Design of a Low-Cost Ventilator to Support Breathing for Patients with Respiratory Failure Arising from COVID-19

Saad Mahmood Ali1,2, Mohammed Saad Mahmood3 and Noor Saad Mahmood1
1 Biomedical Engineering Department, University of Technology – Iraq
2 Corresponding author’s email: 30249@uotechnology.edu.iq
3 College of Medicine, University of Baghdad – Iraq

Abstract. In this work, two new, low cost, lightweight and simple pneumatic portable mechanical ventilator prototypes that offer minimal oxygen consumption were presented in support of treatment during the novel coronavirus (COVID-19) epidemic of 2020. The prototypes were implemented in ANSYS 18.0 and evaluated using Expert Systems 11.0 software. Both prototypes devices were found appropriate for all patients with difficulty breathing, which for patients with COVID-19, includes those with all severities of illness, recovery levels, and ages, no matter what the capacity of the patient’s respiratory system. To ensure the safety of the designed devices, the airway oxygen sensors, valves, and analysers were equipped with programmable alarms and other controllable safety attachments, including a modification to enable the delivery of nitric oxide (NO) for a specified therapy treatment recommended for respiratory failure. The overall prototype device capacity was obtained in terms of tidal volume/min. (TV), which was between 0.2 to 1.6 l/breath, suggesting that the device can be used treat patients of all ages, from children to adults. The prototype device has a range of 10 to 40 breaths/min. (bpm), and for normal spontaneous breathing, at an expiratory to inspiratory ratio E:I = 2:1, the designed prototype can produce a total tidal volume between 2.02 to 32.32 l/min. For patients with moderate breathing difficulties, i.e. with E:I ratios of 1:1, between 3.03 to 48.48 l/min. was estimated, with between 4.04 to 64.64 l/min. for those with high severity of breathing issues, i.e. those with higher E:I ratios above 2:1. The designed ventilator can also be used for most oxygen consumption durations as it uses any oxygen fraction (concentration) of inspired oxygen-enriched in gas (FIO2) at an efficiency at least 0.42% higher than previous similar and standard ventilator devices.

Keywords: Respiratory Failure; Coronavirus COVID-19; Portable Ventilator Prototype; Mechanical ANSYS; E:I ratio; Tidal Volume/breath; Total Tidal Volume/min

1. Introduction
Worldwide medical institutions predicted that cases of respiratory failure at the peak of the pandemic might exceed hospital capacity by 75 to 80%, even taking into account urgent measures applied to accelerate the provision of necessary supplies as COVID-19 spread, emphasising the need to expand and prepare hospitals rapidly. In particular, a shortage of oxygen intensive care units (ICU) and ventilators [1] was highlighted as an issue. The novel coronavirus, when presenting as a respiratory disease, produces similar lung injury-induced respiratory failure to avian flu (H5N1) and (H1N1), as well as asthma, chronic obstructive pulmonary and other chronic respiratory conditions. Such diseases are also widespread, and already constitute a major public health problem in countries across the world. Respiratory diseases and epidemics are exacerbated by air pollution, smoking, and the burning of biomass for fuel, as well as a variety of other lifestyle and environmental challenges [2-3], and patients with underlying lung and immune deficiencies...
may develop severe acute respiratory failure, especially the elderly and children. In a crisis situation such as the coronavirus epidemic, a major mismatch between supply and demand may thus occur, where many patients must be supported by mechanical ventilation [4]. Even with a maximum increase in resources, some countries have predicted being able to meet only a 30% admission rate, causing many patients to die from lack of ventilation [4-5].

In the event of a pandemic, healthcare systems experience an overwhelming influx of patients and hospitals also may not be able to receive patients efficiently or effectively provide both emergency and comprehensive care simultaneously; many major incident plans do not adequately address issues beyond earliest phases of hospital care. Where mass casualties emerge, the role of intensive care specialists must extend well beyond their ventilators and oxygen intensive care units (ICU), and additional non-intensive care personnel might be needed to provide basic intensive care. These principles became evident during the 2003 avian influenza epidemic in Beijing, China, where many trainees from unrelated specialties found themselves managing sealed ICUs while receiving clinical guidance from intensivists in another country by mobile phone [6].

The threat of mass casualties from a respiratory pandemic illness has resulted in several potential solutions, emerging, including ventilator stockpiling and improvements to triage that include the ability to support patients with acute respiratory distress syndrome (ARDS) [7-10]. The ICU admission rate for patients with ARDS, who may develop acute respiratory failure (ARF) caused by pneumocystis carinii pneumonia (PCP) and thus need mechanical ventilation, is high, with a duration of mechanical ventilation equal to or greater than five days; the development of nosocomial infections and pneumothorax are predictive of death within three months [11].

Mechanical ventilators are complex devices, and their high cost makes them impossible to stockpile effectively; a low-cost simple and efficient ventilator that assists patients with inspiration and exhalation is thus required, allowing the exchange of oxygen and carbon dioxide to occur in the lungs with additional support, as with artificial respiration [3]. The ventilators used in modern hospitals are functionally and technologically sophisticated, costing up to $30,000 each, rendering services dependent on such devices too expensive for use in most of the developing world, and even in parts of the developed world when a catastrophic epidemic occurs that requires above average usage. Additionally, these ventilators are often fragile and rendered vulnerable during continued use, leading to the imposition of costly service contracts by manufacturers. An urgent demand for ventilators has also been created due to the large number of people affected by SARS-CoV-2, which has exceeded the capacity of existing supply chains [12]. This has motivated the development of reliable, easy to operate, fail-safe mechanical ventilators that can be produced rapidly at large scale, based on models that have used the pressure of gases to ventilate the lungs of patients in the operating theatre [13].

To facilitate patient transport between and within hospitals, the use of portable ventilators has increased in the last two decades, especially for critically ill patients with respiratory dysfunctions of variable levels [14-15]. The safe transport of these patients requires the use of reliable advanced ventilators capable of supporting complex ventilatory needs [16-17]. Portable ventilators must also have other characteristics, in that they must be able to ventilate patients with both healthy or chronically or acutely injured lungs, be easy to operate and portable, be able to deliver a high fraction of inspired oxygen (FIO2), be able to operate with only an internal battery for a long period without compressed gasses, be able to provide both assisted and controlled ventilation, and incorporate alarms that identify catastrophic conditions [14].

Creative solutions to the ventilation problem may be required in a variety of desperate circumstances; an example of this occurred during the Copenhagen polio epidemic in the 1950s, when relays of medical students manually ventilated the lungs of patients with tracheostomies under the guidance of the head anaesthetist, Bjorn Ibsen [18]. A single pneumatic ventilator can also be used to support multiple patients in need [19-20], although such devices generate high oxygen consumption of 15 to 40 l/min, and thus may
be unsuitable where the oxygen supply poses a major problem as during a respiratory failure pandemic. This problem of limited oxygen supplies and demand surge has been an issue in several emergencies in the past, and the physiologist J. S. Haldane thus developed an oxygen delivery system that provided a high initial fraction (concentration) of inspired oxygen in inspired gas (FIO2) using mechanical ventilation from a modest fresh gas flow [21]. This is particularly useful as high doses of O2, besides being potentially harmful to patients, increase hospital costs due to the costs of O2 [22].

The main aim of this work was thus to design a new, low cost, simple, easy-to-build pneumatic portable mechanical ventilator prototype that facilitates minimum oxygen consumption to serve patients in mass casualty and resource-poor environment, inspired by the emergency timeframe of the COVID-19 epidemic in 2020. This was done using ANSYS 18.0 and the designs were evaluated using Expert Systems 11.0 software. Full factorial design (FFD) and response surface methodology (RSM) were used to study the effects of ventilator input parameters on the output performance parameters. The resulting device delivers air by compressing a self-inflating bag with an eccentric rotation disk cam, and it is thus also capable of delivering a fixed concentration of nitric oxide (NO) in the breathed gas. The prototype was designed for all cases of patients with difficulty breathing and thus sought to achieve standard requirements while ensuring safety for and the ability to treat patients of all ages. The prototype device thus needed to cover the full range of total tidal volume/min., and all E:I ratios seen in normal spontaneous breathing, moderate severity breathing difficulties, and high severity breathing difficulties, such as those seen in a minority of patients with COVID-19.

