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Performance assessment of a ventilator developed for emergency use in a resource-constrained ICU setting during the COVID-19 pandemic

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Abstract

Background: The Masi mechanical ventilator was developed in Peru, designed and manufactured as a rapid-response to the healthcare emergency. Its promising pre-clinical and clinical results allowed it to be approved by the national regulatory authority to be used during the emergency. The key features of Masi are its low manufacturing cost, low dependence on a supply of high volumes of oxygen, low oxygen consumption, and flexibility between non-invasive and invasive ventilation. While Masi lacks some of the advanced features found in commercial ICU ventilators, it was specifically designed for short-term use in resource-limited and high-demand situations as an alternative when conventional devices were unavailable. This study evaluates the survival rate in intubated COVID-19 patients ventilated with Masi as compared to other conventional ventilators.

Methods: This retrospective study was conducted in the ICU of a reference hospital in Lima, Peru, between January and August 2021. Medical records were reviewed for 77 adult patients with suspected or confirmed COVID-19 who required invasive mechanical ventilation. Among them, 42 patients were ventilated with Masi and 35 with commercially available ventilators. Clinical characteristics, laboratory findings, respiratory parameters, and survival outcomes were collected and analyzed.

Results: The survival rate and the relevant parameters observed in patients supported with Masi and commercial ventilators were comparable, despite the device limitations and the resource-constrained conditions.

Conclusions: Masi ventilator was functional and provided essential ventilatory support during the healthcare emergency.

Keywords: Mechanical ventilators, Clinical validation, Biomedical technology, Data analysis, Diffusion of innovation



Background

The translation of novel technologies for intensive care units (ICU) including mechanical ventilators has been mostly about incremental improvements through increasing features assuming the presence of highly trained personnel and dedicated infrastructure such as permanent power supply and high oxygen flow [1]. Despite the long history of use of mechanical ventilators, the COVID-19 pandemic demanded innovation to meet worldwide needs for this type of life support equipment. The inadequacy of the commercially available ventilators has been mostly attributed to weak fabrication and supply chains and inconsistencies between the required sanitary infrastructure and human resources available for which most commercial ventilators have been designed. Diverse approaches addressed the design and development of low-cost and more available mechanical ventilators worldwide achieving various levels of clinical implementation [2].

In Peru, the Masi (companion in Quechua) ventilator [3] was developed based on concepts of the MIT Emergency Ventilator (MIT E-Vent) [4] by automating a resuscitation bag. The Masi initiative showed promising pre-clinical results [5] that allowed the production of more than 250 units under an exceptional permit to be used clinically in Peru only when no other ventilators were available. The key features of this technology are its low manufacturing cost and low oxygen consumption [6]. The main goal of this study is to assess the performance of Masi by comparing the survival rate of respiratory failure patients from COVID-19 supported either with Masi or conventional ventilators at Hospital Vitarte II in Lima between January and August 2021.

Results

Figure 1 shows that from the initial 103 patients, 13 patients were excluded because ten patients did not use a mechanical ventilator and did not have COVID-19, two COVID-19 patients did not use a mechanical ventilator, and one patient who used a mechanical ventilator did not have a COVID-19 diagnosis. Also, three patients were excluded because of incomplete records, and 10 patients were excluded from the analysis because they were ventilated with conventional and Masi at different times.

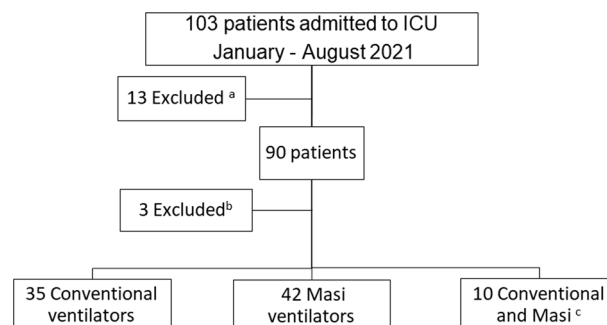


Fig. 1 Distribution of patients involved in the study. Masi is a mechanical ventilator based on an automated resuscitator bag under investigation only to be used when no other conventional ventilators were available. **a** Patients were excluded because 10 patients did not use a mechanical ventilator and did not have COVID-19, 2 COVID-19 patients did not use a mechanical ventilator, and 1 non-COVID-19 patient used a mechanical ventilator. **b** Excluded because of incomplete records. **c** Excluded because both Masi and conventional ventilators were used on the same patient

