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Design and Development of an Emergency BVM-based Ventilator with 2D Look-up Table Control Algorithm

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Since the outbreak of Covid-19 in (2019), the number of people suffering from respiratory diseases has not only internationally increased sharply but also the situation for other patients altered severely; therefore, the demand for inexpensive, portable, and utile ventilation medical devices with a high production rate increased and this need must have been met apace especially in less developed and deprived areas. This fact accordingly concerned academics which led to numerous design concepts with different mechanisms. By hiring a multiple criteria decision-making procedure (TOPSIS); we were able to choose the mechanism which meets requirements of our preference criteria. A dual rack and pinion mechanism provided the possibility of mechanical Ambu-bag based ventilation at any specified rate, and a 2-D look-up table-based control algorithm was applied to this work-developed system which takes the advantage of DC motor's rotational encoder elimination. The calibration procedure and test results are also brought into detail.

Keywords: Portable ventilator, Mechanical ventilation, Bag Valve Mask (BVM), Medical hardware

1 Introduction

Chronic respiratory diseases like asthma and chronic obstructive pulmonary disease affect hundreds of people worldwide in both developed and less developed countries, and are the causes of about 4 million deaths annually[1].

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Air pollution, smoking, fossil fuel consumption, and other environmental factors which are facing an upward trend in developing countries make the condition worse for people suffering from these diseases. Researches show that four in five respiratory disease patients' deaths are in low- and middle-income societies, and the threat is on a growing trend[2]. The above condition has been significantly exacerbated by COVID-19 pandemic. Studies indicate that the novel virus being identified in September 2019 can cause a number of different complications for respiratory system. Furthermore, the acute respiratory distress syndrome (ARDS) caused by COVID-19 is the main proportion of reported morbidity and mortality[3].

World Health Organization (WHO) reported that the majority of people with COVID-19 would face an uncomplicated illness, but those with critical situation; most will require mechanical ventilation which can be defined as the action of moving gas toward and from the patients' lungs through an external device[4]. In a larger scale, Mechanical Ventilation is a vital action to take for patients with acute respiratory failure[5]. Obviously, there has been an urgent need for extra ventilators in hospitals and health centers due to the rapid spread of this virus all over the world[6]. Almost all of the hospitals' ventilators are fully developed and applied with high technological parts which not only make them extremely expensive, but also require a relatively long time of manufacturing[7]; therefore, the need for an inexpensive portable ventilator with possibility of high rate of production is paramount[5].

The conventional method of delivering a certain amount of air to lungs is based on the use of bag valve mask (BVM). Using BVMs is not only one of the simplest and cheapest methods of ventilation but also applied by first responders to patients who cannot breathe on their own[6]. Automating this procedure seems to be an achievable task, and it is not a new concept in mechanical ventilation[7].

One of the most famous emergency ventilators is E-Vent, which uses a gear mechanism in order to push BVM by two curved-shape fingers simultaneously. One DC motor is hired in order to provide motion. The aim of the control algorithm in this system is delivering a controlled volume of air to the lungs in specified time duration in both mandatory and assistive modes[8]. The base design of this ventilator is a work of another team in MIT University back in 2010, which designed a BVM-based ventilator used pivoting cam arms[7].

Another design is developed by RICE University using two rack and pinion mechanisms which are mounted on linear guides to squeeze BVM from both sides. This prototype uses two Arduino Uno, one for motors and the other for controls which is based on a master-slave controller system. The master controller is responsible for display management and user inputs and the slave controller is one that sends commands to the motors. This system has only one mandatory mode of operation and cannot be used for assistive ventilation[9]. Similar to E-Vent, this one is based on a previous work of Bioengineering Department of Rice University on 2019[10].

Using a hinged curved-shaped plate which is connected to a leadscrew mechanism in order to squeeze the BVM from one side is another method which has been hired collaboratively teams in Ireland and Canada. The advantage of this system is using two flow sensors for inlet and outlet and one pressure sensor which provide adequate information for control algorithm to adjust the motor actuation and follow the user inputs. This prototype uses a feedback control loop that runs the system through the cycles and supports both mandatory and assistive modes[11].Kshetry et al provide another mechanism using a single stepper motor to press Ambu bag from two sides. The mechanism of this prototype converts motor's rotation to linear motion compressing the Ambu bag. The control algorithm of this work is based on a feedback control loop which approximately determine the required parameters of motion by pressure variation during the cycle[12].

Another approach of one-sided BVM actuation is developed in Michigan Technological University. This device compresses the BVM from one side using 3D printable rack-pinion mechanism, and the other side is just blocked by BVM holder part. Unlike the previous ones,

this system actuation is based on a stepper motor and an Arduino Nano as the microcontroller. This prototype has only one mandatory mode of operation and assistive mode is in their future scope of work. The control strategy of the mandatory mode is relying on experimental tests, and the air volume pushed into the lungs is calculated by a linear equation of stepper motor position which is an open-loop control algorithm[13].
An alternative approach for BVM-based ventilator has been demonstrated by a team from Oxford University and King's College London. In this approach, called OxVent, the BVM is placed in a sealed plastic box and squeezed by compressed air passing through a number of solenoid valves as actuation mechanism[14]. With regards to this unique way of compression, electro-pneumatic components of this prototype seem to make it more expensive than the previous ones. Additionally, this system compression method provides the required pressure feedback for control system and eliminates the need for extra pressure sensor.
One another BVM-based ventilator called GlasVent with focus on using off-the-shelf components and materials in both mechanical and electrical sections. In GlasVent a crank mechanism is employed in order to convert stepper motor's circular motion into reciprocating motion, which compresses the BVM from both sides, and as an advantage, this mechanism allows operator to actuate the system by hand in case of power shortage by a manual handle. This system provides pressure support ventilation mode in addition to mandatory and assistive. However, they reported that pressure support mode in this prototype might not work properly in all conditions but they believe this will be fixed in their future works[15]. Another innovative design in this area uses a DC gear motor which compress the beg valve-mask by a single strap on a lightweight Plexiglas structure. The respiratory variables in this prototype are controlled using a single Arduino Mega microcontroller, and the pressure feedback input to its control algorithm is provided from a piezoresistive silicon pressure sensor. This device also measures gas flow by a differential pressure sensor to provide better controller results[16].
It can be seen through the previous works that BVM-based mechanical ventilation has not been fully developed yet, and their functionality in some cases are only limited to mandatory ventilation which cannot be hired for conscious patients. Each research team has carried out their design based on their accessibility to the mechanical and electrical systems. The main contribution of this work is that the design procedure of the ventilator went through a specific way to eliminate the need of encoder on DC motors' shafts relying on a 2D look-up table which needs to be calibrated once for each device before the beginning of service. This would greatly decrease the price and complexity of manufacturing, which in returns make it a suitable device for rural and deprived areas.
The following sections of this paper will completely discuss the mechanical design procedure and electrical circuits and software development of the prototype, in which different mechanical design models of emergency ventilators, is discussed completely with regards to a multi-criteria decision analysis method (TOPSIS). The next section is devoted to the calibration procedure and requirements, control algorithm and implementation. Finally, the last section will demonstrate prototype's basic functionality test, discuss the results, and talk about the future works.