2. Pneumatic Ventilator Device Design

For the prototype device, a self-inflating bag squeezer of bag-valve-mask (BVM) type was used. The device components can thus be mass-produced at low cost during emergency conditions such as a pandemic situation, where the standard high cost conventional medical ventilation devices may not be available in sufficient quantity to handle the large numbers of patients. The device was also constructed to evaluate the test lung model and is capable of delivering nitric oxide (NO) in the breathed gas.

2.1. Design considerations

The main considerations for designing a portable mechanical ventilator, according to the ASTM F920-93 standard, can be separated into the following categories [23]:

1. **Medical**: user-specified breath/min, insp./exp ratio and tidal volume; assist control and positive end-expiratory pressure (PEEP); maximum pressure limiting, humidity exchange; infection control; and limited dead-space.
2. **Mechanical**: portable; standalone operation; robust mechanical, electrical, and software systems; readily sourced and repairable parts; minimal power requirements; and battery powered.
3. **Economic**: low-cost, currently <$400.
4. **User interface**: alarms for loss of power, loss of breathing circuit integrity, high airway pressure, and low battery life; settings and status displays; and standard connection ports.
5. **Repeatability**: indicators within 10% of correct readings and breath frequency accurate to one breath per minute.

2.2 Air Delivery Compression Mechanism

In this work, the ventilator breath delivery system works on the principle of discontinuous gas delivered by compression of a gas reservoir with an eccentric disc cam, reducing the need for expensive pneumatic components. The resulting portable volume-displacement ventilator can thus be operated with existing, inexpensive, technology. The gas reservoir is a bag-valve-mask (BVM), which costs approximately $10 and which is already frequently used in hospitals and ambulances. This is equipped with an air reservoir and a complete safety valve system. During long operations, it may suffer fatigue damage; however, the bag can
be easily replaced. To avoid any damage to a patient’s lungs by over-compression of the bag, especially during epidemics, where many untrained operators or volunteers may have to work the mechanical device, the proposed design adds basic functional safety protocols, as required by standard ventilators.

2.3. The First Prototype Design
The first portable mechanical ventilator prototype design was implemented during the Coronavirus epidemic (COVID-19), by application of ANSYS 18.0. It can be used for patients with complex breathing needs associated with multiple respiratory diseases. The device is actuated by compression of an Archimedes cam mechanism, which employs a discontinuous rolling contact along the surface of the bag to simulate the process of inspiration and expiration, as shown in figure 1. The device is inexpensive and consists of transparent or coloured thin Perspex polymeric sheet materials, which are easy to form, and manufacture, with a small multi-speed DC motor rotating at a rate of 10 to 40 RPM and between two and four one-way valves, along with one breathing solenoid valve and an oxygen source. This device can thus be easily produced using the 3D printing method or it may be put into mass production.

2.4. The Second Prototype Design
The second design of a lightweight and portable mechanical ventilator was presented as a modified version of the first prototype; this can be used to treat patients anywhere, whether in emergency situations, in institutions, and at home as shown in figure 2. It is actuated as a pneumatic mechanism by an eccentric compression cam disk that employs a rolling discontinuous compression contact along the surface of a single-use self-inflating bag valve mask (BVM), as shown in figure 3, all the required safety devices and valves needed of a ventilator are already contained within the BVM. This system can thus be incorporated readily into a mechanical bag squeezer ventilator. Self-inflating bags such as those produced by Intersurgical Ltd, Berkshire, UK, have safety pressure relief valves to prevent barotrauma to the lungs and to allow patients to take additional spontaneous breaths without impediment. The waste oxygen from the drive mechanism can also be deposited into the existing reservoir and provided at the inlet of the self-inflating bag.

The designed device contains an eccentric compression cam disk mounted on a hollow shaft connected to the main DC motor shaft. As the cam disk discontinuously rotates, it compresses and expands the bag to produce gas delivery with a smooth, low-noise, space-efficient mechanism with lower power requirements and repeatable deformation to ensure a constant air delivery. The air volume delivered can be controlled by adjusting the position of the BVM hollow shaft, which offers access to four eccentric pressure cam strokes spaces on the bag at 10, 20, 30, and 40 mm, as shown in figure 4. The fully annotated 2D designed drawings for this second portable mechanical ventilator respiration device are shown in figure 5: the dimensions for the device and its components were specifically selected to take up the least possible space and to utilise accessories, measuring devices, sensors, medical connections, standard mechanical components, and electric motors readily available in the markets and in health institutions’ own stores.

The assembly process should take place in self-sterilizing and ventilated areas that meet at least the sixth level criteria of the FDA Medical Device Manufacturing Instructions Guidance for Industry-2015. The assembly steps may differ according to the quantities produced, though in the case of an epidemic, given the limited time available, manual assembly may be preferred. The device can be assembled with two assembly lines, the first assembling the Oxygen Generator device (1 ft³/min), currently under development, and the second line assembling the ventilation device itself.

The second prototype, the inexpensive portable ventilator designed device, can be made completely from cheap plastic materials such as the polymerizing vinyl chloride (PVC), acrylic, or polyolefins (polyethylene, polypropylene, EVA), or from styrene derived polymers (PS, ABS, SB), reducing cost by allowing the use of injection or plastic blowing machines. It can also be produced from aluminium alloys using more advanced casting methods, with a coating layer against rust; the rotating parts can then be producing using
a CNC turning machine. It can also be produced from stainless steel 304L or 316L using TIG welding methods and a CNC turning machine. The modified respiration device can thus be produced in mass quantity. It can also be made manually from Perspex or coloured acrylic plastic sheets, which are easy to cut and paste. The device is equipped with a simple mechanical gearbox driven by a single O-ring, which controls the required number of breaths/min. in the absence of a variable speed DC motor.

Figure 1. The first portable mechanical ventilator prototype design, actuated by Archimedes cam mechanism compression

In both prototypes, all moving components are contained inside enclosure structures. The maximum motor torque required for rolling compression of the BVM is equal to 1.5 Nm [2], and for the prototype design, a programable closed-loop, servo 24V DC geared motor, with torque = 3.17 Kg.cm, type 42BYGH47-0806A, which allowed complete control of the device was selected, as shown in figure 6 (a). To control the expiratory to inspiratory E:I ratio, a 12V photoelectric optical sensor JL-205C&JL-200Z-14 was added, as shown in figure 6 (b), to mimic either normal spontaneous breathing, where the expiratory
time is about twice the inspiratory time (2:1), or the inverse ratio, 1:2, or even higher, which is typically used to ventilate non-compliant lungs as is the case of acute breathing difficulty in certain patients with coronavirus. In the event that a servo geared motor is not available, however a single-speed, 12V, 25RPM, DC type “Uxcell” worm gear motor (rated torque: 2kg-cm, (1.7lb-in) and net weight 145g), as shown in figure 6 (c), can be used with the mechanisms in the device, and this can still achieve the highest performance for all ages, levels of lung compliance, and causes of breathing difficulty, whether due to viruses such as Coronavirus or any other reason.
Figure 2. The first portable mechanical ventilator prototype design components actuated by compression of an eccentric compression disk

As shown in figure 5, a silicone rubber O-Ring (14) was put on the multi-diameter gearbox driver pulley (4), with diameters = 52, 75, 90, 102 and 112 mm and driven to a diameters = 70, 78, 90, 107 and 130 mm to determine the eccentric cam (3) speed, which represents the number of breaths/min.; five speeds can thus be obtained using the 25 RPM Gear Motor based on the following calculations: S1 = 25 RPM X 52/130 = 10 RPM; S2 = 25 RPM X 75/107 = 17.5 RPM; S3 = 25 RPM X 90/90 = 25 RPM; S4 = 25 RPM X 102/78 = 32.5 RPM; and S5 = 25 RPM X 112/70 = 40 RPM. These speeds were chosen to allow matching to the severity of the patient's breathing, age, size, and average air rate required. The air rate can also be controlled using a different size of flexible bag.

