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COVID-19 Ventilator:
A Variable Compression Model

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ABSTRACT

This study is focussed on the design and modelling of a low-cost ventilator design that can be developed using locally sourced materials in Nigeria. This is meant to aid in the country's fight against the current COVID-19 pandemic where there is a shortage of ventilators. The ventilator design in this research was based on a mechanical AMBU bag compression principle using the volume-control ventilation (VCV) mode, which will eliminate the need for manual compression, which can be tedious and uncontrolled. The design is powered by an electric motor with variable speed and tidal volume control. It also features an alarm that alerts medical personnel of unstable conditions in the system parameters. This prototype shows that the mechanical compression systems is a viable and more economical option that provides the essential features required in the standard existing technologies.

KEYWORDS

Bag Valve Mask (BVM), Compression, COVID-19, Pandemic, Respirator, Ventilator

1. INTRODUCTION

Clinical ventilators are intended to convey breaths to patients with breathing difficulty. These are equipment that should be present in every medical facility, however, due to the cost of obtaining standardised equipment, ventilators are usually not found in most facilities in developing countries (Jha, 2017). Furthermore, the high-resilience advanced pressure sensors and, pneumatic segments with multi-layered programming, add to the significant expense and mechanical or electrical risk of numerous advancements in the standardised ventilators. This, therefore, requires the presence of skilled personnel to operate.

There is increasing pressure on the Nigerian healthcare system which is grossly underinvested. Statistical data showed that approximately 20% of COVID affected patients requires hospitalisation with 7.5% requiring the need for intensive care according to the United Nations Development Program (UNDP) (Ferguson et al., 2020). Presently, there are only 330 ICU facilities in the country as well as five testing centres and treatment facilities for the pandemic as part of the Nigerian Centre for Disease Control (NCDC) measures to contain the infection. It is very obvious that these numbers are highly discouraging and cannot be feasible in meeting the need of the population of over 200 million. To make matters worse, most of these facilities are not even up to international standard. The impact of

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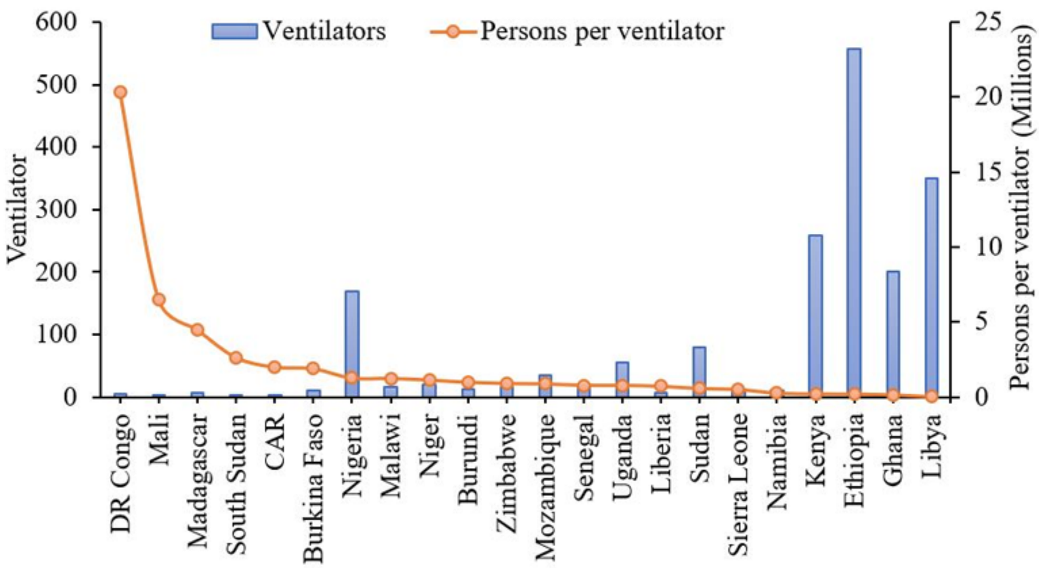
Figure 1. Statistics showing ventilator capacity of African countries (Ruth & Marks, 2020)



COVID-19 has also been significant in the older population than the younger population with the average mortality age being 79.

