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Quality characteristics of the Masi Peruvian mechanical ventilator manufacturing process*

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Abstract— **Three hundred and ten rapid-manufactured mechanical ventilators, named Masi, were produced and validated in Peru, according to applicable standards. From these, a sample of 30 was taken and two ventilation parameters, tidal volume and peak inspiratory pressure, were statically analyzed using control charts and histograms. Results show that several points were outside estimated limits for Shewhart means and ranges charts, which could possibly be due to the quantity of equipment used for data recollection and the fact that the Masi team had over 20 engineers. Nevertheless, Masi ventilators met the tolerance required by their user´s manual and MHRA standard and Peruvian DIGEMID for every parameter.**

Clinical Relevance— **This article shows the performance in the validation stage of the peruvian mechanical ventilator MASI built as an emergency response for the COVID-19 crisis.**

I. Introduction

Five innovation-centered institutions in Peru (Zolid Design, Energy Automation Technologies, DIACSA, Brein and the Pontificia Universidad Catolica del Peru, PUCP) gathered and conceived the Masi project as an alternative to respond to the effects if COVID-19 pandemic in the country. The project's team developed a rapid-manufactured mechanical ventilator with sufficient functionality to treat safely COVID-19 patients with Acute Respiratory Distress Syndrome (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, provides control and monitoring of oxygen concentration and can be used as invasive and non-invasive ventilator types, both mandatory and spontaneous. In principle, this device 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 [1, 2]. Technical specifications for Masi Ventilator are show in Table I.

Three hundred and ten Masi ventilators were produced following Good Manufacturing Practices, supervised by the Quality Institute of Pontificia Universidad Catolica del Peru.

The manufacturing process was performed by independent groups for each part of the device, this is, mechanical, electronic and pneumatic. Then, all the pieces were assembled and a twelve-hour pre-validation was performed for each ventilator in order to check general functioning, alarms and other relevant settings.

At that point, the team performed validation tests required by the RMVS001 Specification from the Medicines & Healthcare products Regulatory Agency [3] that involves the use of calibrated flow analyzers. Finally, ventilators were taken into a clean room where the latest quality testing and final packaging is performed. From this last step, a sample of the 10% of the total production tests registers were randomly selected for this analysis, for which Shewhart charts for means and ranges were generated, both for peak inspiratory pressure (PIP) and tidal volume.

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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II. METHODS

A. Data collection

Once ventilators were produced, were transported to the Laboratory of Metrology and Validation, where measurements were performed for each of them, using calibrated Fluke VT650 flow analyzers and variable resistance and compliance test lungs, following the parameters detailed in RMVS001-Specification, which are based on ISO 80601-2-12:2020 considerations. Thus, for each ventilator, the following tests described in [3] were performed: Volume Controlled Ventilation Test (Compliance), Volume Controlled Ventilation Test (Resistance), Volume Controlled Ventilation Test (Tidal Volume), Pressure Controlled Ventilation Test (15 cmH_2O), and Pressure Controlled Ventilation Test (30 cmH_2O). These tests were performed by 20 trained engineers, using 10 workstations installed in the lab for this purpose. Error and percentage error were registered in validation reports for each device. These five tests were compiled into two reports, one containing pressure tests and the other one that includes volume tests with different resistances and compliances. For each ventilator, every parameter set for each test was recorded by a calibrated Fluke VT650 flow gas analyzer during 2 minutes, generating 120 individual measurements. An arithmetic mean for each ventilator parameter was estimated from these and reported in the validation reports.

B. Shewhart Charts and Histograms

From the data registered in the validation reports of 30 Masi ventilators, 6 specific measurements (obtained as described in A) were selected (20 cmH_2O of peak inspiratory pressure (PIP) and 400 ml of tidal volume), corresponding to the settings shown in Table II and Table III. For each of them, percentage of error was estimated as the difference of the average measured value and the set value in the ventilator above the set value on the ventilator. This quality characteristic was selected for this analysis, as a critical factor for its implementation in the clinical environment.

TABLE II. SETTINGS FOR PRESSURE CONTROLLED VENTILATION TEST

Pressure Controlled ventilation test			
PIP (cmH2O)	***Frequency (bpm)***	***I:E***	***PEEP (cmH2O)***
20	20	1	8
20	20	1	12
20	12	1	12
20	12	1	8
20	12	1	12
20	20	2	8

TABLE III. SETTINGS FOR VOLUME CONTROLLED VENTILATION TEST

Volume Controlled ventilation test			
Tidal Volume (ml)	***Frequency (bpm)***	***I:E***	***PEEP (cmH2O)***
400	20	1	8
400	12	1	8
400	20	1	12
400	12	1	12
400	20	2	8
400	12	2	8

The percentage errors selected corresponding to the settings shown in table II and table III for PIP and tidal volume, respectively, were taken and from these, media and range were estimated for each of the 30 ventilators selected.