Figure 3. Single-use self-inflating bag with the required safety devices and valves

Self-inflating resuscitator bags that can be compressed with gas of 50 psi (345 kPa) are produced in six air capacities and mask sizes. For a standard adult, a 1.5 l. bag with a maximum mask size (no. 5) is recommended, while for a small adult, a 1.0 l. bag and with a maximum mask size no. 4 can be used. For paediatric use, a 0.550 ml. bag with mask size no. 1 or 3 can be used, while for infants, a 0.280 ml. bag with mask size no. 1. All these bags are equipped with a pressure relief valve for 40cm H2O, with the exception
of the adult 1.5L bag, which has a pressure relief valve of 60cm H2O. The size 5 mask is shown in figure 6 (d). Each BVM resuscitation kit, when fully assembled, uses the single-use bag’s robust construction to offer the reliability needed to withstand ongoing use, including a positive end-expiratory pressure (PEEP) valve adapter with a pressure manometer, seen in figure 6 (e), an adjustable PEEP valve 2.5-20cm H2O/M22, as shown in figure 6 (f), three meters of kink-resistant oxygen tubing, and a standard 15F/M22 connector that allows the attachment of alternative face masks and endotracheal tubes or supraglottic airways as required. The mask, with its supplementary oxygen connector, head strap, and one-way protection valve allows gases to pass from the rescuer to patient without any physical contact between the two filters; the BVM is also equipped with a one-way and safety overpressure valve from which extra oxygen can be returned to the air intake tube of the flexible bag [24].

Figure 5. Fully annotated 2D drawings of the second portable mechanical ventilator respiration device

1- Liquid oxygen cylinders; 2- Medical pump; 3- Nitric oxide and nitrogen cylinders; 4- Oxygen, NO and Air inlet oxygen flow regulator; Qty=3; 5- One-way oxygen and air check valve, Qty=4; 6- Oxygen and air stainless steel tank; 7- Structure; 8- Servo or single speed DC motor; 9- Eccentric disk; 10- Gearbox pulley (Qty =2); 11- Silicone flexible rubber bag or bag-valve-mask; 12- Support pad (Qty= 4); 13- Pulley shaft; 14- Silicone rubber O-ring; 15- Stainless steel bolts (Qty= 22); 16- Eccentric disk shaft; 17- Inlet air tube; 18- Outlet air tube; 19- Washer (Qty=2); 20- Bracket (Fixed), Qty =4; 21- Bracket (Adjustable), Qty =2; 22- Flexible bag shaft; 23- Transparent cover 24- One-way oxygen and air check valve V1 and V4; 25- Breathing monitoring oxygen flow meter; 26- Mechanical valve for inspiratory pressure; 27- Valve to prevent any negative pressure (V3); 28- MX300 Oxygen monitoring sensor with alarms (OS); 29- Sensor for Nitric Oxide Monitor (NO-S); 30- High pneumatic differential absolute pressure sensors (PS-1 to4); 31- Integrated solenoid pressure relief medical check three-way valve; 32 Oxygen filter; 33- Artificial test simulated lung; 34- Inspiratory Filter (RF); 35- Condensate trap (CT); 36- The mechanical PEEP valve V5; 37- Expiratory controls flow valve V6; 38- Expiratory pressure relief valve.

The ventilator is connected to three source lines to deliver pressurising (2 to 6 bar) medical oxygen, medical air, and nitric oxide (NO); these inlets have sintered filters, F1, 2, and 3, to remove any suspended particulate that may be harmful. The supply lines are then connected to a small oxygen and air stainless steel blender tank, with electro-static plastic jetting of type ET-8L and 8 L capacity, with a maximum pressure of 3 to 5 bar, as shown in figure 6 (g). A 50 psi four flow regulator model type RMI-08ST as shown in figure 6(h), can also be connected to the inlets for the oxygen and air stainless steel tank in order to set the FiO2 and NO fractions manually. The first of the three-air tank inlets specified is for the oxygen inlet source (from an oxygen cylinder such as aluminium 50 L liquid, 7,500 L gas, oxygen cylinders per ISO9809-1, at 150 bars, or from a central hall supply or from the oxygen generator (1 ft3/min) currently under construction.
The second inlet, for nitric oxide (NO), uses two 6061 aluminium 7.5 L liquid, 1,750 L gas, nitric oxide (NO), and nitrogen cylinders of type CGA870/ M60 at 150 bars. The third inlet is for compressed air, generated using the DC 12V air electric inflatable pump for medical equipment type HZ-120A, at 0.1MPa, 120W, and 125 L/min, as shown in figure 6 (i). The three inlets and the inlet and the outlet of the BVM are connected with one-way (non-return) oxygen and air check valves of 150 psi, type HK-LOK, as shown in figure 6 (j).
A flow meter of type ARHOR DFG-6T, made of high-performance OEM acrylic with a low flow rate gas-air rotameter oxygen flow meter, as used in anaesthesia machines, at 0.1 to 100 l/min., with a control valve as shown in figure 6 (k) is included. The airway is connected with an MX300 oxygen analyser sensor, used to continuously monitor the fraction of inspired oxygen (FiO2), as shown in figure 6 (l). A precision spirometer (SP) is also connected to monitor the inspiratory flow rate, with a silicone membrane filter (SMF) included for wet flow. The breathing system is connected to the tracheal tube with two plastic tubes of size 22mm that connect respectively to pressure valves V-1 and V-4, and to a mechanical valve to measure the inspiratory pressure (20 to 80 mm H2O, V2) and to the valve to prevent any negative pressure in the system (V3); a smaller plastic tube connects to the differential pressure sensors PS-1, PS-2, PS-3, and PS-4, to monitor the flow rate and pressure. The valve is controlled by the three-way solenoid valve PS-2. To remove condensed vapour from the patient's breath, the expiration tube passes through a condensate trap (CT). The PEEP valve, V5, is a mechanical valve that defines and controls the positive end-expiratory pressure in the range 5 to 20 cm H2O. To control the expiratory flow, the expiration valve V6 is used as a high throughput valve with low pressure-drop to guarantee flow corresponding to the expiration of a proper respiratory volume at the given PEEP values (normally open).

2.5. Safety Features

To ensure the safety performance of the designed device, and in particular to ensure that the patient cannot be injured by the device, the airway pressure is connected to a pressure regulation end-expiratory cycle, achieved by setting the desired minimum positive end-expiratory pressure (PEEP) valve to discharge the expiratory flow. Four pneumatic differential pressure sensors (DPS) of 0-10V 4-20mA (-100KPa-0-60MPa) are connected to this to monitor the pressure and flow at different points of the breathing system, as shown in figure 6 (m). This pressure sensor also assists control by triggering an alarm if the pressure level rises, alerting the physician to the patient’s needs. To ensure that the maximum pressure delivered does not exceed a pre-set value, an adjustable pressure limiting valve is connected to the inspiratory line, and further safety measure to prevent over-inflation include a mechanical pressure relief valve type, the MV008 oxygen plastic solenoid pressure relief medical check three-way valve at 2 kPa, as shown in figure 6 (n). During patient assisted ventilation, these check valves are used to avoid negative pressure. In this mode, the patient is active and can spontaneously request more air, yet as long as there is a positive pressure in the air respiratory lines, this valve remains closed. Prior to the valve, a bacterial and viral filter is installed to prevent any air contamination upstream.

