Systematic Design, Control, and Parametric Testing of an Automated Resuscitator Bag Mechanical Ventilator

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The COVID-19 crisis has revealed and exacerbated a shortage of mechanical ventilators in hospitals around the world, regardless of their government's resources. Where some countries can respond to the situation by ordering more high-end ventilators, the price is often too high for low- and middle-income countries (LMICs) and securing them can be difficult. The goal of this work is to design, prototype, and test a low-cost ventilator, called ETH breathe, based on the automated compression of a resuscitator bag. A holistic and systematic design approach is taken to create a compact and adaptable device that can safely meet the current requirements. This is achieved by using 72% standard parts out of 33 (72%) and prioritizing compactness in the mechanical design. The control system is developed to provide both continuous mandatory ventilation (CMV) and spontaneous breathing support or assist control (AC), which significantly extends the potential use cases beyond patient sedation. The prototype is tested for accuracy, modularity, and oxygen response using a full physiological artificial lung. The results show for the first time in literature that the design operates within the defined requirements, based on emergency government regulations, and can be used with different sizes of resuscitator bags and different positions of the flow sensor. This provides a sound basis for further development of a low-cost, portable mechanical ventilator for potential use in LMICs.
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1 Introduction and Background

The COVID-19 crisis is overwhelming healthcare systems around the world. Even developed countries struggle, in part, to keep up with the increasing demand for medical equipment and supplies to combat the pandemic. One particular challenge has been to provide mechanical ventilation to patients suffering from acute respiratory distress syndrome (ARDS). Universities, medical facilities, and companies have been under pressure to design and produce alternatives to the established medical devices as their countries are put under increasing demand. However, many of the proposed solutions are tailored to first world markets, where an average intensive care unit (ICU) ventilator can cost between US $25,000 and US$50,000 [1,2]. Due to the prohibitive cost, low- and middle-income countries (LMICs) were already in shortage of mechanical ventilators before the COVID-19 crisis started [3,4]. Some LMICs do not even have a single ventilator [3].

Many companies and universities are thus investing considerable resources into the development of low-cost ventilators, often focused on their own country's needs [2]. Of two types of mechanical ventilation, pressure and volume-controlled, low-cost efforts have been mostly centered around volume-controlled solutions using resuscitator bags. Manual resuscitator bags are commonly used for emergency manual ventilation and are widely available around the world at a low cost. However, manual ventilation incurs both a large need for trained manpower and the risk of aerosolizing of the virus [5]. The focus has been to design systems that replace the

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Table 1 Overview of six well documented low-cost ventilator projects stemming from universities and research organizations and the ventilator presented in this work, the ETH breathe

Project	Size	Control	Modes	Testing	Target price	Target market	Open source
ETH breathe	30 × 25 × 35 cm	Volume (VCV), manual resuscitator	CMV and AC	Accuracy, modularity, robustness, oxygenation, AC breathing, and alarms	$1000	Ukraine, LMICs	Yes
MIT E-Vent[a]	Approx. 35 × 38 × 20 cm	Volume (VCV), manual resuscitator	CMV and AC	In-vivo and usability	Not given	US, pandemic	Yes
OperationAir, Delft	Approx. 40 × 40 × 100 cm	Pressure (PCV)	CMV	"Extensive," no results shown	Not given	Pandemic stricken states	Yes
ApolloBVM resuscitator, Rice University, [7]	36 × 40 × 18 cm	Volume (VCV), manual resuscitator	CMV	24 h test	Under $250	US, pandemic	Yes
Coventor, University of Minnesota, [8]	"Cereal box"—Approx. 30 × 40 × 15 cm	Volume (VCV), manual resuscitator	CMV	FDA approved for emergency use operation	Not given	US, pandemic	No
Spiro Wave—E-Vent inspiredt[b]	"Compact"	Volume (VCV), manual resuscitator	CMV	FDA approved for emergency use operation	$2500–$5000	US, pandemic	No
HEV, Cern, [9,10]	50 × 50 × 35 cm	Pressure (PCV)	PRCV, SIMV-PC, CPAP	None specified	Not given	Pandemic stricken states (developed)	No

[a]See Note 4.
[b]See Note 3.

manual ventilation by compressing the bag mechanically and controlling the volume output [6].

Building on earlier publications [4], university-based groups designing these devices, such as the Massachusetts Institute of Technology (MIT) E-vent, the Delft OperationAir, and Rice University's ApolloBVM resuscitator, have been forthcoming with their data, publishing their design online as open-source and reporting on their findings and testing. In Table 1,[2] a brief overview of the most well documented low-cost ventilator projects reveals some of the gaps in current efforts.

The first gap is the lack of a holistic, systematic design approach that moves beyond functional prototypes and provides information on parametric design studies and systematic testing of alternatives. The second gap is in the control system. All volume-controlled designs, except for the MIT E-vent, only provide continuous mandatory ventilation (CMV) without patient triggering, for which a patient needs to be sedated and which prohibits the use on patients with spontaneous breathing activity. The process of weaning, which requires the patient to breathe on their own, represents roughly 40% of the duration of mechanical ventilation and is essential in the rehabilitation of a patient [11]. Only the E-Vent from MIT currently supports an assist control (AC) mode allowing for a synchronization of the ventilator with the spontaneous breathing effort of the patient, which is an essential step in a patient's recovery. The two pressure controlled projects in Table 1 that also have additional ventilation modes are built for integration in resource-rich hospitals and cannot be used as standalone devices [9,12].

The third gap is that of testing documentation and peer-review, archival publication of design documentation and test results. Although two of the six examples shown above, Coventor and Spirowave, have emergency FDA approval to use their devices during the crisis[3] [13,14], test results and protocols are sparsely documented openly, if at all [15,16]. Some governmental requirements for ventilators during the pandemic are available online [14,17] and roughly outline which tests are required for the authorizations. However, the use of the new ventilators is limited to the duration of the pandemic and each country has its own test requirements and approval procedure.

The general lack of open-source documentation in testing is also a drawback for the whole research community. Although producing an initial design rapidly and openly of the initial response was key, consistent documentation and reporting of the projects, including parametric studies and results, allows others to better build on each other's findings.

In this work ETH breathe, a mechanical ventilator design using a manual resuscitator bag is presented. The design focus is to produce a low-cost, portable, and adaptable device for potential used in LMICs. Low cost is addressed by mainly using standard and widely commercially available parts, which also promotes replicability in different countries and facilitates maintainability. The compactness and portability of the device is a key motivation in the choice of several of the mechanical components. The adaptability is assured on two levels. First, the desire to produce a standalone device that can support patients through the whole ventilation process motivates the inclusion of both CMV and AC. The patient adaptive control adjusts automatically to the patient's lung size and stiffness, and supports any type of adult manual resuscitator bag. The device also successfully fulfills a list of requirements defined that is based on the Medicines and Healthcare products Regulatory Agency (MHRA) guidelines for Rapidly Manufactured Ventilator Systems in the COVID-19 crisis [18], the Code Life Ventilator Challenge [19], and the ISO80601-2-12 standard. The main system requirements are detailed in Sec. 2.

The structure of this work is as follows: first, the design rationale, design requirements, and mechanical design are explained in detail. Next, the control system is described. The testing protocol and five main test categories and their desired outcomes are presented. The results and main parameters are then summarized and discussed with respect to the intentions of this work. Finally, the outlook for the design presented is discussed.

