The Vanderbilt Open Source Ventilator

From Napkin Sketch to Ready to Save Lives in Three Weeks

By Joshua Gafford, Kevin Galloway, Scott Webster, Max Emerson, Katherine Riojas, Dominick Ropella, Andrew Tumen, Fabien Maldonado, Matthew Bacchetta, Eric Barth, S. Duke Herrell, and Robert J. Webster III

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The coronavirus disease (COVID-19) crisis has placed enormous strain on global health care due to the sudden and exorbitant caseload burdens, compounded by insufficient access to the requisite supplies and equipment necessary to treat patients. Most notably, critical shortages of mechanical ventilators, which are essential for oxygenating patients who cannot breathe on their own, have forced physicians to make difficult decisions between who will and will not receive treatment, especially in resource-limited communities. In this article, we describe the efforts undertaken by a consortium of engineers, roboticists, and clinicians from Vanderbilt University to develop an easily reproducible mechanical ventilator out of core components that can be sourced locally, inexpensively, and en masse.

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The COVID-19 Pandemic

COVID-19, caused by the novel human coronavirus, is a severe acute respiratory disease that has wreaked havoc on global public health, with more than 84 million confirmed cases and 1.83 million deaths worldwide as of the beginning of 2021 [1]. As of this writing, there have been 23 million confirmed cases in the United States alone, with more than 380,000 lives lost [1].

Patients presenting with COVID-19 can develop severe acute respiratory distress syndrome (ARDS) [2], [3], which is characterized by low respiratory compliance and a life-threatening impairment of pulmonary gas exchange [4], [5]. Approximately 20% of admitted COVID-19 patients require respiratory assistance from a mechanical ventilator to achieve adequate oxygenation [6]. The resource-intensive therapeutic requirements posed by COVID-19, coupled with the sudden and exorbitant caseload onset, have overburdened health-care infrastructures across the globe due to the dwindling supplies of the personal protective equipment and devices (e.g., mechanical ventilators) necessary to protect frontline workers and to treat patients with the disease [7]. The insufficient access to clinically approved ventilation systems has forced physicians to make particularly difficult triage decisions, including the modification or even discontinuation of care for patients for whom the outcome is bleak, in an effort to free up ventilators for those with more favorable prognoses [8].

Ventilator Shortages Galvanize Grassroots Innovation

Recognizing these critical supply shortfalls, many communities across the globe have banded together to bootstrap ad hoc solutions in an effort to bridge the supply gap. These efforts range from breweries and alcohol distilleries bottling hand sanitizer instead of beer and whiskey [9] to large automotive companies (General Motors [10], Tesla [11]) and aerospace companies (Virgin Orbit [12], SpaceX [13], NASA [14]) retrofitting and retooling entire factories to mass manufacture mechanical ventilators and requisite components at scale. A particularly inspiring example of grassroots ingenuity in the fight against COVID-19 comes from the engineering and "maker" communities, who have mobilized to develop custom, open source designs for mechanical ventilators that can be rapidly manufactured with fairly simple processes and easily sourced components. These concepts range from mechatronic systems designed to compress clinically approved bag-valve masks (Ambu bags) at digitally programmable rates [15]–[17] to pneumatic systems that deliver ventilation directly through digitally controlled valves [18] to hybrid systems that use a pressurized chamber to compress an Ambu bag [19]. To list all of the open source designs would require a separate article in itself, so we encourage the reader to consult Pearce's review [20] for a more complete picture of the open source ventilator landscape.

In this article, we describe the work done by a team of engineers, roboticists, and clinicians from Vanderbilt University, beginning in late March 2020, to develop an easily reproducible mechanical ventilator out of core components that can be sourced locally, inexpensively, and en masse. We detail the three-week process that took us from initial napkin sketches to a validated prototype and associated regulatory submission, and we provide design details and experimental validation results that demonstrate the therapeutic efficacy of the proposed design. This process resulted in an open source design that is set apart from other solutions by its manufacturing simplicity and reliance on components that are either readily available locally or ubiquitous enough that they could be sourced quickly, even in the face of pandemic-induced shortages and supply chain disruptions. As a supplement to this archival publication, all of the design files, parts lists, software, and testing results are made freely available in supporting information documents, with the idea that the design can be rapidly built locally, wherever it is needed in the world, by anyone with basic woodworking, soldering, and programming skills.

