DRDO's Portable Low-Cost Ventilator: "DEVEN"

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Received: 10 May 2020 / Revised: 14 June 2020 / Accepted: 23 June 2020 / Published online: 15 July 2020
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Abstract

A reliable, portable and low-cost ventilator named "DEVEN" is designed and developed by scientists of Dr. APJ Abdul Kalam Missile Complex, RCI, DRDO-Hyderabad. This Ventilator is named as DEVEN—DRDO's Economical Ventilator. DEVEN has features comparable to high-end ventilators and would serve the requirements of a large number of ventilators under the present COVID-19 pandemic situation. Also, DEVEN being a portable ventilator can be used in field application using a portable air compressor and reservoir. Hence, it can be used in an ambulance, any mobile vehicle or for application in any remote/rural area. DEVEN has a micro-controller-operated solenoid valve-based design and is developed by tweaking existing technology being used for hot gas reaction control systems (HRCS), employed in attitude control of exo-atmospheric missiles. HRCS is achieved by actuating solenoid valves through a micro-controller to control the flow of oxidizer as well as fuel. Existing controllers being used for control of electro-mechanical actuators are tweaked for control of the above-mentioned solenoid valves for inspiratory as well as expiratory lines of DEVEN.

Graphic abstract

Keywords Portable ventilator · Solenoid valves · Controller · Pressure regulators

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Technology

Developed a low-cost portable ventilator with precise measurement and control/adjustment of important patient parameters such as inspiratory pressure, respiration (breathe) rate, inhaling–exhaling (I:E) ratio, tidal volume, and percentage oxygen (FiO_2).

All the above-mentioned parameters are controlled using manual valves/touch screen and are displayed using serial communication link onto a touch-screen LED display. Once displayed, the doctor/hospital attendants can vary these parameters depending upon the patient's breathing requirement. Different categories of patients have different respiration rates and hence require different inhalation and exhalation of air as well as oxygen. All the parameters (except FiO_2) are controlled on the touch screen which in turn controls the opening and closing times of the solenoid valves. FiO_2 is controlled manually by suitably positioning the knob of a three-way valve. Air and oxygen enter through this valve at two inlets and a mixture of both air and oxygen comes out from the outlet of this valve and this mixture of both gases is subjected to the patient through the inspiratory solenoid valve.

Methodology for Design and Development of DEVEN

The following methodology was adopted for design and development:

- (i) Essential technical features of low-cost ventilators for COVID-19 situation, put forth by empowered technical committee of DRDO, were studied.
- (ii) Requirements of medicine and healthcare products regulatory agency (MHRA)-UK for rapidly manufactured ventilator system (RMVS 2020) were also studied.
- (iii) Existing open-source designs for low-cost ventilators were studied which were mostly AMBU bag-based designs (Emergency Ventilation Alternative System 2020; Read 2020) and have inherent disadvantages.
- (iv) A new design was conceptualized using solenoid valves actuated by a micro-controller. It was ensured that all commercially-off-the-shelf (COTS) available parts having low cost are used.
- (v) A functional prototype was developed using available parts and functioning of the same was demonstrated to doctors from various hospitals in Hyderabad.
- (vi) Detailed design review was conducted by a committee with Director DEBEL-DRDO as chairperson, many senior scientists from DRDO and two doctors as members. This Committee was satisfied with the simplicity of the design of DEVEN and its features such as control of parameters, display and alarms.
- (vii) Order has been placed for the realization of ten DEVEN ventilators on industry partner. These units would be subjected to further testing, evaluation and approvals.
- (viii) Endurance testing for 5 days and battery backup testing are in progress.
- (ix) Future tasks planned are as follows:

- (a) Testing using a calibrator set-up for confirmation of all patient parameters and their displayed values/alarms.
- (b) Demonstration to empowered technical committee of Central Government for regulatory approval and clearance for mass production.

Working Principle of DEVEN

Overall schematic and electrical block diagram are shown in Figs. 1 and 2, respectively.

