A Low-cost, Automated, Portable Mechanical Ventilator for Developing World*

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***Abstract*—A large portion of world's population, especially in developing world, gets affected by the respiratory diseases. Often these patients need a medical device called a ventilator for assistance with their breathing. The ventilator is an expensive and complicated equipment and is often unavailable to patients, leading to severe complications and mortality. In this paper, we present a system that automates the use of a conventional bag valve mask (BVM) and regulates its operation to mimic the response of an ICU Ventilator for life saving applications. The system consists of motorized actuators, sensors, valves and a control system to achieve controlled volume ventilation. This paper presents system design and implementation techniques for this low-cost design. The system has been tested extensively using ventilator testers and is being developed into a product for use in under-resourced settings.**

***Index Terms*—Respiratory disease, Ambu Bag, automation, developing world, COVID - 19**

I. Introduction

Various diseases related to respiration become the cause of illness for a big number of people worldwide. According to a WHO (World health organization) report regarding respiratory diseases, about 65 million people suffer from chronic obstructive pulmonary disease (COPD), globally [1]. And these numbers are continuously growing. About 339 million people worldwide suffer from asthma [2]. Currently, more than 25 million people in the United States are suffering from asthma. Approximately 14.8 million adults have been diagnosed with COPD [3]. The situation regarding respiratory diseases is more complex in the developing world due to severity, frequency and economic impacts. More than 90 % of COPD-related deaths occur in low and middle income countries [4]. For example, in Pakistan there are 15 million episodes of ARI (acute respiratory infection) observed every year among under-fives [5]. A multi-country survey (BREATHE) reported a 2.1 % prevalence of COPD among Pakistani adults aged above 40 years [6]. Almost 20 % of the overall pediatric population is affected with asthma disease [7]. Furthermore, a large number of patients (mostly kids and elderly) have to tolerate seasonal respiratory diseases and need acute treatment in critical situations. Many such patients die each year due to unavailability of suitable medical resources on time. The circumstances with respect to respiratory diseases and their treatment in other low and middle income countries are very similar as well. Moreover, COVID-19 pandemic has worsened the situation. It became the cause of the deceleration of performance of hospitals in the developing world. With small number of required life saving equipment and increasing emergency cases due to COVID-19, many hospitals and entire healthcare systems crumbled under the weight of patients. This situation led to rapid outspread of COVID-19 and high mortality rate. In Pakistan, from 3 January 2020 to 25 June 2021, 951,865 confirmed cases of COVID-19 with 22,108 deaths are reported to WHO [8]. Besides the novel COVID-19 pandemic, the world has faced and is at risk of many other viral diseases including SARS (Severe acute respiratory syndrome), MERS (Middle East respiratory syndrome) and Swine flow [9] [10] [11]. Most of such viral epidemics impact lungs and cause respiratory disorders. Hence, it is necessary for every country to have a strong healthcare system, equipped with modern and state of the art machinery to face such viral diseases or pandemics.

II. Problem

Mechanical ventilation is necessary for the treatment of patients suffering from severe respiratory diseases [12]. The condition of the patient determines the required period of this treatment which can be acute (few hours) or chronic (few months). As per standards of healthcare, at least 50% of beds with ventilators, of a hospital should be available for patients in emergency room [13]. However, this number of the required ventilator beds becomes too large for a dense populations in most of the low and middle income countries where public hospitals do not have the capacity to fulfill the needs of all patients. Moreover, the ventilators which are available currently are big and bulky and are only suitable for

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hospitals in developed world and hence have been proven to be difficult to use in developing countries. In addition to this, emergency use ventilator are very expensive for the hospitals in the developing world. That is why it is the need of time to design a low cost, smart, portable emergency use ventilator which can be easily used and maintained in the hospitals of low and middle income countries.