Table 1 Demographic information of patients with COVID-19 diagnosis with respiratory distress admitted to ICU and mechanical ventilation

	Masi (N=42)	Conventional (N=35)	Total (N=77)	P-value
Sex				
Number of female/male	9 / 33	13 / 22	22 / 55	0.129
PaO2/FiO2 pre-intubation				
Median [IQR]*	59.0[27]	53.65[18.25]	58.0[25]	0.991
Age				
Median [IQR]	48.5[14]	50[16]	49[16]	0.858
BMI				
Median [IQR]**	29[4.3]	31.1.[6.45]	29.15[5.2]	0.721
Older adult status (older than 60 years old)				
Percentage (N)	14% (6)	11% (4)	13% (10)	0.71
Presence of comorbidities				
Percentage (N)	67% (28)	69% (24)	68% (52)	0.859
Comorbidities, percentage (N)				
Rheumatoid arthritis	0	3% (1)	1% (1)	0.633
Asthma	0	3% (1)	1% (1)	
Diabetes mellitus and/or metabolic syndrome	57% (24)	51% (18)	55% (42)	
Arterial hypertension	2% (1)	3% (1)	3% (2)	
Other	7% (3)	9% (3)	8% (6)	

* Data available in 65 patients (33MASI/32Conventional)

** Data available in 20 patients (13MASI/7Conventional)

Table 2. Distribution of COVID-19 diagnosis in patients with respiratory distress admitted to ICU and started on mechanical ventilation

COVID-19 diagnosis	Frequency (N=77)
Severe COVID-19 symptoms	23 (30%)
Antigen test	43 (56%)
PCR test	4 (5%)
Antibody test	4 (5%)
Based on medical record	3 (4%)

The final comparisons were performed between 35 patients who were supported by conventional mechanical ventilators and 42 patients who were supported by Masi (total N=77).

The demographic data show that most patients were male (71%) with a median age of 48 and 87% were younger than 60 (Table 1). No differences were found in the ratio of female/male (p-value=0.129), age (p-value=0.858), BMI (p-value=0.721), age older than 60 years old (p-value=0.71), and percentage of comorbidities (p-value=0.859). Concomitant diseases were captured in 52 subjects. 55% of the total patients (77) had diabetes mellitus with or without metabolic syndrome. Overall, the demographic details between the patients assigned the Masi or conventional ventilators are not significantly different. Also, an important number (30%) of patients were diagnosed based on clinical signs due to a lack of available test kits (Table 2).

Figure 2 shows that the respiratory parameters improved with ventilation regardless of the device assigned. In addition, there was no difference in the distribution of respiratory parameters between the ventilators at the beginning or within the first 12 h after mechanical ventilation started (*Supplementary Table 2*). In addition, the blood chemistry parameters were not significantly different between the two groups assessed (*Supplementary Table 3*).

At the extubation or censoring time, 17 patients were alive, and 60 died. Nevertheless, we observed no statistical difference in the survival rate whether they were assigned Masi or conventional ventilatory support (Fig. 3). After running the analysis on day 14, we did not observe a statistical difference in survivability between

