Calibration and Testing of the Integrated Ventilator Scalar Measurement Module for a Bag-Valve-Mask-Based Emergency Ventilator

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***Abstract*—** Open-source ventilators (OSVs) are considered as an immediate response for the shortages of ventilator equipment in hospitals due to the ongoing global pandemic caused by the Coronavirus disease 2019 (COVID-19). One of the designs explored for OSVs utilizes a bag-valve-mask as a source for mechanical ventilation. Despite its availability for use and being medically accepted, proper calibration must be observed in measuring ventilator scalars such as inspiratory pressure, inspiratory flow, and tidal volume to promote the safe use of the OSV and prevent OSV users to do more harm to the patient. This study discusses different calibration techniques to properly acquire ventilator scalar measurements using an integrated ventilator scalar measurement module. All in all, different calibration setups and bag-valve-mask-based mechanisms were tested and documented to determine an effective means to acquire accurate and precise ventilator scalar measurements.

Keywords*— *open-source ventilators, bag-valve-mask ventilators, COVID-19 ventilator, ventilator scalar measurement

I. INTRODUCTION

An open-source ventilator is a disaster-situation ventilator developed using an open-source design, and, ideally, readily available parts and components to assist patients who are physically unable to breathe through mechanical ventilation or by moving breathable air into and out of the lungs [1]. This device is typically used as an alternative for hospitals and medical facilities that are experiencing shortage of clinical-grade ventilators. Examples of these devices are the E-Vent Project of MIT [2], the VentilAid by the polish company Urbicum [3], and the Ventilator Intervention Technology Accessible Locally (VITAL) by the National Aeronautics and Space Administration (NASA) [4]. All these devices are currently developed to aid the worldwide healthcare response against the Coronavirus Disease 2019 (COVID-19) pandemic [5].

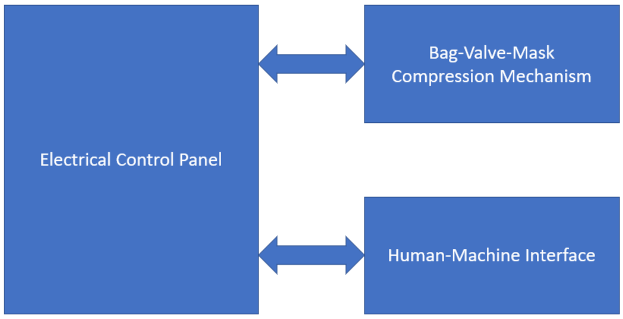

Figure 1. Bag-Valve-Mask Emergency Ventilator System

The open-source design is composed of several features to ensure the safety of the patient. This includes a way of measuring and controlling the volume pumped and the breath rate to avoid volutrauma or physical injury due to difference in body pressure [6], a monitoring for inspiratory pressure, respiratory rate (in beats per minute), and inspiratory-to-expiratory time (I/E) ratio [7], a method for humidification to avoid drying and cooling the alveoli [8], a mechanism that will assist non-sedated patients by increasing the inspiratory pressure whenever the patient inhales [9], and a support for fitting the positive end-expiratory pressure (PEEP) for patients with acute respiratory distress syndrome (ARDS) [10].

This study aims to discuss the calibration techniques used to properly acquire ventilator measurements. Section II will discuss the overview of the bag-valve-mask ventilator system the proponents are currently designing, specifically the integrated ventilator scalar measurement module. Section III will present the results of the different calibration techniques performed on various bag-valve-mask compression mechanism prototypes and conclusions will be drawn in Section IV.

