
Proportional Valve	Brass/FKM	SFOA*	Burkert, Type 2873 239081
Solenoid Valve	Brass/PTFE	SFOA*	Burkert, Type 6027 184683
Flow sensor	Multiple**	Compatible	Sensirion, SFM3000
Pneumatic hose	Polyamide	Compatible	Tameson (high pressure applications)
Hose fittings	Polyamide	Compatible	Generic
Tubings	Copper	Compatible	N/A

* SFOA stands for "Suitable for Oxygen Applications"

** PPE+PS blend (medical grade: biocompatible; ISO 10993 or USP Class VI), Si, Si3N4, SiOx, Gold, Epoxy, Polyurethane, stainless steel (annealed) [26]. The flow sensor used, according to the manufacturer datasheet, is designed for critical care ventilation and for respiratory devices [26].

Oxygen compatibility analysis is a critical aspect related to fire hazards in any oxygen system. According to ASTM Manuals 36, ASTM G63 (non-metallic materials) and ASTM G94 (metallic materials), test data of evaluated materials includes the information about the ignition and combustion characteristics [35,36].

Copper and nickel-based alloys are the best choice in terms of compatibility, due to their ignition resistance. The lower the heat of combustion, the greater the oxygen compatibility of the metal. In the case of copper, the heat of combustion is ~ 2500 J/g and its thermal conductivity is around 407 W/(mK) [33], corresponding to a high thermal conductivity value.

In the case of polymers, the use of polytetrafluoroethylene (PTFE) for sealing within valves is common in oxygen systems because of its resistance to ignition by mechanical impact (LOX) (0/20 98J), high auto-ignition temperature (AIT) (512ºC -527 ºC), high oxygen index (OI) (100) and low heat of combustion (5334 j/g) [34]. In general, fluorinated materials such as polytetrafluoroethylene (PTFE Teflon®), are preferred for use in oxygen systems because of their oxygen compatibility characteristics [32].

Fluorinated elastomers, such as polyhexafluoropropylene-co-vinylidene fluoride (FKM) are useful to approximately 520 K (475°F) above their transition temperature; considering that the transition temperature normally is below room temperature. Because of this, they are commonly used in oxygen systems [34]. In fact, only tested and certified oxygen compatible sealants should be used in oxygen systems.

Polyamides (PA), or Nylon, is a high-performance thermoplastic class. This material has been used in oxygen systems for its superior mechanical properties. PA or Nylon ignition and combustion characteristics are not as favorable as the fully fluorinated materials [32]. In the selected pneumatic hose, the PA is in the outer layer of the hose [35].

Fig. 4. Intermittent Positive Pressure MV during a preclinical test.

The selection criteria of non-metallic materials for oxygen service are as follows [36,38]: few reactions when tested by mechanical impact, high auto-ignition temperature (AIT), low heat of combustion, high oxygen index (OI), low flame temperature, high threshold pressure and low burn rate.

Materials with combustion heat less than 6.3 MJ kg-1 (1500 cal g-1) generally do not promote ignition at oxygen pressures up to 17.2 MPa (2500 psi) [40,41]. In general, metals are harder to ignite than non-metals because of their high AIT and high thermal conductivity, that helps to dissipate local heat. AIT temperatures of metals are in the range of 900 °C to 2000 °C. In the case of non-metallic materials, AIT temperatures are in the range of 150 °C to 500 °C [33].

Based on these criteria, all materials used in our IPPV device were suitable for use with oxygen [42,43]. After verifying material compatibility, it was necessary to verify the ignition probabilities relative to the design parameters.

C. Ignition Hazards

Ignition hazards can occur when localized, high temperatures arise from conditions such as flow velocity, foreign particle impingement, vibrations, rapid gas compressions or static discharges [40].

Copper and nickel-based alloys are resistant to ignition by particle impact and do not propagate combustion, making them generally suitable for oxygen service [31]. Ranking for the oxygen compatibility of metals and alloys using data from tests of particle impact, friction ignition, promoted ignition and oxygen index is shown in BS EN ISO 15001:2010 [33].

A risk assessment procedure was implemented to evaluate ignition hazard probability [31], as shown in Table 2.

TABLE II. IGNITION HAZARD PROBABILITY

Ignition mechanism	*Ignition hazard*	*Notes*
Particle impact	0	Maximum flow speed lower than 30 m/s (3.5 m/s*)
Rapid pressurization	0	Upstream pressure less than 275 psia (65 psia*)
Resonance	0	No use of sonic gases
Mechanical impact / Galling and friction	0	Regulators and relief valves are in use but frictional forces due to side loads and forces needed to produce ignition are not present

Ignition mechanism	*Ignition hazard*	*Notes*
Thermal runaway	0	Continuous heating due to valve operation is present but filtered medical-grade gaseous streams prevent particle accumulation
Chemical reaction	0	No other chemical reactions present
Electrical arc	0	Use of oxygen-compatible valves

*: maximum design values.

Since materials used are suitable for use with oxygen and had no identified ignition hazards, we concluded that the ignition risk was minimum. It is important to mention that the compatibility analysis considers the history of use of every component and material used in similar conditions (oxygen management).