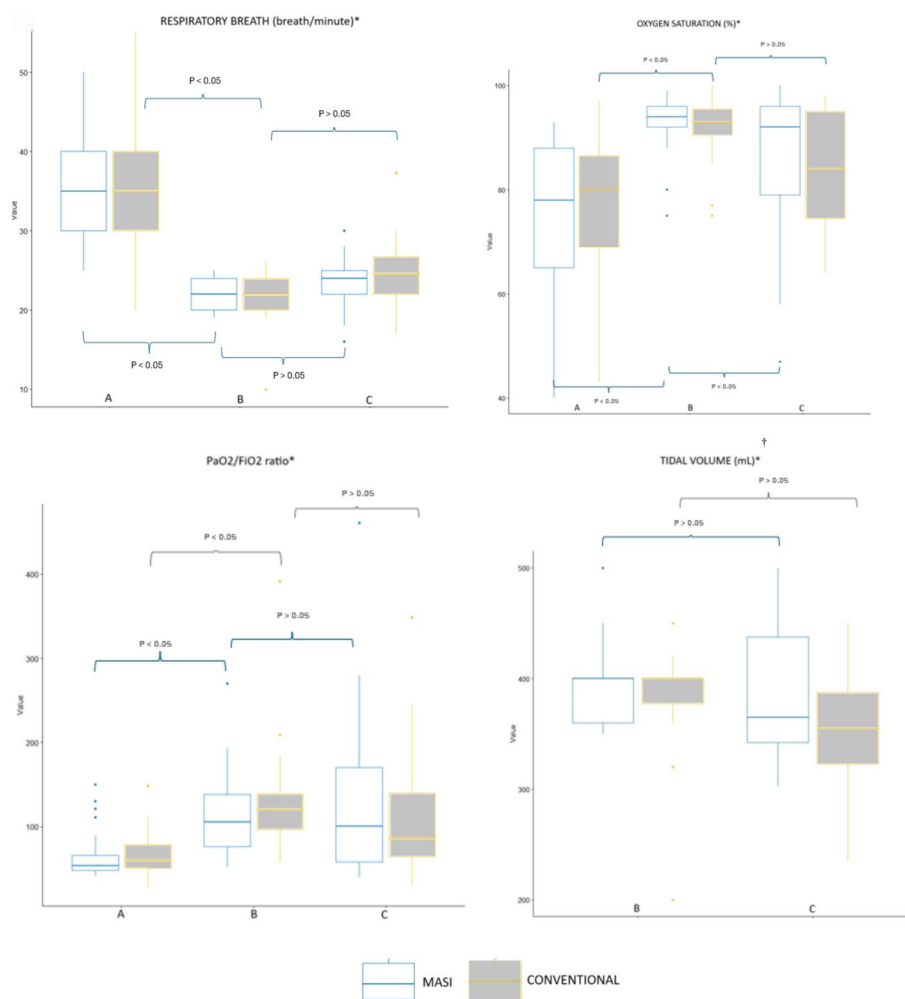


Fig. 2 Box and whiskers graphics showing respiratory parameters of patients ($N = 77$) according to the type of mechanical ventilators used: Masi ($N = 42$) and conventional ($N = 35$). Data were registered at three points: **A** before mechanical ventilation, **B** after mechanical ventilation, and **C** during the last measurements. *Comparisons using an ANOVA test were done between moments and ventilators. All of the p-values ≥ 0.05 showed no statistical difference between ventilators or moments. †For the tidal volume, comparisons were only between **A** before **B** after mechanical ventilation, and **C** during the last measurements for both ventilators. Results had p-values ≥ 0.05 showing no statistical difference between ventilators. PIP was not shown because it was only captured for 3 patients, all of them using Masi

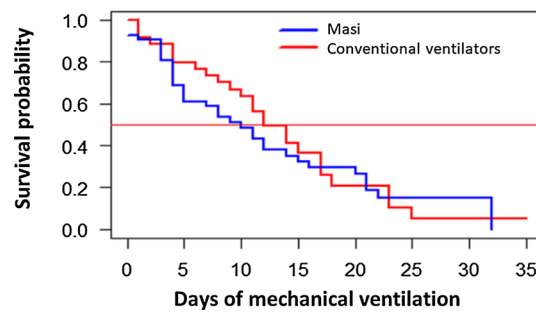


Fig. 3 Survival was comparable between patients who were mechanically ventilated with Masi or conventional ventilators. Kaplan–Meier survival curve. $P > 0.05$ – (P-value not significant)

ventilators (*Supplementary Fig. 1*). No adverse events related to mechanical ventilators like barotrauma, pneumothorax, other were reported in the clinical chart.

Discussion

Surviving or not is a multicausality phenomenon, assigning a mechanic ventilator to maintain respiratory parameters under control is crucial, however having values for other variables are critical too, in this retrospective cohort study probably due to emergency situation many of these variables were not clearly enough registered in the clinical chart to transcribe and categorize them, key variables such as time for first hospitalization, time from first hospitalization to ICU, time for intubation, pharmacotherapy type and dosage, sedatives, muscle relaxants and position of a patient’s body during mechanical ventilation are just examples of missing variables that limit the findings of this study. The clinical context in which the study took place, including human and technical resources, is described in detail in *Supplementary Table 4*. Diverse approaches addressed the design and development of low-cost and more readily available mechanical ventilators worldwide achieving various levels of clinical implementation [2]. As a result, a more sophisticated understanding of the intended use of mechanical ventilators is available now. For instance, the requirements in the ISO technical standard ISO 80601-2-12 published in 2023 after a previous version from 2020, clearly specify that they referred to ventilators “intended for use in an environment that provides specialized care for patients whose conditions can be life-threatening and who can require comprehensive care and constant monitoring in a professional healthcare facility”. While Masi was developed during the scenario of a sanitary emergency brought by the pandemic, its intended use is a critical care environment such as the one presented in this work. Our data show that this implementation achieves the necessary tidal volumes and that the resuscitation bag can withstand these demands for weeks. This study is particularly relevant as it was conducted during a public health emergency using a ventilator entirely designed and manufactured in Peru, which received approval from the national regulatory authority. It provides valuable clinical outcome data comparing this emergency-use device with commercial ventilators in a real-world setting involving a significant number of patients.