The Vanderbilt Open Source Ventilator

The Vanderbilt Open Source Ventilator (VOV) is a volume-controlled, intubation-style ventilator (see Figure 1). We took this device from a napkin sketch to a prototype in three weeks. After a successful animal study, doctors deemed this device able to save a life. Over the following three weeks, we manufactured 100 units and submitted documentation to the U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) clearance. Throughout this whirlwind process, we undertook multiple design iterations, informed by continuous clinical input, literature review, and experimental testing, enabling us to converge on a design that is low cost, easily manufactured, and potentially life-saving. Our device implements a simple, inexpensive design; it is largely constructed from plywood, and we did away with expensive, specialized dc/stepper motors and optical encoders. Instead, we relied on widely available windshield wiper motors and a simple reciprocating transmission design based around a Scotch yoke mechanism (SYM) and drawer glides. The purpose of the device is to mechanically compress an Ambu bag—a widely available medical device that is normally squeezed by hand to provide ventilation for patients while transporting them to the hospital or while they are within the hospital and having difficulty breathing on their own. By leveraging medical Ambu bags and requisite ventilator/endotracheal (ET) tubing, the VOV is directly compatible with many standard oxygenation and humidification sources. The only components that come into contact with the patient's airway are clinically approved and disposable or otherwise subject to rigorous reprocessing protocols. We added Arduino-based control electronics that, when combined with mechanical inputs, enable physicians to set the volume of air delivered per breath [tidal volume (TV)], the respiratory rate in breaths per minute (BPM), the amount of the breathing duty cycle devoted to inspiration versus expiration (the I/E ratio), and the pressure thresholds at which alarms will sound during operation [designed in accordance with International Standards Organization (ISO) 60601]. Experimental

validation in both calibrated mechanical test lungs and live animals has demonstrated that the VOV is capable of delivering consistent, repeatable, and reliable respiratory therapy under variable loading conditions.

VOV Development Process

The development timeline of the VOV is presented in Figure 2.

Rallying Cry and Rapid Prototype Iteration

The project began in earnest on 21 March 2020, when physicians at Vanderbilt University Medical Center deemed the risk of severe local ventilator shortages high enough to make all efforts that could be brought to bear on the problem. Sensing the urgency in their clinical colleagues, the engineering team came together quickly—a team consisting of faculty and graduate students with all of the skill sets required to quickly build a mechanical ventilator prototype. Within a matter of hours after this clinical call to action, a napkin sketch made by one of the engineers [Figure 2(a)] was converted into a first prototype [Figure 2(b)] that demonstrated the concept of using a motor-driven mechanism to compress an Ambu bag at a consistent rate to deliver mechanical ventilation. The need for accurate, continuous TV adjustment led to the development of version 2.0 on 24 March 2020 [Figure 2(c)]. Version 2.0 implemented the SYM that would become the preferred transmission mechanism of the design (described in more detail in the "Mechanical Design" section). In version 2.0, the TV is adjusted by physically sliding the SYM to increase or reduce the compression of the Ambu bag on a single stroke. This TV-adjustment mechanism was further improved with a manually actuated leadscrew in version 3.0 [Figure 2(d)].

At the time, the system was powered by an off-board, adjustable lab power supply—meaning that the BPM could be only crudely adjusted by changing the voltage setting of the power supply. Realizing the need for more accurate control, sensors, and safety features, an embedded system (centered around an Arduino Uno) and an associated user interface (UI) were developed in parallel [Figure 2(e)] that would enable the digital configuration and control of the ventilation profile as well as the ability to report anomalous events to the caregiver through an ISO 60601-standardized alarm profile. As the design progressed, extensive manufacturing and assembly instructions were created [Figure 2(f)] that would enable others to manufacture the VOV and would be continually updated throughout the remainder of the project to reflect all design modifications. A complete Institutional Animal Care and Use Committee (IACUC) protocol was drafted and approved by Vanderbilt in two days, enabling us to move forward with animal experiments.