2 Design Description and Methods

The requirements for the device are established based on a thorough analysis of the emergency COVID-19 requirements that were

[2]https://www.operationair.org/en/
[3]https://ventilatorresponse.com/

Table 2 List of requirements for the ETH breathe prototype

Medical requirements, MHRA rapidly manufactured ventilator system guideline (RMVS)	Must	Should	Could
Continuous mandatory volume-controlled ventilation (non-triggered) (CMV-VCV)	x		
Continuous mandatory volume-controlled ventilation (triggered/assist control) (CMV-VCV/AC) setting			x
Tidal volume settings: 350 mL, 400 mL, and 450 mL		x	
Breathing rate settings: 10–30 bpm in at least increments of 2	x		
Inspiratory-expiratory ratio (I:E) settings: 1:1–1:3		x	
High-pressure alarm limit settings: 15–40 cm H_2O in at least increments of 5 cm H_2O	x		
Low pressure alarm setting 0–20 cm H_2O in at least increments of 5 cm H_2O	x		
Flow trigger settings: −3 to 7 L/min in at least increments of 1 L/min			x
Positive end-expiratory pressure (PEEP) settings: 5–20 cm H_2O in at least 5 cm H_2O increments	x		
Monitoring, ISO 80601-2-84 Subsection 201.12.4 and RMVS			
Displayed airway pressure	x		
Displayed expiratory volume		x	
All Medical Settings are clearly discernable at all times	x		
Alarms, IEC 60601-1-8:2006; ISO 80601-2-84:2020; IEC 62366			
High pressure alarm	x		
Low pressure alarm	x		
Low/high expiratory volume		x	
Electronics failure	x		
Power supply failure	x		
Alarm silence feature up to 120 s	x		
Visibility of the highest priority alarms (distance from the operator)	x		
Visibility of the lower priority alarms (distance from the operator)	x		
Light indicators	x		
Assignment of the alarms' priority	x		
Safety, ISO 5356-1:2015 and BS EN ISO 5359:2014 + A1:2017; ISO80601-2-84 Subsection 201.101.3.2.2			
Expiratory gas must be able to pass through an appropriate filter that can be fitted using standard connections to reduce contamination of the immediate environment.	x		
The tubing system must consist of medically approved standard parts.	x		
The gas connectors shall be a 15 mm or a 22 mm connector.	x		
All external surfaces must be cleanable in the likely event that they get respiratory secretions or blood splatter on them. Cleaning would be by healthcare workers manually wiping using an approved surface wipe with disinfectant or cloths and approved surface cleaning liquid.	x		
All parts coming into contact with the patient's breath must be either disposable or designed to be reusable	x		

published by the FDA in the US [14] and MHRA of the UK Government [18]. The list of requirements in Table 2 is compiled mainly from Ref. [18] and the ISO80601-2-12 norm [20].

We focus on the automated compression of a resuscitator bag to turn commonly available medical equipment into automated ventilators that can provide multiple ventilation modes and are intuitively usable, as resuscitator bags are commonly known and can also be easily replaced. In Fig. 1, the complete system is shown and can be broken down into four modules: mechanical system, breathing circuit, controls and electronics, and user interface. Signals are depicted with dashed lines, while air is depicted with a solid blue line. The breathing circuit, shown in grey, consists of commonly available parts that can be sourced and plugged directly into the system. To reduce cost and accelerate the medical approval process, it is advantageous to use as many standard, medically approved parts as possible. The custom mechanical parts are all within the compression mechanism, which is explained in detail in this section. The sensors are chosen and calibrated to monitor flow and pressure. In particular, the output of the pressure sensor is displayed and can trigger alarms. A comprehensive parts list is available in the Supplemental Materials on the ASME Digital Collection.

2.1 Compression Mechanism and Breathing Circuit. The compression mechanism replaces the compressing action of a hand on the manual resuscitator bag. The main requirements are to make it as compact as possible, capable of delivering the maximum tidal volume (the volume of air pushed into the lungs for each breathing cycle), adapt to different resuscitator bag sizes and provide stability so as not to distort the input and output signals.

It is composed of four main subsystems: the motor and holder, the gear system, composed of the gears and the paddles for compression of the bag, the bag holders and the assembly mounting structure. In this section, the gear system, paddle design, and the holders are described in detail. The mechanical design is inspired from the MIT Emergency Ventilator Project,[4] or MIT E-vent, and so clear distinctions from that design are also given.

The mechanical compression system, as shown in Fig. 2, is composed of three gears: one driving gear (pinion) that is connected to the motor ($D = 33$ mm) and two driven gears ($D = 48$ mm) mounted on parallel shafts. A gear-based compression system enables modulation of the tidal volume to ensure that the system can be used for different patient sizes and different manual resuscitator bag sizes as well as providing a compact design. The fingers are attached to the driven gears using three M4 screws and a heavy-duty dowel pin. The gears undergo high torques and are sized using the ANSI/AGMA 2001-D04 standard; see Sec. S1 available in the Supplemental Materials for more details. Standard hardened steel gears with a module of 1.5 are used, which are compact, easily maintainable and cheaper than the stainless-steel alternative. They need little lubrification, especially if they are shielded from dust. The gears are the function critical parts of the design; see Supplemental Materials for more details. The design is simplified and standardized from the MIT E-vent in that it uses three separate standard gears instead of adding teeth features to the paddles.

The shape of the fingers and paddles is designed systematically through a parametric study. Due to the compression of a soft bag, which would be difficult to simulate and optimize, it is not intuitive what profile is best. The design objective is to maximize compression volume of any type of manual resuscitator bag in relation to the paddles' width, profile, and height. The four main shapes obtained