III. Solution

Considering the need of the time, we have developed smart breathing support device, UT1, that can be manufactured and maintained in developing countries and can provide life-saving support to patients. This system is capable of working as a traditional hospital breathing support device. In addition to this, it can also provide the remote monitoring functionalities that allows a much smarter and efficient use, data collection and decision making processes. UT1 is low cost (only 1000$ per system) as compared to existing ventilators [14] [15]. In addition to this, our system's battery life is 20+ hour. It means that it can provide uninterrupted breathing support for more than 20 hours without the need of main supply, once fully charged. This feature makes it suitable even for those low-resourced places where continuous supply of electricity is not available. Moreover, most of the current ventilators use proportional solenoid valve to provide oxygen with proper volume, flow rate, pressure and mixture [14] [15]. In addition to this, there are certain other ventilators which use manual spring valve for oxygen supply. The PSOL (Proportional Solenoid Valve) is often quite costly and difficult to handle which leads to expensive and complex ventilator design. On the other hand using a manual spring valve for oxygen supply can have adverse effects on the patients who are already having life-threatening health situation [16] [17]. That is why our system uses a direct acting solenoid valve that is much cheaper and easier to use than PSOL and still satisfies all performance requirements. Considering all these features, we can conclude that UT1 provides necessary life saving breathing support, continuously, with maximum safety and in minimum price. Due to all these features, this system can easily be implemented and maintained in the hospitals of low and middle income countries. It can save countless lives in the developing world and in places where portability is required.

The TABLE I compares the key features of other ventilators with our proposed system.

TABLE I
System Comparison

System	*Battery*	*Delivery*	*Cost$*
Puritan Bennett 980 [14]	1Hr+	PSOL	32,000
GE Carescape R860 [15]	30+min	PSOL	29,000
Spiro Wave [16]	N/A	Manual Spring Valve	5,000
Umbulizer [17]	2Hr+	Manual Spring Valve	2,000
UT1 [18]	20Hr+	Direct acting SV	1,000

IV. System Design

This paper describes a novel, low-cost ventilator design which provides a scalable architecture that fulfills the medical safety and efficacy requirements. The design is based upon medically accepted Bag Valve Mask (BVM) or 'Ambu Bag' that is used manually by hospital staff and patient's attendants for required period of treatment (hours, weeks and sometimes months) to provide breathing support when a proper ventilator is not available. The Ambu bag is clinically accepted and can save lives of the patients in the absence of required advanced ventilators. However, manual operation for extended time, often required in hospitals is not practical and safe. Therefore, our design is focused to automate the operation of the ambu bag along with all required sensors to allow for a low-cost, yet practical and safe system. This system implements a efficient feed back control mechanism depending upon different medical grade sensors i.e. pressure and flow sensors. The ventilator is designed to be battery-powered as AC power can be unreliable or even unavailable in low resource settings.

A. Ambu Bag

The Ambu bag is actuated using a motorized mechanism, eliminating fatigue and human error for extended use. It also senses patient breathing and synchronizes the ambu bag operation with it, thus eliminating possible pressure build up that can be dangerous to the patient. Fig.1 is the block diagram which illustrates the proposed design on the ventilator.

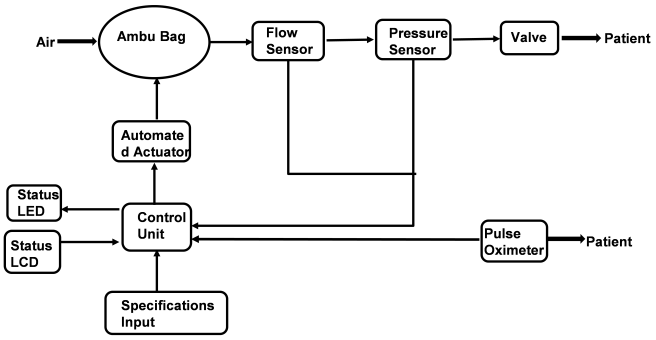

Fig. 1. System level architecture of the proposed ventilator

The air or air-oxygen mixture is passed to the ambu bag. When the ambu bag is compressed via the motor and actuators, the air goes through a set of sensors and optional temperature and humidity controller which passes it to the patient via an inlet with a valve. The output of all sensors and the input provided by user (e.g. through a keypad) are given to the control unit which proportionally controls the motor operation as well as display (e.g. LCD) and controls powering of the system from a power source (e.g. battery, AC mains).