Concept Refinement and Testing

The integration of the UI/embedded controller with version 3.0 led to the creation of version 3.1 [Figure 2(g)] on 2 April. Version 3.1 would be the first unit tested in an in vivo setting on the next day. At our first live swine experiment on 3 April, we observed insufficient gas exchange from our device, resulting in the animal breathing out of synchronization with our ventilator. This was found to be due to the existence of substantial dead space in the ventilation circuit (specifics of which are provided

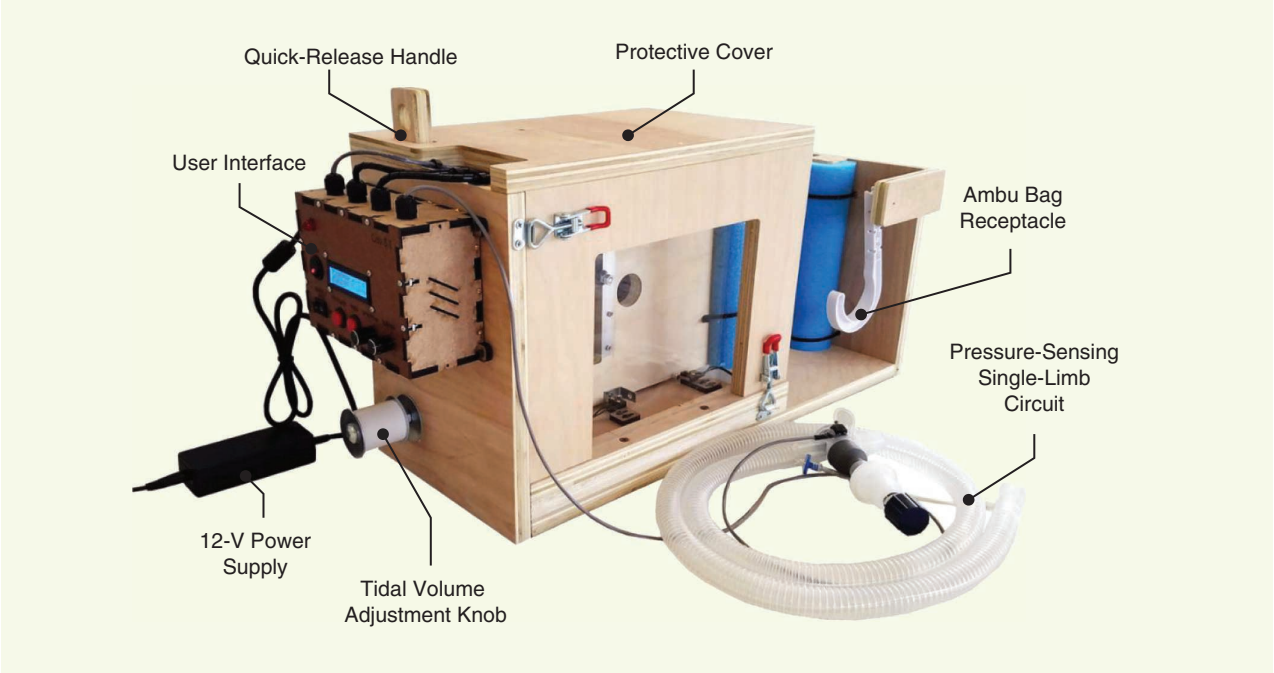


Figure 1. The Vanderbilt Open Source Ventilator (VOV), version 4.0. The device is designed to compress a standard Ambu bag, which is a widely available hand-squeezed device used to provide breathing support when transporting patients. The design features a car windshield wiper motor, Arduino-based control, and the valves and sensors needed to effectively and safely provide mechanical ventilation to COVID-19 patients.