In the proposed mechanical ventilation design, PEEP is used to prevent the collapse of distal alveoli and to promote the recruitment of collapsed alveoli, which have been seen in patients with COVID-19. PEEP
affords maintenance of the positive pressure (above atmospheric levels) at the airway opening at the end of expiration, which acts to distend the distal alveoli, assuming no airway obstruction. The optimisation of PEEP is a controversial topic involving the optimisation of oxygenation and minimisation of ventilator-induced lung injury (VILI), and it must thus be individualised for each patient’s situation. High PEEP is used for Acute Respiratory Distress Syndrome (ARDS) as part of an open lung approach to ventilation, while in spontaneous ventilation using non-invasive ventilation (NIV), continuous positive airway pressure (CPAP), in which the pressure applied is maintained throughout the respiratory cycle (during both inspiration and expiration) is used. Extrinsic PEEP is applied by placing the threshold resistor to flow minimally once the threshold pressure is reached in the expiratory limb of the ventilator circuit [25]. The mechanical MV008 Oxygen plastic solenoid pressure relief medical check three-way valve at 2kPa is used in this ventilator as a threshold resistor.

2.6. Prototype Device Interface
The vital signs monitor used is an MT-80 Medical portable capnograph patient oximeter CO2 monitor with a 12.1-inch high-resolution colour TFT LCD display, as shown in figure 6 (o). This displays figures for tidal volume, number of breaths per minute, controllable inspiration to expiration time ratio, and PEEP capabilities; it also features an assist-control mode and an alarm to indicate any over-pressurisation of the system. This monitor is used for measuring all six standard patient parameters, with options for electrocardiogram (ECG) and high blood pressure reflecting heart/pulse rate, two independent channels of temperature (T1 and T2) monitoring (2-TEMP), oximetry and non-invasive blood pressure (NIBP), continuous non-invasive monitoring of oxygen saturation (SpO2), respiratory rate in number of breaths per minute (RESP), pulse/heart-rate (PR/HR), and central monitoring system. It provides fast and reliable results for both adults and children, including babies. Its other features including real-time S-T segment analysis, pace-maker detection, simultaneous multi-lead ECG waveform channels, CO2 concentrations in breathing gases based on light absorption, two hours working capacity from the built-in rechargeable lithium battery, and alarm volumes of 45dBA to 85 dBA at a 1-metre distance (adjustable).

The speed of the servo motor is controlled using pulse width modulation (PWM). A CP-C24 analogue to digital to analogue 2.5 to 6V DC conversion type (C PCF8591 AD/DA) was used, as shown in figure 6 (p) to obtain analogue results with digital means. The user interface consists of four H-23-6A potentiometer input knobs for tidal volume, bpm, E:I ratio, and PWM, as shown in figure 6 (q). The device is designed as a fully gas-powered ventilator offering over six hours maximum operation without the need for additional oxygen cylinders or backup power. The power delivery to the ventilator device is a DC/AC 220V, 600W output solar generator power system type YB101-20Ah,5V/12V/19V DC, with a grade A polycrystalline solar panel offering 8 to 10 hrs. working time, as shown in figure 6 (r).

2.7. Modification of Nitric Oxide (NO) Delivery
The proposed device contains a modification facility to enable the delivery of nitric oxide (NO) for specified therapy treatments recommended for respiratory failure in an epidemic, although NO has not been shown to confer any mortality benefit in acute respiratory distress syndrome and in patients with acute lung injury [26-27], especially for adults [28]. Inhaled NO is, however, considered a promising therapy for severe lung disease due to its ability to provide selective pulmonary vasodilatation and improve ventilation-perfusion mismatch [29]; NO was used as an adjunct in the management of respiratory failure during the severe acute respiratory syndrome (SARS) epidemic in 2002 to 2003. A rescue trial in Beijing where NO was administered to patients with SARS during the epidemic showed promising results [6], suggesting that NO may inhibit the replication cycle of SARS coronavirus in vitro [30]. Accuracy and stability of NO doses were found at 5% or 3 nmol in the validated range of 3±1,000 nmol [31]. The NO delivery in the proposed device is intended to maintain a constant inspired nitric oxide concentration of 16 volumes per million (13.8 to 18 VPM) for tidal volumes of 500, 700, and 900 ml. [28].
Nitric oxide (NO) was blended with nitrogen (N2) instead of air using two 6061 Aluminium 7.5 L liquid, 1,750 L gas, Nitric oxide (NO) and Nitrogen cylinders type CGA870/ M60, at 150 bars. The NO (800 ppm in Nitrogen (N2) was mixed using a blender from Bird Products, Palm Springs, CA, and set at 50 lb/in2. The outlet of the blender was delivered to the high-pressure air inlet section of the designed ventilator. The Safety and Health Administration has set safety limits for NO2 at 5 ppm; however, airway reactivity and parenchymal lung injury have been reported with inhalation of as little as 2 ppm [32-33]. The rapid response NO Gas sensor analyser can thus be used as a ventilation monitor control with a range of between 0 to 300 ppm NO (Japan Figaro Sensor FECS41-250).

2.8. Total Tidal Volume/ Breath (VT)
A study was made of the effect of various ventilator input parameters, including different patients’ lung compliances such as E:I ratio, breath/min, and cam pressure stroke, on the output performance parameters, including tidal volume/ breath (VT), total tidal volume/min, and the delivered FIO2 oxygen consumption. The final results were obtained using the silicone artificial simulated test lung for children and adults with a capacity 0.2-1.5 L/breath, as shown in figure 6 (s).