2020 IEEE 12th International Conference on Humanoid, Nanotechnology, Information Technology, Communication and Control, Environment, and Management (HNICEM) | 978-1-6654-1971-0/20/$31.00 ©2020 IEEE | DOI: 10.1109/HNICEM51456.2020.9400118

II. BAG-VALVE-MASK EMERGENCY VENTILATOR SYSTEM

The bag-valve-mask emergency ventilator system developed by the proponents is composed of an electrical control panel, a human-machine interface, and a bag-valve-mask compression mechanism as presented in Figure 1. The electrical control panel manages the measurements and actuations of the emergency ventilator system. The human-machine interface allows the users of the emergency ventilator system to monitor the status of the device. The bag-valve-mask compression mechanism is responsible for the delivery of air necessary for mechanical ventilation.

Delving further into the bag-valve-mask compression mechanism, the integrated ventilator scalar measurement module is responsible for determining the values for the ventilator scalars needed for mechanical ventilation with respect to time such as the inspiratory pressure, inspiratory flow rate, and tidal volume [11]. The inspiratory pressure determines the amount of force exerted along the airway of the patient per given unit area. The tidal volume identifies the amount of air displaced within the lungs of the patient. The inspiratory flow rate determines the rate of change of the tidal volume with respect to time. Such measurements are necessary so that medical personnel will be able to accurately diagnose the breathing status of the patient.

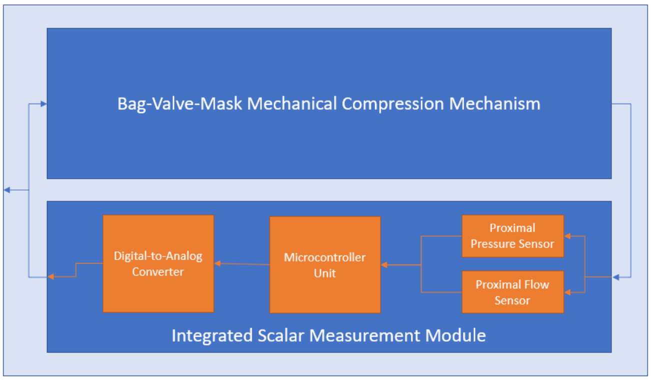

Figure 2. Composition of the Bag-Valve-Mask Compression Mechanism

As presented in Figure 2, the integrated scalar module consists of a microcontroller unit, a proximal pressure sensor, a proximal flow sensor, and digital-to-analog converter (DAC) units. The proximal pressure sensor is responsible for acquiring the inspiratory pressure measurement in kilopascals. The proximal flow sensor acquires the inspiratory flow rate measurement in standard litres per minute. The microcontroller unit is responsible for converting the acquired measurements from the sensors into medically known measuring units (centimetre H_2O for inspiratory pressure) and calculates the tidal volume from the flow rate measurements. The digital-to-analog converter converts the measurement signals that will be fed to a programmable logic controller in the electrical control panel for control of the mechanical compression mechanism. All in all, the integrated scalar measurement is considered as a part of the bag-valve-mask automated compression mechanism alongside with the bag-valve-mask mechanical compression mechanism.

III. RESULTS AND DISCUSSION

To test the effectiveness of the integrated scalar measurement module, our company has managed developed two prototypes for calibration, namely, the scotch-yoke compression mechanism [12] and the ball-screw compression mechanism [13].

A. Calibration and Testing using the Scotch-Yoke Compression Mechanism

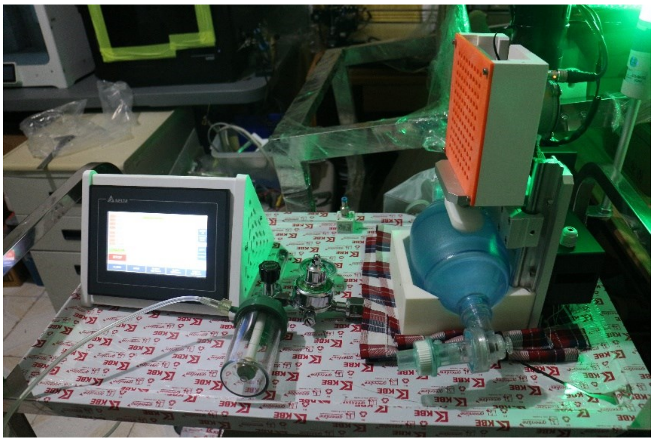

Figure 3. Scotch-Yoke Compression Mechanism Prototype

The scotch-yoke compression mechanism, as shown in Figure 3, utilizes a windshield wiper motor that is commonly available in local automotive shops. It uses the concept of linear oscillating motion to compress the bag valve mask resulting to mechanical ventilation. The scotch-yoke compression mechanism is being controlled by the programming logic controller located at the electrical control panel through the human-machine interface.

