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MASI Ventilator: Implementing Peruvian Technology in Regions at High Altitude

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Abstract — **The expanded use of the Masi ventilators to more regions of Peru is important, particularly for regions located at high altitudes, due to the ventilatory support latent need, which also represents a challenge in the calibration and the adjustment of metrological parameters to ensure its correct performance. In a previous study, in Puno city at 3800 m.a.s.l., it was found an error above 15.0% (minimum tolerance) in the tidal volume, for which a negative correction of 25.0% was applied. In the present study, a Masi ventilator was transported to Chachapoyas city, at an altitude of 2400 m.a.s.l. to continue evaluating the effect of altitude on the parameters of the device. Once there, ventilators were acclimated and calibrated. Tidal volume, inspiration-expiration ratio (I:E), positive end-expiratory pressure (PEEP), peak inspiratory flow (PIF) and peak inspiratory pressure (PIP) were tested, and the maximum percentages errors presented were 13.5% and 13.9% in the tidal volume and the PIF, respectively. For that reason, although errors were under 15.0%, an update of the software of Masi was needed, applying a negative correction of 14.0%. Then, the parameters were tested again obtaining results with errors below 6.0% and 8.0% in volume controlled an pressure controlled ventilation modes, respectively. These results allowed the use of the Masi ventilator at ICU area. Finally, a software update for the Masi ventilator is performed by applying a linear equation that relates altitudes and percentage errors tested.**

Keywords — **Ventilators, COVID-19, high altitudes, parameters, percentage errors, calibration, adjustment.**

I. INTRODUCTION

The Masi ventilator was created in response to the health crisis caused by COVID-19, in 2020. It is composed of an automatically controlled actuator based on electronic and mechanic components which are used to inflate the manual resuscitator to provide air into the patients airways. The initiative was developed by five Peruvian institutions focused on innovation: DIACSA, Energy Automation Technologies, Zolid Design, Brein and Pontificia Universidad Catolica del Peru (PUCP), with the main objective of contributing immediately with a cost-effective alternative to fight the technological shortage in the Intensive Care Unit (ICU), in patients with Acute Respiratory Distress Syndrome (ACDR). The technical specifications of Masi include three ventilation modes with default values and intervals for optimal performance: volume controlled ventilation (VCV) and pressure controlled ventilation (PCV), pressure support ventilation (PSV) [1]. The Massachusetts Institute of Technology (MIT) has recognized Masi as one of the world's best devices developed during health emergencies for developing countries, which also generates a real impact at the clinical level. Masi project has donated 340 ventilators to hospitals and clinics throughout the country, which have been tested in clinical trials and validated according to the RMVS001 specification [2] [3], at sea level and, currently, expanding to higher altitude regions. It is necessary to expand the use of Masi throughout the different regions of the country, especially in those at high altitude since this represents a challenge in the quality assurance of ventilators in terms of the calibration and the adjustment of metrological parameters to ensure its correct performance. Therefore, there are already four cities in Peru that have Masi ventilators: Lima, Chiclayo, Iquitos and Puno, which are located at different altitudes above the sea level. Particularly, in Puno, city located at 3800 m.a.s.l., was determined that the accuracy of the equipment sensors in volume controlled ventilation mode is strongly affected by the change in altitude. In detail, it was found that the parameters of the Masi ventilator present an error below the 15.0% (maximum tolerance) except for the tidal volume, for which it was necessary to apply an adjustment of 25.0% to guarantee the correct performance of the ventilator [1]. In the present study, the effects of the altitude on the metrological parameters of Masi will be evaluated in the Intensive Care Unit (ICU) of the Hospital Regional Virgen de Fatima of Chachapoyas city, which is located at an intermediate point of altitude (2400 m.a.s.l.).

II. MATERIALS AND METHODS

A. *Materials*

The elements transported to the city of Chachapoyas were the case, the pedestal and the Masi´s ventilation peripherals. The peripherals are the inspiration/expiration valve, PEEP valve, flow sensor, corrugated tube to the ventilator and HMEF filter. In addition, the evaluated parameters for the Masi ventilator were tested by using the flow analyzer Fluke VT650 set on Ambient Temperature and Pressure (ATP), previously calibrated (Fluke Biomedical, August 2021), which has been designed to operate at up to 3000 m.a.s.l.

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B. *Initial verification*

Before being transported to Chachapoyas, the parameters of the Masi ventilator were tested, in the city of Lima, under two ventilation modes: VCV and PCV. The programmed values were set for the following parameters: tidal volume, respiratory frequency, I:E ratio, PIF, PIP and PEEP. These values are shown in Table I and Table II for VCV and PCV modes, respectively.