D. Electronics

As in the BVD device, pressure sensing was done with a MPX5010. The digitization of the sensor's outputs was done with a low-cost, 16-bit Analog to Digital converter ADS1115 (Adafruit, NY, USA). Air flow was measured with a low pressure drop, mass flow meter SFM3000 (Sensirion, Stäfa, Switzerland). Despite its higher cost, this sensor was preferred to the classical proximal sensor approach because of its high accuracy, and direct measurement instead of using estimations. Flow measurement accuracy in a IPPV device is more critical than in a BVD device since the bag's air volume will not exceed a fixed value. The flow sensor was connected in series after the inspiratory valve (as shown in Fig. 3). In this way, it does not encounter the patient's exhalation gases, thus, it minimizes any contamination risk.

For this device, the algorithm was embedded in a Teensy 4.0 (PJRC, Sherwood, OR, USA) due to its low cost and high processing capabilities. A logic level converter was needed to shift the logic level coming from the ADS's output for the Teensy's inputs and the control was done through a MOSFET and a PWM signal for the actuation of the valves.

E. Algorithm

In the IPPV MV, the algorithm was implemented as a closed loop On/Off controller. First, during the inspiration phase, the exhalation valve is closed, and the proportional valve remained open while the measured pressure was lower than the support pressure plus the PEEP, and while the tidal volume was lower than the set value. The tidal volume was estimated as the integral of the values measured from the flow sensor. After either the measured pressure or the estimated tidal volume reached their maximum values, the inhalation valve closes for the plateau time (hold phase). After the hold phase, the exhalation valve opened for the set exhalation time. The IPPV MV also had an assisted control mode which works equally as in the BVD MV.

IV. Results

Table III shows the functional test results for a 5-minute benchmarking test using an IMT Analytics PF-300 Flow Analyzer as reference. In this test, a desired pressure value was set, and the sensor's measurements were recorded. An extract from the pressure and flow profiles can be seen in Fig. 5. Beside the pressure measurements, both devices were tested against the minimal emergency MV requirements, such as stable functionality, alarms and changeable set up thresholds, and compliance with safety operation.

TABLE III. Functional Test Results

Device	*Test Value (cmH2O)*	*Pressure (cm H2O)*			*Flow (L/min)*	
		Mean	*% error*	*Std*	*Mean*	*Std*
BVD-MV	60	62,44	4,07	0,18	94,87	0,47
	40	40,37	0,92	0,06	58,6	0,12
IPPV-MV	60	59,12	1,47	0,3	25,46	0,12
	25	25,42	1,68	0,09	25,53	0,07

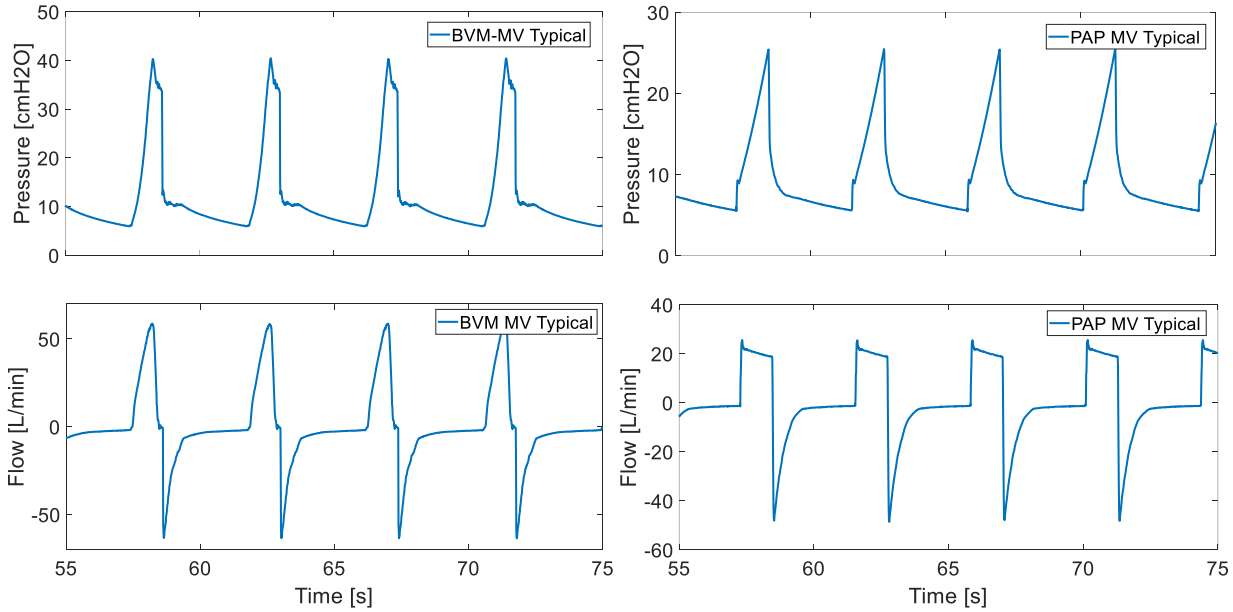

Fig. 5. Pressure and airflow profile samples obtained during the functional testing of the Bag-Valve Mask Mechanical Ventilator and the Intermittent Positive