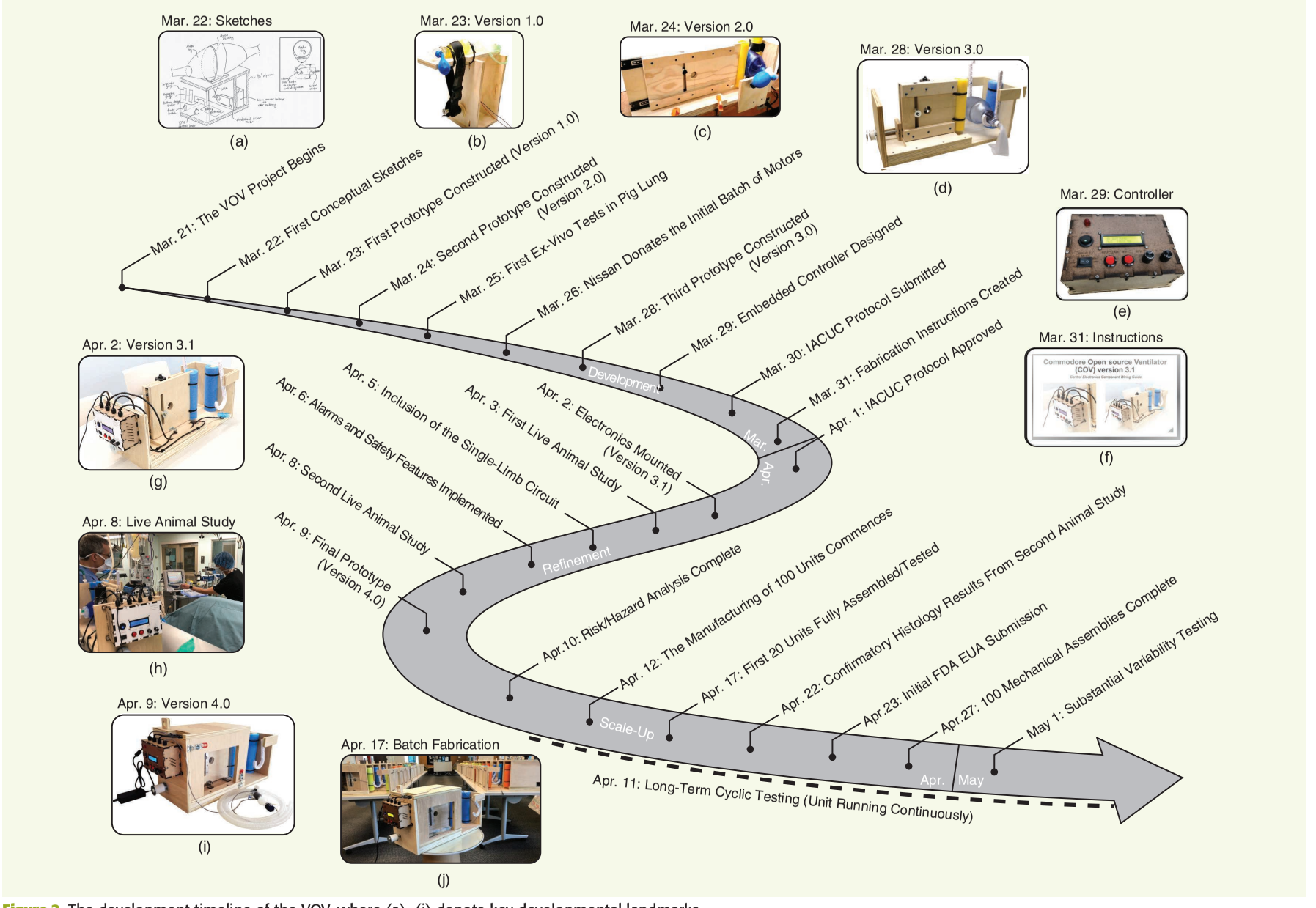


Figure 2. The development timeline of the VOV, where (a)–(j) denote key developmental landmarks.

in the "In Vivo and In Vitro Testing" section). To rectify this, we integrated a pressure-sensing, single-limb circuit into the design that places the valves at the patient's mouth rather than remotely at the outlet of the Ambu bag. A second four-hour live swine experiment [Figure 2(h)], in which the device worked flawlessly, was conducted five days later. After the second swine study, the VOV prototype was given the "thumbs-up" from clinical collaborators as a system that they would be comfortable using to support COVID-19 patients if no clinically approved ventilators were available. A thorough FDA risk analysis was then performed and informed some design modifications to enhance safety, creating version 4.0 [Figure 2(i)], which we describe in the remainder of this article.

Design Lock-In and Manufacturing Scale-Up

Immediately following the approval from our clinical collaborators, we began working with several local Nashville companies to ramp up production. Part kits and assembly instructions were distributed to a volunteer workforce consisting of Vanderbilt graduate students, faculty, and staff as well as local, unaffiliated "makers" and tech enthusiasts in the greater Nashville area. One hundred windshield wiper motor assemblies were generously donated by Nissan Smyrna, a local automobile assembly plant. A local marketing agency (Abel+McCallister+Abel, Nashville, Tennessee) volunteered its facilities and personnel to computer numerical control (CNC) route all of the plywood components, which were subsequently assembled by a group of volunteers from two local makerspaces: Fort Houston and Make Nashville. Electronic control boxes were wired and assembled by a group of Vanderbilt University graduate students. All manufacturing and assembly instructions were communicated to volunteers using the documents made available in the Supplementary File. Over the course of the next two weeks, we assembled the mechanical frames for 100 units [Figure 2(j)]. By 17 April, 20 of these mechanical units were outfitted with fully wired control boxes for immediate use, with parts on hand for 80 more if needed. An EUA application was submitted to the FDA on 23 April (just over one month from the project's inception), based on the version 4.0 design, and subsequent work focused on rigorous parametric and durability testing to supplement the regulatory submission and to validate the VOV performance against a wide range of operating conditions.