| Table 1. Approximate bill of materials for one device |
|------------------------------------------------------|
| Item. No. Description of Part | Volume (cm³) | Weight (Kg) | Piece (USD) (PVC, Al Alloy, St. St.) | Piece (USD) (PVC) | Piece (USD) (Al Alloy) | Piece (USD) (St. St.) |
|------------------------------------------------------|
| 1- Device Structure | 1728 | 2.25, 4.67, 6.91 | 18 | 45 | 70 |
| 2- -Closed-loop, Servo 24V DC geared motor, torque = 3.17 Kg.cm, type 42BYGH47-0806A), or - Single speed 12V 25RPM DC type Uxcell worm gear motor (Rated Torque: 2kg-cm (1.7lb-in) - | - | 0.227 | 10 | 10 | 10 |
| 3- Eccentric Disk (hollow) | 300.6 | 0.39, 8.12, 1.20 | 4 | 8 | 12 |
| 4- Gearbox Pulley, Qty =2 | 392.5 | 0.51, 1.06, 0.30 | 5 | 10 | 30 |
| 5- A Silicone self-inflating bag-valve-mask (BVM) s type Intersurgical Ltd, Berkshire, UK, with accessories: - Pressure relief valve (40cm H2O), or (60cm H2O). - Positive end-expiratory pressure (PEEP) valve. - Pressure manometer and adjustable PEEP valve 2.5-20cm H2O/M22. - Three meters of kink-resistant inlet and outlet oxygen tubing. - Standard 15F/M22 - The mask with supplementary oxygen connector, head strap, one-way protection valve, and filter. - One-way and safety overpressure valve. | - | - | 10 | 10 | 10 |
| 6- Support Pad, Q= 4 | 256.8 | 0.33, 0.69, 1.98 | 3 | 6 | 8 |
| 7- Gearbox Pulley Hollow Shaft | 80.12 | 0.13, 0.25, 0.73 | 2 | 3 | 6 |
| 8- Silicone Rubber O-Ring | 12.3 | 0.016 | 2 | 2 | 2 |
|   | Description                                                                 | Quantity | Dimensions/Specifications |
|---|-----------------------------------------------------------------------------|----------|--------------------------|
| 9 | St. Steel Bolt (M8 and M6, L=35mm), Q= 22                                   |          |                          |
| 10| Eccentric Disk Hollow Shaft                                                 |          | 179.35 0.24, 0.49, 1.39  |
|   |                                                                             |          | 2.5 5 14                  |
| 11| Inlet air tube                                                             | 20.2     | 0.04, 0.06, 0.18          |
|   |                                                                             |          | 1 2 4                     |
| 12| Outlet air tube                                                            | 20.2     | 0.04, 0.06, 0.18          |
|   |                                                                             |          | 1 2 4                     |
| 13| Washer, Qty=2                                                              | 8.8      | 0.01, 0.03, 0.08          |
|   |                                                                             |          | 0.2 0.4 1                 |
| 14| Aluminium 50L. liquid, (7500 L gas), Oxygen cylinders ISO9809-1, 150 bar,  |          |                          |
|   | Qty=1, (Optional), (USD 80) or Oxygen Generator (1 ft3/ min), Under        |          |                          |
|   | Development.                                                                |          |                          |
| 15| 660L Aluminium 7.5L.liquid, (1750 L gas), Nitric oxide (NO) and Nitrogen   |          |                          |
|   | cylinders CGA870/ M6; 150 bar, Qty=2, (Optional). (USD 30 each)             |          |                          |
| 16| DC 12V air electric inflatable pump for medical equipment type HZ-120A,    |          |                          |
|   | 0.1MPa, 120W, 125L/min                                                     |          |                          |
| 17| Oxygen, NO, and Air inlet and one outlet,50 psi Oxygen Flow Regulator       |          |                          |
|   | Model RML-08ST, Qty=3, (2 optional).                                        |          |                          |
| 18| One-way (non-return) oxygen and air check valve, 150 psi, type HK-LOK,     | 0.10     | 5 5 5                     |
|   | Qty=4,(at the BVM inlet), (3 optional).                                    |          |                          |
| 19| Small oxygen and air carbon steel tank, finished by electro-static plastic |          |                          |
|   | jetting type ET-3L, 8Lit. capacity, max pressure (3.5 bar),                |          |                          |
| 20| One-way (non-return) oxygen and air check valve, 150 psi, type HK-LOK,     | 0.10     | 5 5 5                     |
|   | at the BVM outlet, Qty=1,                                                   |          |                          |
| 21| ARHOR DFG-6T high-performance OEM acrylic low flow rate gas air             |          |                          |
|   | rotameter oxygen flow meter for Anaesthesia Machine, 0.1-1, 0.2-2 ...100   |          |                          |
|   | l/min.                                                                      |          |                          |
| 22| Japan Figaro Quick response NO Gas Sensor for Nitric Oxide Monitor          |          |                          |
|   | Industrial Ventilation control 0 ~ 360 ppm FECS41-250                      |          |                          |
| 23| MX300 Oxygen monitoring and analyser with programmable alarms.             | 0.18     | 40 40 40                  |
| 24| Mechanical MV008 Oxygen plastic solenoid pressure relief medical check     |          |                          |
|   | three-way valve, 2Kpa (Option).                                            | 3 3 3     |                          |
| 25| 0-10V 4-20mA high pneumatic differential absolute atmospheric pressure      |          |                          |
|   | sensor transmitter transducer, -100KPa-0.60MPa for gauge pressure;          |          |                          |
|   | Absolute pressure; Negative pressure types.                                | 25 25 25  |                          |
| 26| Artificial for child and adult test simulated lung 0.5-3 L/berth size       |          |                          |
|   | Non-latex ventilator simulated test lung.                                  | 0.23     | 3 3 3                     |
| 27| Bracket (Fixed), Qty =4                                                     | 21.4     | 0.03, 0.06, 0.17          |
|   |                                                                             |          | 4 8 16                    |
| 28| Bracket (Adjustable), Qty =2                                               | 24       | 0.04, 0.07, 0.19          |
|   |                                                                             |          | 4 8 16                    |
| 29| Flexible Bag Hollow Shaft                                                  | 179.35   | 0.24, 0.49, 1.39          |
|   |                                                                             |          | 2.5 5 14                  |
| 30| Transparent Cover                                                           | 650.50   | 0.75 10 10                |
| 31| CP-C24 analogue to digital to analogue 2.5-6V DC conversion C PCF8591 AD-DA |          |                          |
|   | converter.                                                                  | 3 3 3     |                          |
| 32| H-23-6A user potentiometer inputs knobs (tidal volume, bpm, and I:E ratio),|          |                          |
|   | Qty=4).                                                                     | 6 6 6     |                          |
| 33| DC and AC 220V, 600W output solar generator power system type YB101        |          | 75 75 75                 |
During the lung test, the percentage of oxygen fraction in the delivered gas was measured using the MX300 oxygen analyser with programmable alarms. Its features include touch pad-controlled calibration, automatic diagnostics, a smart memory, and a connector to the air inlet of the device. To test NO delivery, the Japan Figaro quick response NO gas sensor for nitric oxide, with control ranging between 0 to 300 ppm FECS41-250, was used to simulate NO delivery, as shown in figure 6 (t). The approximate bill of materials for one device, based on a production run of 10,000 devices, is listed in table 1.

The tidal volume (VT), is the amount of air taken into the lungs in a single breath, and this is about 0.5 l/breath for the average adult. The lungs can hold a total vital capacity of about 4 to 6 litres, based on the maximum volume expelled after maximal inspiration during strenuous exercise. The total lung capacity (TLC) is the total volume of the lungs, including the vital capacity (the total usable volume of the lungs that can control) and that quantity of air that cannot be voluntarily exhaled, known as the residual volume (the volume remaining in the lungs after maximal expiration). The average total lung capacity volume is about 5.8 l in males and 4.3 l in females, being dependent upon weight, sex, age and activity. Males tend to have a 20 to 25% larger capacity than females, while shorter people have lower total lung capacities than tall people. The residual volume is usually 25% of the TLC [34]. The tidal volume (VT), for infants must be measured more accurately, as should be self-evident. An infant weighing 0.4 to 1.0 Kg requires a tidal volume in the range of 0.2 to 0.3 l/breath [35]. To calculate the tidal volume/breath for the E:I ratio 2:1 for the designed ventilator, the following equation was used, taking into account the associated calculations related to figure 4 above:

\[
\text{Tidal Volume / breath (Lit./breath)} = \frac{1}{3} \left( \frac{\text{Eccentric cam length} \times 1.1 \times \pi \times \text{Cam Pressure}}{\text{Thickness} \times \text{Average Cam Diameter} \times 0.75} \right)
\]

(1)

For the E:I ratio 1:1, as seen in cases of moderate breathing complexity, the tidal volume/breath can be calculated using the following equation:

\[
\text{Tidal Volume / breath (Lit./breath)} = \frac{1}{2} \left( \frac{\text{Eccentric cam length} \times 1.1 \times \pi \times \text{Cam Pressure}}{\text{Thickness} \times \text{Average Cam Diameter} \times 0.75} \right)
\]

(2)

For the E:I ratio 1:2, for patients with difficulty breathing and complex needs, such as those arising within the breathing process of some patients with COVID-19, the tidal volume/breath can be calculated using the following equation:
The total tidal volume/min for each selected parameter can be calculated using the following equation:

\[
\text{Tidal Volume/min (Lit./min.) = (Breath Per Minute (b / min) \times Tidal Volume / breath (Lit./breath))}
\]

(4)

3. Results and Discussion

The ventilator prototype was designed to suit all patients with difficulty breathing, being envisioned mainly for patients COVID-19, for all severity levels of disease, and all recovery, age, and respiratory capacity parameters. The input parameters include the expiratory to inspiratory E:I ratio, (2:1 for normal spontaneous breathing, with the expiratory time about twice as long as the inspiratory time; 1:1 for moderate severity; and the inverse 1:2 ratio or higher used to ventilate complex cases such as COVID-19 patients). The second input parameter is the number of breaths/min (equal to one of 10, 17.5, 25, 32.5 and 40 breath/min) The third input parameter is the cam pressure stroke (equal to 10 to 20 mm for children aged 0 to 12 years and adolescents (12 to 18 years), equal to 20 to 30 mm for young adults (19 to 25 years) and equal to 30 to 40 mm for adults aged over 26. The output performance parameters include the tidal volume/breath (VT) and the total tidal volume/min. To study the effect of the ventilator input parameters on the output performance parameters, a full factorial design (FFD), with response surface methodology (RSM) and Expert System-11 software were used.
Figure 7. Portable mechanical ventilator prototypes in solved mathematical models using the finite element method (FEM) and ANSYS 18.0.