Data acquisition consists of programming each test with a specific value for every parameter and starting the measure of each one for about one minute. In total, 12 tests were performed for both ventilation modes. The modal value was considered as the measured value.

TABLE I
PARAMETERS TESTED IN VCV MODE

Parameter	Set point
Tidal volume (ml)	[200, 400, 600]
Respiratory frequency (rpm)	[12, 20]
I:E Ratio	[1:1, 1:2]
PEEP (cmH2O)	[8, 12, 16]

TABLE II
PARAMETERS TESTED IN PCV MODE

Parameter	Set point
PIP (cmH2O)	[20, 30]
Respiratory frequency (rpm)	[12,20]
I:E Ratio	[1:1, 1:2, 1:3]
PEEP (cmH2O)	[8, 12, 16]

C. *Masi Transportation*

The Masi ventilator was transported by plane from Lima to Jaen and then by car to Chachapoyas city. For that purpose, the case and its pedestal were properly packaged and labeled into two different boxes, which had symbols printed for their proper transportation. In addition, inside each box, the case and pedestal were bagged and stabilized with cardboard protectors to prevent damage and contamination of the equipment during transportation. Once arrived, it was acclimated in a room at ambient conditions overnight before being assembled and turned on to begin the measure procedures.

D. *Sensor calibration*

The ventilator was tested in the VCV mode, the parameters and its programmed values are shown in Table III. Three trials for each configuration of the tidal volume were performed. A total of 27 tests were carry out. Data from the VT650 and the Masi ventilator was acquired after one minute of stabilization.

TABLE III
PARAMETERS TESTED IN VCV MODE

Parameter	Set point
Tidal volume (ml)	[200, 250, 300, 350, 400, 450, 500, 550, 600]
Respiratory frequency (rpm)	[12, 20]
I:E Ratio	[1:1]
PEEP (cmH2O)	[8]

The tests were carried out in an empty ICU room inside the hospital, the environmental conditions were suitable and there were no considerable sources of error.

E. *Sensor adjustment*

Error and percentage of error for all parameters were calculated by acquiring the data from the VT650 as the real value and the data from the sensors of the Masi ventilator as the unit under test. Subsequently, the obtained values from each test were averaged to calculate the total percentage error for each configuration according to the tested parameter. When it was calculated, a new software version to the Masi ventilator was applied with the specific correction value obtained according to the altitude level of Chachapoyas city.

F. *Final verification*

After the sensor calibration stage, the parameters of the Masi ventilator were tested again under both ventilation modes: VCV and PCV, these performance tests were carried out with the same configuration for the parameters described in the section B, except for the I:E ratio, where additionally the configuration of 1:2 was considered. Finally, the percentage error was calculated as previously detailed for each parameter.

III. RESULTS

A. *Initial verification*

Errors for all parameters were below to the 5.0%. Fig. 1 and Fig. 2 show the results of the parameters in the VCV and PCV modes, respectively.

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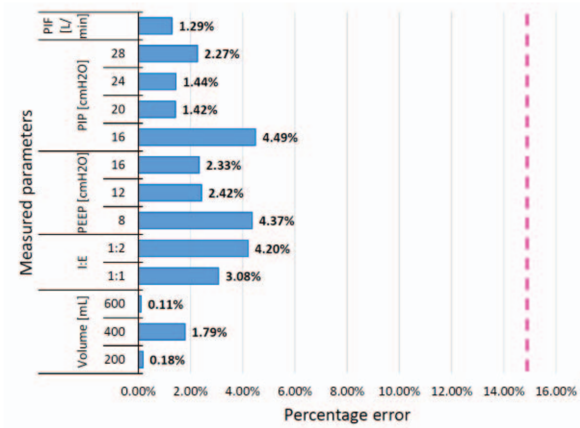

Fig 1. Percentage errors for the initial verification in Lima: VCV mode.