B. Actuator Design

The actuation system is used for automatic actuation of the BVM. The design philosophy is to include the minimum the number of failure prone moving parts. We compared the

efficiency of different actuation mechanism including electromagnetic actuation, linear actuators, cam shafts, DC motors. The actuation mechanism, used in this system, replicates the manual actuation from human hands as the BVM is designed specifically for such operation [18].

V. SYSTEM IMPLEMENTATION

Fig.2 shows the higher level diagram of the implementation of the proposed control system. A user interface (e.g. Keypad and LCD) is connected with the microcontroller. Microcontroller controls actuation mechanism by controlling a DC (Direct-Current) motor via PWM (Pulse width modulation) by monitoring embedded motor encoder, Tidal Volume and Peak Inspiratory Pressure. This section provides the implementation details of different components of the system. Fig.3 is the block diagram illustrating the interface of the proposed ventilator to the patient. To actuate Bag Valve Mask (BVM), actuation mechanism is actuated by a DC motor which is controlled by microcontroller directly based upon user input parameters and sensors feedback. Breathable air is then delivered by creating positive pressure by BMV through a flow rate sensor, a pressure sensor and a humidifier. The humidified breathable air passes through a one way valve before reaching to standard ventilator-patient interface like face mask and Endotracheal Tube (ET).

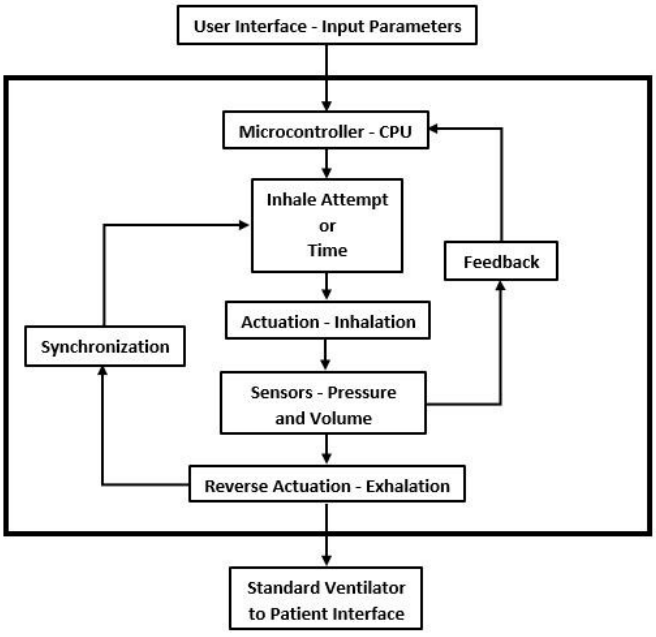

Fig. 2. High level description of system operation

A. Actuation Mechanism

The mechanical actuator selected for implementation, consists of a pair of rounded metal pieces i.e. 'the Jaws' on top and on bottom, the ambu bag to compress and release it. The mechanical assembly is coupled to the actuation mechanism (e.g. motor) using some sort of circular-to-translinear motion converter. An example is the use of a pulley mechanism to achieve this. The motor is also connected with an encoder to provide feedback of its position to the system to compensate for any missed actuation [18]. Fig.4 shows an implementation of the actuation system. The system consists of pair of mechanical actuators i.e. the jaws connected to a wire that is attached to a pulley rotated by a motor. The mechanism is attached with a support with the help of bearings. The motor is supported by a holder assembly. A DC gear motor is used to provide sufficient torque as well as smooth operation.