2 Design and prototyping

The previous section described that emergency ventilators play a vital role in keeping patients alive and increase the chance of getting them back to life, so design and development of these devices should follow a set of special principles and constraints in order to pass the requirements and regulatory conditions.
In this way, the following set of parameters and specifications are considered for the design of a low-cost emergency BVM-based ventilator of this work.

2.1 Medical requirements

There are some medical variables which should be well defined. They include Respiratory Rate (RR) – (Breaths per minute), Tidal Volume (TV) – (air volume pushed into lungs), I/E Ratio (inspiratory/expiration time ratio), Working mode (Assist or Mandatory), Maximum allowable pressure (This parameter is adjustable on BVM's passive blow off valve) and Positive end-expiratory pressure (PEEP) – (The positive pressure that will remain in the airways at the end of the respiratory cycle (end of exhalation)).

- RR : 6-40 (adjustable) [8]
- TV : 8-10 mL/kg (adjustable) [17]
- I/E Ratio : 1:1 – 1:4 (adjustable) [8]
- Assist control mode needs to be developed based on trigger sensitivity, especially when patients try to inspire on their own, in order to avoid excess of air pressure in their lungs.[18]
- Maximum allowable pressure should be 40 cm H2O. [8]
- PEEP: It should be between 5-15 cm H_2O,while many patients need 10-15 cm H_2O. [17]

In addition to the mentioned medical requirements, the following mechanical and functional requirements are set as design specifications to provide a reliable and user-friendly ventilation system.

2.2 Mechanical requirements

The mechanical requirement for ventilation system can be addressed as follows:

- Portable and Standalone operation.
- Robust mechanical, electrical and software systems.
- Design and development based on standard available mechanical parts in order to avoid costs of manufacturing, in addition to ease the procedure of development and maintenance.

2.3 Functional requirements

In addition to mechanical and medical requirements, there are requirements which are related to the functionality of ventilation system. They can be discussed as follows:

- User-friendly interface.
- Display of settings, pressure feedback and status.
- Alarms for all unusual situations through system operation.
- Repeatability and accurate working routine.

In the previous section it was mentioned that one of the main aim of this design is to manufacture an emergency ventilator which has a low price in addition to the possibility of mass production, but it is O that designers find multiple approaches for a set of required specifications, but one of the most complicated and time-consuming tasks for a designer is the selection of the most suitable design that meets all the needs of the defined task between a numbers of alternatives, since it is generally seen to be a multi-criterion decision-making (MCDM) problem. In order to ease this procedure in this research, the TOPSIS method which is a widely used MCDM technique due to its simplicity is employed[19].

With regards to the previous works, the concept designs for the BVM-based emergency ventilators can be divided into three groups of rotational actuation, linear actuation, and one-sided actuation, so indeed there are three alternatives for TOPSIS method. In order to choose the most suitable option base on the design requirements, criteria for design mechanisms are considered as follow:

- Design and Manufacturing: evaluate the feasibility of the design in order to ease manufacturing process and assembly procedure in case of emergency.

- Control Methodology: consider the method of system control after development in order to provide the most suitable required functionality.
- Performance and Functionality: As it was mentioned in design requirements, there are a number of medical requirements which should be addressed by the final product. This criterion would evaluate the design based on medical requirements.
- Total Price: As the main goal of this project is to design and develop a low-cost BVM-base emergency ventilator, this criterion will evaluate the total price of the device.

It should be mentioned that a higher value to all above criteria except "Performance and Functionality" has a negative impact on the final ranking. Furthermore, the value of each alternative in different criterion is given by a number of experts based on their experience in each field. In the Table (1), there is the evaluation matrix of TOPSIS method which contains alternatives, criterion, criterion's weight, and alternatives value in each criterion. The value of each alternative in a criterion is between 1 (weak) and 9 (strong).

In order to clarify weights and grades, in the following section all alternatives are shortly reviewed.

- Design and Manufacturing: Each alternative design can be divided into three sections of body, power transmission, and actuator. All bodies in these designs can be produced using acrylic laser cuts and all designs are the same in this section, but in power transmission section each criterion need a different method of production. The power transmission of Rotational and One-sided Actuation requires parts that need to be produced in different machining process, while linear actuation mechanism can be assembled using only standard parts, which is a beneficial point for this design. The most accessible actuators for these mechanisms are DC motors and due to the ease of use and wide range of production it cannot be replaced by any other devices. Rotational and One-side actuation only require a single high torque and speed DC motor in order to fulfill the breath cycle speed and air volume, but the other one requires two DC motors with half the output power of the first two alternatives' DC motors.
- Control Methodology: Emergency ventilators need to provide a number of critical features based on the patients' requirements. The most important items to control in a basic emergency ventilator are Tidal Volume, Breaths per Minute (BPM), I/E ratio. As these systems need to be provided in a reasonable price, using a high torque and speed DC servo motor might not meet the cost limit of the project. DC motors with encoders are the most suitable options for these designs. It is worth mentioning that rotational actuation needs a more precise control algorithm than the others. The fingers of these designs multiply the final error of power transmission system which might be destructive in some cases.
- Performance and Functionality: While considering that there are some prototypes of the first two alternative around the world which have undertaken a number of tests in order to clarify the functionality of the devices and it seems that accurate design will lead to a fully functional emergency ventilator, the third one seems to face problems in high respiratory rates due to the speed requirements.