Working Principle of DEVEN can be Explained as Follows

DEVEN ventilator system has two modes of operation (as shown in Fig. 1):

- (a) Hospital mode.
- (b) Stand-alone mode.

In hospital mode, DEVEN draws compressed air and oxygen, both available at 5 bar pressure from centralized hospital compressed air and oxygen supply lines.

In standalone mode, compressed air at 5 bar pressure is supplied from compressor and air reservoir, and oxygen is supplied from an oxygen cylinder, through a pressure regulator. This pressure regulator reduces the pressure of oxygen (from cylinder) to 5 bar.

Further Working is Same for Both the Modes of Operation and is Explained as Follows

Compressed air and oxygen supplies at 5 bar pressure are available at the inlet of low-pressure air and oxygen regulators built into the ventilator (Al Hussein 2010). The outlet pressure of these pressure regulators is adjustable between 10 and 50 cm H_2O .

There is a three-way (01 no.) or two-way (02 nos.) manual control ball valve(s) at the outlet of these two pressure regulators. Mixing of air and oxygen takes place in these valves. Also, these valves are used to control the flow of air/oxygen being subjected to the patient at a pressure between 10 and 50 cm WC (adjustable). 100% air, 100% oxygen or a mixture of the two can be given to the patient using this ball valve(s).

Mixture of air/oxygen is fed to the inspiratory limb of the patient through solenoid valve. Opening and closing of this solenoid valve will start/stop the inspiration. Frequency of operation of solenoid valve, i.e. its ON/OFF time, is controlled by a micro-controller depending upon the requirement of respiration rate (BPM), I:E ratio and tidal volume.

There are three sensors in the inspiratory line for measuring FiO_2 , inspiratory pressure and flow rate of air/oxygen being

Fig. 1 Overall schematic diagram of DEVEN

delivered to the patient. Values of FiO_2 , inspiratory pressure and flow rate of air/oxygen being delivered to the patient are read by the controller and displayed on to an LED display. Also, the limits of these parameters can be set from the LED touchscreen using touch and alarms are programmed in case the measured values cross these limits in case of any abnormality. If necessary, a non-return valve (NRV) can be provided in the inspiratory line to avoid any backflow from the patient.

During exhalation, solenoid valve in the inspiratory line will close and solenoid valve in the expiratory line will open. Hence, flow can take place from the patient through the expiratory line. If necessary, a non-return (NRV) valve can be provided in expiratory line to avoid any backflow to the patient. Frequency of operation of these two solenoid valves will decide the BPM, I:E ratio, tidal volume, PEEP, etc.

Display of all these parameters on an LCD screen is shown in Fig. 3.

Safety Features

Since a ventilator works as a life support system, various safety features are required. Safety features provided in DEVEN are as follows.

Alarms (Audio Visual)

- (i) High- and low-level alarms for inspiration pressure, tidal volume, BPM, I:E ratio, FiO_2 and PEEP.
- (ii) 'Patient disconnected' alarm in case the inspiratory or expiratory limbs are disconnected accidentally.
- (iii) 'Ventilation abnormal' alarm in case the breathing pulse is not detected by the ventilator system.
- (iv) 'Power failure' alarm.

Fig. 2 Electrical block diagram of DEVEN

Fig. 3 Display screen of DEVEN

These alarms will alert the hospital staff in case any abnormality is detected. Alarm history of the last 200 alarms is provided which can be retrieved on the screen if desired by the hospital staff.

Interlock During Switching Off

There is an interlock provided in case the ventilator gets accidentally switched off. This is ensured with an over-rider command on the touchscreen display to accept switch-off. Hence, double confirmation is achieved for switching off the ventilator, if someone wants to switch off.

Power Back-Up

Redundancy for power failure is provided with the help of a UPS, which can keep the ventilator operational for 2 hours in case of main power failure.

Results

DEVEN has been successfully developed and functioning has been demonstrated to various hospitals. All the parameters were checked for display and all the alarms have been tested. Endurance testing, i.e. continuous working of DEVEN for 5 days and battery backup testing is in progress. Subsequently, DEVEN will be tested using a calibrator unit to validate the values of various parameters read by sensors and displayed on the screen.