V. Discussion

From the results shown in Table III, we can see that both devices perform correctly, as the error percentage is lower than 5% for the desired pressure values and a standard deviation less than 0.5 for all cases. It is worth noting that the control scheme for both devices is different, as their functioning principles differ. For the BVD-MV, a modification of the air flow to have a constant inspiration time was achieved, as it is mostly influenced by the BVD's compression time. Conversely, varying the desired pressure in the IPPV MV does not adjust the inspiration time, accordingly, meaning that the inspiration time increases considerably. In the IPPV MV, flow remains constant unless the proportional valve's input voltage is modified. To modify the inspiration time, manual tuning must be performed by varying the voltage applied to the inspiration valve. At the end, this translates into multiple variables the clinician needs to vary to achieve a desired functioning of the IPPV MV and, being voltage one of these variables, it might be a source of confusion in an emergency scenario and increased training time when comparing the IPPV MV vs the BVD MV.

The BMV MV has other advantages such as ease of production, less components, and a safer operating principle, because at its core, it makes use of a medical device already designed for this purpose. This greatly reduced the prototyping time of this device, which took roughly 2 months to develop. Conversely, the IPPV MV took significatively more time (7 months) because parts needed were not available in the local market and these parts were not accessible from the international market because of the import restrictions. However, it is worth noting that, even if the IPPV MV is a more complex device, most commercially available MV use this principle of operation. Thus, this is a more versatile device, capable of achieving all options present in a professional MV.

Before receiving the bioethics committee approval for animal procedures, exhaustive testing regarding the stability and precision of the functional parameters was performed on artificial lungs. Both devices had to comply with the minimum requirements for emergency mechanical ventilators regarding respiratory parameters setting, reading and alarms [41]. The lack of skilled operators was another key issue during the period with the highest infection rate. In Panama, this was palliated by having the pneumologists, anesthesiologists and internists handle the patients, under direct supervision from the intensivist physicians. For this reason, the final human-machine interface (HMI) for both prototypes were designed to be identical and was developed mimicking the aspect and behavior of a commercial mechanical ventilator, translating into ease of use and reduced training time (Fig. 6). This usability aspect was assessed by the intensivist physician that was part of our research group and the local association of respiratory therapist that were also assisting us in this project.

In the context where this study was carried out, which is that of a developing country, the development of these MV is an unprecedented feat. This is the first time in Panama that a medical device is designed and deployed locally and allowed to perform preclinical tests under the approval of the national bioethics committee, with the conjoint efforts between public and private institutions and the academia. The design and development of the devices was done as part of the "Ventilators for Panama" initiative that was established after the health authority in the country projected a catastrophic public health system collapse in May 2020 if no interventions were implemented. Access to most of the crucial components needed was impossible either because of the multiple national lockdowns or because of the manufacturer's exports ban. At the end, both developing teams had to make three prototypes before arriving to a final device approved by clinicians and the leadership team for the initiative. Each prototype was the result of a balance between the minimally viable *buildable* design for emergency use when needed, and the risk of causing increased harm.

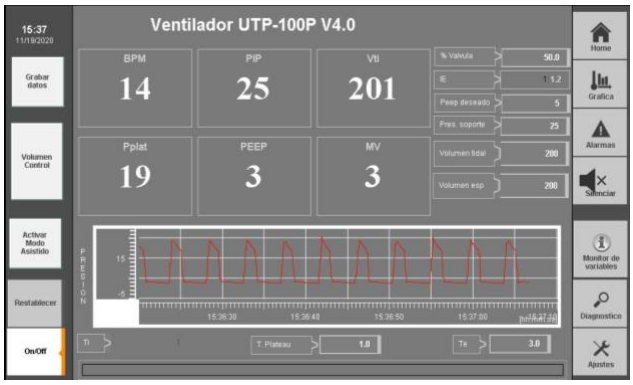

Fig. 6. Final version of the Human-Machine Interface for both prototypes, mimicking a traditional mechanical ventilator for ease of use and reduced training time.

Despite complying with the minimum/simplified functional parameter requirements, the devices were not used during the pandemic. Panama was able to control the infection rate through strict national lockdowns, which gave the health authority time to acquire enough commercial MV to cover demand. The lack of urgency for the use of locally manufactured devices held back the impetus to pave the regulatory pathway for emergency use authorizations of this class of device. The lack of experience in the manufacturing of biomedical devices and local manufacturing regulations, lack of political will, and cultural motives such as the underestimation of the local talent and low investment in research and development, could have contributed as well to the lack of regulatory preparedness.

The COVID-19 pandemic has revealed the weakness of the global supply chain. While developed countries could still satisfy their needs, developing countries needed to rely entirely on their scientific communities to address the situation, which may be unrealistic in most cases. Our study highlights the need for developing countries to improve emergency preparedness, such as increasing investment in research and development, establishing biomedical device stockpiles and implementing emergency-use regulations.

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