From the point of view of innovation in medical devices, Masi is the first medical device to be designed, implemented, and mass-produced in Peru in an unprecedented

timeline and with logistic limitations. Thus, it took a month to go from idea to prototype, 2 months to achieve regulatory approval including pre-clinical testing, four additional months to scale up from prototype to manufacture, and 2 more months to validate the 350 units. We demonstrated that these tasks can be performed in only 9 months.

Our calculations indicate that the material costs are about USD 3,500 for pieces plus USD 1,500 for personnel, and USD 5,000 for logistics and commercialization efforts. Therefore, Masi's commercial calculated cost of around USD 10,000 is still a fraction of conventional MV that starts at USD 40,000 and up to USD 80,000 while offering convincing basic functionality. The clinical implementation provides evidence that besides the decreased cost of the device when accounting for its ubiquitous parts, there are lower costs associated with its power reliability due to its robust electronics, and lower demands for pressurization of the oxygen supply needed to run the instruments which was highly appreciated by the medical personnel.

No major adverse events could have been attributed to the Masi ventilators despite some concerns about the confidence and experience of the operators as evidenced by a qualitative study of the perceptions regarding the new technology from the health personnel [9]. While survival rates were dismal compared to most ICUs, these values for Masi and conventional ventilators were comparable to what has been reported elsewhere and in Peru during the second wave of the COVID-19 pandemic and reflect the systemic strain on the healthcare system during these months [10–12].

Because this is a retrospective cohort observational study, the discretionary decisions to assign patients to Masi were not under the study's control. The DIGEMID indication was to use Masi only when other available brands were unavailable. Based on the registered initial respiratory parameters and accepting limitations due unavailable clinical key variables, there were no major differences in the initial patient conditions when assigned to Masi versus conventional ventilator.

Potential future applications beyond COVID-19 ARDS, could include short-term ventilation during patient transport or resource-limited emergency settings. While Masi could have potential for non-ARDS indications and use outside of critical care environments, further studies are needed to validate its reliability and safety [13].

Conclusions

The performance was assessed by a retrospective analysis of the clinical outcomes of ARDS patients who received mechanical ventilation with Masi and commercial ventilators. Masi lacks many of the advanced features of commercial ICU ventilators, however it was designed specifically for crisis conditions where access to standard equipment are limited.

Our findings suggest that, in this constrained setting, Masi was able to provide essential ventilatory support, with survival rates and key respiratory parameters that were comparable to those observed in patients supported by conventional ventilators. These results do not imply equivalence in performance between Masi and advanced commercial systems. Rather, they highlight the functionality of Masi and its potential utility in extreme scenarios, particularly where time, infrastructure, and resources are limited.

Masi should not be considered a replacement for standard critical care ventilators in routine clinical practice. However, its role as a temporary, life-saving solution in public

health emergencies—such as pandemics, natural disasters, or in remote areas—warrants further exploration. Future studies should focus on validating its reliability and safety in different clinical contexts, and on defining clear indications for its appropriate use.

Importantly, this study does not aim to propose Masi as a replacement for the standard of care in routine clinical practice. Its use should remain restricted to exceptional circumstances, such as pandemics, natural disasters, or remote settings. Further development, rigorous evaluation, and context-specific guidelines are needed before considering broader or long-term applications.

Methods

Study design and ethical considerations

This is an observational retrospective cohort study. The study protocol was approved by the Research Ethics Committee for Life Sciences and Technology of the PUCP (002–2021-CEICVyTech/PUCP) on September 23, 2021. A total of one hundred and three (103) patients were admitted to the ICU between January 19, 2021 until August 27, 2021, which coincides with the second Peruvian wave of the COVID-19 pandemic in the Hospital Vitarte II in Lima, Peru. Data from patients who were diagnosed with COVID-19, with signs of acute respiratory distress syndrome (ARDS), intubated, and connected to a mechanical ventilator in the ICU were de-identified for this study. From the 132 variables collected into the Electronic Health Records, only 120 selected variables were transcribed into a digital database using Microsoft Excel (Microsoft Corporation, 2021). The data were standardized and entered by a physician trained in Good Clinical Practice (Data Entry Investigator).