[4]https://emergency-vent.mit.edu

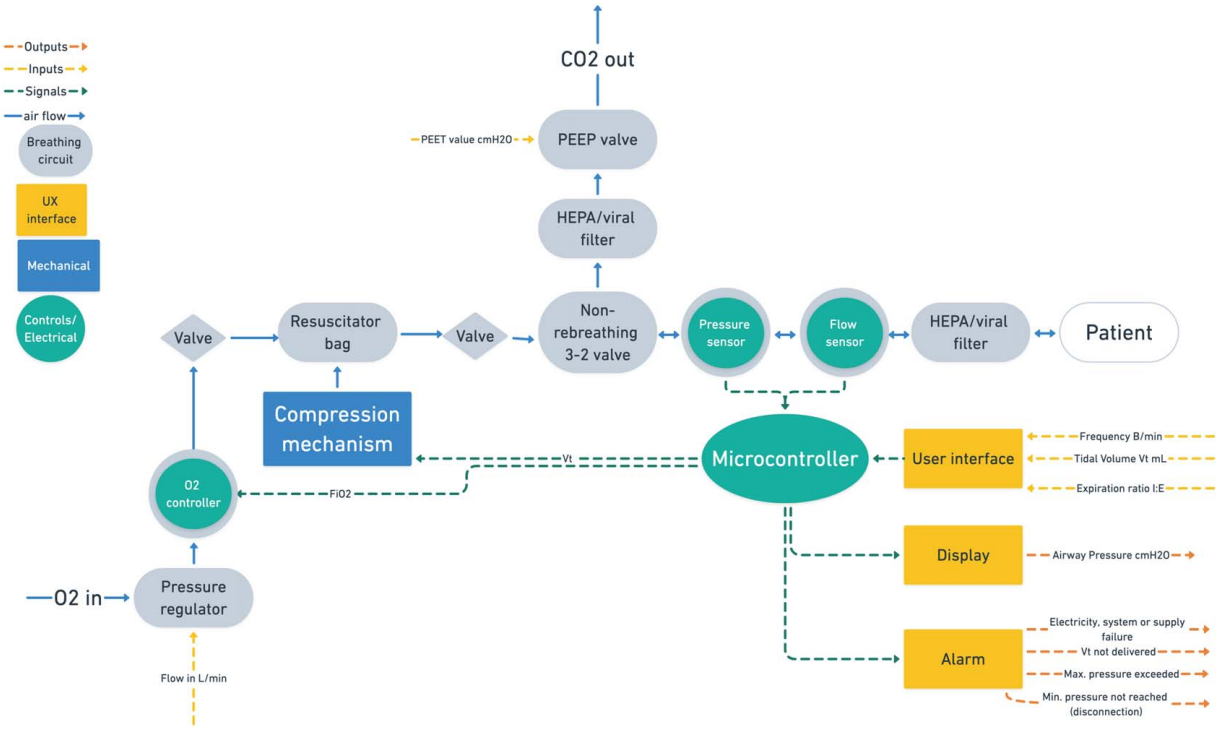

Fig. 1 System overview of the design

through the study are shown in Fig. 3. Each shape is tested for identical settings and is evaluated based on the achieved tidal volume. Results show that a thickness of 45 mm compresses the bag fully; larger dimensions interfere with the stiff ends of the manual resuscitator and do not add volume. A convex profile whose apex coincides with the largest point of the resuscitator achieves an even compression of the bag and ensures there are no air pockets remaining. The asymmetry of the profile ensures that the paddles do not collide before the complete volume is compressed. Adjusting the paddle height to 155 mm in combination with the convex profile with a maximum width of 73 mm ensures that the top of the bag is not left uncompressed. The parameter value for the four profiles and the main variable ranges for the parameter study are found in Fig. 3.

The paddles are 3D printed in ABS using FDM, however, the shapes are designed in 2.5D so that they could also be cut from plastic or hard foam, thus making them straightforward to fabricate and replace. The final paddle design, design 4 in Fig. 3, achieves the required tidal volumes of 350 mL, 400 mL, and 450 mL for all required frequencies and I:E ratios.

The resuscitator bag holder mechanism is a key feature for the adaptability of the design. Different hospitals use different types and sizes of bags and during the COVID-19 crisis not all types and sizes are always available, thus making adaptability crucial. The holders accommodate changes in length and height and consist of two main parts: a front holder and a back holder. The back holder is fixed on both shafts and the front holder can slide up and down so that the height can be adjusted in steps of 5 mm. The two adjusting rings at the front and the back of the holders set the changes in length. Since the bag contracts when it is compressed, it is important that the material of the holders is flexible enough to compensate for the length changes.

To standardize the design, thus potentially reducing cost and making it more reproducible, 23 out of 33 parts are standard (72%) and nine are custom. Of the nine custom parts, eight can be made by hand in a machine shop, using laser cutting or water jetting; the ninth can be made by hand in a machine shop. Of the nine custom parts, only the fingers, which transmit the compressing force, could be prone to breaking; they are made of steel to avoid this problem. The supply chain in this work is centered around Switzerland, but all standard parts could also be sourced in many other countries. A complete list of parts can be found in the Supplemental Materials.

The breathing circuit provides the connection between the resuscitator bag and the patient and consists of standard, medically approved parts. The main requirements for the breathing circuit shown in Figs. 1 and 4 are as follows:

- Dead-space in the tubing is minimized to prevent re-inhaling CO_2.
- Exhalations from the patient are filtered by a HEPA filter (Gibeck® Iso-Gard® Filter, Teleflex, Morrisville, NC, USA).
- The positive end-expiratory pressure (PEEP) is controlled with a standard, mechanical PEEP valve (Ambu® Reusable valve, Ballerup, Denmark).
- The flow (SFM3019-240, Sensirion, Zurich, Switzerland) and pressure (MPX50100P, Farnell, Leeds, England) sensor are easily integrated in the tubing.
- Only standardized and certified medical equipment are used.

In Fig. 4, the manual resuscitator is connected to the PEEP valve with a tube of variable length; the PEEP valve is connected to the flow sensor with a similar tube; the non-rebreathing 3–2 valve is included in the PEEP valve and serves as an air-flow diverter for the exhale; the pressure sensor is connected to the patient side of the HEPA filter, which is directly connected to the patient through an endotracheal tube, which requires sedation or a mask. The flow sensor is tested in several positions to optimize performance and test the system sensitivity. These positions are indicated by the numbers 1, 2, and 3.

2.2 Controls and User-Interface. The function of the control system is to drive the paddles to compress the resuscitator bag so as to achieve the desired settings. The control architecture is illustrated in Fig. 5 showing the low level position control of the motor actuating the paddles of the ventilator on the right, and an adaptation mechanism from breath to breath ensuring the accurate tracking of tidal volume and I:E settings. This adaptive mechanism is necessary not only to allow for operation with different size resuscitator