Table 1 Weights and grades of mechanisms in different aspects

	Design and manufacturing	Control methodology	Performance and functionality	Total price
Weight	0.25	0.10	0.4	0.35
Rotational actuation	5	4	9	5
Linear actuation	3	6	9	4
One-sided actuation	7	5	7	7

As it was discussed, Table (1) is filled based on different experts' experience and in their point of view the latter cannot meet all the requirements.

- Total Price: The manufacturing process costs are the largest proportion of total price. In this regard and based on the previous criteria, linear actuation uses of only standard parts and therefore has lowest price of manufacturing, although it requires two DC motors.
- The Table (2) is the final results of the TOPSIS method is called weighted normed matrix [19].
- In order to drive TOPSIS formulation, the normed matrix shall be defined based on Table 1 which is decision matrix of TOPSIS. In this paper only "Performance and Functionality" criterion is defined as benefit and the others are defined as cost.

The normed matrix is derived as the Eq. (1).

$$n_{ij} = \begin{cases} \dfrac{x_{ij} - minx_{ij}}{\sqrt{\sum_{i=1}^{m} x_{ij}^2}} \; if\ criterion\ is\ benefit \\ \dfrac{maxx_{ij} - x_{ij}}{\sqrt{\sum_{i=1}^{m} x_{ij}^2}} \; if\ criterion\ is\ cost \end{cases} \tag{1}$$

At this point, the weighted normalized decision matrix is derived by multiplying the normed matrix and each criterion weight as it was in Table 1. The fourth step in this calculation is determination of the worst and best alternatives by choosing the maximum and minimum cells in weighted normalized decision matrix at each column. Then the L^2-distance between the target alternative "i" and the worst and best condition is based on Eq. (2).

$$d_{iw} = \sqrt{\sum_{j=1}^{n} (t_{ij} - t_{wj})^2}\,, i = 1,2,3$$

$$d_{ib} = \sqrt{\sum_{j=1}^{n} (t_{ij} - t_{bj})^2}\,, i = 1,2,3 \tag{2}$$

The last step before ranking the alternatives is calculation the similarity to the worst condition. The formula is derived by Eq. (3).

$$s_{iw} = {d_{iw}}/{(d_{iw} + d_{ib})} \tag{3}$$

After derivation of previous formula, the TOPSIS method will provide a value for each alternative which the highest is dedicated to most suitable one. Table 2 values are weighted normed matrix of TOPSIS method and the Ideal and Worst alternative in each criterion. Calculation of L^2-distance between target alternatives and the worst and best condition is neglected and last column of this table shows the ranking between different alternatives.

Table 2 Final results of TOPSIS method and ranking

	Design and manufacturing	Control methodology	Performance and functionality	Total price	Final rank
Rotational actuation	0.1118	0.0894	0.1069	0.1941	2
Linear actuation	0.2236	0	0.3207	0.2912	1
One-sided actuation	0	0447	0.2138	0	3
Ideal	0.2236	0.0894	0.3207	0.2912	-
Worst	0	0	0.1069	0	-

The TOPSIS method indicates that linear actuation is the closest design method to the ideal alternative based on the input values and weights. As it was mentioned in previous sections, the inputs of this method are completely based on experience, and it might provide different results under different circumstances.

2.4 Design procedure

In the following section the mechanical design of the system is introduced in details.

2.4.1 Mechanical design

The emergency ventilator design as it can be seen in Figure (1) is consisted of two identical mechanisms being set in front of each other, and work simultaneously. In each part, rotation of the DC motor is converted to linear motion using a rack and pinion mechanism where rack is located on a linear guide wagon. A segment cylinder Teflon is connected to the end of linear mechanism in order to squeeze the Ambu bag. Additionally, each side of mechanism has two mechanical micro limit switches to avoid providing feedback for control system and any out-of-range motion. Obviously, except the acrylic plates that need to be cut by laser based on required sketches, the rest of items are standard available parts.

Figure 1 Two identical actuator sets connected to the structure (3D Model and Real One) and the final ventilator

DC motors' procurement needs required power and speed to satisfy the medical design goal of the system. MIT has calculated the required power by a single DC motor in order to compress an Ambu Bag. This calculation is based on use of two grippers from sides and indicates a 42W DC motor is required to develop a fully-functional emergency ventilator[8]. As the assumptions of this calculation by MIT are the same as design's goals, DC motors required power need to be at least 21W. Additionally, nominal speed of DC motors is calculated in the worst-case scenario as follows:

$$\begin{gathered} MLD^{1} = 6\ cm\ (Standard\ Ambu\ Bag\ Radius) \\ RR_{max} = 40\ bpm, \\ IE_{ratio,min} = 1:4 \\ Time\ Cycle = \frac{60}{40} = 1.5\ sec, \\ Inhale\ Time = \frac{1.5}{5} = 0.3\ sec \\ V_{Inhale} = \frac{6}{0.3} = 20\ (\frac{cm}{\sec}) \end{gathered} \tag{4}$$

$$\begin{gathered} V_{Inhale} = r_p \times w_{DC\ motor} = 1.6 \times w_{DC\ motor} \\ w_{DC\ motor} = 12.5\ \left(\frac{rad}{\sec}\right) \approx 120\ RPM \end{gathered} \tag{5}$$

Where r_p is pinion radious and $w_{DC\ motor}$ is rotational speed of pinion.
Based on abovementioned calculation, the following DC motor of Dunker Motor has been chosen with 24-volt DC, 25 Watt and nominal speed 200 rpm.
It worth mentioning this DC motor has not provided with an encoder but instead an end-shaft designed on it in order to ease installation of external encoder. As it was mentioned in previous section, a high precision motion control is not necessary in this design, and additionally, purchase of servo-motors would increase the costs and results in an expensive final product, so this selection has been made in order to fulfill all aspects of the design requirements.
The main structure of the emergency ventilator is created by aluminum profile. These profiles are easy to connect, light weight, and durable which satisfy design requirements. Additionally, the main parts of this structure have been designed with 60 degrees toward the horizontal line which provides the system an adequate amount of space for other electrical devices, and also make the whole system to be required less space than the similar devices as it can be seen in Figure (1).