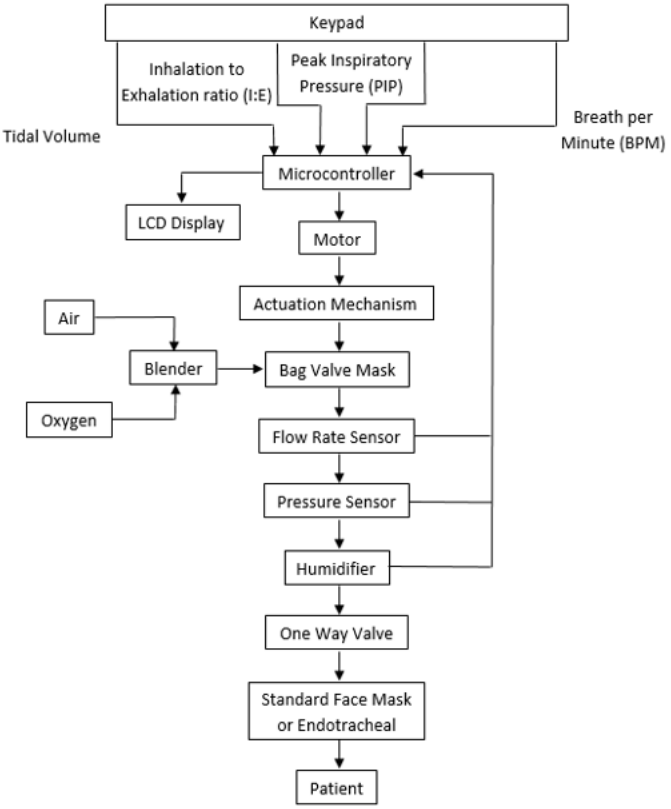

Fig. 3. Description of Ventilator-Patient Interface

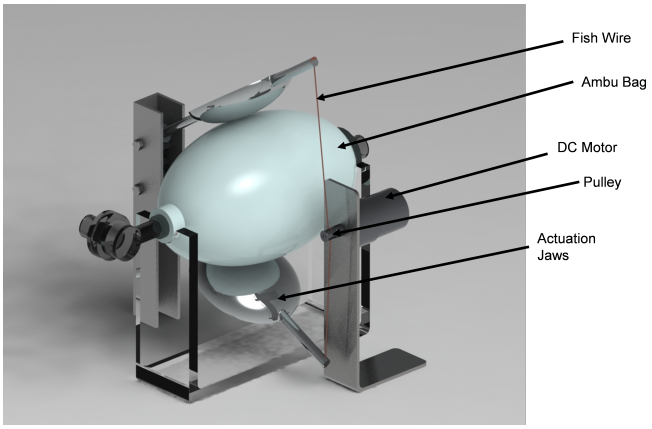

Fig. 4. Actuation mechanism of the proposed ventilator

B. Electrical System

A printed circuit board (PCB) acts as the backbone of electrical operation of the system. An embedded system is designed and implemented on the PCB using a microcontroller (e.g. PIC18F) [19] with some usual electrical input/output devices for example switches, LEDs (Light emitting diodes), relays, connectors. An arduino [20]is used at first for rapid prototyping. High current motor drivers are also included in the electronics design. Typical current requirements for motor are from 100mA to 1A. A power management solution is designed according to the design requirements. Similar to the design used in laptop computers, AC mains power can be used to charge system batteries and power the system if it is available (as in major government hospitals). The backup power source e.g. a battery is beneficial for the cases of short power interrupts and for portable use as in ambulances and in rural areas with shortage of continuous power supply. This competent system design leads to several hours of uninterrupted operation of system with the battery. Two different batteries are used, one (bigger) to power the and other (smaller) for the control system. These are either lead-acid batteries or dry cell batteries. Lead-acid batteries are usually economical but have high weight and comparatively shorter life time . Dry cell batteries are high priced but are light weight and have longer life time. We used lead-acid in our design for initial prototyping and testing.