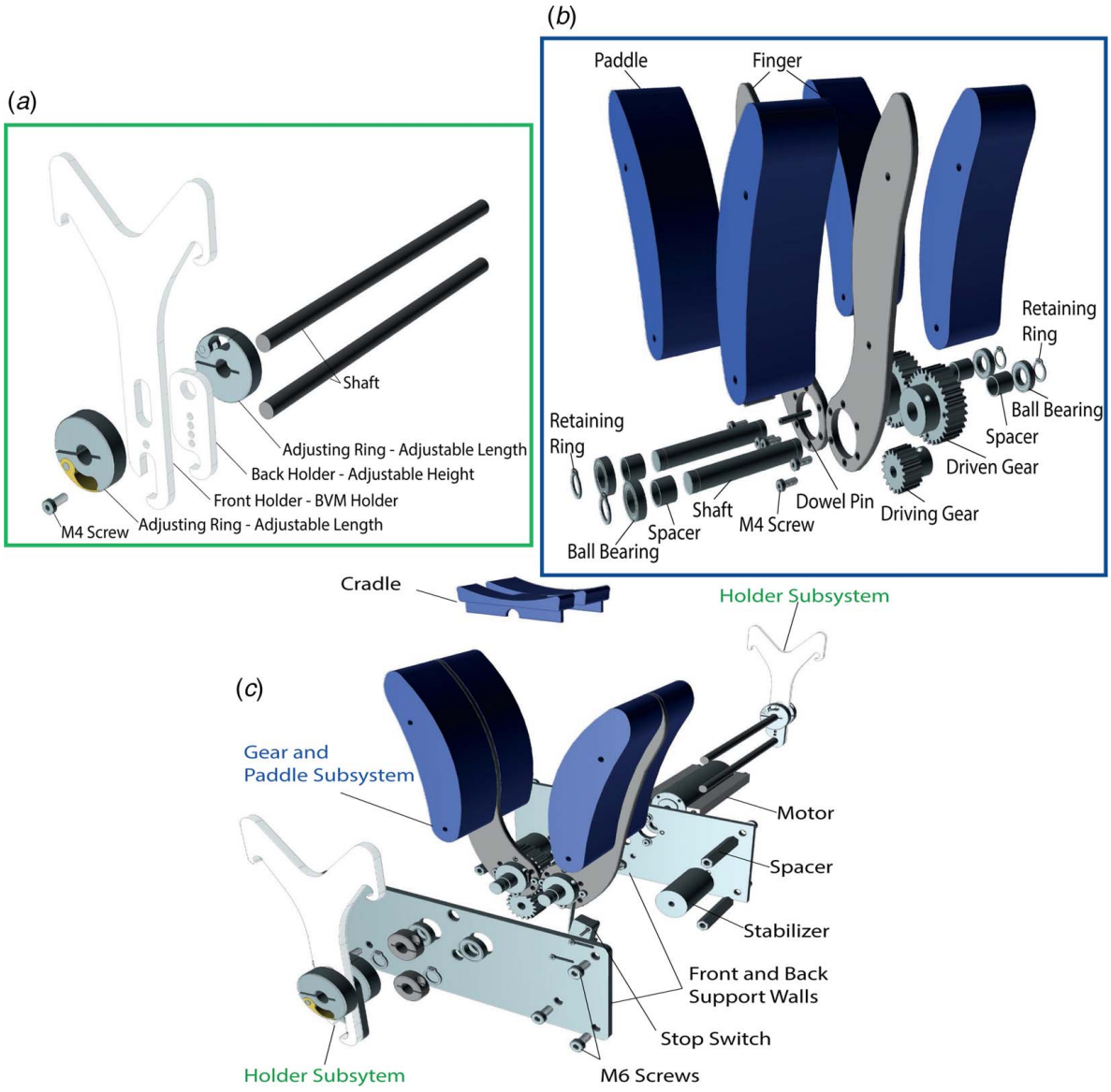

Fig. 2 Mechanical design exploded model: (*a*) holder assembly, (*b*) gear and paddle assembly, and (c) exploded view

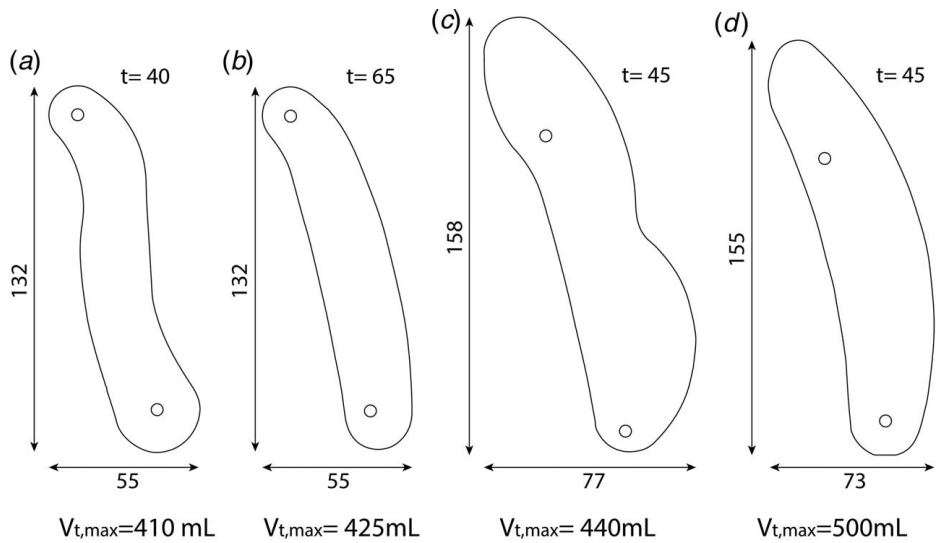

Fig. 3 Profile progression of the paddles during a parametric study, and all measures are given in millimeters

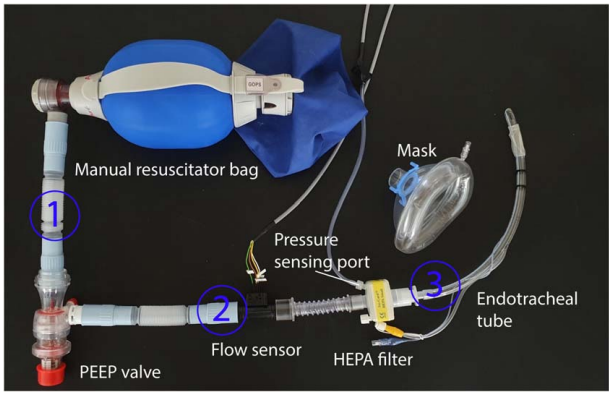

Fig. 4 Breathing circuit setup excluding exhalation filtration; the tubing is adapted from standard medical components; the system works both with a mask or an endotracheal tube; the HEPA filter keeps the virus from being aerosolized; the numbers indicate the three options for testing the flow sensor placement.

bags but also to achieve the desired accuracy for different patient pathophysiologies, showing the low level position control of the motor actuating the paddles of the ventilator on the right, and an adaptation mechanism from breath to breath ensuring the accurate tracking of tidal volume and I:E settings, which is discussed in detail in Ref. [21]. The interface between low-level motor position control and the adaptation mechanism is given by a trajectory generation, providing a sawtooth motor position reference signal which is adjusted based on the desired BPM, as well as on I:E ratio and tidal volume measurements, which are derived from flow sensor measurements. The controller is implemented using MATLAB/SIMULINK/STATEFLOW R2020a on an Arduino Mega 2560 (Arduino®, Somerville, MA).

A distinctive feature of our system compared to other projects[5] [7,10] is the multiple functionalities enabled by the flow sensor: its integration powers not only the alarms but also supports the automatic adaptation of tidal volume based on the patient and the operating conditions. Additionally, the flow sensor is used to detect spontaneous breathing activity of the patient, which can be used to synchronize breathing support in the AC mode. A breath is initiated if the volume flow during the exhale phase exceeds an adjustable trigger value of [−3, …, 5] L/min. Flow triggering can be optionally turned off so the ventilator remains in CMV mode. Given the key role of the flow sensor, the impact of its position in the tubing with respect to the patient is assessed during testing. The tubing, valve components, proximity to the manual resuscitator, and proximity to the patient can all affect the sensor measurements. The quality of the AC mode of the system is then assessed in a series of tests of breath detection and response. The general control system functionality and reliability are assessed through the testing protocol described later. For technical reasons, only the eight most significant bits of the flow sensor measurements are used.

The code can be downloaded online.[6] The control strategy is discussed in detail in Ref. [21].

2.3 Testing. The test protocol is divided in six parts. Volume and pressure measurements are evaluated based on regulatory criteria given in Refs. [18,20]. The detailed list of requirements and test protocol are provided in Sec. S2 available in the Supplemental Materials. The detailed test setup is given in Fig. 6.

2.3.1 Test Setup. All tests are performed using a TestChest® full physiological artificial lung (Organis, GR, Switzerland). All results presented below are direct outputs from the artificial lung that has been calibrated before use and an additional flow sensor used for validation, to increase the precision of the results. Such devices are generally used to train medical personnel. It can replicate complex breathing patterns in different ventilation modes, can measure the gas exchange to the patient, and can validate all the functionalities of a mechanical ventilator.