In the developed countries, where advanced clinical facilities are broadly accessible, the issue is of an alternate sort(Namatovu, & Semwanga, 2020). While there are enough ventilators for customary use, there is a need for readiness for instances of mass setback such as pandemics, catastrophic events etc (Netland, 2020). There have been several cases where health personnel were forced to resort to manual BVM ventilation when there were insufficient numbers of ventilators such as the Hurricane Katrina disaster. Currently, the coronavirus pandemic (COVID-19) keeps spreading all over the world at a rapid rate and most countries are having difficulty in curbing the pandemic spread (Mishra & Mishra, 2021; Mustafa, 2021; Das 2021; Sahoo 2021).

Countries with a large population in Africa such as Nigeria, South Africa etc have struggled to contain the virus and there is a high risk of large number of cases going by the extremely negligible amount of test which has been carried out. Needless to say, it is only logical that more people might be infected thereby putting significant strain on the medical infrastructures due to the lack of essential equipment necessary for combating this viral infection. Be that as it may, there is a requirement for an economical convenient ventilator for which production can be scaled upon request.

The figure above shows the ventilator capacities of some African countries in relation to the total population. The chart indicates an obvious lack of adequate ventilating capacity that will be required in case of an unprecedented increase in coronavirus infection rate which could be potentially deadly as a result of acute respiratory distress syndrome (ARDS).

The use of a low-cost ventilator with less functional capacity than the standardised unit is only peculiar to situations where the intended attributes are met, coupled with simplicity, accessibility and rapid manufacturability. One such case is in emergencies as is the case of COVID. Thankfully, recent developments in open-sourced technologies have made it easy to conveniently design and develop ventilator models which can easily be replicated in remote locations to counteract the shortage of ventilators. One problem with this, however, is that it is almost impossible to identify open-sourced designs that meet the clinical requirement. This paper, therefore, focuses on the deficit of existing design by implementing variable tidal volume control in the operation of these ventilators. Furthermore, the generic designs are power dependent which is not suited for use in remote locations where there is n electricity access. The solar panels installed therefore soles this issue while providing extended continuous use even at night by implementing batteries for energy storage. Technologies such as the fused filament fabrication in tabletop 3D printers can be comfortable used to replicate the design presented in this paper.

In this study, the first section presents an introduction to the problem as well as the motivation of this research. Section two focuses on the existing pieces of literature on the subject. Section three details the materials and method implemented in this study, design parameters and operating principle. Section four presents the design analysis and test results obtained from the prototype design. Finally, section five presents the conclusion as well as future works to improve the design output.

2. RELATED LITERATURE

Numerous design which meets the regulatory requirements have been developed. The three main modes of a ventilator are pressure regulated volume control, volume control where the tidal volume can be controlled with limiting pressure and the pressure-controlled mode ventilation mode. It is worth noting that the most rapidly developed and low-cost ventilators design as alternatives during the pandemic have been based on the modification of the AMBU bags via compression mechanisms (Tharion et al., 2020). This however does not favour volume control which is critical when it is being applied to an intubated patient. Furthermore, there are a variety of commercially available bags which may not fit the specifications of some low-cost ventilators or affect the output parameters significantly.