C. Sensing System

Four types of different sensors(temperature, pressure, humidity and oxygen sensors) are used in the system for reliable, safe and accurate operation of the system. In order to measure the flow of air provided to the patient, a spirometer/flow-rate sensor, is used. A pressure sensor is included in the system to measure pressure of air flow to the patient. The pressure of the air flow is dependent upon the condition of the patient and the percentage of natural respiration process that may be present. Moreover, during the actual implementation of system, a patient's self-respiration can change and therefore it is necessary to use feedback control mechanism to adjust the system [21]. The design system also includes optional valves to adjust air/oxygen ratio as required in some cases [22]. In some of the applications, the ratio is automatically selected based upon the house supply and hence is directly used. Humidity is controlled automatically by passing the air intake through a water/steam chamber [18]. An example of the sensors include flow sensors (e.g. HAFUHH0050L4AXT Analog Airflow sensor from Honeywell) [23], Pressure Sensors (SSCSANN001PGAA5 Analog Pressure Sensor from Honeywell [24]) and composition sensors (e.g. Oxygen sensor such as KGZ-10 Series from Honeywell [25]). Tidal volume is calculated by integrating the flow rate over time.

$$Q = \int qdt \tag{1}$$

For the discrete sensor, the formulation becomes

$$Q = \sum q\Delta t \tag{2}$$

The sampling rate is chosen based upon the rate of change of flow rate, according to Nyquist criteria [26]. The sampling rate used in our application was 1KHz. This results in Δt of 1ms. Pressure is directly measured by the pressure sensor. The Inhalation:Exhalation (I:E) ratio is set by controlling the time window for inhalation and exhalation. The patient's effort is detected by a drop in pressure on the patient side that triggers a new breathing cycle in assist mode. The pressure is kept within a compliance range to avoid any damage to the respiratory system of the patient. This is achieved by monitoring the pressure on the pressure sensor and by terminating the flow cycle at that point with the next cycle starting with more motor current through the driver to achieve more flow within the same pressure range.

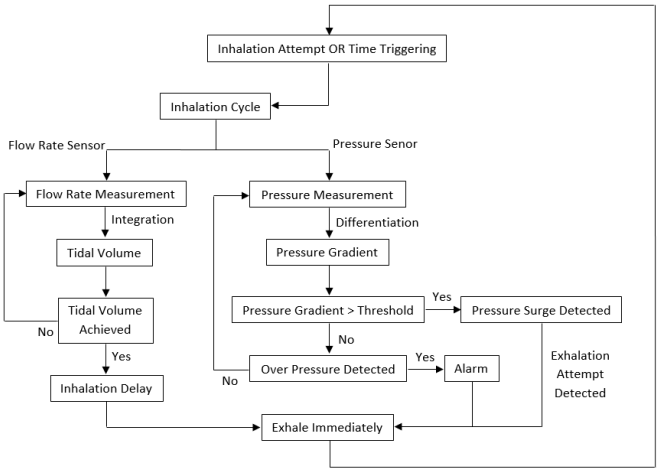

Fig. 5. Ensuring patient safety using Flow and Pressure Sensors

All the sensors used in the system play important role for safe, accurate and reliable operation of the system. The pressure sensors help maintain safe pressure limits in the system and for the patient. The flow sensor ensures adequate flow is being provided. The position sensors for example hall-effect sensors ensure the proper position of all moving parts all the times.

D. Operating Modes

The operating modes(a simple, normal and a smart mode) are included in the system. The simple operating mode automates the operation of ambu bag without any feed back control. This mode is implemented for the treatment of the patients with no effort of their own and provides 'ambu bag like' operation but without the need of any manual operator. The normal mode of the system uses the data from different sensors to achieve the desired parameters e.g. volume, pressure etc. by considering patient's efforts as well. Further testing of the system can help to enable the smart mode of the system through used cases. In the smart mode, the ventilator will be able to use machine learning to adjust its operation based