2.4.2 Electrical design

The electrical circuit of the system consists of an Arduino Mega 2560 which is mounted on a designed PCB through pin headers and these two boards work as power and control circuits simultaneously. The designed PCB as power circuit is responsible for running DC motors, and also provides a suitable connection between sensors and microcontroller on Arduino in the control circuit. The Figure (2) shows the architecture of circuit. The MPXV7002DP pressure sensor and buzzer are installed on the PCB.

[1] Maximum Linear Displacement

The pressure sensor reads the air pressure of the breath tube for controlling commands and user-interface plotting. Due to the difference between Arduino and other electrical parts, a LM2596 voltage regulator module is installed to convert 24V to 5V. Additionally, a L6203 IC is used in order to drive DC motors at a higher current level than the other sensors and Arduino. Regarding safety factors, an emergency stop button is added to the system concerning the possibility of immediate system shot down; additionally, the device is designed to be operated by a battery in case of power shortage or emergency situations. In order to improve the quality of visual user-interface, this system has a Nextion NX4832T035 touch screen LCD instead of usual knob and character display, which provides the operator with a real-time pressure plot through the system operation, and two blue LEDs in shape of human lungs are connected to the device body which blinks with patient's breath synchronously.

2.4.3 Medical equipment and connections

As it was fully discovered in previous sections, this emergency ventilator is designed and developed based on a manual resuscitator or BVM. In normal situation, manual resuscitators are connected to patients through the mask, but in the emergency ventilators it is not possible to connect manual resuscitators' output directly to patients and the pressurized fresh air should pass an extension tube in order to reach patients. The Figure (3) shows the breathing path of the developed emergency ventilator. It shows that using two 3D printed fittings easily tackles the dead space issue in this design, which prevents the exhale gas going back through the extension tube. This is one of the most important issues that other emergency ventilators have encountered, which in a long run will avoid fresh air to reach patients' lungs. As it can be seen pop-off valve is still connected to the manual resuscitator but the peep-valve and its exhaust valve are placed in the closest position to the patient. It worst mentioning when this system is going to be used with a mask, the peep-valve should be taken off from its place since using these two items simultaneously may lead to gastric regurgitation and pulmonary aspiration, and it should be only used for invasive ventilation and when Endotracheal intubation is necessary[20].
Finally, the most critical components of the system are noted in the block diagram in Figure (4).