The mechanical ventilation cycle is typically composed of an inspiration phase where an exhalation valve stays closed to allow airflow to the patient lungs, subsequently cycling occurs during the period of change from inspiration to exhalation. After this, the exhalation valves are opened to allow the expiration of air from the patient lungs before the triggering phase occurs when there is a change from exhalation back to inspiration (Pearce, 2020). This cycle governs all form of ventilator control model however, in pressure-controlled systems, the flow is stopped once a target pressure value is met which is different from the volume-controlled systems where a predefined volume of air is delivered at each cycle

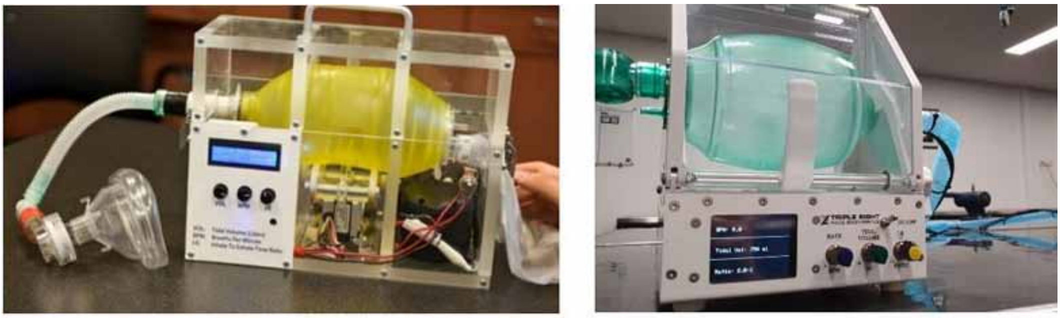
Far Frowar Life Support System ventilator unit had one hour run time battery power which incorporated physiologic sensors fitted in a standard backpack (Kerechanin et al., 2004). Similarly, Abdul Mohsen's design utilized a BVM compression mechanism which is a less complex exemplification of a volume-displacement ventilator. This design was further replicated by Husseini et al., (2010) in which a BVM is robotized precisely to develop a compact mechanical ventilator. Cam system was utilized in his design to create the ideal movement of the BVM. The fundamental distinction between both designs is the utilization of mechanical arms and servo engines rather than a cam system to incite the pressure of BVM.

Darwood et al., (2019) designed a compact positive pressure which autonomously checks the persistent condition and significant safety parameters, the model ventilator was developed and assessed utilizing an anaesthetic test-lung as a patient surrogate. It is a low-cost alternative ventilator that uses a novel pressure-sensing approach and control algorithm nonetheless requires further work in progressing the device for clinical trials.

Further research of various low-cost ventilators often utilized the standard ventilation bag mechanism of operation. The generated compressive action is usually generated through an electromechanical or pneumatic system usually controlled by microcontrollers such as Arduino. Another mechanism of operation involves the use of ventilation blowers whose operational performance varies substantially in terms of breath parameters and level of automation (Degner, et al., 2017).

From the aforementioned designs and due to the current demand for ventilators to help in combating the pandemic, the design of choice in this work is based on a variable compression system intended for rapid development and deployment.

Figure 2. Compression ventilator mechanism



(a)

The design concept introduced is based on the requirement of high mobility, compactness, low cost and ability to operate in remote environments. The system is designed to operate with minimal noise which is a better option compared with existing low-cost models while adhering to Electrical and clinical safety, Electromagnetic compatibility with minimal interference and susceptibility (ISO 80601-2-80:2018).

3. MATERIALS & METHOD

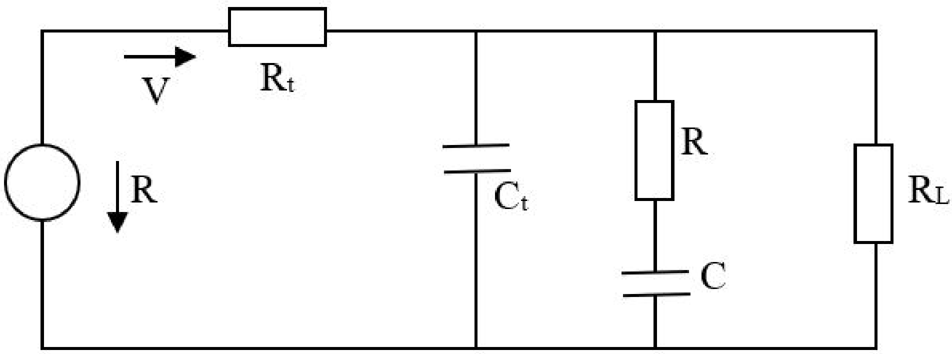
The mechanism of breath delivery works on the mechanical compression of the BVM bags which are easily deployable and disposable. In addition to their economical consideration as availability around the globe, these bags meet the basic needs of the standard ventilator systems. The BVM bags provides a source of feeding breathable air to patients through the use of a unidirectional valve upon compression which delivers a fixed, pre-determined Tidal Volume (V_T) irrespective of the pressure applied on the bag.