As data was taken randomly from the validation reports of each ventilator, factors as operator, specific equipment used to record measurements, date of the tests and environmental conditions were not taken into account for this analysis, which means that data was not categorized under these factors.

For every variable, PIP and Tidal Volume, Shewhart Charts [5] for ranges and means were generated according to (1) and (2). Means were estimated as the arithmetic mean of the six percentage errors. Ranges were calculated as the maximum of the six percentage errors for every device minus the minimum of them.

Equation (1) shows the parameters for the ranges chart, where $\bar{R}$ is the average Range of the percentage errors of the 30 ventilators selected, and D_4 and D_3 are constants selected for $n = 6$ (Sample size).

$$\begin{aligned} Upper\ Limit &= D_4\bar{R} \\ Central\ Line &= \bar{R} \\ Lower\ Limit &= D_3\bar{R} \end{aligned} \tag{1}$$

Equation (2) shows the parameters for the means chart, where $\bar{\bar{X}}$ is the average of the percentage errors average of the 30 ventilators selected, and A_2 is a constant selected for $n = 6$ (Sample size).

$$\begin{aligned} Uper\ Limit &= \bar{\bar{X}} + A_2\bar{\bar{R}} \\ Central\ Line &= \bar{\bar{X}} \\ Lower\ Limit &= \bar{\bar{X}} - A_2\bar{\bar{R}} \end{aligned} \tag{2}$$

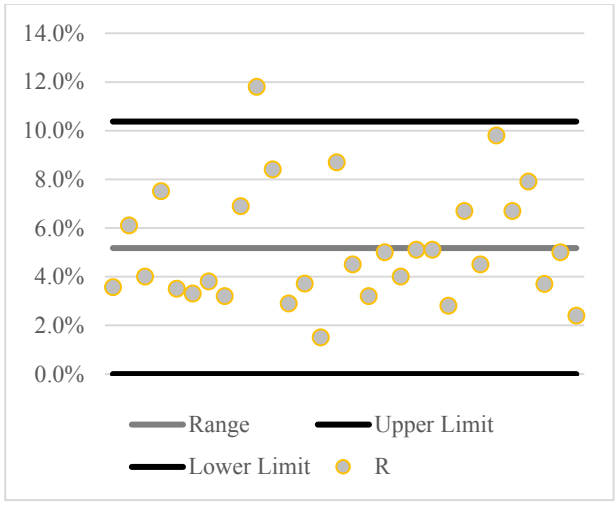
Additionally, using the same data, a histogram was generated for PIP and tidal volume.

III. RESULTS

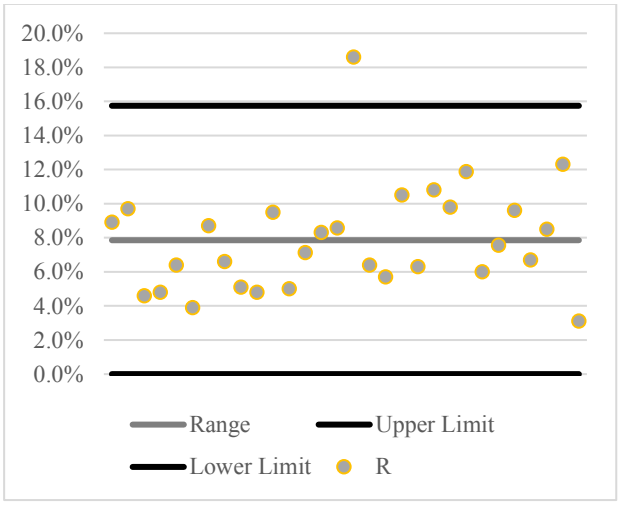
Shewhart Charts of means and ranges, both for PIP and tidal volume, are shown in Graphs 1 to 4.
Histograms for PIP and tidal volume are shown in Graphs 5 and 6, respectively.