Novelty in Technology

Simple circuits both pneumatic and electrical are planned which have novelty in-built into the system. Low-cost components available commercially-off-the-shelf (COTS) are being used. DEVEN uses electrically controlled solenoid valves which have not been used in the field of low-cost ventilators till date. These valves are reliable and can be controlled using an electronic controller.

Advantages Over Other Low-Cost Ventilators

(a) Pneumatic and electrical circuits used are simple, reliable and of low cost. Thus, DEVEN has advantage over other low-cost/portable ventilators. DEVEN employs a solenoid valve-based, micro-processor-controlled technology; hence, its design is different from most of the low-cost ventilators. Mostly, low-cost ventilators make use of AMBU bag and an electro-mechanical assembly to compress and release the AMBU bag (Al Hussein

2010). According to some of the articles (Al Hussein 2010; Emergency Ventilation Alternative System 2020; Read 2020), these designs although cheap and an easy way to force air inside patient's lungs are not fit for use since they can be fatal to the patient, resulting in barotrauma. Most of the low-cost ventilator designs are based on a robotic way to squeeze and release the AMBU bag which cannot control the inspiration pressure accurately; hence, there are high chances of damaging the alveoli (very delicate tissues as last part of the lung).

The risk of lung damage by mechanical ventilation is even higher in COVID-19 patients when the lungs are filled with undesirable fluid, causing higher pressure inside lungs. These AMBU bag-based low-cost ventilators (Al Hussein 2010) deliver volume of air as per the stroke provided by an actuator to compress the AMBU bag and hence can work only when the patient is paralyzed/unconscious. They require the patient to be sedated to the point of near-paralysis to disable them breathing naturally, till the patient has recovered. They are used in do-or-die situations, as a last resort for mandatory breathing, but cannot be considered for situations like COVID-19. In this type of situation, pressure support is required, where breathing sequence is triggered by the patient. Also, they are generally used for adults and cannot cater for pediatric cases.

- (b) Various important parameters such as inspiration pressure and its status, tidal volume (V_T), FiO_2 , breathe rate, inhaling–exhaling (I:E) ratio, PEEP (positive end-expiratory pressure), sigh inhalation, etc. can be controlled and adjusted manually as well as in automated mode. DEVEN can be operated in three modes, and each mode gets displayed on the LED screen. There is continuous mandatory ventilation (CMV) mode, where these parameters are adjusted manually. There are two other modes, pressure support (PS) mode and synchronized intermittent mandatory ventilation (SIMV) mode, where DEVEN can be automatically controlled by sensing the patient's breathing effort.
- (c) Control of various parameters: Ranges of certain parameters which can be controlled are as follows:
 - (i) Respiration (breathe) rate: 8–30 BPM (breathes per minute).
 - (ii) Inhaling–exhaling ratio (IER) (including inverse ratio ventilation): from 4:1 to 1:4 (4:1, 3:1, 2:1, 1:1, 1:2, 1:3, 1:4).
 - (iii) Tidal volume (V_T): 50–500 ml (depending on pediatric or adult use).
 - (iv) Inspiration pressure: 5–50 cmH₂O.
 - (v) Percentage of oxygen (FiO_2): 0–100% of oxygen.

- (d) Safety features such as alarms, interlock for switching off and power backup give DEVEN an edge over other low-cost ventilators.
- (e) Display of all the parameters on an LCD screen with inbuilt alarms.
- (f) Pressure support (used in high-end ventilators) is not available in any low-cost ventilator. This function is also incorporated in DEVEN design, using pressure values of the inspiration line and appropriate supply of air/oxygen as required for various patients. Decision-making is possible by a doctor for providing oxygen in the inspiration line of the patient. Doctors can provide either compressed air available in hospitals, or mix oxygen in the required proportion, or provide up to 100% oxygen depending on the patient's requirements. Oxygen sensor (% O₂) measures the actual percentage of oxygen going to the patient in real time and displays the same on the screen. The flow sensor gives the idea of tidal volume being supplied to the patient.
- (g) Dual use:
 - (i) Hospital use (where 5 bar compressed air and 230 V AC power is available in hospital).
 - (ii) Stand alone (employing air compressor and UPS with battery).
- (h) The exhaled air can be contained in a line and can be vented safely for any chemical treatment if it is contagious.
- (i) Feature of adjustable PEEP is provided.
- (j) Low cost/economical: Rs. 50,000/– (for basic model in hospital use) when produced in numbers of 500 or more.