2.3.2 Types of Test. According to the MHRA of the UK Government, it is accepted that within the timeframe required for mechanical ventilator development, full demonstration of compliance with ISO 80601-2-12:2020 is not feasible. On March 20, 2020, the MHRA released a condensed specification for RMVS [18]. However, compliance with the essential safety standards must be demonstrated to ensure patient safety. A set of characteristics for mechanical ventilator testing and its documentation is defined based on the MHRA recommendations and the ISO 80601-2-12:2020.

The test cases can be divided into the following categories:

(a) Accuracy of mechanical and control system
(b) System modularity using different manual resuscitator bags
(c) Effect of flow sensor positioning
(d) Efficacy of oxygen delivery
(e) AC: spontaneous breathing support
(f) Alarm signals and Monitoring

The results from the tests a, b, and c described below are given in terms of the relative mean error and the standard deviation, which are defined as follows:

$$\text{Relative mean error: } \varepsilon = \frac{\sum_{i=1}^{n} |x_{meas,i} - x_{target,i}|}{n}$$

$$\text{Standard deviation: } \sigma_{dev} = \sqrt{\frac{x_{meas,i} - \varepsilon}{n-1}}$$

with $n = 5$ breath cycles.

The TestChest® and user-set parameters for each test are given in Table 3. The artificial lung represents the lung of the simulated patient. These parameters are different in Test e to reflect the lung condition of a patient suffering of ARDS, which is not relevant for the rest of the testing.

(a) Control accuracy

The control settings accuracy is determined with the following procedure:

(1) Set-up the ventilator with an intubation tube. For this experiment, no mask is used as this test is intended to test the accuracy of individual settings.
(2) Set the ventilator to the parameters given in Table 3, varying the tidal volume, rate, and I:E ratio one at the time. Wait until steady-state conditions are achieved. Record the pressure and volume signals for at least 60 s in steady-state.
(3) Determine the airway pressure at the end of the inflation phase as the average over the preceding 50 ms. Determine the tidal volume via integration of the flow signal provided by the calibrated flow sensor.
(4) Determine the inspiration phase as the onset of a positive flow until the first negative value. A zero-flow after the inspiration is part of the inhalation phase. The expiration phase is determined as the onset of a negative flow until the first positive flow value. A zero-flow after the expiration is part of the expiration phase.
(5) All measurements are recorded for 1 min and for each variable setting shown in Table 3.
(6) Report the results as relative mean error and standard deviation.

The exact test protocol can be found in Sec. S3 available in the Supplemental Materials.

[5]See Note 4.
[6]https://breathe.ethz.ch/technical-information.html

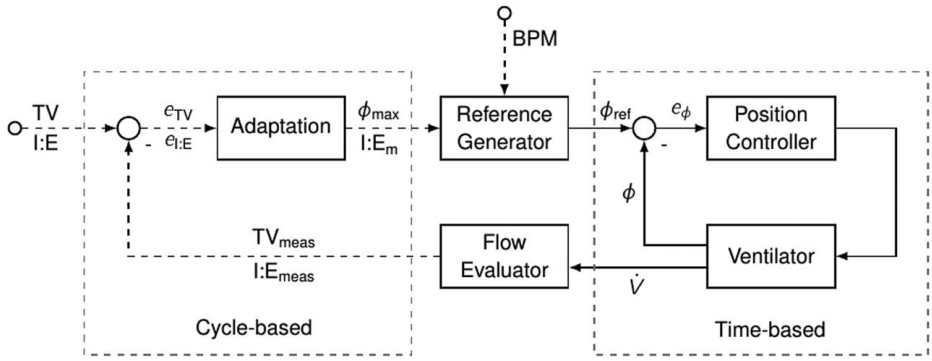

Fig. 5 Illustration of the control architecture as a block diagram. Cycle-based signals computed once per breath cycle are highlighted as dashed lines. The architecture consists of a cycle-based volume controller, which compares the previously achieved tidal volume measurements TV_{meas} to the desired tidal volume TV at the beginning of each breath cycle. The maximum closing position φ_{max} is adjusted based on the difference e_{TV} and fed to the Reference Generator. The Reference Generator provides the motor position reference signal φ_{max} in addition to the I:E ratio and BPM, which is then tracked by a standard closed-loop motor position controller providing the ventilator actuation. The resulting volume flow $\dot{V}$ is measured by the flow sensor and integrated over time of each breath cycle to determine the tidal volume measurement TV_{meas}, which closes the control loop. This is step is carried out by the "Flow evaluator" that provides derived quantities such as the inhale volume per cycle, which are used in the control loop.

(b) System modularity

The system modularity is verified by testing three manual resuscitator bags from different manufacturers under the conditions specified in Table 3 and following the same procedure as the control accuracy testing; each bag is tested three times for variable tidal volume (350 mL, 400 mL, 450 mL). The test protocol and bag specifications are given in Sec. S3 available in the Supplemental Materials. The relative mean error and standard deviation of each parameter are calculated individually for each bag. This test validates the modularity and adaptability of the mechanical and control systems.

(c) Flow sensor positioning

In this test, three flow sensor positions are tested, see Fig. 4. Position 1, which is closest to the manual resuscitator bag, produces better quality measurements for the flow from the bag but could fail to perceive flow triggers from the patient. It also does not register the losses in volume due to leaks in the tubing, which weakens the adaptive flow control. Position 2, closer to the patient, is a compromise in measurement quality for the ventilator air flow and the patient's breath triggering. Position 3, closest to the patient, measures best patient breath triggering and registers all leaks but can be contaminated.

Each position is tested under the conditions specified in Table 3 and following the same procedure as the control accuracy testing; each position is tested for variable tidal volume (350 mL, 400 mL, 450 mL). The relative mean error and standard deviation of each parameter are calculated individually for each position. This test verifies the control system's reliability and accuracy and determines whether proximity to the manual resuscitator bag or the patient are essential for the system's function.

(d) Efficacy of oxygen delivery

The efficacy of oxygen delivery is assessed using two procedures:

– The oxygen saturation is measured for three oxygen flows (2 L/min, 5 L/min, 10 L/min) under the conditions specified in Table 3. The input oxygen level is controlled by a regulator attached directly to the oxygen tank

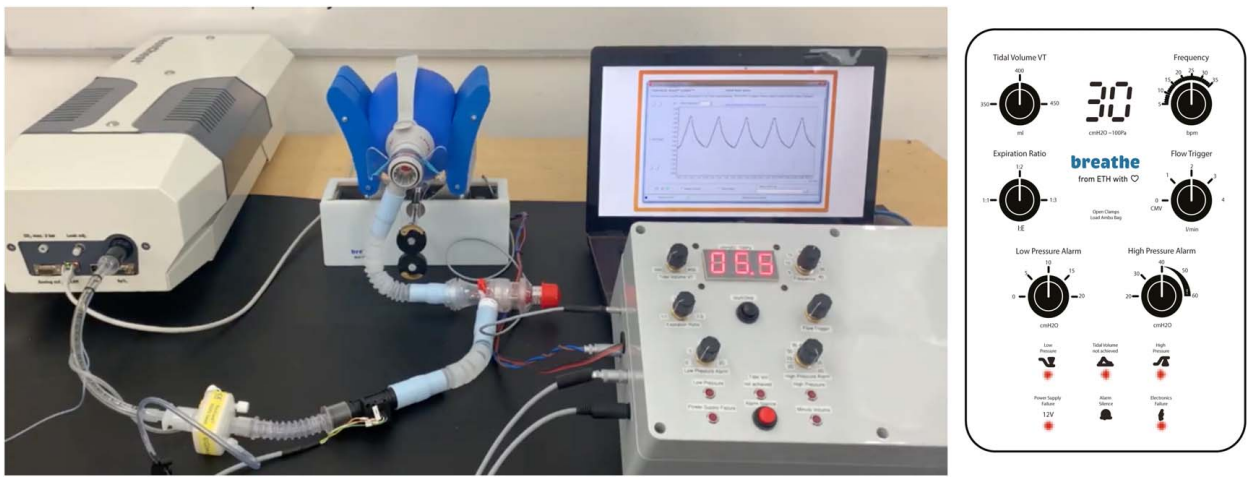

Fig. 6 Test setup; left: TestChest®, center: mechanical ventilator, upper right: test readouts, lower right: prototype user interface; far right: user interface