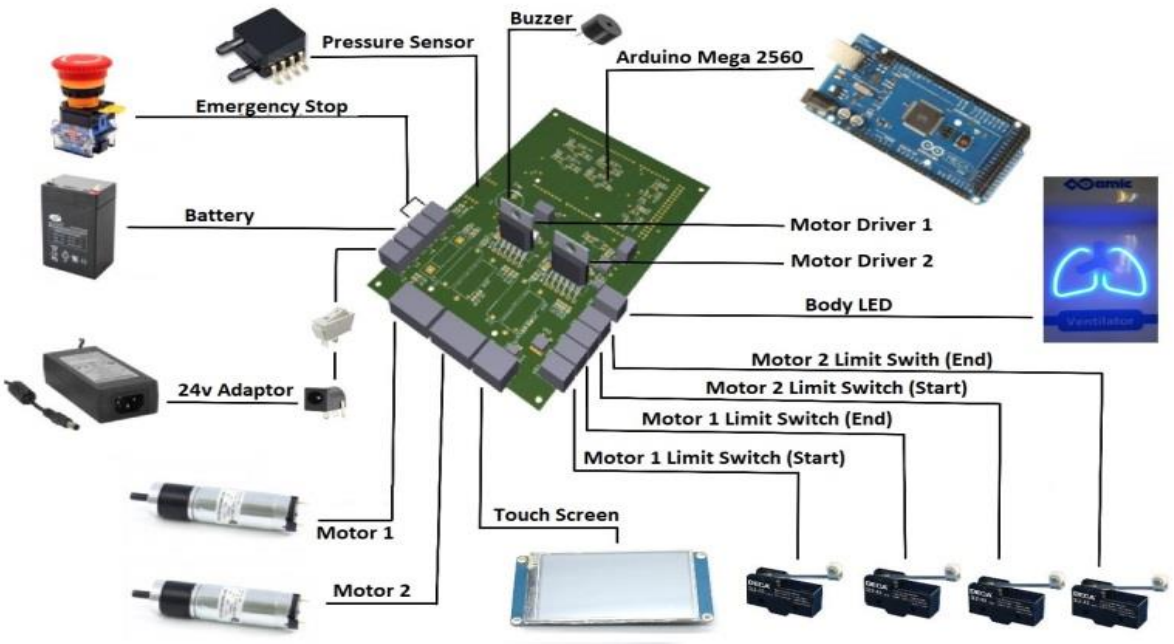

Figure 2 Electrical devices and connections

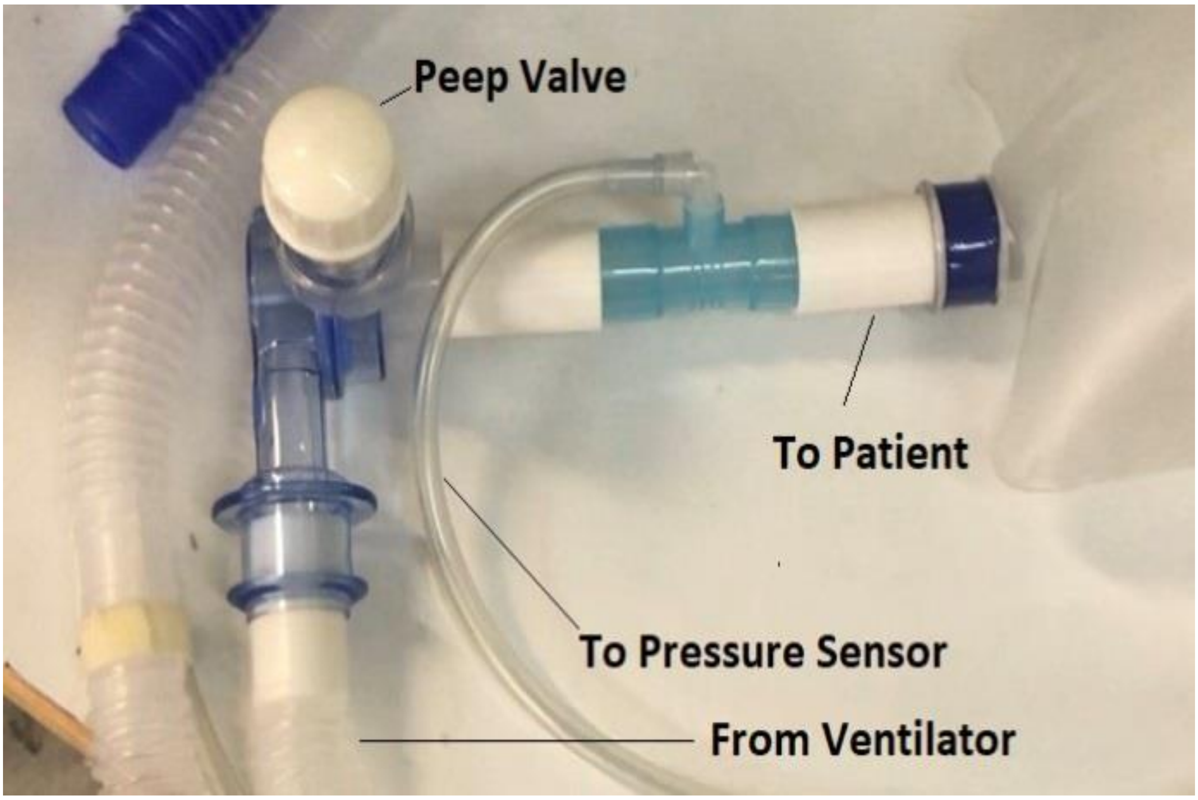

Figure 3 Medical equipment and connection

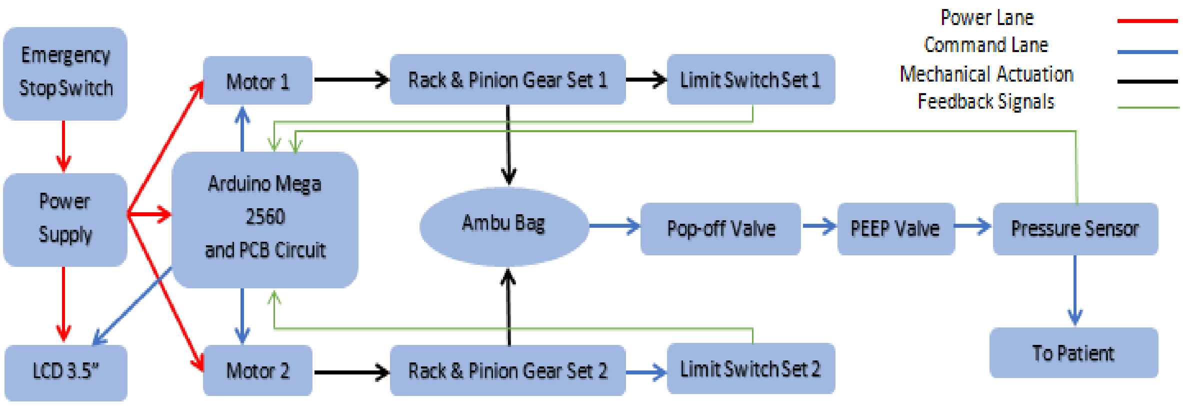

Figure 4 Block diagram of the emergency ventilator

3 Control implementation of operation modes

Patient ventilation techniques are based on two different methods of volume controlled and pressure controlled [21]. In pressure-controlled ventilators a uniform pressure of air is applied to lungs, and the compliance of them determines the delivered volume. Because the amount of driving pressure applied to the airway is preset, the delivered volume is variable and dependent upon the patient's inspiratory effort, pulmonary mechanics, rise and inspiratory time[22].
On the other hand, in volume-controlled ventilation, a set tidal volume is supplied by the ventilator at a constant flow rate, so an Ambu Bag can be used instead of an air compressor in this type of ventilation. The value controlled and kept at the target value by the equipment is the tidal volume (VT) [23]. The developed emergency ventilator in this paper is based on the latter method.

3.1 Ventilator input parameter

The developed ventilation system has five input variables that respiratory rate (RR), Tidal Volume (TV), and I/E ratio were introduced beforehand, and two more input variables are as follows:

- Threshold Pressure (TS): The ventilator in assistive mode is programmed to sense changes in the system pressure when a patient initiates a breath, the negative pressure in air path would triggerH2 a breath by passing a threshold pressure which is usually set up by a therapist[24]. ThH$_2$OH$_2$Oe available range of TS is from 1 to 9 cmH$_2$O.
- Maximum Period (MP): The maximum time with no inspiration in assistive mode is defined by this parameter. It means that the syH2
- H2H2H2Hlstem will provide at least one breath cycle in this period whether or not the threshold pressure is triggered by patient. This parameter can be adjusted from 0 to 99 seconds.