A. PIP Results for Control Charts

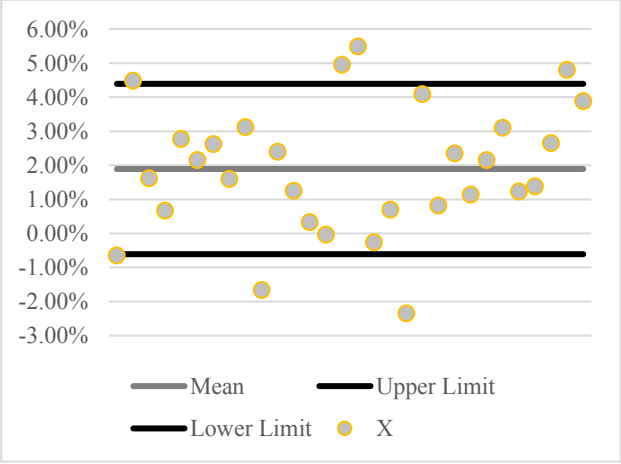
As it can be seen in Graph 1, the majority of points are inside the control limits estimated, except for one of them, which corresponds to a specific ventilator where a significant



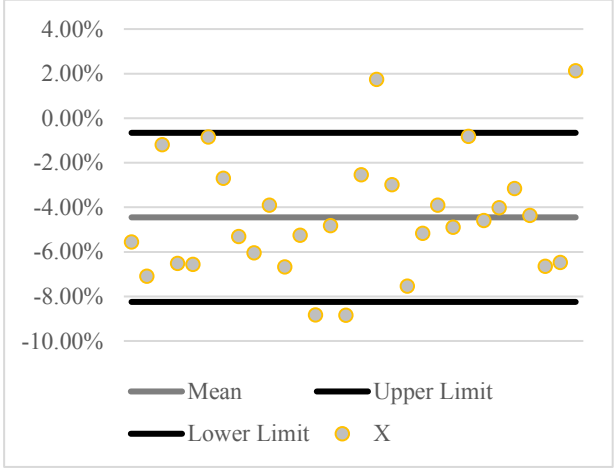
Graph 1. Ranges chart for PIP, where: *Range* is the mean of the ranges of each ventilator, the *Upper and Lower Limits* are estimated according to [5] and R individual ranges for each ventilator tested. The points are randomly scattered and only one of them outside the limits.



Graph 3. Ranges chart for tidal volume, where: *Range* is the mean of the ranges of each ventilator, the *Upper and Lower Limits* are estimated according to [5] and R individual ranges for each ventilator tested. The points are randomly scattered and a few of them outside the limits.



Graph 2. Means chart for PIP, where: *Mean* of percentage errors of 30 ventilators, the *Upper and Lower Limits* are estimated according to [5] and *X* refers to the mean of six percentage errors for each ventilator tested. The points are randomly scattered and a few of them outside the limits.



Graph 4. Means chart for tidal volume, where: *Mean* is the arithmetic mean of the mean of error percentages of 30 ventilators, the *Upper and Lower Limits* are estimated according to [5] and *X* refers to the mean of 6 error percentages for each ventilator tested. The points are randomly scattered and a few of them outside the limits.

difference among percentage error was found. This fact is important because it influences the limits of the means chart. It is noticeable that the points in the ranges chart have a random behavior and do not follow a specific pattern, like a cycle or a trend.

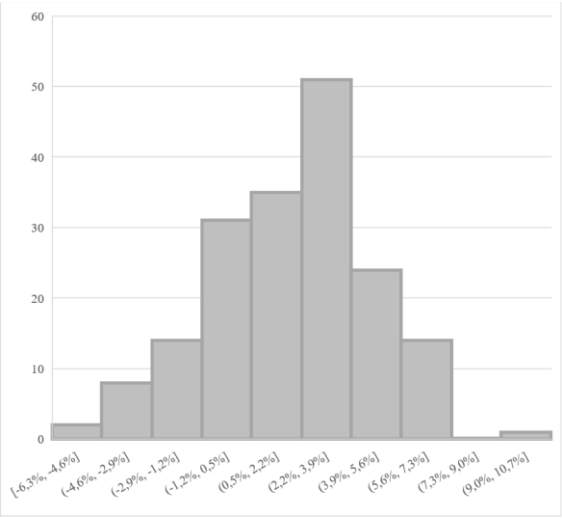
According to Graph 2, six of the total 30 points, are outside of the control limits estimated. It can also be seen that there is a large variability for the mean of the process, as the points plotted are found distributed in the chart. Similar to the ranges chart, the points do not follow a specific pattern and appear to behave randomly.

All of these, suggest that the process is unstable, as points outside the control limits, both for the mean and the range, indicate that there are special causes for variation that need to be investigated

A. Tidal Volume Results for Control Charts

As shown in Graph 3, just one of the points plotted is outside the control limits. It seems to be less variability in ranges for the tidal volume, as the vast majority of the points plotted are located closer to the center line, compared to the same chart for PIP. There is no evidence of patterns like periodic cycles or any other trend for the points under analysis.

In terms of the mean of the process for the tidal volume, Graph 4. shows that four of the 30 points plotted fell outside the estimated control limits, indicating that there are special causes of variation that lead to an unstable process. For the rest of the points, there are not visible patterns of behavior.