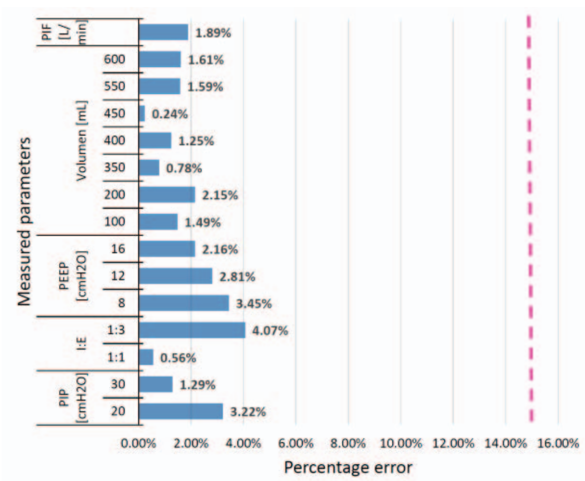

Fig 2. Percentage errors for the initial verification in Lima: PCV mode

B. *Sensor characterization*

Errors for all parameters were below to the tolerance of the Masi ventilator, defined as 15.0% of the set point as shown in Fig. 3. It can be seen that the maximum errors presented were 13.5% and 13.9% in the tidal volume and the peak inspiratory flow, respectively.

Fig 4 shows the errors in detail for the tested values of the tidal volume. The minimum and the maximum errors were presented at 500 ml (11.8%) and at 250 ml (14.9%).

Finally, Fig 5 is a linear regression graphic of the error regard to the tidal volume, which shows that the error volume is 11.0% with a positive offset of 8.0%.

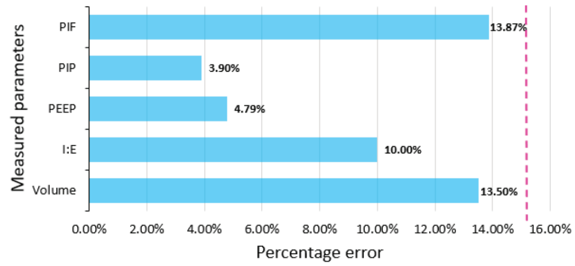

Fig 3. Average percentage errors of all the parameters in Chachapoyas: VCV mode

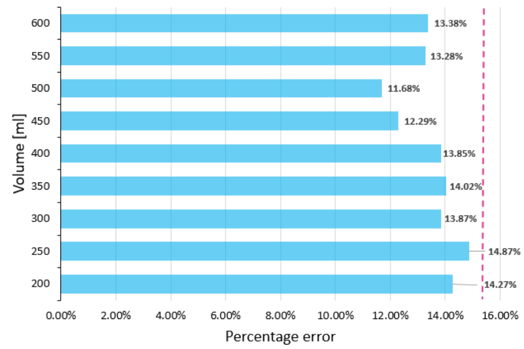

Fig 4. Percentages errors of tidal volume in Chachapoyas: VCV mode

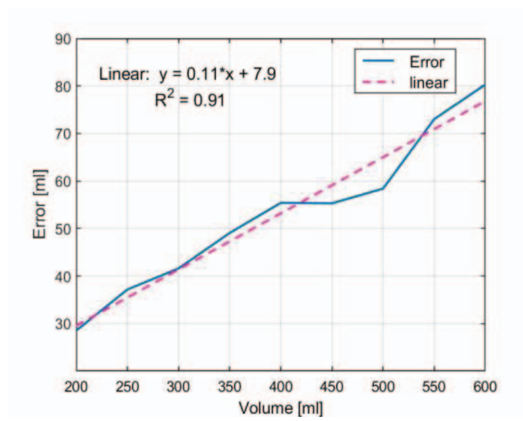

Fig 5. Tidal volume error for the initial verification.

A. *Sensor adjustment and final verification*

The software of Masi ventilator was updated with a negative correction of 14.0% for the tidal volume. Fig. 6 shows the results in the VCV mode, as it can be observed all the parameters tested were below the 6.0%. In addition, Fig. 7 shows the results of the PCV mode, where the parameters also were under 6.0%, except for the volume of 350 ml (Percentage error = 8.4%).

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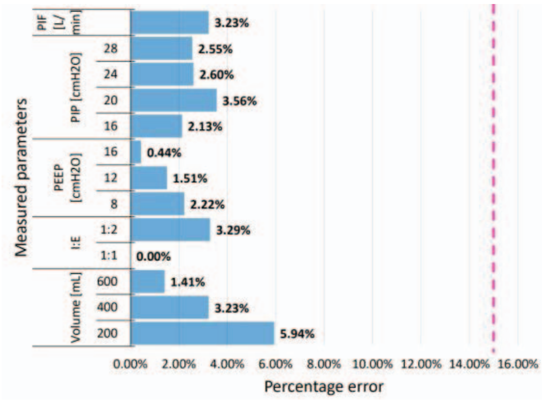

Fig 6. Percentage errors in the final verification in Chachapoyas: VCV mode.