The prototypes were designed in ANSYS 18.0, with mathematical models created using ANSYS FEM discretisation meshing for the device components, with 39,886 triangle elements with a minimum edge length of 0.125 mm, and 91,763 nodes. The initial boundary conditions, represented by a pressure of 75 psi (500 kPa) from the eccentric cam disk on the self-inflating bag, was set, with the positions of fixing supports being the eccentric cam disk and the self-inflating bag shaft brackets, as shown in figure 7 (a). The model was solved using the finite element method (FEM). Figures 7 (b and c) indicate that the maximum strain energy and the total deformation values derived were very low, at 0.027 mJ and 0.005 mm, respectively, offering evidence of smooth compression loading that will provide a longer life for the self-inflating bag.

Table 2. Analysis of variance (ANOVA) with an E:I ratio = 2:1 for tidal volume/breath values produced by the prototype

| Source                  | Sum of Squares | df  | Mean Square | F-value | p-value |
|-------------------------|----------------|-----|-------------|---------|---------|
| Model                   | 1343.68        | 9   | 149.30      | 78815.02| < 0.0001significant |
| A-Cam Pressure Stroke   | 46.53          | 1   | 46.53       | 24562.98| < 0.0001 |
| B-Breaths Per Minute    | 58.56          | 1   | 58.56       | 30913.51| < 0.0001 |
| AB                      | 116.13         | 1   | 116.13      | 61304.80| < 0.0001 |
| A²                      | 0.0000         | 1   | 0.0000      | 0.0000  | 1.0000  |
| B²                      | 0.1207         | 1   | 0.1207      | 63.73   | < 0.0001 |
| A²B                     | 0.0000         | 1   | 0.0000      | 0.0000  | 1.0000  |
| AB²                     | 0.0241         | 1   | 0.0241      | 12.75   | 0.0051  |
| A³                      | 0.0000         | 1   | 0.0000      | 0.0000  | 1.0000  |
| B³                      | 0.0810         | 1   | 0.0810      | 42.76   | < 0.0001 |
| Residual                | 0.0189         | 10  | 0.0019      |         |         |
| Cor Total               | 1343.70        | 19  |             |         |         |

Table 3. Analysis of variance (ANOVA) with E:I ratio = 1:1 for tidal volume/breath values produced by the prototype

| Source                      | Sum of Squares | df  | Mean Square | F-value | p-value |
|-----------------------------|----------------|-----|-------------|---------|---------|
| Model                       | 2943.71        | 9   | 327.08      | 427.29  | < 0.0001significant |
| A-Cam Pressure Stroke       | 90.26          | 1   | 90.26       | 117.91  | < 0.0001 |
| B-Breaths Per Minute        | 117.09         | 1   | 117.09      | 152.96  | < 0.0001 |
Table 4. Analysis of variance (ANOVA) with E:I ratio = 1:2 for tidal volume/breath values produced by the prototype

| Source               | Sum of Squares | df  | Mean Square | F-value | p-value  |
|----------------------|----------------|-----|-------------|---------|----------|
| Model                | 0.0580         | 9   | 0.0064      | 200.32  | <0.0001  significant |
| A-Cam Pressure Stroke| 0.0003         | 1   | 0.0003      | 8.68    | 0.0146   |
| B-Berth Per Minute   | 0.0003         | 1   | 0.0003      | 9.35    | 0.0121   |
| AB                   | 0.0056         | 1   | 0.0056      | 173.01  | <0.0001  |
| A²                   | 0.0034         | 1   | 0.0034      | 105.75  | <0.0001  |
| B²                   | 0.0032         | 1   | 0.0032      | 99.47   | <0.0001  |
| A²B                  | 0.0008         | 1   | 0.0008      | 25.71   | 0.0005   |
| AB²                  | 0.0009         | 1   | 0.0009      | 26.77   | 0.0004   |
| A³                   | 0.002          | 1   | 0.0002      | 7.61    | 0.0202   |
| B³                   | 0.0003         | 1   | 0.0003      | 10.23   | 0.0095   |
| Residual             | 0.0003         | 10  | 0.0000      |         |          |
| Cor Total            | 0.0583         | 19  |             |         |          |

Figures 7 (d and e) show that the maximum equivalent elastic strain and the von-Misses stress values reached 0.001 mm/mm and 3.20 MPa, respectively, while the obtained minimum safety factor was 5.92, indicating that the designed device is highly safe and durable, as shown in figure 7 (f).
To calculate the values tidal volume/breath for the E:I ratio 2:1 as produced by the prototype, the cubic transforms: quadratic design model was used. The model F-value of 78815.02 implies that the model is significant, while P-values less than 0.0500 indicate that the model terms are significant. The analysis of variance (ANOVA) for this is given in table 2. For the E:I ratio 1:1, the tidal volume/breath values were calculated using the cubic design model. The model F-value of 427.29 and the P-values less than 0.0500 imply that the model is significant. The analysis of variance (ANOVA) for this is given in table 3. For greater difficulty breathing, which requires the use of a ratio E:I of 1:2, the resulting values for tidal volume/breath were calculated using the inverse cubic design model. The model F-value of 200.32 and P-values less than 0.0500 indicate that the model is significant. The analysis of variance (ANOVA) for this is given in table 4. To calculate the values of the total tidal volume/min., for all E:I ratios, the inverse transform quadratic design model was used. The model F-value of 18.97 implies that the model is significant, while P-values less than 0.0500 indicate that the model terms are significant. The analysis of variance (ANOVA) for this is given in table 5. Table 6 thus gives details for setting input parameters manually or by means of programmable operation, as well as the calculated output results for the prototype device including the tidal volume/breath and the total tidal volume/min. for all age groups and severities of disease conditions, with a specific colour specified for each age group.

The 3D diagrams in figure 8 show the relationship between number of breath/min. and the cam pressure stroke based on the tidal volume/breath values for different E:I ratios produce by the ventilator. These diagrams show that the tidal volume/breath values increase with increases in the number of breath/min. and cam pressure stroke. Figure 8 (a) shows that for normal spontaneous breathing, when the expiratory time is about twice as long as the inspiratory time, at E:I=2:1, the designed prototype can produce tidal volume/breath of between 0.20 to 0.81 l/breath. This amount is suitable for males and females of all ages, assisting normal patient breath and allowing ventilation during surgical operations and with various health conditions. Figure 8 (b) shows that for patients with moderate severity breathing issues, such as those with coronavirus and similar diseases, i.e. at E:I=1:1, the designed prototype can produce tidal volume/breath of between 0.30 to 1.21 lit./breath.

Table 5. Analysis of variance (ANOVA) for all E:I ratios for tidal volume/breath produced by the prototype
| It. No. | Human Age                  | Breath Per Minute (b/min) | E:I Ratio | Cam Pressure Stroke (mm) | Tidal Volume/breath (Lit./breath) | Total Tidal Volume/ min. (Lit./min.) |
|--------|----------------------------|---------------------------|-----------|--------------------------|-----------------------------------|-------------------------------------|
| 1      | Child (0-12 years)         | 10.0                      |           |                          |                                   |                                     |
| 2      | Adult (26-up years)        | 10.0                      |           |                          |                                   |                                     |
| 3      | Adult (26-up years)        | 10.0                      |           |                          |                                   |                                     |
| 4      | Child (0-12 years)         | 10.0                      |           |                          |                                   |                                     |
| 5      | Adult (26-up years)        | 10.0                      |           |                          |                                   |                                     |
| 6      | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 7      | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 8      | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 9      | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 10     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 11     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 12     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 13     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 14     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 15     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 16     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 17     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 18     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 19     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 20     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 21     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 22     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 23     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 24     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 25     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 26     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 27     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 28     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
| 29     | Adolescence (12-18 years)  | 10.0                      |           |                          |                                   |                                     |
|   | 30 | 40.0 | 24.24 |
|---|----|------|-------|
|   | 31 | 10.0 | 9.09  |
| 32 | 32  | 17.5 | 15.91 |
| 33 | 33  | 25.0 | 22.78 |
| 34 | 34  | 32.5 | 29.54 |
| 35 | 35  | 40.0 | 36.36 |
|   | 36 | 10.0 | 12.12 |
| 37 | 37  | 17.5 | 21.21 |
| 38 | 38  | 25.0 | 30.30 |
| 39 | 39  | 32.5 | 39.39 |
| 40 | 40  | 40.0 | 48.48 |
|   | 41 | 10.0 | 4.04  |
| 42 | 42  | 17.5 | 7.07  |
| 43 | 43  | 25.0 | 10.10 |
| 44 | 44  | 32.5 | 13.13 |
| 45 | 45  | 40.0 | 16.16 |
|   | 46 | 10.0 | 8.08  |
| 47 | 47  | 17.5 | 14.14 |
| 48 | 48  | 25.0 | 20.20 |
| 49 | 49  | 32.5 | 26.26 |
| 50 | 50  | 40.0 | 32.32 |
|   | 51 | 10.0 | 12.12 |
| 52 | 52  | 17.5 | 21.21 |
| 53 | 53  | 25.0 | 30.30 |
| 54 | 54  | 32.5 | 39.39 |
| 55 | 55  | 40.0 | 48.48 |
|   | 56 | 10.0 | 16.16 |
| 57 | 57  | 17.5 | 28.28 |
| 58 | 58  | 25.0 | 40.40 |
| 59 | 59  | 32.5 | 52.52 |
Table 6. Input and calculated output results for the prototype