In the estimation of respiration parameters, factors such as patient's compliance and resistance are used to model the lungs. This modelling follows a standard approved methodology that was implemented in the work of Werner (Werner, 2014). The implementation follows an assumption that there is no system leakage i.e., R_l = ¥. The relation which then describes the airway pressure, lung resistance, flow rate and compliance is therefore given as

Figure 3. Blower mechanism (Ruth & Marks, 2020)

(b)

Figure 4. Standard model of the lungs



$$P = V.R + \frac{1}{C}\int V\left(t\right).dt$$

Where P, V, C and R represents the pressure, airflow, compliance and resistance consecutively. Given that there is now flow of air at the end of either the inspiration or expiration, the static lung compliance increases with an increase in the Tidal Volume (V_T) for any given applied pressure, given that lungs compliance is express as;

$$Compliance = \frac{\Delta V}{\Delta P}$$

Hence,

$$\text{Static Compliance} = \frac{VT}{Pplat - PEEP}$$

Where, $V_{T,}$ P_{plat} and PEEP are the tidal Volume, plateau pressure and positive end-expiratory pressure respectively. The figure below indicated the representation of the lungs given that the parameters R_t and C_t represent the tubes resistance and compliance.

The mechanical compression force in the proposed design is provided from several cams mounted on a DC motor shaft. This compression system is synchronised such that it mimics the ideal motion as will be applied by a nurse. The proposed cam system consists of varying sizes of cams to allow for variation in the compression volume of the bags.

This assembly is then mounted on a horizontal slider which can be used to select the desired volume of compression as required by the patient. The advantage of this mechanism is that the BVM bags are allowed to be fully expanded back to their initial state hence this can control the volume of fluid coming out of the valve for each cycle.

Similarly, the figure below shows the mechanism for tidal volume variation

The two geared motors were installed to control operating speed as well as the bag compression volume. This can be adjusted using the potentiometer knobs on the front panel. The screen provides a visual output of the ventilators operating parameters such as the breathing ratio, pressure, breath per minute etc.