Graph 5. Histogram for PIP, *x* axis is the frequency and *y* axis is the error percentage interval. This Graph shows an approximately centered process. Percentage error do not exceed tolerance of ± 15% established in Masi user´s manual.

B. Histograms

Graph 5 for PIP shows that the percentage errors for this variable are found inside the interval (-6.3% , 10.7%), which is consistent with the 14% tolerance defined by standard applicable [3] for 20 cmH_2O. In general, data tend to left side of the plot, where percentage errors are smaller in magnitude. A significant amount of data tends to fall between -1.2% and 3.9%, which is considered satisfactory considering the tolerance stated.

Graph 6 for tidal volume shows what it appears to be a left skewed distribution, in which the majority of the data tend to be between -14.2% and 0,9%. Compared to the PIP histogram, it is noticeable than tidal volume presents larger errors, however errors meet the tolerance of 16% for 400 ml [3]. Both for PIP and tidal volume, percentage errors are lower than the 15% tolerance established in Masi user's manual for both of them.

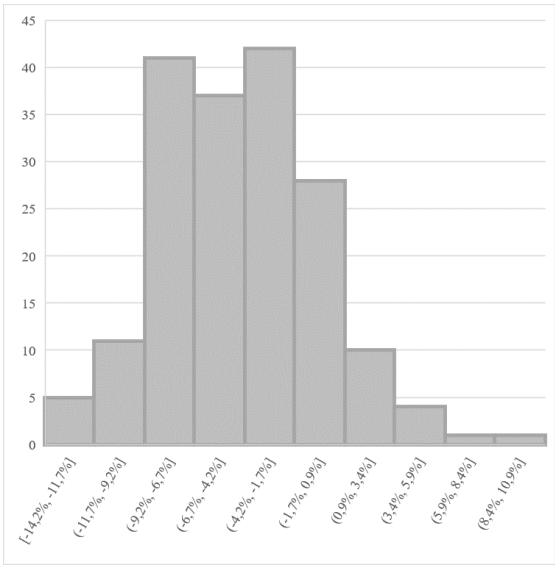
For reference, Table IV shows tolerances taken from [3] and tolerances established for Peruvian Masi ventilator, also tolerances for a commercial ventilator are shown. For tidal volume, a set value of 400 ml is considered and this same value is assumed for the volume expired, which in practice could be under or above this value. 20 cmH2O are selected to compare tolerances in PIP, and similar to the tidal volume, a reading of the same value is assumed for this value.

IV. DISCUSSION

The fact that there are points that fall outside the control limits in a control chart, means that there are variations in the process that are not due to the common causes of variation and these should be investigated in order to find and define actions to control the variation of the process. Typically, these variations come from any of these sources: manpower, method, machine, material, milieu and measurement, which are commonly known as 6M of production.

TABLE IV. COMPARISON AMONG TOLERANCES

	Tidal Volume 400 ml		**PIP 20 cmH2O**	
	Spec	**Result (ml)**	**Spec**	**Result (cmH2O)**
MHRA	±(4,0 +(15 % of the volume expired)) ml	64	15%	3,0
Masi Ventilator	15%	60	±(2 +(4 % of the actual reading)) cmH2O	2,8
Puritan Bennet 560	±10 ml +10 %	50	±1 cmH2O +10 %	3,0



Graph 6. Histogram for Tidal Volume, *x* axis is the frequency and *y* axis is the error percentage interval. This Graph shows a left-centered process. Percentage error do not exceed tolerance of ± 15% established in Masi user´s manual.

Since Masi Project was developed in the context of a sanitary emergency, regular conditions for ventilator manufacturing could not be fully implemented.

Nevertheless, each of them was validated according to applicable standards and, in order to perform all the test required for all the 310 ventilators developed, a significant amount of manpower and machines were used. This fact is considered as the major cause of variability observed in the control charts, both for PIP and tidal volume.

Despite this variability, it can be seen that the ventilators produced were capable of meet the tolerances of 15 % for each parameter established in their user manual, as well as the tolerances of the applicable standard of 14 % for PIP and 16 % for tidal volume, as shown in Graphs 5 and 6. Also, it can be seen from table IV that Masi tolerances are very similar to a commercial ventilator widely used in Intensive Care Units.

V. CONCLUSION

Although a considerably variability is found in control charts for both PIP and tidal volume, ventilators developed under the Masi project are capable of meeting the tolerances required by MHRA [3] and Masi user´s manual [2] as shown in histograms (Graphs 5 and 6). Which was a quality criterion that was considered to obtain the authorization by Peruvian DIGEMID for manufacturing and use of Masi ventilators.

It is considered that this variability is due to common causes, as for testing ten different gas flow analyzers were used and 20 engineers performed validation. In future projects, statistical tools should be used in the manufacturing processes to control the common and special sources of variation.

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