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Performance of the Masi Peruvian ventilator at high altitude

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Abstract— **In response to Covid-19 crisis, 310 Masi ventilators were produced and validated in Lima, Peru, according to applicable standards. Four of them, were transported to Puno, in order to strengthen ICU Services there, but this set a major challenge to Masi team as effects of altitude on ventilators were unknown. Once there, ventilators were acclimated and calibrated. Volume tidal, I:E ratio, respiratory frequency and PEEP were tested, all of them presenting errors under 15%, except for tidal volume, for which a 25% negative correction was applied. After the installation of a new version of Masi software, parameters were tested again, all of them presenting results with errors below 15%, which allowed the Masi team to take them to ICU services for use.**

Clinical Relevance— Masi Peruvian Ventilators are able to perform according to their specifications at extremely high altitude, after the adequate calibration. These devices are an alternative to treat COVID-19 patients in the middle of the crisis.

I. Introduction

In response to COVID-19 crisis, five innovation-centered institutions in Peru –DIACSA, Energy Automation Technologies, Zolid Design, Brein & Pontificia Universidad Catolica del Peru, PUCP) gathered a team to develop a ventilator with sufficient functionality to safely treat patients with ARDS, while reducing the production time, logistical complications and cost to make ventilators available to assist and sustain the already saturated Intensive Care Units (ICU) system or any emergency point of care.

Masi ventilator is composed of mechanical, electronic and pneumatic parts. Its design makes use of a manual resuscitator as core driver to insufflate air into the patient airways via a mask and includes basic alarms indicating high or low pressure or volume to notify the healthcare provider when desired parameters are not being met or if there is a significant problem with the system. Additionally, control and monitoring of oxygen concentration is provided and this device can be used as invasive and non-invasive ventilator types, both mandatory and spontaneous [1]. Masi technical specifications are shown in table I.

Three hundred and ten Masi Ventilators were produced with the aim that these would be donated to different hospitals in Peru. For each of them, the team performed the validation tests required for RMVS001-Specification [2, 3], the standard applicable, using calibrated flow analyzers. These tests were performed in Lima, at the sea level, where the majority of ventilators are used in critical care environments, being this city the capital and largest city of the country. However, due to the extension of the emergency, it was necessary to place 4 of the ventilators in the city of Puno, at an altitude of 3800 meters above the sea level, in order to strengthen the ICU services at the Hospital Regional Manuel Núñez Butrón in Puno.

TABLE I. MASI VENTILATOR TECHNICAL SPECIFICATIONS

Ventilation mode	Parameter	Default Value	Interval	
			Min. Value	Max. Value
General	Trigger	5	5	10
	FiO2	21	21	100*
	PEEP	0	0	20
VC-CMV	VT	400	200	800
	RPM	15	4	35
	Ti	1.0	0.7	7.5
PC-CMV	PC	15	5	35
	RPM	15	4	35
	Ti	1.0	0.7	7.5
PC-CSV	PS	10	5	30
	Cycle	20	5	40
	Tap	15	2	20

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This supposed an enormous challenge to the Masi team as effects of high altitude on Masi ventilators were unknown and previous studies on ventilators used for air transport show significant effects due to altitude, in particular with regard to accuracy of tidal volume and breathing frequency [3]. In addition, tests performed in these studies to evaluate performance of ventilators at altitude have been made using a hypobaric chamber [4, 5, 6, 7, 8, 9, 10], but similar test in cities at high altitude could not be found.

II. METHODS

A. Sensor characterization

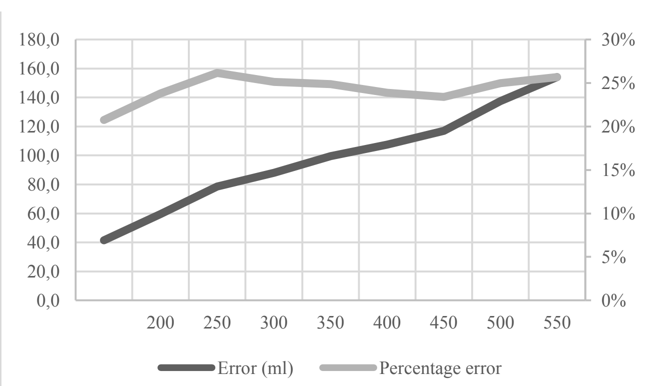
Four Masi ventilators were transported from Lima to Puno by airplane. Once there, they were acclimated in a room at ambient conditions overnight, at barometric pressure of approximately 641 mbar. Next day, all of them were assembled and turned on. Oxygen calibration was performed for each ventilator using a reference at 96 % O_2.

Using a calibrated (Fluke Biomedical, April 2020) flow analyzer Fluke VT650 set on Ambient Temperature and Pressure (ATP), actual humidity [11] mode, ventilators were tested, in both Volume Control and Pressure Control modes, for the following parameters: tidal volume, I:E ratio, respiratory frequency, peak inspiratory pressure (PIP) and positive end of expiration pressure.