For the testing and calibration of the scotch-yoke compression mechanism, at least 120 trials were performed. For each trial, the depth of compression (set as either 7cm, 8cm, or 9cm) and the expected inspiratory pressure measurement (set as either 5, 10, 15, or 20 cmH2O) were varied. Trials are repeated for at least 10 times to acquire reliability from procured measurements. The depth of compression is measured from the homing plate of the scotch-yoke compression mechanism to the surface of the bag-valve mask.

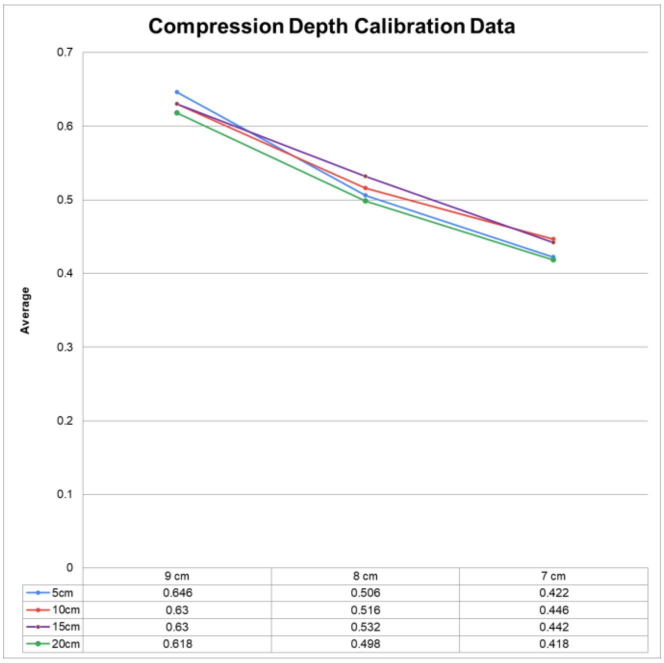

Figure 4. Compression Depth vs. Average Tidal Volume Measurement (Varying Pressures)

Figure 4 presents the summary of measurements of tidal volume (averaged for ten trials) at varying instances of pressure (in cmH2O). It is observed that the measurements vary at +/- 0.02 L or an estimate of 3-5% measurement variation. This variation has successfully met the guidelines presented by DOST (tidal volume measurement of 250mL-800mL with +/- 10% variation) [14]. Figures 5, 6, 7, 8 presents the compression depth vs. average tidal volume measurement at the instances of pressure at 5, 10, 15, and 20 cmH2O, respectively.

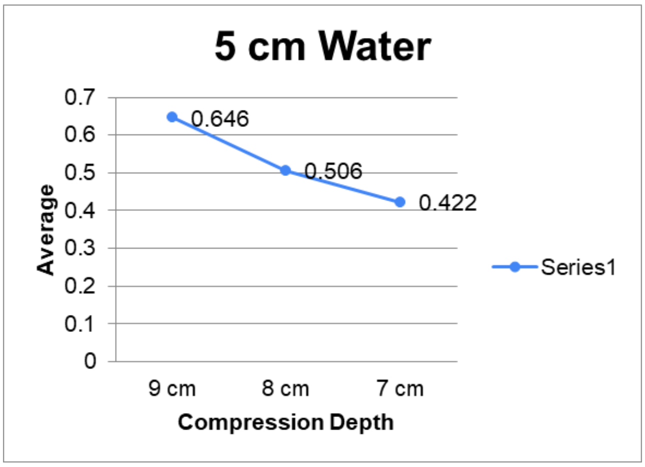

Figure 5. Compression Depth vs. Average Tidal Volume Measurement (at 5 cmH2O pressure)