upon a training algorithm which will be used to optimize its operation for each patient [18]. The smart mode will use the data from all the different sensors used in the ventilator and at the exhale and inhale port near the patient. It will allow the system to converge to optimal flow, pressure and humidity ranges compared to the normal mode. In this mode, the system will also track the maximum pressure and will adjust its operation to ensure that this pressure is never exceeded, ensuring patient safety. Fig.5 illustrates the technique used by the system to ensure safety of the patient by use of regulated pressure. During the inhalation cycle, pressure is continuously measured and differentiated to avoid over-pressure and to detect patient exhalation attempts. During inhalation, a patient exhalation attempt is detected by a surge or sharp increase in pressure. If pressure becomes greater than allowable Peak Inspiratory Pressure (PIP), system alarms and exhales immediately. Similarly, if the pressure gradient becomes greater than a threshold showing a pressure surge, the system exhales immediately. The Assist Control mode is the most utilized mode for a ventilator for life saving situations. The Ambu bag is used in this mode by design. For a typical application of the newly designed Ambulator, the system works in Assist-Control (AC) mode in which a breath cycle may be started by patient or otherwise by internal microcontroller-timers based upon Inhalation to Exhalation Ratio (I:E) and number of breaths required per minute. After the breath cycle starts, continuous monitoring is done in feedback for safety and patient-ventilator synchronization purposes. After acquiring Tidal Volume set by user, exhalation starts and system again starts to wait for patient or internal timer's inhalation triggering [18]. For other modes (e.g. pressure controlled mode), more advanced control systems are used (for example a PID (proportional integral derivative) controller to control the pressure at gas outlet). Continuous Positive Air Pressure (CPAP) is an alternative breathing support mechanism which provides a continuous positive pressure for patients who can breathe on their own. This mode is mostly used to support less critical patients and hence is part of future development of the system The system currently uses population based default values for adjusting operating parameters. The care team can adjust those based upon personal information of the patient like weight, age and severity of disease.

E. Breathing Synchronization

An important feature of a ventilator is to detect breathing effort by the patient and to synchronize its breathing cycle with partial breathing of the patient. This is important to avoid any excessive increase in internal pressure during long term ventilator operation. Our device has been optimized for this feature. It utilizes data from sensors to detect any breathing effort by the patient and then synchronizes its cycle with the patient. The adjustment is instantaneous and the very next cycle after detecting patient effort is adjusted based upon the timing of the effort. The system continuously works to look for changes in breathing pattern and adjusts itself accordingly. This is a significant improvement over the manual Ambu bag operation where it might take operator more time to notice such effort and the effort might be too small to detect at times, causing dangerous breathing patterns enforced by human error leading to fatal conditions. Fig.6 shows the synchronization of UT1's breathing cycle with the breathing cycle of the patient. There are two ways to trigger breathing cycle i.e. patient-triggered and time-triggered. Time triggering is dependent upon the required number of breath per minute while the Patient-triggering is dependent on the patient, when patient wants to take a breath. Pressure-drop and flow rate surge is continuously measured to detect patient inhale attempt. As the pressure gradient becomes less than a threshold and flow rate becomes greater than threshold, patient-triggered inhalation starts. During inhalation, pressure is again continuously measured and differentiated to stop inhalation if patient attempts exhalation. If pressure gradient becomes greater than a threshold, pressure is detected which is a sign of positive pressure by patient i.e exhalation. So, the system exhales immediately