Figure 5. Variable compression mechanism

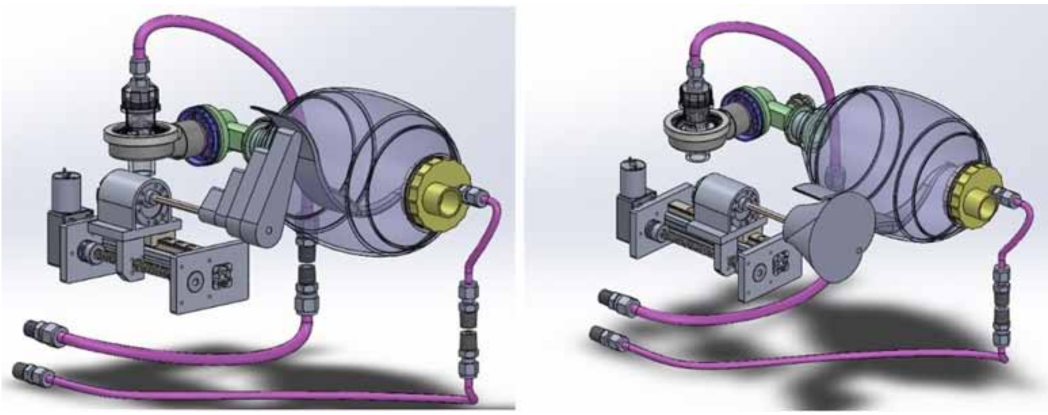


Figure 6. Cam volume variation mechanism

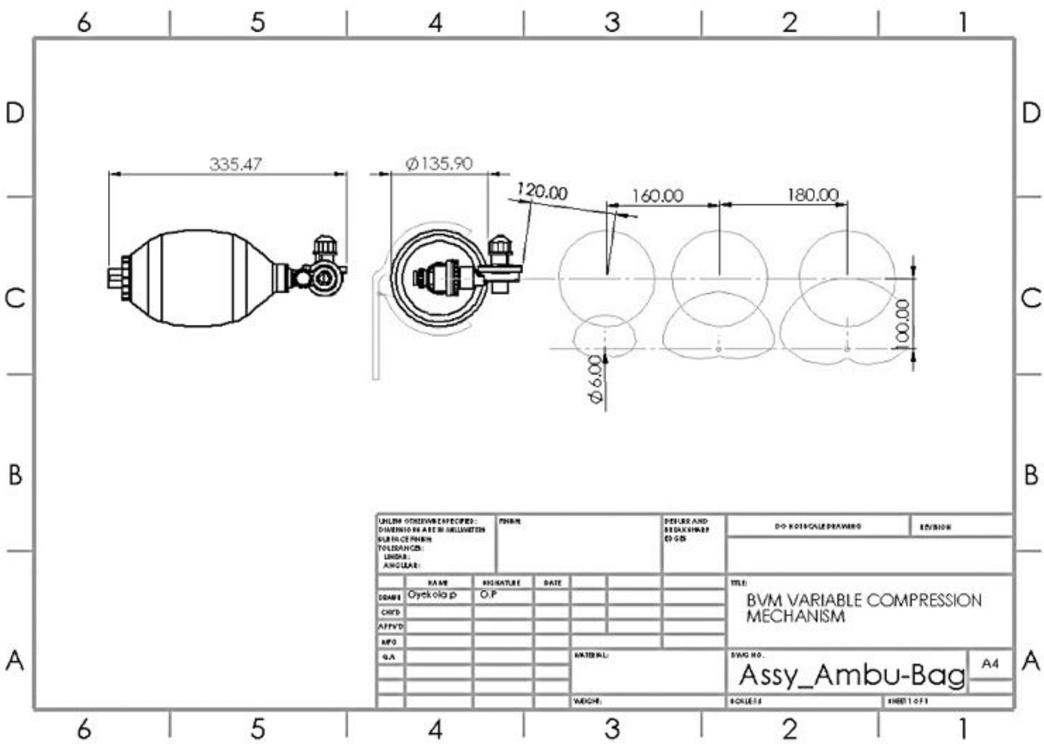


Figure 7. Final rendered assembly

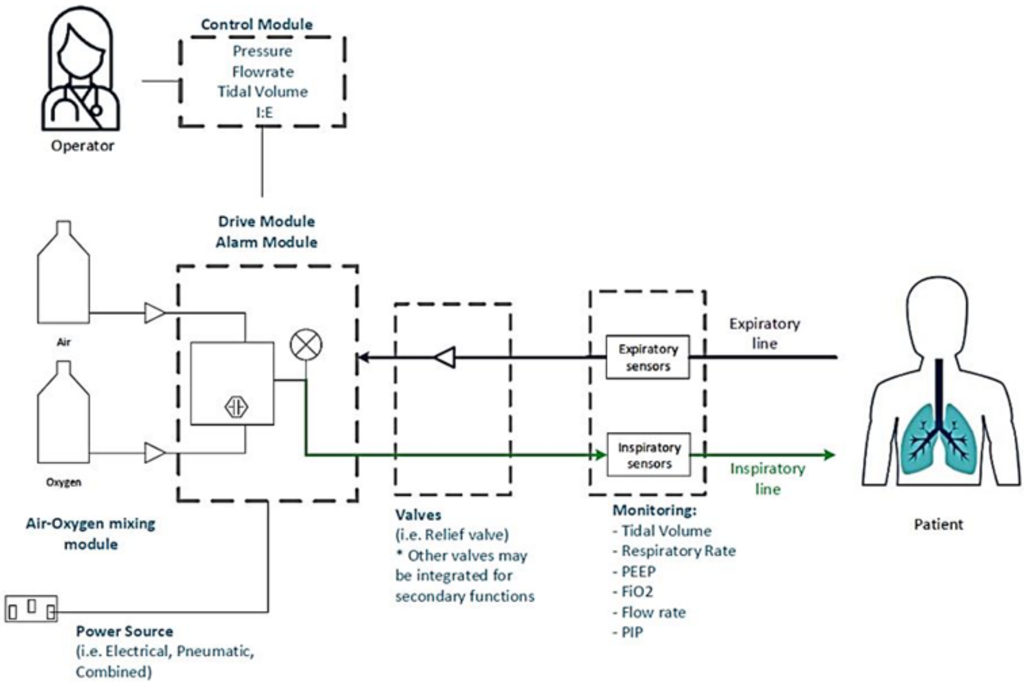
Additionally, due to the general instability of the electrical power supply in developing countries, this system is powered by the regular electric supply as well as a 12V solar panel mounted on the top of the assembly. This will provide an alternative power source for field use. The twin solar panel also serves as a compartment cover where the necessary ventilator accessories such as tubes, masks etc can be stored to allow for portability.

A pressure switch can be used to monitor the flow pressure required by the patient and can be varied between 10–45 cm H_2O using a control knob. Also, the expiration gas from the patient is released from an exhaust valve which is found on the disposable BVM. This significantly reduces the risk of contamination.

The ventilator out tubes which provides the required breathing assistance is connected to the patient through the use of an endotracheal tube placed in the patient's mouth or nose up to the windpipes. Other applications have seen the connections of the system to the patient through the use of surgically created holes in patients' neck where the tube supply breathing assistance. The ventilator is capable of providing the necessary PEEP pressure which will prevent the collapse of the air sacs by holding the lungs open. The final design was based on an inspiration pressure up to 40cm H_2O and an expiration pressure of up to 25cm H_2O, breathing rate of 6-40 Bpm, variable inspiration and expiration ratio, tidal volume of 200 to 750mL for adults, system humidity and temperature monitoring, FiO_2 from 21% to 100% in 10% increments; room air, 30, 40, 60 and 100%, connection with standard equipment such as oxygen connectors, mask and tubes etc (Fuchs et al., 2017).

The material specification for the proposed design is based on the utilisation of 3D printed plastic materials such as PLA or ABS. this will ensure rapid deployment in smaller units especially in countries where the possibility of machines for mass production will take time to set up. The use of acrylic clear plastic was also used for the compression chambers. This is a cheaper alternative when compared with the use of standard glass. It also removes the need for extreme handling as well as higher mobility due to reduced weight.

Figure 8. Standard ventilator architecture (XIMEDICA, 2020)



4. TESTING & VALIDATION

The prototype performance was evaluated using the benchtop approach to determine if the system meets the functional parameters obtainable in standard models. The volume rate is determined by the contacting angles of the cam with the compression plates using the inspiration time as well as tidal volume.

50 psi air source was used to test the ventilators. This was connected to the ventilator while pressure gauges were used to measure the pressure at the inlet and exit points of the ventilator. A flow sensor was also used to measure the flow rate in and out of the lung model used in the experiment.

The table below shows the ventilator parameter setting for two cases. The first case is the average setting with a lower tidal volume and frequency than the second. The output graphs in figure 9 and 10 indicate the airflow rate with time for both settings which assumes a similar pattern as the conventional ventilators.