3.2 Code structure and state-machine block diagram

In this section the behavior of the state-machine which consists of all states and operation test cases is described.
In self-test procedure, two predefined tests will be operated automatically by the system to ensure that all components of the system work properly. As Figure (5) shows, the tests procedure includes different sections. In Homing state and after that in next section, both motors move forward (out of reverse limit switches) with a predefined velocity. As soon as motors reach to limit switches, the generated signal by switches will approve the functionality and the system stops the motors. The system will drive motors on opposite direction in the same manner to trigger reverse limit switches and check their functionality. Finally, the state of the system will change to 'Homing done' as if all the limit switches are triggered by DC motors. The system also will provide a notification on the screen if the system cannot recognize any signal from each of them, and prevents system from being started. After this procedure, the state will change to 'Forward Trigger' and system is ready to start actuation. The control algorithm will send the 'Forward command' to motors at a defined velocity and for a specified amount of time which is calculated based on the given parameters to the system by operator, then motors will move backward to the starting position and wait for the next cycle.

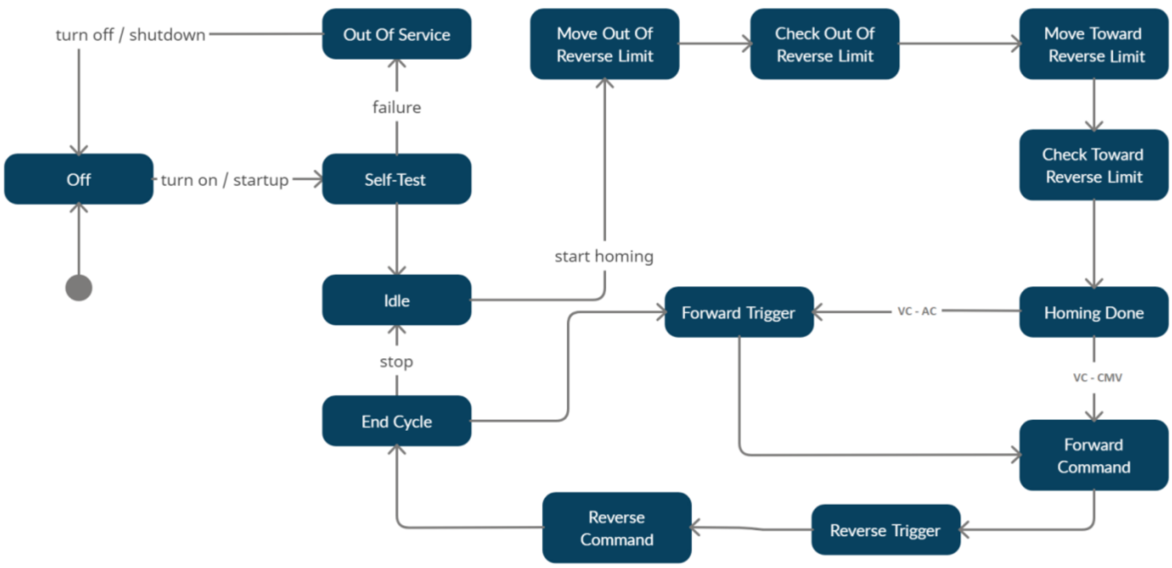

Figure 5 Self-tests block diagram

3.3 Calibration algorithm

The developed system is being controlled with an open-loop control algorithm. As the development of a BVM-based emergency ventilator with a reasonable price and functionality was the main goal of this project, DC motors of the system have not been provided with rotary encoders, so a calibration procedure is defined to set actuation parameters based on input variables. A 2-D lookup table is generated through the calibration algorithm with which the velocity of DC motors can be calculated during each cycle.

3.4 Describe equipment and requirements

The developed system needs to be calibrated once at the beginning to provide the required TV, ensure its functionality and obtain motors' velocity when they move forward to squeeze the Ambu Bag. The ranges of set parameters on system for the calibration are as follows:

$$\begin{gathered} 6 < RR < 40 \ \& \ 1 < I/E < 4 \\ Period = \frac{60}{RR} \rightarrow 1.5 < Period < 10 \\ Time_{Forward} = \frac{Period}{IE+1} \rightarrow 0.3 < Time_{Forward} < 5 \\ Velocity_{max} = Velocity_{motor} \times \frac{\pi}{30} \times \frac{1}{Gear\ Ratio} \\ 0 < Velocity_{Forward} < 23.5\ ({}^{cm}/_{sec}) \end{gathered} \tag{6}$$

After calibration and extraction of required parameters, a 2-D look-up table will be provided which requires forward actuation time and TV in order to calculate the forward velocity of motors.

3.5 Calibration procedure

Figure 6 Spiro analyzer used for calibration process (ST-300 Spiro analyzer)

In calibration procedure, the output air volume of the system (TV) is calculated from two pairs of the time and velocity of forward motion of actuators by the ST-300 Spiro analyzer, Fukuda Sangyo (Figure (6)). The instrument carries out measurements of a patient's Slow Vital Capacity (SVC), Minute Ventilation (MV), Forced Vital Capacity (FVC), and, Maximum Voluntary Ventilation (MVV) by capturing instantaneous air flow data at discreet intervals of time while the patient does a prescribed breathing maneuver. The flow data pattern being displayed graphically on a screen display. Its capability also extends to the storage and analysis per patient for three (3) series of VC and FVC data, respectively; and, two (2) series of MVV data that may be displayed in tabulated data-form on the same screen.
The required range of different defined parameters in previous section is discretized as:
$time_{forward} = 0.3, 1, 2, 3, 4, 5$ (sec)
$Velocity_{forward} = 1, 5, 10, 15, 20, 23.5$
According to above discretization, first the tidal volume corresponded for each pair of time-forward and velocity-forward is measured by spirometer and lookup table is created. Secondly, linear interpolation method is used to calculate the time and velocity for other tidal volume. Finally, using interpolated diagram in (Figure (7)), the time-forward (which is function of IE and RR) and tidal volume (which is input parameter), the velocity-forward can be calculated. In other words, the system just needs to read the forward motion speed from the diagram and the required TV will be delivered to the patient.
The calibration block diagram is shown in Figure (8).