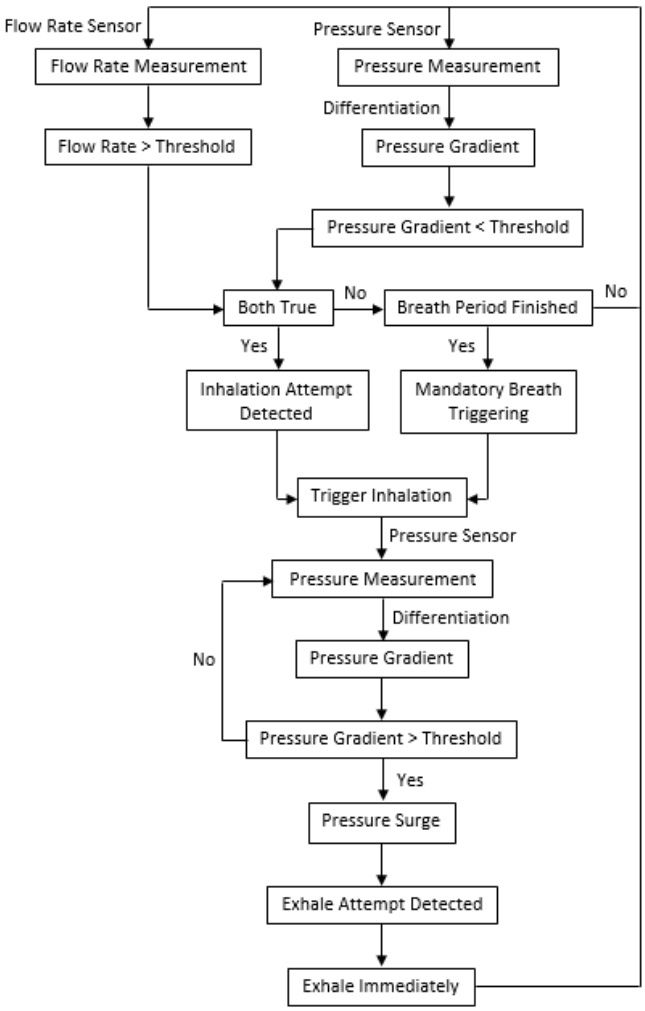

Fig. 6. Breathing Synchronization Mechanism

VI. Testing

UT1 was first tested without any load to determine the repeatability and reliability of operation. The system was run for one hour and flow rate, tidal volume and pressure were continuously monitored. The ambu bag was also actuated manually for same time to quantify the difference in system performance in both cases. It was quite evident from the results (Fig.7 and Fig.8) which are showing, performance comparison of automated and manual operation, that the Ambulator performed much better compared to the manual operation of the Ambu bag. Next, the system was tested under load conditions. This was achieved by use of an artificial lung that is often used to characterize the ICU ventilators. This testing was to determine system performance while it has to maintain proper flow conditions under pressure limitations due to the artificial lung. The system performed adequately and was able to provide desired tidal volume within the safe pressure limits. The testing was repeated under different conditions and extremities to ensure safe operation throughout the labeled range of the system. Moreover, PEEP stability test was also carried out over more than 21000 data points on proposed system and Fluke VT900A reference device [27]. The results from both systems are compared in Fig.9.

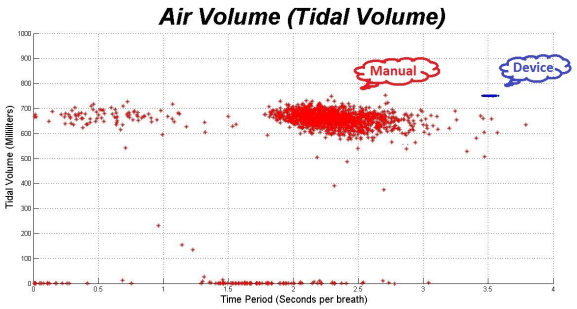

Fig. 7. Tidal Volume

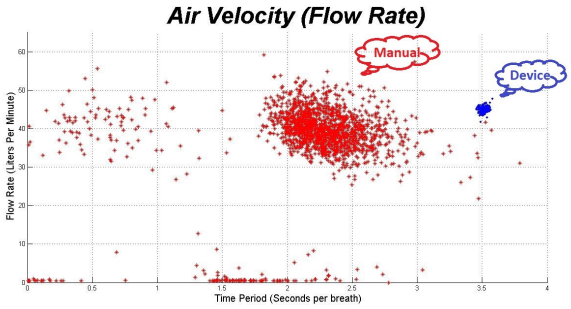

Fig. 8. Flow Rate

The system also went through Constant Compliance Test. This test emulates the conditions when the patient is totally sedated or paralyzed and thus has no breathing effort. Table II consists of input and output values of this test.