Table 3 Base settings of the lung mechanics of the artificial lung for test types a to e

	Parameter	Test a	Test b	Test c	Test d	Test e
TestChest® parameters—patient	Chest wall compliance (mL/cmH_2O)	200	200	200	200	93
	Total compliance (mL/cmH_2O)	60	60	60	60	35
	FRC@ZEEP (mL)	1500	1500	1500	1500	1102
	Airway resistance (cmH_2O/(L/s))	5	5	5	5	5
	Lower inflection point (cmH_2O)	5	5	5	5	12
	Upper inflection point (cmH_2O)	35	35	35	35	35
	Compliance below LIP (mL/cmH_2O)	25	25	25	25	8
	Compliance above UIP (mL/ cmH_2O)	20	20	20	20	8
User set parameters	Peak inspiratory pressure (cmH_2O)	NA	NA	NA	NA	20
	Tidal volume (mL)	350, 400, 450	350, 400, 450	350, 400, 450	400	450
	Rate (breaths/min)	10, 15, 20	10	10	10	8 (ventilators)—10 (patients)
	I:E ratio	1:1, 1:2, 1:3	1:2	1:2	1:2	1:2
	O_2 peak flow (L/min)	NA	NA	NA	2, 5, 10	NA
	PEEP (cmH_2O)	5, 10, 15	10	10	10	10

that outputs an analog signal. The output oxygen level is measured by the test lung.

– The time response to a change of oxygen flow t_{90} (0–10 L/min) is assessed with the following procedure:

(1) Ventilate the test lung with a set oxygen concentration of 21% volume fraction.
(2) Wait until equilibrium is reached in the inspired oxygen concentration at the patient connection port.
(3) Change the set oxygen concentration to the maximum volume fraction that the ventilator permits.
(4) Measure the time delay between setting the new concentration and achieving 90% of the final oxygen concentration during inspiration at the patient-connection port. Care should be taken to allow sufficient time for the gas mixture in the test lung to reach a stable concentration

The exact test protocol can be found in Sec. S3 available in the Supplemental Materials.

This test measures how efficiently the whole ventilation system transmits oxygen to the patient at given flows and how quickly the system can provide a desired level of oxygenation.

(e) AC: spontaneous breathing support

During mechanical ventilation, there are two ventilatory pumps acting simultaneously: the ventilator and the patient's own respiratory muscles. These two pumps may work in harmony but can interact in several ways harmful to the patient. Patient-ventilator asynchrony is quite common in patients during non-invasive ventilation (NIV) and invasive ventilation (IV). Asynchronies may occur on two levels: during inspiratory triggering (AC), when there is a mismatch between patient inspiratory effort and ventilator triggering (i.e., ineffective inspiratory effort, double triggering or auto-triggering), or when the ventilator respiration cycle does not correspond to the patient's (i.e., premature or delayed cycling) [22].

The TestChest® can simulate respiratory activity with a range of different settings. The ventilator should respond to the unknown patient breathing and support accordingly (volume or pressure setting, breathing rate).

The following tests are performed in an intubation setting (IV). Four scenarios are tested: no breath signal, strong breath signal (150 mL of air) to apnea, weak breath signal (75 mL of air), and strong breath signal (150 mL of air).

All the simulated patient scenarios first breathe through the ventilator while it is off. The ventilator is then be switched on and the trigger signals set. This allows to qualitatively analyze the breathing resistance through the ventilator by comparing it to the same patient without the ventilator. The TestChest® patient setting used are given in Table 3.

The volume, flow, and pressure outputs are analyzed for each test, evaluating how quickly the assisted breathing control adapts to the patient's varying behaviors.

Additional information regarding alarm settings for the AC testing can be found in Sec. S3 available in the Supplemental Materials.

(f) Alarms signals and monitoring

IEC60601-1-8:2006, ISO 80601-2-84:2020, and IEC 62366 are the relevant standard for alarms for RMVS. Alarms, alarm limits, and prioritization of alarms are complex areas to optimize for human safety. The key is to have enough alarms to ensure patient safety, but not too many and in the correct order of importance so that more urgent patient safety issues are highlighted more prominently. All the alarms relating to a value (pressure or volume) are adjustable. An alarm silence is implemented.

The alarms given in Table 2 are all tested and function correctly, i.e., the alarms are triggered once values above the set limits are reached or in the case of a system failure. Details of the alarm testing results can be found in Sec. S5 available in the Supplemental Materials

Additional alarms derived from the relevant standards that will be implemented in the future are given in Sec. S3 available in the Supplemental Materials.

3 Results

In this section, the results for the five test types defined above are described in detail. The results for system accuracy, modularity, and flow sensor positioning are given in Table 4.

3.1 Control Accuracy. The control accuracy of the mechanical ventilation system verifies its performance during use. It is measured according to four main parameters: the tidal volume, the breathing rate, the PEEP, and the I:E ratio. The results are shown in Table 4.

The MHRA guideline requires "±(4.0 +(15% of the actual volume expired through the patient-connection port)) mL" [18] accuracy for the tidal volume, which is the main parameter in a volume-controlled system. The test results fulfill this requirement. The requirements available in the Supplemental Materials specify that the breathing rate accuracy needs to be under 10% deviation, as are all non-volume- or pressure-related measurements, so the

Table 4 Test results overview for accuracy, modularity, and flow sensor positioning; error and standard deviation are calculated according to Sec. 2.3

	Tidal volume		Breathing rate		PEEP		I:E ratio	
	ε in % $\varepsilon_{max} = 15$	σ_{dev}	ε in % $\varepsilon_{max} = 10$	σ_{dev}	ε in % $\varepsilon_{max} = 15$	σ_{dev}	ε in % $\varepsilon_{max} = 10$	σ_{dev}
Control accuracy measurements	4.64	1.84 mL	1.57	0.03 bpm	9.63	0.11 cmH_2O	3.6	0.02
System modularity								
Resuscitator bag 1	0.89	1.67 mL	0.90	0.02 bpm	9.36	0.1 cmH_2O	3.47	0.00
Resuscitator bag 2	1.22	1.26 mL	0.90	0.02 bpm	12.2	0.14 cmH_2O	2.09	0.02
Resuscitator bag 3	1.79	1.38 mL	0.92	0.03 bpm	12.3	0.15 cmH_2O	3.81	0.03
Flow sensor positioning								
Position 1	1.36	1.33 mL	0.82	0.02 bpm	13.23	0.13 cmH_2O	12.3	0.01
Position 2	0.89	1.65 mL	0.90	0.02 bpm	9.36	0.10 cmH_2O	3.47	0.00
Position 3	1.57	1.73 mL	0.88	0.02 bpm	12.18	0.08 cmH_2O	3.47	0.02

results are again well within the acceptable range. The largest relative error is in the PEEP. However, the set values for the PEEP are low and the deviations are below two cmH_2O, the acceptable limit is stated by Ref. [18].