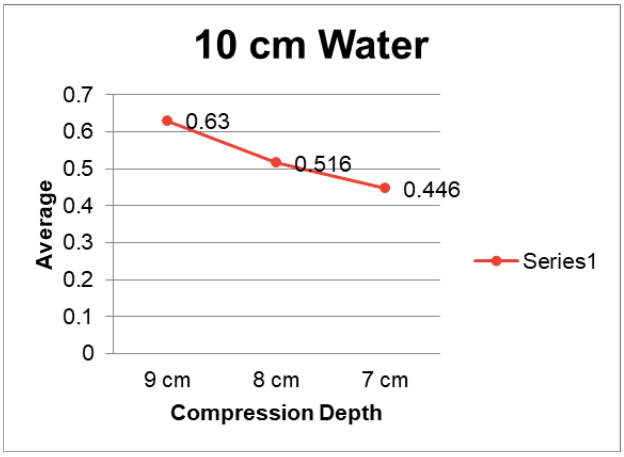

Figure 6. Compression Depth vs. Average Tidal Volume Measurement (at 10 cmH2O pressure)

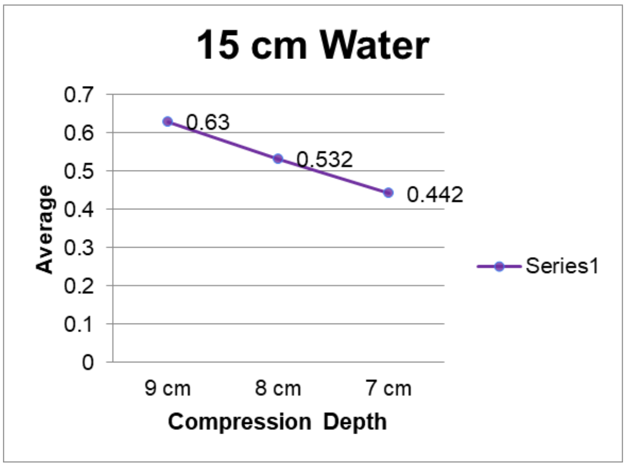

Figure 7. Compression Depth vs. Average Tidal Volume Measurement (at 15 cmH2O pressure)

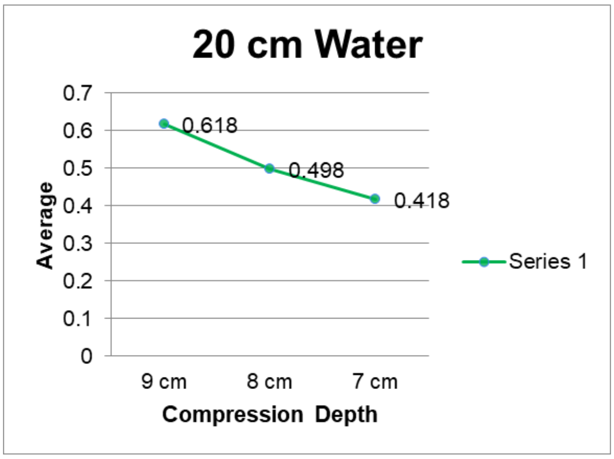

Figure 8. Compression Depth vs. Average Tidal Volume Measurement (at 20 cmH2O pressure)

B. Calibration and Testing using the Ball-Screw Compression Mechanism

Figure 9. Ball-Screw Compression Mechanism Prototype

The ball-screw compression mechanism, as shown in Figure 9, utilizes a hybrid stepper motor to compress the bag-valve mask resulting to mechanical ventilation. This mechanical design was considered by the proponents to address the drawbacks from the scotch-yoke mechanism. For the testing, tidal volume is measured at different depths of compression, ranging from 45 millimeters to 70 millimeters at increments of 5. For each instance of compression depth, the tidal volume is measured at least ten (10) times.