Summary of the VOV Design Process

As the previous sections highlight, the VOV's hardware development, refinement, and manufacturing took place rapidly (as displayed in Figure 2), which was made possible through continuous, daily collaboration among engineers, clinicians, and volunteers. The following sections address engineering specifications as well as details regarding the mechanical and electronic design. We also provide VOV testing data in in vitro and in vivo analogs to show that the VOV can provide reliable ventilation over a range of use cases and parameter settings.

Ventilator Requirements and Specifications

Clinical ventilators are very complex systems with many sophisticated ventilation modes and closed-loop control abilities—much more than we sought to replicate in the VOV—and we consciously made the decision to prioritize a minimum viable ventilator with the necessary functionality to meet immediate emergent potential needs during the pandemic. Through many conversations between clinicians and engineers, we arrived at the following understanding of what is required to ventilate COVID-19 patients.

Dynamics of Mechanical Ventilation

Clinical mechanical ventilators operate by the principle of intermittent positive-pressure ventilation (IPPV), wherein the patient's lungs are inflated by applying positive pressure to the airways. There are two primary modes of IPPV: volume-controlled ventilation (VCV) and pressure-controlled ventilation (PCV). As the names imply, VCV operates by modulating the volume of air delivered to the lungs, whereas PCV modulates the airway pressure. The VOV described in this article provides ventilation by compressing an Ambu bag by a programmable amount, implementing the VCV paradigm.

Under VCV, since the ventilator is configured to deliver a fixed TV, the airway pressure profile develops passively as a function of airway mechanics and dynamics. Typical VCV waveforms generated by the VOV are presented in Figure 3. The P_{PIP} is the maximum pressure delivered during inspiration at peak airflow and is affected by airway resistance and the lung's dynamic compliance, C_{dyn}. P_{PIP} should be monitored closely as high P_{PIP} (above 40 hPa) has been linked with barotrauma [21]. The P_{plat} is the pressure that develops within the lung when there is no airflow and is largely dictated by the lung's static compliance, C_{stat}. Monitoring P_{plat} offers the physician a surrogate estimate of pulmonary health, and the relationship of P_{plat} with P_{PIP} can alert the physician to underlying and potentially deadly pulmonary conditions (e.g., if P_{plat} is well above 30 hPa and is very close to P_{PIP}, it may indicate an issue with the patient's alveoli due to pneumothorax, bronchospasm, or a host of other potential causes). The P_{PEEP} is the amount of pressure held within the lungs between cycles and is typically a therapeutic parameter set by the ventilator. For COVID-19 patients who present with ARDS-like pneumonia, lung compliance can deteriorate over time, leading to an increase in airway pressure for a fixed tidal volume [22]. Therefore, when mechanically ventilating a patient using VCV, it is of paramount importance to be able to accurately monitor the airway pressure at various points in the respiratory cycle, report anomalous or excessive pressure events to the physician, and automatically adjust TV to limit P_{PIP} to within acceptable levels.

Functional Requirements

From understanding the dynamics of VCV, reviewing current literature, and consulting with our clinical collaborators at