For What this Technology was Developed

This technology was developed for hot gas reaction control system (HRCS) used in Attitude control of exo-atmospheric missiles. Primarily, this technology employs hypergolic fluids to be mixed at high pressure to give necessary combustion which in turn are used as hot gas reaction control systems (HRCS). HRCS employs fluids (fuel and oxidizer) at high pressure, which when mixed give combustion and are used for the correction of missile attitude. HRCS in a missile is achieved using solenoid valves which are controlled by an on-board computer. This on-board computer operates solenoid valves using digital outputs and the status of operation of these valves is read using digital inputs. HRCS is used to give attitude correction to missiles in exo-atmospheric region where aero-dynamic control is not effective.

Digital signal controllers being used for control of electro-mechanical actuators in missiles are used for control of the abovementioned solenoid valves.

How the Technology Can be Tweaked to Make it Relevant to COVID-19

Existing solenoid valve technology being used for hot gas reaction control systems (HRCS) is being tweaked for the development of DEVEN. Also, existing controllers being used for control of electro-mechanical actuators in missiles are tweaked for the control of solenoid valves in DEVEN. This controller is pre-programmed to operate the solenoid valves depending upon a patient's requirement of I:E ratio and respiration rate (BPM) or as set by hospital staff. Analog to digital converters (ADCs) in the controller circuit are used to read pressure, flow and oxygen sensor outputs.

DEVEN is reliable, portable and involves features available in high-end ventilators. It would serve the purpose of the requirements of a large number of ventilators in the event of an outbreak of COVID-19 pandemic. Also, DEVEN being a portable ventilator can be used in field application using air compressor and battery. Hence, it can be used in an ambulance, any mobile vehicle or any remote/rural area.

Timeline and Resources Envisaged for this Conversion

A fully functional prototype was realized in 1 week's time using available components in our laboratories such as solenoid valves and controllers. This ventilator has been developed in consultation with various doctors and demonstrated to five doctors across India as follows:

- (a) Dr. P. Gopinath, ESIC Medical College and Hospital, Sanathnagar, Hyderabad.
- (b) Dr. Amlendu Yadav, ABVIMS & Dr. Rammanohar Lohia Hospital, New Delhi.
- (c) Dr. Rakesh Sahu, MM Medical College & Hospital, Kumarhatti, Solan, Himachal Pradesh.
- (d) Dr. P. Balakrishna, Apollo DRDO Hospital, Hyderabad.
- (e) Dr. Mamatha Kondura, Medical Officer, MI Room DRDL.

Presently 10 (Ten) nos. of such ventilators are under realization for testing at different hospitals. The simple design of DEVEN enables high production rates.

Availability of low-cost components during the period of lockdown has been mainly time consuming. However, testing of DEVEN as well as its approval from ICMR/ other medical authorities would require some more time.

Once approval is completed, these ventilators can be mass produced.

In view of the above pre-requisites of testing and approval from medical authorities, this may require a timeline of almost 1 month.

Technology/Solution that is Being Tweaked

- (a) HRCS technology used for attitude control of missiles, involving pressure regulators and solenoid valves: This technology was used for hot gas reaction control system (HRCS) of exo-atmospheric missiles and is being tweaked for the development of DEVEN.
- (b) Control of electro-mechanical actuation systems used in missiles: Existing controllers used in electro-mechanical actuation systems, with digital input/outputs (DIOs) for control and display of important parameters are tweaked for control of solenoid valves and instrumentation.

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