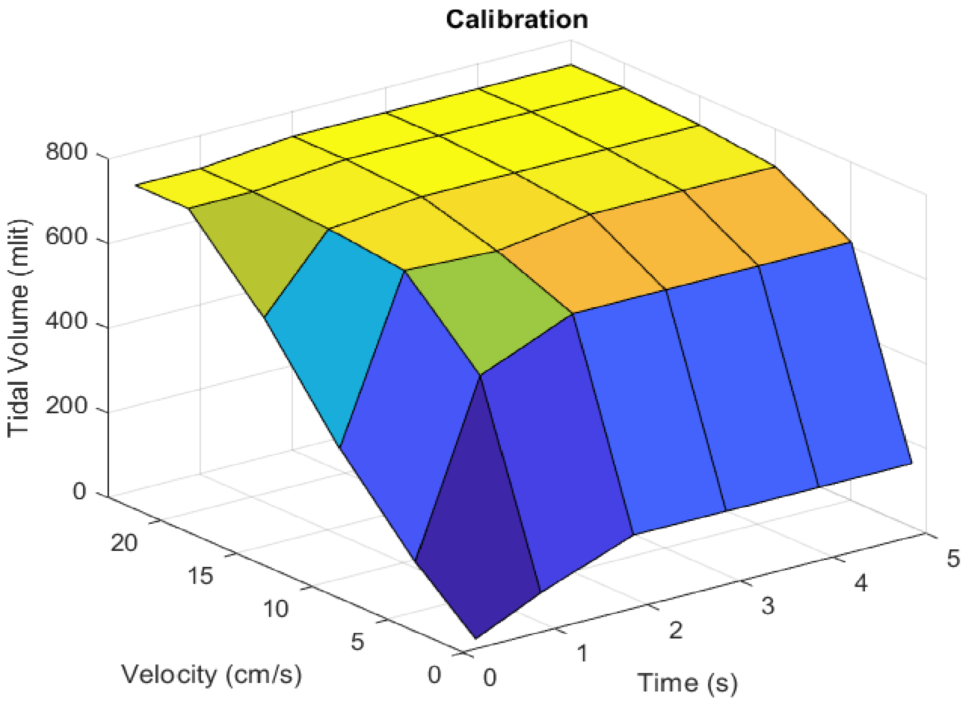

Figure 7 Control algorithm block diagram

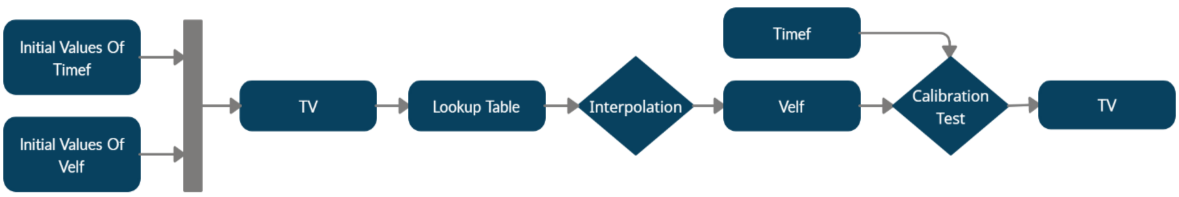

Figure 8 Control algorithm block diagram

4 Results and challenges

In order to clarify the functionality of the introduced prototype, the system was carried out a simple experiment. In this test, an unstretchable bag was placed under a specific amount of weight connected to the emergency ventilator in order to simulate lungs functionality. Unstretchable bag is used so the pressure inside the bag can be controlled. It should be noted that the test was just taken to validate the functionality of ventilator's mechanism and its air path. The Figure (9) shows an ideal ventilator breath cycle pressure.

The fact about this chart is that in volume-controlled ventilation, only I/E ratio and PEEP pressure can be controlled by the operator and other parameters are in direct correlation with patient's lungs. The developed emergency ventilator parameters were set in 4 different situations and the results from HMI is shown in Figure (10). Pressure sensor's data are completely in alignment with the curve in Figure (9). The I/E ratio and also PEEP parameter which should be set manually are correctly sensed by the pressure sensor, other inputs of the system through each test can be read on the left side of HMI during the test.

The test parameters are shown in Table (3).

This system is meant to provide air for both conscious and unconscious patients and additionally can provide invasive and non-invasive ventilation. The simplest method of non-invasive ventilation is breathing through a mask in which the peep valve should not be used since it would put stomach under peep pressure in addition to lungs. The first two figures are with a manually set peep valve and in the latter, peep valve was taken out from its place so it can be seen that the pressure drops from maximum to 0 but in two others it stays above zero, near 5 cmH_2O.

It is obvious that the tests are not adequate to prove full functionality of the developed emergency ventilator and it would be tested on CPR manikins and after passing the necessary regulation on patients in near future, but it shows that the designed mechanism and valves in the air path are correctly matched and working properly.

As it was fully discussed in previous sections, the conventional ICU ventilator cannot be replaced by these BVM-based emergency ventilators, but the fact is BVM-based ventilators advantages are much more than the concept could be neglected. BVM-based ventilators can be used not only in poor and deprived areas in a pandemic situation but also, they can be used in emergency situations or transportations.