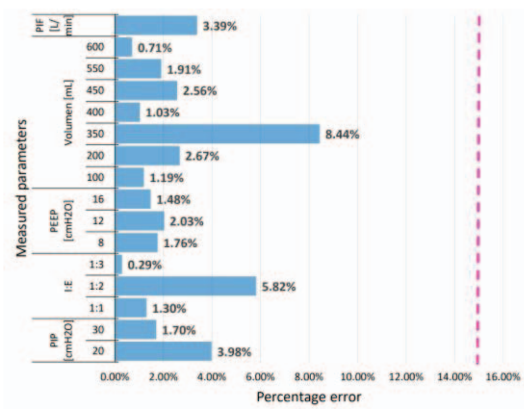

Fig 7. Percentage errors in the final verification in Chachapoyas: PCV mode.

IV. SOFTWARE UPDATE

A new version of the software of Masi can be proposed by calculating a linear equation that relates altitudes with the average percentage errors. For this purpose, the altitudes and the average percentage errors of three cities are considered (Table IV), the resulting graphic is shown in Fig. 8.

From this, the linear equation of the relation between the average percentage error and the altitudes is obtained as $y = 0.006x - 0.128$, where x is the altitude entered manually by the operator, while y is the resulting percentage error. Once this percentage error is calculated, the software is able to automatically adjust its values according the altitude.

TABLE IV
ALTITUDE VALUES CORRESPONDED TO EACH CITY WHERE MASI VENTILATORS WERE IMPLEMENTED

City	Altitude (m.a.s.l.)	Average percentage error (%)
Lima	96	1
Chachapoyas	2400	14
Puno	3800	25

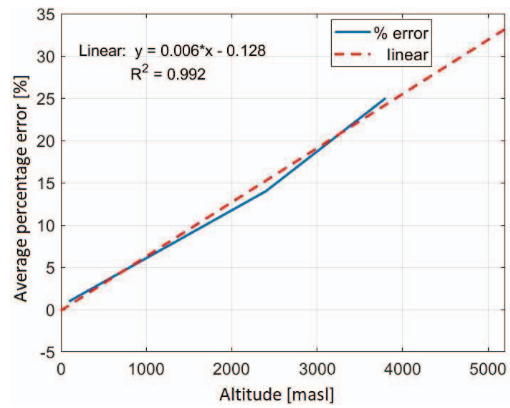

Fig 8. Linear fit of the relation between the average percentage errors and the altitudes.

V. DISCUSSION

The percentage errors in the tidal volume found in Lima and Chachapoyas were 1.0% and 14.0%, respectively. Both errors were within the permitted tolerance for Masi; however, a correction of 14.0% was applied in Chachapoyas to ensure a good performance of Masi in clinical practice during an event of possible fluctuations, which may affect the accurate results in the ventilator measurements. These two average percentages errors were compared with the study previously conducted in the city of Puno, where a correction of 25.0% was made. Therefore, it was possible to establish a linear relationship between altitude and the percentage error in tidal volume. Nevertheless, it would be necessary to use more ventilators in future investigations, in order to demonstrate this linear relationship.

As it was shown in Fig. 3, the highest percentage errors were founded in two parameters: PIF (13.9%) and tidal volume (13.5%), whose values are quite close to each other.

This can be due the fact that the differential pressure sensor, presented in the electrical circuit of Masi, measures both parameters [4]. For that reason, an adjustment on tidal volume would also decrease the PIF error. However, it must be considered a larger sample and more robust tests including not only the tidal volume as the key parameter but also the other associated parameters such as the PIF value.

Furthermore, as shown in Fig. 7, it was obtained a high value of average percentage error (8.4%) for a tidal volume of 350 ml in comparison to the set values (<6.0%) tested in the final verification stage. This percentage error is not considered to be atypical because this value is the average of two tests with similar results in terms of the percentage of error (7.8% and 9.1%), for the same set value of 350 ml. More likely, these results can be since the tests were performed by using a fixed lung and a PIP value of 30 cmH2O with 20 rpm, which could be very demanding for this lung because of its

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compliance of 25 ml/cmH2O that can decrease and result in smaller volumes than expected. However, further studies on this are required.

Finally, it is important to mention that ventilator performance tests were mostly presented in hypobaric chambers, according to previous studies [5,6,7,8,9,10,11]. However, due to the different altitudes and climatic diversity of Peru, it was imperative to develop the present study in real conditions, in order to continue implementing Masi and improve access to health services throughout the country.

VI. Conclusion

This work shows that Masi ventilator could be a good alternative for COVID-19 patient's treatment in high altitude regions from Peru considering the linearity between the percentage error and the altitude level. This is an enormous achievement and contribution to strengthening Peruvian health services in the emergency context.

Acknowledgments

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