Tests for all the parameters in volume controlled mode were repeated using a different gas flow analyzer Fluke VT650 which was also calibrated in April 2020 by Fluke biomedical, in order to verify the measured values indicated by the two references, reducing the possibility of an erroneous measurement, as this type of equipment is designed to operate at a maximum altitude of 3000 meters [11].

TABLE II. PARAMETERS TESTED FOR FINAL VERIFICATION

Parameters Tested		
Parameter	**Set Point**	
Tidal Volume (ml)	200	400
Respiratory Frequency (rpm)	20	12
I:E Ratio	1:2	1:1
PEEP (cmH_2O)	12	8



Graph 1. Error and percentage error in tidal volume for sensor characterization.

Additionally, both gas flow analyzers were calibrated for volume in 300 ml using a calibrated syringe, at the same environmental conditions tests were performed, to ensure results were valid and errors found in Masi ventilators were due to the ventilators instead of the flow gas analyzers.

B. Sensor Calibration

Data collected for sensor characterization was used to generate an equation for the correction in tidal volume.

Thus, Masi Ventilator software for these four ventilators was updated to contain a correction of -25 % over the delivered Tidal Volume. This new version of the software was applied to all the devices, which were assembled again and let cycling for half an hour.

C. Final verification

Once the appropriate correction was applied to tidal volume of each Masi ventilator, they were tested again with a calibrated flow analyzer set in ATP mode, in volume controlled mode. Each ventilator was tested according to the parameters described in table II.

III. RESULTS

A. Sensor characterization

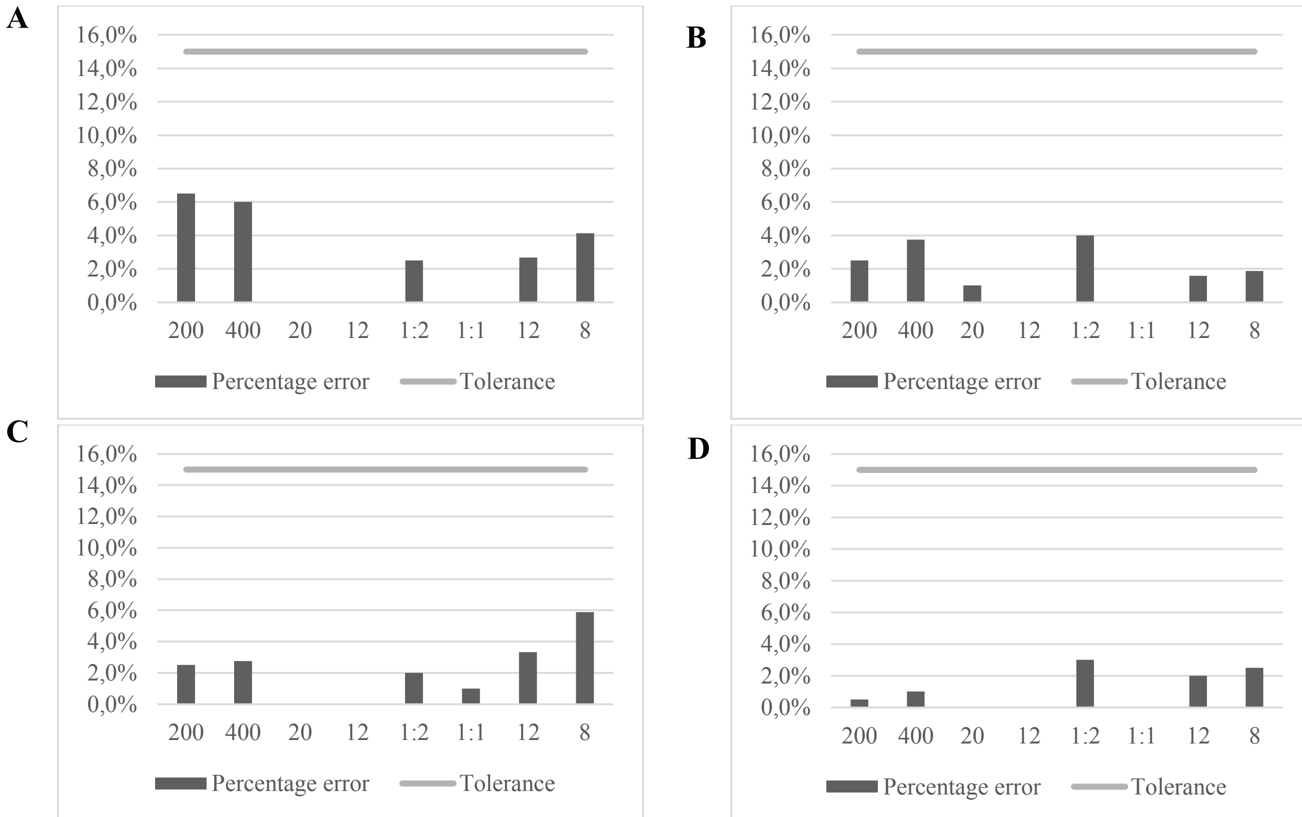
Errors for all the parameters were inferior to the tolerance of the Masi ventilator, defined as 15% of the set point, except for Tidal Volume that showed larger errors for every value of volume tested. Data for tidal volume from the first ventilator tested on Volume Controlled mode, was collected and it is reported in table III. Error percentage was constant and close to 25% for every value tested. Graph 1 shows the behavior of error, which is approximately linear and increases when the value of tidal volume tested does.