Hence the prototype unique functionality which enables varying the cycle frequency and tidal volume during operation presents an advantage over other low-cost models as they can be applied to a wider range of conditions.

Machine durability and power storage system were also tested by running the prototype continuously. During daytime when the solar panels are charging the batteries, the system works perfectly without interruption. However, at the point when the system is operating on the backup battery alone, a seven-hour runtime was observed after which inconsistencies start setting in.

The experimental data showed that the prototype design complied and compares considerably with the MHRA regulations on rapidly manufactured ventilators which are applications for short term stabilisation only, more than one ventilation mode, percentage oxygen control, alarm system

Table 1. varying setting for administering invasive ventilation

VOLUME CONTROLLED VENTILATION	Normal	High
Set tidal volume, ml	400.00	500.00
Set frequency	10.00	12.00
Inspired oxygen, %	100.00	100.00
Set PEEP	10.00	10.00
Set peak inspiratory flow, lpm	60.00	60.00
Inspiratory pause duration, seconds	0.00	0.00
Observed tidal volume, ml	400.00	500.00
Observed minute ventilation, liters	4.00	6.00

Figure 9. Ventilator average parameter setting

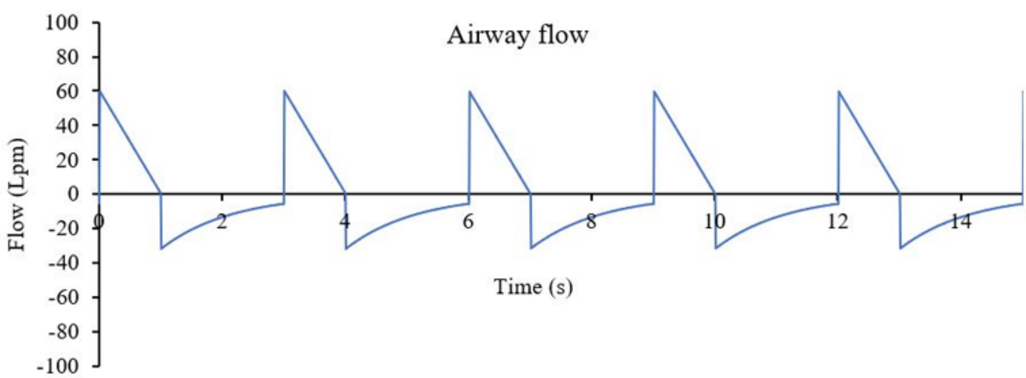
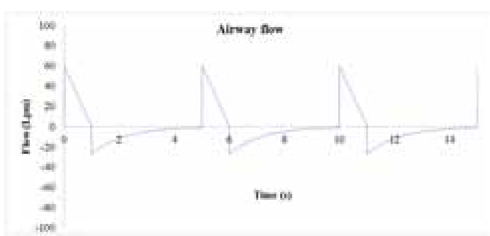


Figure 10. Ventilator setting with increased volume and frequency



in the case of power failure or shutdown while in operation, usability with less training requirement and finally, made from locally sourced materials.

5. CONCLUSION

From the requirement of ventilators capable of delivering oxygen to patients, the design presented in this paper is capable of delivering a variable tidal volume of oxygen supply as well as monitoring the pressure which triggers the alarm for unsafe conditions of use. Similarly, a manual override control mode is incorporated into the design which can be activated upon experiencing unexpected occurrence. This fail-safe system can be used to operate the device pending the unit replacement.

The design also shows that the simple mechanical approach is capable of providing robust and reliable assistance to help in the fight against the current pandemic. Additionally, the design offers a low cost and low maintenance system capable of rapid development and deployment for use as well as meet remote power requirements.

Efforts have to be made however to extend the operating time of the batteries when access to the solar source is limited. This could be achieved by selecting more efficient batteries or having duplicated backup which could be plugged in without affecting operation.

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