| Source            | Sum of Squares | df  | Mean Square | F-value | p-value | significant |
|-------------------|----------------|-----|-------------|---------|---------|-------------|
| Model             | 1.87           | 5   | 0.3742      | 18.97   | 0.0013  | significant |
| A-Cam Pressure Stroke | 1.45           | 1   | 1.45        | 73.43   | 0.0001  |             |
| B-E:I Ratio       | 0.3433         | 1   | 0.3433      | 17.41   | 0.0059  |             |
| AB                | 0.1259         | 1   | 0.1259      | 6.38    | 0.0449  |             |
| A²                | 0.0084         | 1   | 0.0084      | 0.4264  | 0.5379  |             |
| B²                | 0.0030         | 1   | 0.0030      | 0.1543  | 0.7081  |             |
| Residual          | 0.1183         | 6   | 0.0197      |         |         |             |
| Pure Error        | 0.0816         | 1   | 0.0816      |         |         |             |
| Cor Total         | 1.99           | 11  |             |         |         |             |

With certain conditions, patients of all ages need greater tidal volume/breath ratios to treat the accompanying respiratory disorders, with increases in inspiratory time at the expense of expiratory time until these are equalised. For higher severity breathing issues, such as seen in severe cases of coronavirus and breathing diseases, a higher E:I ratio of 2:1 is required, and the prototype can produce a tidal volume/breath of between 0.40 to 1.62 l/breath, as shown in figure 8 (c).

Figure 9 shows the 3D diagram for the relationship between the cam pressure stroke values and the different E:I ratios produced by the prototype based on total tidal volume/min values. This figure shows that the total tidal volume/min values increase with increases in the cam pressure stroke and decreases in the E:I ratio. For normal spontaneous breathing at E:I=2:1 for a 0.34 ratio, the designed total tidal volume/min values range between 2.02 and 32.32 l/min. For moderate breathing issues, at E:I=1:1 for a 0.5 ratio, the device can produce a total tidal volume/min of between 3.03 and 48.48 l/min. Between 4.04 and 64.64 l/min can be produced in the most severe cases showing an E:I=2:1 or 0.67 ratio.

The prototype device can supply between 10 to 40 breaths/min. (bpm) and 0.2 to 1.6 L tidal volume/breath. This yields a minimum assured ventilation volume (Ve) of 1.0 L/min and a maximum volume of 65 L/min. The operator can adjust this to match the patient’s required tidal volume, usually 6 to 8 mL/Kg of patient body weight [2], as well as adjusting the rate for the number of breath/min., and the inspiratory to expiratory time ratio I:E; this is done manually in the case of mechanical operation, where there is no available programmed step multi-speed motor, using three analogue knobs located on the outside of the ventilator.
As mentioned in the bench test protocol, the gas consumption is based on the duration of ventilator function with one full E-size oxygen cylinder (capacity 660 L), with the ventilator set to deliver a tidal volume (VT) of 1.0 L/breath at a respiratory rate (RR) of 10 breaths/min. and an FIO2 of 1.0. The battery life is the time the ventilator can function on a fully charged battery at these TV and RR values, but with an FIO2 of 0.21 [36]. In the proposed ventilation device, where oxygen may be scarce, in order to reduce the oxygen consumption, several fractions (concentration) of inspired oxygen-enriched in gas (FIO2) at augmentation ratios of 20, 40, 60, 80, or 100% can be adopted, with air collected and mixed in the tank before being transferred to the inlet of the self-inflating bag reservoir; this depends on the degree of complexity of the patient’s condition. Some patients require a higher FIO2 fraction. To control oxygen consumption, the pneumatic components can also be set to operate at a low gas pressure (2 bar).

The designed ventilator can be tested using aluminium 50L liquid, 7,500 L gas, oxygen cylinders of type ISO9809-1 at 150 bar; however, commercial packaging, for safety, generally adopts a packing pressure not exceeding 100 bar for a capacity 5,000 litres of oxygen gas. The duration time taken to exhaust the cylinder i.e. the oxygen consumption for each patient, based on lung compliance and total tidal volume/min for the designed ventilator when using the maximum (100%) oxygen fraction (concentration) of inspired oxygen-enriched in gas (FIO2) is between 2.6 and 41.3, 1.7 and 27.5, and 1.3 and 20.6 hrs. for the 2:1, 1:1, and 2:1 E:I ratios, respectively.

When using an ordinary (21%) oxygen fraction in gas (FIO2), the duration times are between 13 to 206.5, 8.5 to 137.5, and 6.5 to 103.0 hrs. for the relevant E:I ratios, respectively. As mentioned in the bench test protocol, the device can reach a duration time for gas consumption of 94 min., which is higher than that produced by Williams et al [1] by 41% and exceeds the standard device type Dräger Oxylog 1000 by 352%. Thomas et. al. (2013) evaluated four portable ventilators types, including the Impact EmV, CareFusion LTV 1200, Newport HT70, and Hamilton T1; they reported that gas consumption ranged from 9.2 to 16 lit/min., thus between 41 to 72 min [37], while Daniel et al [14] found that oxygen cylinder duration ranged from 30 min to 77 min, based on a study of 15 available transport ventilators with comparable physical characteristics.
Figure 8. 3D diagram of the relationship between breaths/min. and the cam pressure stroke with tidal volume/breath values for different E:I ratios produced by the prototype.
Figure 9. 3D diagram of the relationships between the cam pressure stroke and different E:I ratios produced by the prototype based on the total tidal volume/min values

4. Conclusions
Two inexpensive mechanical ventilator prototypes were designed during the COVID-19 epidemic using ANSYS 18.0. These were evaluated using Expert Systems 11.0 software. To study the effect of ventilator input parameters on output performance parameters, a full factorial design (FFD) and response surface methodology (RSM) were used. The main conclusions from this were as follows:

1. The designs offer a new, low cost, lightweight, and simple pneumatic a portable mechanical ventilator with minimum oxygen consumption, capable of delivering nitric oxide (NO) in the breathed gas, that can be mass-produced during emergency conditions such as pandemic situations.
2. The ventilator prototypes suit all cases of patients with difficulty breathing, with a focus on patients with COVID-19, and are thus suitable for all severity levels of the disease and patient variations.
3. The main design considerations, based on ASTM F920-93 standards, were achieved, including a complete safety system to avoid any damage to patients’ lungs, which had been an issue with standard ventilation during the peak of the epidemic.
4. To ensure the safety performance of the designed device, the airway pressure was connected with a high-pressure sensor, a mechanical pressure relief valve, an oxygen solenoid pressure relief medical check three-way valve, an oxygen analyser with programmable alarms, and other controllable safety attachments.
5. The designed ventilator had an overall capacity in tidal volume/ min. of between 0.2-1.5 L/breath.
6. The prototype device has a range of 10 to 40 breaths/min. (bpm) and 0.2 to 1.6 L tidal volume/breath.
7. For normal spontaneous breathing at E:I=2:1, the designed prototype can produce a total tidal volume/min of between 2.02 and 32.32 l/min. For moderate severity cases, i.e. those at E:I=1:1, a total tidal volume/min of between 3.03 and 48.48 l/min. was produced, while a tidal volume of between 4.04 and 64.64 l/min was created for high severity breathing issues, such as severe coronavirus cases and those with respiratory diseases.
8. The designed ventilator managed a duration time least 40% higher than all known similar designed or standard ventilator devices at all examined oxygen fractions (concentration) of inspired oxygen-enriched gas (FIO2).