After data cleanup, this study retrospectively analyzed data from 77 patients who had a positive COVID-19 diagnosis and used a mechanical ventilator machine. According to the Peruvian regulatory agency, DIGEMID, Masi was indicated only when no conventional ventilator was available, and a patient needed one as determined by the ICU physician. ClinicalTrials.gov Identifier: NCT06667375, registration date 2024-10-28, from Pontificia Universidad Católica del Perú with Protocol Record “002-2021-CEICVyTech/PUCP Conventional Versus Automated Bag-based Mechanical Ventilator to Support ARDS Patients”.

Medical devices

During the described period, the ICU of the Hospital Vitarte II had seven beds and four conventional ventilators: Evolution (EVL100001-T-NF), Vela (16,532–07), Newport (e360) and Draeger (Savina 300). Eight new individually validated ventilators known as Masi [7] were provided to the ICU, and the medical personnel were trained regarding its clinical use. Figure 4 shows the schematics when using Masi in a critical care environment. Figure 5 shows photographs of the device. Supplementary Table 1 summarizes the technical specifications of the ventilator Masi. This device was approved to be used in Peru during the sanitary emergency by the local competent authority: Dirección General de Medicamentos, Insumos y Dispositivos Médicos (DIGEMID, Spanish acronym) based on preclinical evidence of safety [5].

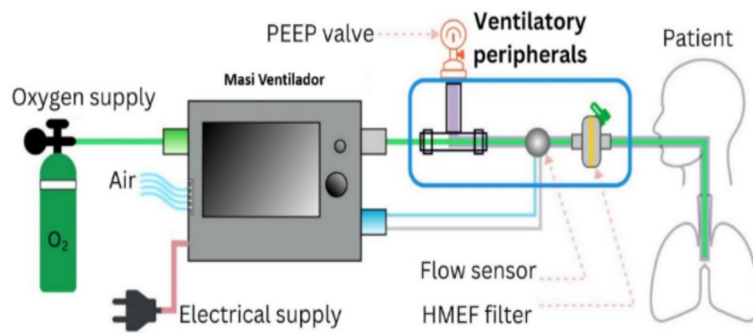


Fig. 4 Setup to use Masi in a critical care environment intended to be operated by a healthcare professional operator for ventilator-dependent patients



Fig. 5 Photographs of the device: **a** front view, **b** top view, **c** touch screen and interface buttons, **d** control and power boards

Technical limitations of Masi

Masi was developed and manufactured during the most critical phase of the COVID-19 pandemic, under conditions of extreme urgency and global supply chain disruptions. Due to severe restrictions on the acquisition of components, the design and

construction of the hardware relied on available materials and components, which influenced certain engineering choices. The ventilatory parameter ranges of Masi were configured based on the typical physiological needs of the average Peruvian patient and aligned with the Rapidly Manufactured Ventilator System (RMVS) Specification issued by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) for emergency-use ventilators during the pandemic [8]. Although Masi does not include some advanced features present in high-end ICU ventilators, it incorporated essential monitoring capabilities, including a graphical interface that displayed real-time volume, pressure, flow curves, and pressure–volume loops. The compliance of the respiratory system was estimated using theoretical calculations based on measured parameters, such as tidal volume and plateau pressure, previously compared against calibrated test lungs representing the most common compliance values seen in COVID-19-related respiratory failure.

Data analysis

To minimize bias associated with convenience sampling in a single-site study, the Data Entry Investigator initially reviewed the medical charts of all patients ($n=103$) admitted to the ICU during the study period. From this cohort, cases involving mechanical ventilation with Masi or commercial ventilators were selected for inclusion. Of the 132 variables originally recorded, a subset was chosen based on their relevance to the objectives of the present study. The selected variables were uploaded into R Studio for analysis. All variables and values were reviewed by two independent data analysts and cross-checked with the data entry assistant when necessary. The dataset was thoroughly cleaned to address missing values, inconsistencies, and outliers. No normalization was applied. Each variable was evaluated through univariate analysis, followed by bivariate analysis comparing values between pre- and post-intubation, and post- and last-intubation measurements. The main factors used for comparison were the respiratory parameters before and after the intubation between the mechanical ventilators Masi versus conventional (Fig. 2). An additional analysis was done to compare survival rates by using the Kaplan–Meier estimator and COX analysis. The censoring time was defined as the last follow-up, discharge from the ICU, or death—whichever occurred first.

Abbreviations

ICU	Intensive care units
ARDS	Acute respiratory distress syndrome

Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s12938-025-01432-2>.