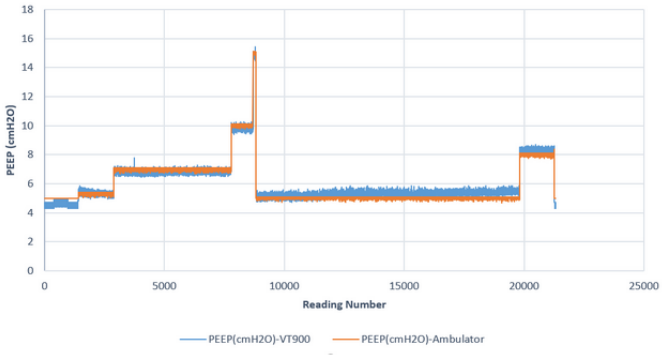

Fig. 9. PEEP Stability

TABLE II
Constant Compliance Test

Set Tidal Volume	*Mean*	*Median*	*Standard Deviation*
400 ml	400.15 ml	400.14 ml	0.09 ml

VII. Results

The ventilator has been successfully tested using an artificial lung that is often used to test commercial ventilators. It also went through PEEP Stability and Constant Compliance Test and showed satisfactory results. Making it user friendly, we have also added a keypad and simple analog knobs to enter different parameters as per requirements. The parameters that can be controlled are shown in table III.

Fig.10 shows the complete prototype of the ventilator system, named as 'Ambulator'. It contains an input port where input gas (air/air-oxygen mixture) is connected and the output port which is connected to the patient via a tube.

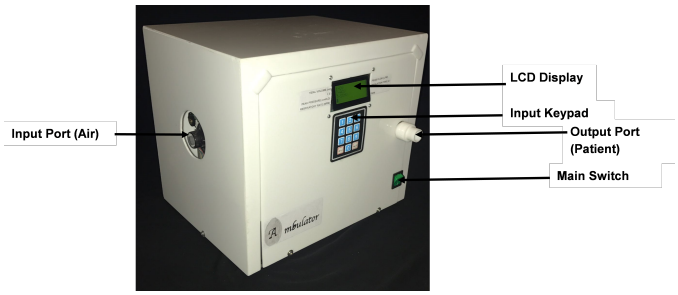

Fig. 10. Implemented Ventilator System

To sum up, this paper presents a unique, versatile and innovative low-cost, portable mechanical ventilator UT1. The design of this system is based on automation of the already

TABLE III
Ventilator Parameters

	Parameter			
	Flow rate	*Tidal Volume*	*Pressure*	*I:E Ratio*
Units	(LPM)	(mL)	(cm H2O)	
Range	20-50	200-800	0-35	1:1 to 1:3

existing and clinically accepted Portable Emergency ventilator (PEV) i.e. the ambu bag. The system uses electrical motors and sensors based feedback control mechanism to provide safe, reliable and regulated operation comparable to high priced Intensive care unit's ventilators for life-saving. Currently, this system do not provide the advanced functionalities of big ICU ventilators at this point but can provide lifesaving support in most of the cases till the patient recovers or a better alternative becomes available. Therefore, this system can save the lives of thousand of patients worldwide.

VIII. Conclusion

This paper presents a simple yet efficient and low-cost mechanical resuscitator device that can save thousands of lives each year in developing and underdeveloped countries. With further testing, it is hoped that the system can be used in hospitals as an alternative to Portable Emergency ventilator (PEV) or to an ICU ventilator if one isn't available. It can also be used where portability is required i.e. emergency vehicles and field hospitals. The simple yet effective design presented in this work has been verified. UT1 is being tested further to determine the best route for its deployment for use by patients in need. Moreover, application has been submitted to get Emergency Use Authorization (EUA) by The Food and Drug Administration (FDA).

IX. Acknowledgement

The authors declare that they have no competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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