5. References
[1] Williams D, Flory S, King R, Thornton M, and Dingleym J, 2010 A low oxygen consumption pneumatic ventilator for emergency construction during a respiratory failure pandemic, Anaesthesia, 65, 235–242.
[2] Abdul Mohsen A, Heon J L, Justin N, Stephen P, Amelia S, Alexander S and Jussi S, 2010 Design and Prototyping of a Low-cost Portable Mechanical Ventilator, Proceedings of the 2010 Design of Medical Devices Conference, DMD2010, 1-9.
[3] Chan-Yeung M, Ait-Khaled N, White N, Ip M S, Tan W C, 2004 The burden and impact of COPD in Asia and Africa, Int. J. Tuberc. Lung Dis., 8, (1), 2-14.
[4] Erwan L, H and Annie R, 2011 Bench Tests of Simple, Handy Ventilators for Pandemics: Performance, Autonomy, and Ergonomy, RESPIRATORY CARE, 56 NO 6., 751-760.
[5] Anderson T A, Hart G K and Kainer M A, 2003 Pandemic influenza – Implications for critical care resources in Australia and New Zealand, J Crit. Care, 18, (3), 173-180.
[6] Chen L, Liu P, Gao H, et al., 2004 Inhalation of nitric oxide in the treatment of severe acute respiratory syndrome: a rescue trial in Beijing, Clinical Infectious Diseases, 39, (153), 1–5.
[7] Richard D B, Thomas C B, Bryce R and Jay A J, 2012 Use of a Single Ventilator to Support 4 Patients: Laboratory Evaluation of a Limited Concept, Respiratory Care, 57, (NO 3), 399-403.
[8] Rubinson L, Branson R D, Pesick N and Talmor D, 2006 Positive pressure ventilation equipment for mass casualty respiratory failure, Biosecur Bioterror, 4, (2), 1-12.
[9] Daugherty E L, Branson R D, Rubinson L, 2007 Mass casualty respiratory failure, Curr Opin Crit Care, 13, (1), 51-56.
[10] Rubinson L, Hick J L, Curits J R, Branson R D, Burns S, Christian M D, 2008 Task Force for Mass Critical Care. Definitive care for the critically ill during a disaster: medical resources for surge capacity, Chest, 133, (5 Suppl), 32-50.
[11] Confaloni M, Calderini E, Terracciano S, Chidini G, Celeste E, Puccio G, Gregoretti C and Umberto G M, 2002 Noninvasive ventilation for treating acute respiratory failure in AIDS patients with pneumocystis carinii pneumonia, Intensive Care Med, 28, 1233–1238.
[12] Galbiati C, Abba A, Agnes P, Amaudruz P, Arba M and Ardellier-Desages F, 2020 Mechanical Ventilator Milano (MVM): A Novel Mechanical Ventilator Designed for Mass Production in Response to the COVID-19 Pandemic, arXiv:2003.10405v3, physics.med-ph, 10.
[13] Feldman S, 1995 The Manley ventilator, Anaesthesia, 50, 64-51.
[14] Keszl M, 2009 State of the art in conventional mechanical ventilation”, Journal of Perinatology, 29, 262–275.
[15] Austin P N, Campbell R S, Johannigman J A and Branson R D, 2002 Transport Ventilators”, Respir Care Clin N Am, 8, (1), 119-150.
[16] Nakamura T, Fujino Y, Mashimo T, Nishimura M, 2003 Intrahospital transport of critically ill patients using ventilator with patient triggering function, Chest, 123, (1), 159-164.
[17] Battisti A, Didier T, Janssen J P, Michotte J B, Jaber S and Jolliet P, 2005 Performance characteristics of 10 home mechanical ventilators in pressure-support mode: a comparative bench study, Chest, 127(5), 1784-1792.
[18] Lassen H, 1953 A preliminary report on the 1952 epidemic of polio, Lancet, 261, 37–41.
[19] Neyman G and Irvin C B, 2006 A single ventilator for multiple simulated patients to meet disaster surge, Academic Emergency Medicine, 13, 1246–1249.
[20] Paladino L, Silverberg M, Charchaflijh J G, et al., 2008 Increasing ventilator surge capacity in disasters: ventilation of four adult-human-sized sheep on a single ventilator with a modified circuit, Resuscitation, 77, 121–126.
[21] Goodman M, 2007 Suffer and Survive: The Extreme Life of J. S. Haldane, London: Simon and Schuster.
[22] Luana P, Cabral M G, Fabricio C D, Flavia P de Faria, Gislane F de Melo. and Gustavo de Azevedo C, 2013 Adequacy of oxygenation parameters in elderly patients undergoing mechanical ventilation, Einstein, 11, (4), 467-71.
[23] ASTM F920-93, 1999 Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use with Humans.
[24] Intersurgical Complete Respiratory System Ltd., 2000 Quality, Innovation and Choice in Respiratory Care, *Crane House*, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ, UK.

[25] Nickson C, 2020 Positive End-Expiratory Pressure (PEEP), https://litfl.com/positive-end-expiratory-pressure/.

[26] Adhikari N K, Burns K E, Friedrich J O, Granton J T, Cook D J and Meade M O, 2007 Effect of nitric oxide on oxygenation and mortality in acute lung injury: systematic review and meta-analysis, *British Medical Journal*, **334**, 779–86.

[27] Houghton I, 1981 The triservice anaesthetic apparatus", *Anaesthesia*, **36**, 1094–1108.

[28] YOUNG J D, 1994 A universal nitric oxide delivery system, *British Journal of Anaesthesia*, 73, 700–702.

[29] Calfee C S and Matthay M A, 2007 Nonventilatory treatments for acute lung injury and ARDS, *Chest*, **131**, 913–920.

[30] Akerstrom S, Mousavi-Jazi M, Klingstrom J, Leijon M, Lundkvist A and Mirazimi A, 2005 Nitric oxide inhibits the replication cycle of severe acute respiratory syndrome coronavirus, *Journal of Virology*, **79**, 1966–1969.

[31] Heinonen E, MerilaÈinen P and HoÈgman M, 2003 Administration of nitric oxide into open lung regions: delivery and monitoring, *British Journal of Anaesthesia*, **90** (3), 338-342.

[32] Masaji Nishimura M D, Robert M K and William E H, 1995 Nitrogen Dioxide Production during Mechanical Ventilation with Nitric Oxide in Adults, *Anesthesiology*, **82**, 1246-1254.

[33] Aït-Khaled N, Enarson D and Bousquet J, 2001 Chronic respiratory diseases in developing countries: the burden and strategies for prevention and management, *Bulletin of the World Health Organization*, **79**, (10).

[34] Daly M, Miller P R, Carr J J, Gayzik F S, Hoth J J, Meredith J W and Stitzel J D, 2008 Traumatic pulmonary pathology measured with computed tomography and a semiautomated analytic method, *Clinical Imaging*, 32, No. 5, 346–354.

[35] Keszler M and Durand D, 2001 High-frequency ventilation, *Clinics in Perinatology*, 28, (3), 579–607.

[36] Austin P N, Campbell R S, Johannigman J A and Branson R D, 2002 Transport ventilators, *Respir Care Clin N Am*, 8, (1), 119–150.

[37] Thomas C, Blakeman and Richard D B, 2013 Evaluation of 4 New Generation Portable Ventilators, *Respiratory Care*, 58, No 2, 264-272.