Additional file 1.

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Author contributions

SGS: study design, data analysis, and manuscript revision; GAS: data entry, analysis, and manuscript revision; JLBM: study design, data entry, and manuscript revision; RAH: study design, data analysis, and manuscript revision; BCA: study design

and manuscript revision; CGSN: data analysis, and manuscript revision; AHK: data analysis, and manuscript revision; SMPB: study design and manuscript preparation and revision; FLC: study design, data analysis, and manuscript preparation.

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Data availability

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Research Ethics Committee for Life Sciences and Technology of the PUCP (002–2021–CEICV/Tech/PUCP) on September 23, 2021. The study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Based on Guideline 10 of the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS), the committee granted a waiver of informed consent, as the study used anonymized data records and posed minimal risk to participants.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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References

1. Mantena S, Rogo K, Burke TF. Re-examining the race to send ventilators to low-resource settings. *Respir Care*. 2020;65(9):1378–81.
2. Pearce JM. A review of open source ventilators for COVID-19 and future pandemics. *F1000Research*. 2020. Available from: /pmc/articles/PMC7195895/
3. Chang J, Acosta A, Benavides J, Reategui J, Rojas C, Cook J, et al. Masi: A mechanical ventilator based on a manual resuscitator with telemedicine capabilities for patients with ARDS during the COVID-19 crisis. *HardwareX*. 2021;9: e00187.
4. Kwon AH, Slocum AH, Varelmann D, Nabzdyk CGS, Araki B, Abu-Kalaf M, et al. Rapidly scalable mechanical ventilator for the COVID-19 pandemic. *Inten Care Med*. 2020;46:1642–4.
5. Carazas MMG, Gavidia CM, Fernandez RD, Zuñiga JAV, Paiva AC, Bocanegra W, et al. Biological evaluation of a mechanical ventilator that operates by controlling an automated manual resuscitator. A descriptive study in swine. *PLoS ONE*. 2022;17(3): e0264774. <https://doi.org/10.1371/journal.pone.0264774>.
6. Perez-Buitrago S, Gomez-Alzate D, Cordova M, Rojas C, Chang J, Castaneda B. Performance of the Masi Peruvian ventilator at high altitude. *Proc Annu Int Conf IEEE Eng Med Biol Soc EMBS*. 2021;5031:4.
7. Gomez-Alzate D, Perez-Buitrago S, Cordova M, Bornas M, Castaneda B. Quality characteristics of the Masi Peruvian mechanical ventilator manufacturing process. *Proc Annu Int Conf IEEE Eng Med Biol Soc EMBS*. 2021;1557:61.
8. Medicines and Healthcare products Regulatory Agency (MHRA), "Rapidly Manufactured Ventilator System (RMVS) Specification", UK Government. 2020. <https://www.gov.uk/government/publications/specification-for-ventilators-to-be-used-in-uk-hospitals-during-the-coronavirus-covid-19-outbreak/rapidly-manufactured-ventilator-system-rmvs>
9. Montero S, Morón G, Arrunategui-Salas G, Casado FL, Castaneda B, Salmon-Mulanovich G. Enablers and barriers to adopt the locally developed Masi mechanical ventilator amid COVID-19 pandemic in Peru. *Heliyon*. 2023;9(9): e19586.
10. Richardson S, Hirsch JS, Narasimhan M, Crawford JM, McGinn T, Davidson KW, et al. Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area. *JAMA*. 2020;323(20):2052–9.
11. Zhou F, Yu T, Du R, Fan G, Liu Y, Liu Z, et al. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. *Lancet*. 2020;395(10229):1054–62.
12. Aguirre-Milachay E, León-Figueroa DA, Chumán-Sánchez M, Pinedo-Castillo L, Vásquez-Bueno JF, Aguirre-Milachay E, et al. Supervivencia en pacientes con COVID-19 ingresados en UCI en un hospital de tercer nivel de Lambayeque, Perú. *Rev del Cuerpo Médico Hosp Nac Almanzor Aguinaga Asenjo*. 2023;16:2.
13. G. Malaga, G. Salmon-Mulanovich, B. Castaneda and F. L. Casado, Ventilator-Dependent Patients With no Respiratory Illnesses in an Intermediate Care Unit are Successfully Supported by a Resuscitator Bag-Based Mechanical Ventilator, 2024 IEEE ANDESCON, Cusco, Peru, 2024, pp. 1–4, <https://doi.org/10.1109/ANDESCON61840.2024.10755637>.

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