3.2 System Modularity. The modularity of the mechanical system ensures its correct functioning independent of the type of resuscitator bag used, since these may vary due to availability. The results in Table 4 show how three different types of manual resuscitator perform during the same test protocol. Bag 1, which is reusable, generally shows a more consistent performance since its standard deviation results are lower than the other two. The biggest differentiating points are the PEEP and I:E ratio values, but even there the errors that are small with respect to the target values. The results for the breathing rate are almost the same for all bags.

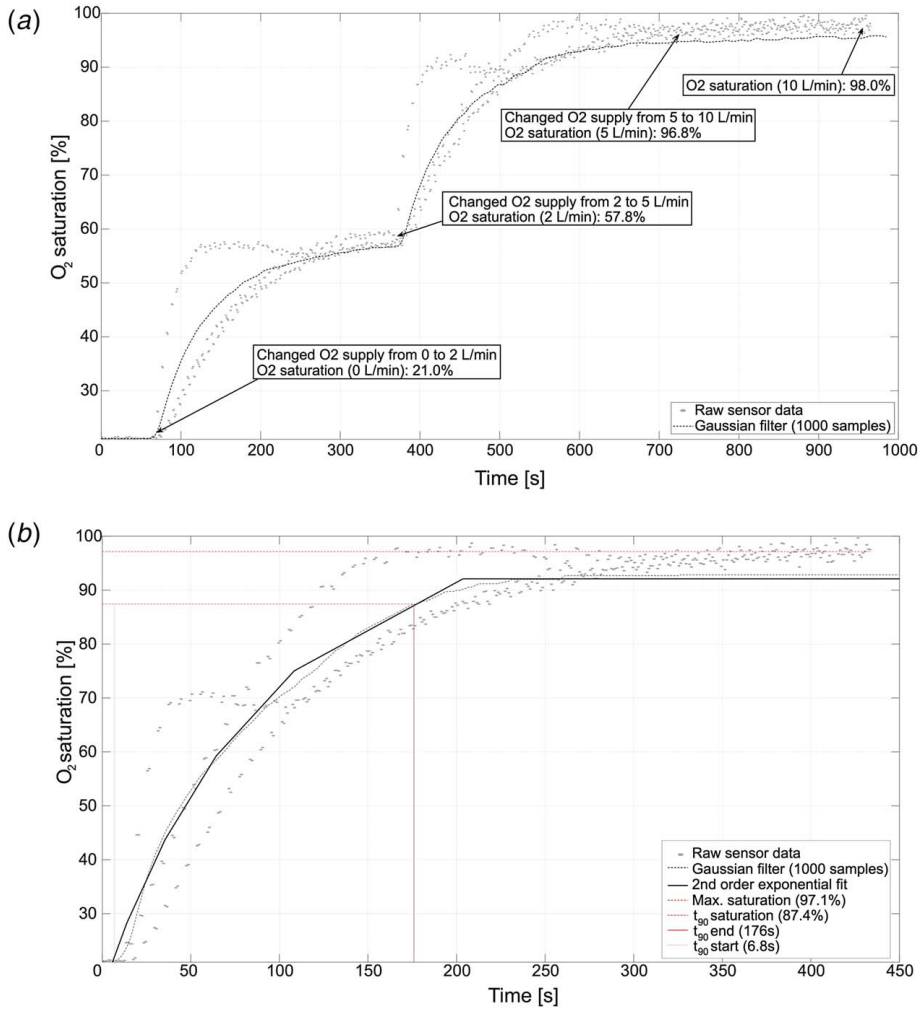

Fig. 7 (*a*) Oxygen saturation response for three flowrates: 2 L/min, 5 L/min, and 10 L/min and (*b*) saturation versus time for 10 L/min

3.3 Flow Sensor Positioning. Analyzing the effect of different flow sensor positions promotes the control system's reliability and safety. The results in Table 4 show that Position 2 achieves marginally better values than Position 1 and 3, especially concerning the I:E ratio for position 1. The largest relative errors concern the PEEP and I:E ratios for all three. As in the system modularity testing described earlier, these errors are however on a very small scale. The similar performance of all three systems shows that the controls compensate for the difference in flow sensor position.

Position 1, which is closest to the resuscitator bag, achieved a standard deviation 20% and 25% lower than Position 1 and 2 respectively with respect to tidal volume. Position 1 is closest to the resuscitator bag so there are the least losses in flow registered at this position. Position 2, which is between the PEEP valve and the HEPA filter, outperforms the two others. It registers 35% and 23% less error in tidal volume and 29% and 23% less error in PEEP value than Position 1 and 3, respectively. Position 3, which is closest to the patient, achieves a standard deviation 40% and 20% lower than Position 1 and 2, respectively with respect to PEEP. It is closest to the valve so there is little possibility of leaks caused by the PEEP valve for this measurement.

3.4 Efficacy of Oxygen Delivery. The oxygen response graph in Fig. 7(*a*) shows the oxygen saturation levels during inhalation and exhalation. A Gaussian filter is applied to facilitate the interpretation of the sensor's raw measurements. The data above than the Gaussian filter represents the inhalation and the data below the exhalation. The increase from 0 to 2 L/min and 2 to 5 L/min is depicted by stark increases in the oxygen intake. The response levels off at 5 L/min and the increase to 10 L/min only adds roughly 1% of oxygen intake. The ventilation system can thus transfer a variable amount of oxygen to the patient, achieving saturation at roughly 5 L/min.

Figure 7(*b*) shows how quickly the system responds to a change in oxygen intake. About 90% of the desired intake is achieved after three minutes, and the maximum intake of roughly 97% is achieved after twice the time. Hence, patient oxygenation levels can be adapted and controlled in under 5 min.

3.5 Assist Control: Spontaneous Breathing Support. The results from the spontaneous breathing tests are shown in Fig. 8. The benchmark for the ventilator working without breath triggering is shown in Fig. 8(*a*). The differences in between the benchmark and the spontaneous breathing support are in the pressure readouts. Comparing the pressure plots from CMV and AC, without breathing support the pressure peaks with the tidal volume and then evens out at PEEP pressure. With breathing support, the pressure first drops as the patient inhales and then rises as the system triggers the breathing support. Figure 8(*b*) shows how the system automatically switches from AC mode to CMV for simulated apnea within one breath cycle. Regular breathing is then resumed based on the system's settings rather than the patient's breathing pattern. This is visible through the breathing frequency before and after apnea, 8 bpm and 10 bpm, respectively, which is marked by a red dotted line in the plot. After the patient stops breathing, the ventilator continues with its set minimum mandatory frequency of 8 bpm. The system slowly ramps up the tidal volume to make up for the loss in air volume from the patient's breathing effort. The system can detect both strong and weak breaths, with only a slight variation in the regularity of the flow, as shown in Figs. 8(*c*) and 8(*d*). The