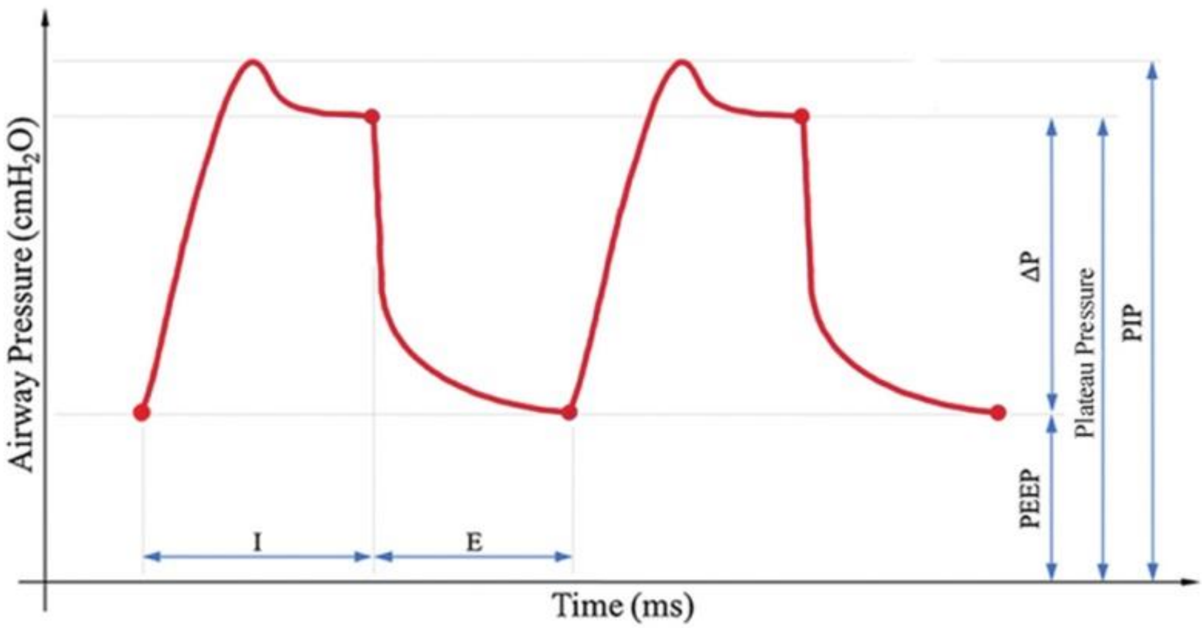

Figure 9 Ideal ventilator breath cycle [15]

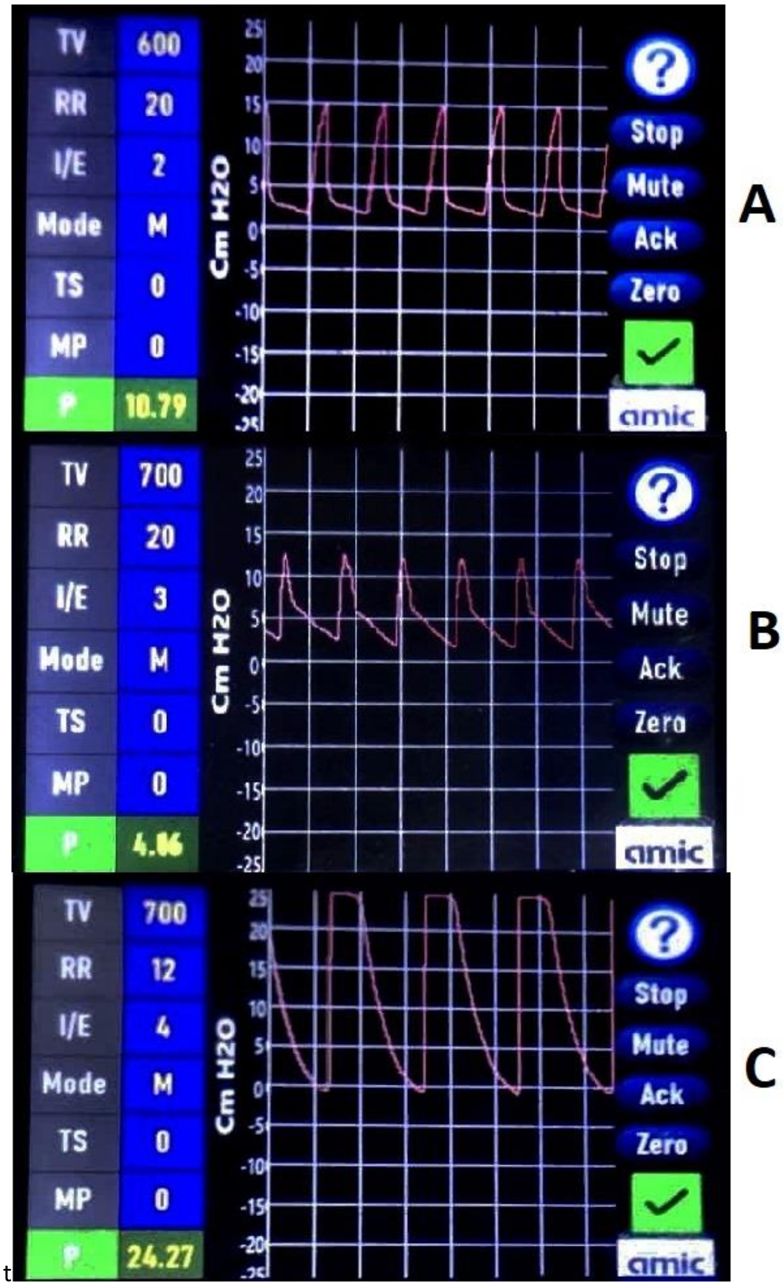

Figure 10 Different test situations' HMI pressure diagram

Table 3 Test parameters

ITEM	Tidal volume (ml)	RR	I/E Ratio	Peep valve pressure (cmH2O)
TEST (A)	600	20	1:2	≈5
TEST (B)	700	20	1:3	≈5
TEST (C)	700	12	1:4	No peep valve

5 Conclusion and future works

The Coronavirus pandemic has increased the need of mechanical ventilation since its destructive effects on humans' lungs. In this situation, a number of groups mainly from different institutions around the world have started working on automation ventilation concept relying on Ambu bag, the simplest device of manual resuscitation. In this way, the main goal of this work is to design and develop an emergency ventilator with the required functionality and lowest possible price in order to ease access of rural and deprived areas to necessary health services during the pandemic. It is worth mentioning that conventional ICU ventilators cannot be replaced by the emergency ones due to their scope of work; however, emergency BVM-based ventilators' high production rate, reasonable price, and functionality shows the potential of these devices on the current situation and even after the pandemic. In order to taking the advantage of this positional opportunity, these devices require further testing and regulatory approval. The future works of this group is also focused on testing and approvals, in addition to increasing the functionality of the device by using CO2/O2 sensors.

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