B. Final Verification

After sensor calibration, errors for all the parameters tested were below the tolerance of 15% as shown in Graph 2. Tidal volume also showed errors below the tolerance for all the ventilators and all the values tested, as it can be seen in Table IV.

TABLE III. DATA FOR CHARACTERIZATION OF SENSOR MASI VENTILATOR AT 3800 METER ABOVE THE SEA LEVEL.

Volume Tidal Errors and percentages of errors			
Set Point (ml)	**Average Reference (ml)**	**Error (ml)**	**Percentage error**
200	241,5	41,5	21%
250	309,5	59,5	24%
300	378,5	78,5	26%
350	438,0	88,0	25%
400	499,5	99,5	25%
450	557,5	107,5	24%
500	617,0	117,0	23%
550	687,5	137,5	25%
600	754,0	154,0	26%



Graph 2. Percentage errors for all the ventilators tested. From left to right: tidal volume, respiratory frequency, I:E ratio and PEEP. Ventilator (A) 1, (B) 2, (C) 3, (D) 4.

In fact, errors maintained under 7%, which shows that the correction applied was adequate and this did not affect the performance of the other parameters.

As performance of these four ventilators was adequate, considering their specifications, Masi team was able to place and install them in the ICU services of Puno Regional Services for their use in COVID-19 patient treatment.

IV. DISCUSSION

Data collected for all four ventilators show that errors in parameters tested are smaller than the tolerance of 15%, which indicates and adequate performance of Masi ventilators at high altitude. However, it is necessary more research in order to determine more accurate relations between altitude above the see level and errors in tidal volume.

Furthermore, an important aspect to consider is that Gas Analyzers Fluke VT650 are designed to operate at up to 3000 meters above the sea level and measurements in Puno were performed at approximately 3800 meters above the sea level. Nonetheless, it is considered unlikely that data collected could be unreliable, as two different calibrated flow analyzers were used and this type of equipment is provided with a barometer that allows it to make corrections for airway flow measurements when needed [11].

Moreover, it is still unknown if the effects of altitude on Tidal Volume are linear, this is, if a correction of around 12,5% could be effective in a city at approximately 2000 meters above the sea level and similarly for other altitudes. This, would allow Masi Team to apply a correction on Tidal Volume that depends on altitude. Further studies on this are required.

In addition, the fact that a sample of only four ventilators was used, leads to consider that more research is needed, both with a larger sample and more robust tests. Also, PIP tests were not analyzed in deep because errors for this parameter were below the 15% tolerance, before and after the sensor calibration, however, this is a critic parameter and an adequate characterization of it might be needed.

Despite all the above, Masi ventilators are a great alternative for COVID-19 patient's treatment in high altitude places, such as several cities that can be found in Peru. Besides, as these ventilators were designed and produced locally, Masi team is willing to adapt to the challenges of local geography and can customize its technology in cities up to 5000 meters above the sea level. This, is an enormous advantage and contributes to strengthen Peruvian health services in the emergency context.

V. CONCLUSION

Four rapid-manufactured Peruvian mechanical ventilators, named MASI, were transported to Puno, Peru, a city at approximately 3800 meters above the sea level, and tested for Tidal Volume, Respiratory Frequency, I:E Ratio and PEEP. Initial tests, showed tolerable errors for every parameter,

TABLE IV. ERRORS AND PERCENTAGE ERRORS FOR TIDAL VOLUME AFTER SOFTWARE UPDATE

	Errors in Tidal Volume after software update			
	DUT (ml)	**Reference (ml)**	**Error (ml)**	**Percentage error**
Ventilator 1	200	213	-13	6,5%
	411	435	-24	6,0%
Ventilator 2	199	204	-5	2,5%
	389	404	-15	3,8%
Ventilator 3	204	209	-5	2,5%
	410	421	-11	2,8%
Ventilator 4	195	196	-1	0,5%
	385	389	-4	1,0%

except for Tidal Volume, which needed a 25% correction made by software update. Once the new software was installed in all four ventilators, they were tested again for the same parameters and results show acceptable errors (<15%) for all of them, including Tidal Volume.

Further research related to performance of Masi ventilators in cities at high altitude is needed.

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