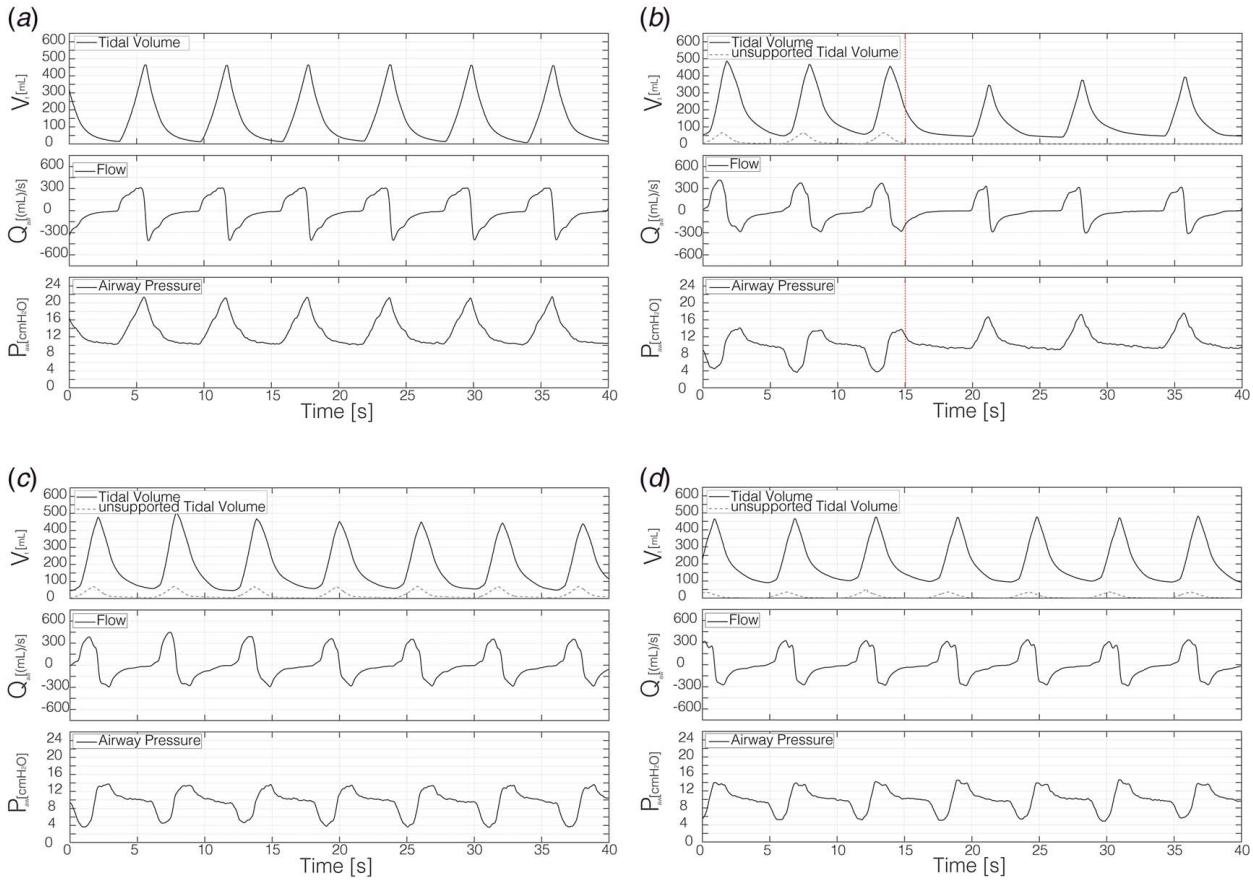

Fig. 8 Tidal volume V_t, flow, and airway pressure readouts for three cases of spontaneous breathing; panel (*a*) shows the ventilator functioning without breath triggering (CMV-VCV); the (*b*), (*c*), and (*d*) graphs compare the tidal volume triggered by the ventilator and the unsupported tidal volume, i.e., the patient's breath; the dotted line in panel (*b*) shows the start of the patient's apnea (all AC)

airway pressure is similar in both cases and the PEEP is clearly visible and within tolerances.

4 Discussion

In this section, the results are discussed in detail first in the context of this work and in the order of the testing. Then, the implications of this work are discussed in the wider context of low-cost mechanical ventilators.

The performance of three types of manual resuscitator bags differs at most by 2.94% for the PEEP values and 1.72% for the I:E ratio. All other values vary by less than 1%. These variations are explained by the differences in bag materials and airtightness. Bag 1, the most expensive reusable manual resuscitator, achieves a standard deviation as low as 0.0 for the I:E ratio and 25% lower than the two others for the PEEP value. Using better quality resuscitator bags thus makes a difference, but it is small enough that the device can be used with single-use ones, which are cheaper, as well.

The three different flow-sensor positions also only marginally affect the system performance. The rationale behind Position 3, closest to the patient, is to ensure that they can be monitored closely. However, this jeopardizes the sensor, since it would be in contact with the unfiltered exhalations from the patient and the results show it is not necessary. The choice between Positions 1 and 2 relies on the accuracy of the measurements and the position's convenience. If directly attached to the resuscitator bag as in Position 1, medical staff would not need to handle the sensor and it would be closer to the controller. However, if placed before the PEEP or bi-directional patient valve, the control performance in particular for the I:E ratio deteriorates, which results in an error 3.5 times larger than for the other positions. This error indicates Position 1 is inadequate with respect to the control system, so Position 2 is preferable. However, all differences are minor relative to the measurements, and the system can perform accurately independently of its setup.

The oxygen intake results show how quickly the system adapts to a patient's needs. It achieves steady-state in roughly 5 min after an increase in flow and achieves 90% of the target oxygenation rate in less than 3 min. At a maximum 97% oxygen saturation, the system shows very few leaks and efficient patient oxygenation. A device using a resuscitator bag can thus not only ventilate a patient but can also provide sufficient oxygenation for their treatment. The device currently does not include oxygen sensors but the oxygen level of a patient can be measured directly using a pulse oximeter and the flow adjusted directly on the oxygen valve. An oxygen flow to oxygenation chart could be derived to assist medical staff qualitatively.

Finally, the AC mode that reacts to spontaneous patient breathing is demonstrated successfully. The system detects both strong and weak breathing signals from the patient, which represent different stages of remission and lung strength. It can adapt to a patient's breathing rhythm and detect when they stop breathing. All these features are essential for continuing patient care beyond sedation. This widens greatly the potential use cases for the ventilator.

5 Conclusion

The COVID-19 crisis has highlighted a global shortage of cost-effective mechanical ventilators.

The automated resuscitator bag mechanical ventilator presented here is demonstrated to provide the required minimum functionality and is adaptable to different size resuscitator bags and flow sensor positions. The mechanical design provides a more compact and standardized solution compared to other projects with 23 out of 33 parts standardized (72%). The test results, including parametric studies, show that the design and prototype meets the requirements set. Both Continuous Mandatory Ventilation and Assist Control ventilation modes are demonstrated successfully along with the inclusion of oxygen. This provides a sound basis for further development and potential use in LMICs.

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Conflict of Interest

There are no conflicts of interest.

Data Availability Statement

The datasets generated and supporting the findings of this article are obtainable from the corresponding author upon reasonable request. Data provided by a third party listed in Acknowledgment.

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