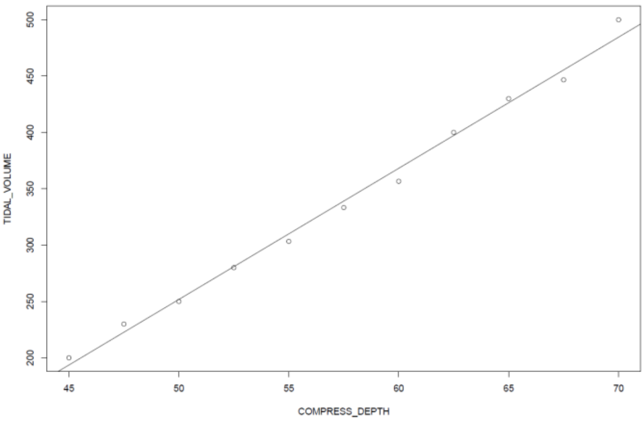

Figure 10. Compression Depth vs. Tidal Volume graph

Figure 10 presents the compression depth versus tidal volume graph based on the calibration of the ball-screw compression mechanism. Calculations have been made and it is observed that the tidal volume as a function of compression depth can be mathematically modelled using linear regression as presented in equation [1]. The tidal volume (V_{tidal}) is in milliliters while the compression depth (D_{comp}) is in centimeters. This means that the increase in tidal volume is proportional to the increase in the depth of compression.

$$V_{tidal} = \left(11.6364\ x\ \left(D_{comp}\right)\right) - 330\ [1]$$

Using equation [1] and the realization that at least 80 pulses is needed to reach a compression depth of 1 cm, one can calculate the number of pulses needed to achieve a given tidal volume as shown in equation [2].

$$D_{comp}\ (in\ pulses) = \frac{V_{tidal} + 330}{11.6364}\ x\ 80\ [2]$$

The following equations generated by the researchers will be implemented to the programming logic controller to improve control of the ventilator scalars.

IV. CONCLUSION

All in all, the proponents were able to calibrate and test the integrated scalar measurement module against two compression mechanism designs for open-source ventilators, namely the scotch-yoke mechanism and ball-screw mechanism. For the scotch-yoke mechanism, a 3-5% measurement variation was observed, and equations were generated to establish the relationship between the tidal volume and depth of compression using the ball-screw mechanism. For the future work, the proponents are exploring the implementation of fuzzy logic control [15] [16] and artificial intelligence [17] [18] to improve the calibration of the ventilator scalar measurements.

ACKNOWLEDGMENT

The authors would like to acknowledge Department of Science and Technology – Philippine Council for Industry, Energy, and Emerging Technology Research and Development (DOST-PCIEERD) for funding and helping us towards the development of a bag-valve-mask-based emergency ventilator system.

REFERENCES

[1] J. M. Pearce, “A review of open source ventilators for COVID-19 and future pandemics,” *F1000 Research 2020,* vol. 9, no. 218, 2020.

[2] MIT E-Vent, "MIT Emergency Ventilator (E-Vent) Project," MIT, 2020. [Online]. Available: https://e-vent.mit.edu/. [Accessed 27 April 2020].

[3] VentilAid, "Open-Source solutions to fight the Coronavirus pandemic," VentilAid, 2020. [Online]. Available: https://www.ventilaid.org/. [Accessed 27 April 2020].

[4] A. Good, "NASA Develops COVID-19 Prototype Ventilator in 37 Days," NASA, April 24 2020. [Online]. Available: https://www.nasa.gov/feature/jpl/nasa-develops-covid-19-prototype-ventilator-in-37-days. [Accessed April 27 2020].

[5] S. Tian, W. Hu, L. Niu, H. Liu, H. Xu and S.-Y. Xiao, "Pulmonary Pathology of Early-Phase 2019 Novel Coronavirus (COVID-19) Pneumonia in Two Patients With Lung Cancer," *Journal of Thoracic Oncology,* 2020.

[6] G. Ioannidis, G. Lazaridis, S. Baka, I. Mpoukovinas, V. Karavasilis, S. Lampaki, I. Kioumis, G. Pitsiou, A. Papaiwannou, A. Karavergou, N. Katsikogiannis, E. Sarika, K. Tsakiridis and I. Kora, "Barotrauma and pneumothorax," *Journal of Thoracic Disease,* vol. 7, no. Supplement 1, pp. S38-S43, 2015.

[7] Rice University, "Anatomy and Physiology," OpenTextbooks, 2020. [Online]. Available: https://opentextbc.ca/anatomyandphysiology/chapter/22-3-the-process-of-breathing/. [Accessed 27 April 2020].

[8] R. D. Restrepo and B. K. Walsh, "Humidification During Invasive and Noninvasive Mechanical Ventilation: 2012," *Respiratory Care,* vol. 57, no. 5, pp. 782-788, 2012.

[9] F. Manzano, E. Fernández-Mondéjar, M. Colmenero, M. E. Poyatos, R. Rivera, J. Machado, I. Catalán and A. Artigas, "Positive-end expiratory pressure reduces incidence of ventilator-associated pneumonia in nonhypoxemic patients," *Critical Care Medicine,* vol. 36, no. 8, pp. 2225-2231, 2008.

[10] F. J. d. A. Pfeilsticker and A. S. Neto, "'Lung-protective' ventilation in acute respiratory distress syndrome: still a challenge?," *Journal of Thoracic Disease,* vol. 9, no. 8, pp. 2238-2241, 2017.

[11] A. M. Dexter and K. Clark, "Ventilator Graphics: Scalars, Loops, & Secondary Measures," *Respiratory Care,* vol. 65, no. 6, pp. 739-759, 2020.

[12] P. Amrutesh, B. Sagar and B. Venu, "Solar Grass Cutter with Linear Blades by Using Scotch Yoke Mechanism," *International Journal of Engineering Research and Applications,* vol. 3, no. 9, pp. 10-21, 2014.

[13] Y. Liu, L. Xu and L. Zuo, "Design, Modeling, Lab, and Field Tests of a Mechanical-Motion-Rectifier-Based Energy Harvester Using a Ball-Screw Mechanism," *IEEE/ASME Transactions on Mechatronics,* vol. 22, no. 5, pp. 1933-1943, 2017.

[14] Medicines & Healthcare Products Regulatory Agency (MHRA), "Rapidly Manufactured Ventilator System (RMVS)," Medicines & Healthcare Products Regulatory Agency (MHRA), London, United Kingdom, 2020.

[15] R. Baldovino and E. Dadios, "Design and development of a fuzzy-PLC for an earthquake simulator/shake table," in *IEEE International Conference on Humanoid, Nanotechnology, Information Technology, Communication and Control, Environment, and Management (HNICEM)*, Puerto Princesa, Palawan, Philippines, 2014.

[16] E. Dadios and D. Williams, "Multiple fuzzy logic systems: a controller for the flexible-pole cart balancing problem," in *IEEE International Conference on Robotics and Automation*, Minneapolis, MN, USA, USA, 1996.

[17] L. Bartolome, A. Bandala, C. Llorente and E. Dadios, "Vehicle parking inventory system utilizing image recognition through artificial neural networks," in *IEEE Region 10 Conference (TENCON 2012)*, Cebu City, Philippines, 2012.

[18] R. Santiago, A. De Ocampo, A. Ubando, A. Bandala and E. Dadios, "Path planning for mobile robots using genetic algorithm and probabilistic roadmap," in *IEEE International Conference on Humanoid, Nanotechnology, Information Technology, Communication and Control, Environment, and Management*, Manila, Philippines, 2017.