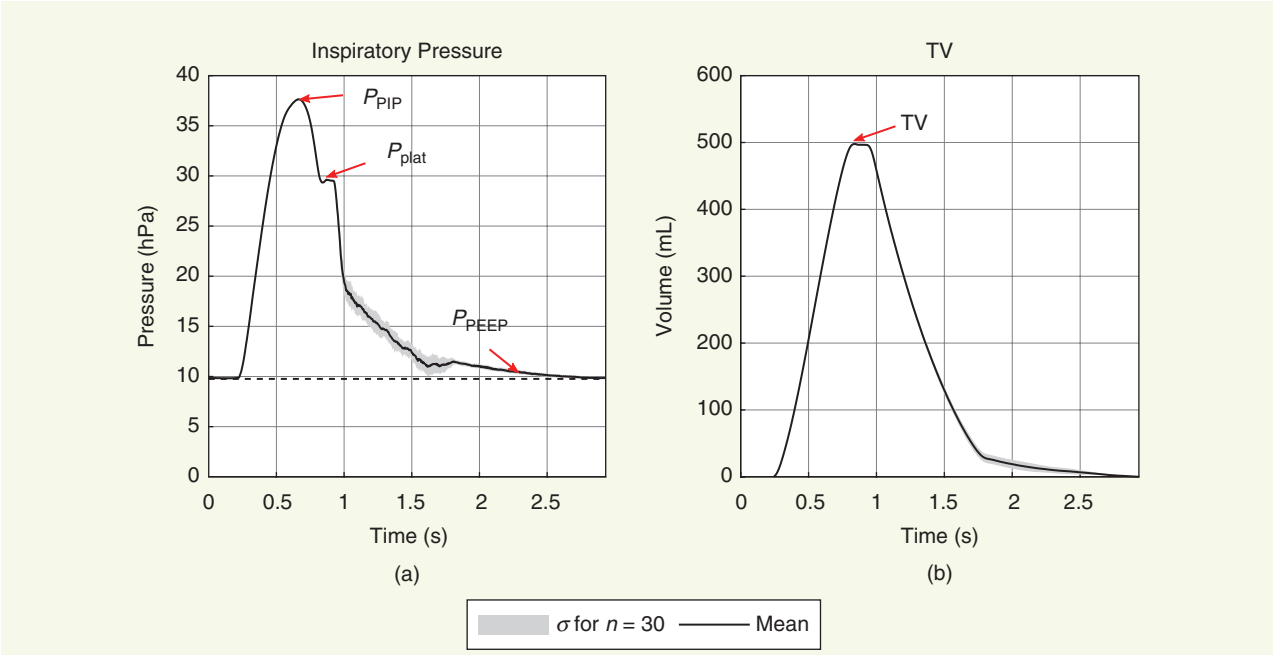


Figure 3. The typical VCV waveforms generated by the VOV, averaged over 30 respiratory cycles: (a) the characteristic airway pressure profile with callouts to clinically relevant pressure landmarks and (b) the characteristic TV.

Vanderbilt University Medical Center, we defined the functional requirements to guide our electromechanical design decisions (summarized in Table 1). We did so with the general goal of generating a design that is low cost, largely insensitive to supply chain disruptions and material accessibility limitations, and easy to manufacture. The range of adjustable TV, BPM, and I/E (reported in Table 1) ensures that our design will be able to accommodate a wide range of patients suffering from compromised respiratory function. COVID-19 patients are typically ventilated at a rate of 20–35 BPM and an I/E ratio from 1:1 to 1:2 [23], while some outlying pathologies may require rates as high as 50 BPM and I/E ratios as low as 1:4 [24]. Clinical wisdom dictates that TV should be initially selected based on patient weight (6 mL/kg) and finely tuned ad hoc according to P_{plat}, P_{PEEP}, and lung compliance [23]. A TV range of 0–800 mL ensures that we can accommodate the 95th percentile American male and 99th percentile American female. Active pressure detection and TV compensation will ensure that patients being ventilated are protected from anomalous and potentially traumatic pressure events and that the physician is subsequently alerted to such events to modify the clinical parameters or convert to manual ventilation if necessary.

Table 1. The list of VOV functional requirements.

Parameter	Value
TV	0–800 [mL] (adjustable)
Maximum TV deviation (long term)	35%
Respiratory rate	5–55 [BPM] (adjustable)
BPM repeatability (over 1 min)	±1 [BPM]
I:E ratio	1:1–1:4 (adjustable)
Continuous operation	>14 [days]
Maximum deliverable P_{PIP}	>40 [hPa]
P_{PEEP}	0–25 [hPa] (adjustable)
Barotrauma pressure limiting?	Yes
Over-/under-pressure reporting?	Yes (adjustable)

Mechanical Design

We approached the VOV design challenge by first identifying the actuator and structural materials, given the general constraints of availability, cost, and manufacturability. We selected the windshield wiper motor for its low cost, global availability, and ease of sourcing (from auto manufacturers to junk yards). Furthermore, the worm gear mechanism inside the motor is designed to generate large forces at a range of speeds under extreme conditions, from subfreezing to extremely hot (>37 C°) environments. These features make windshield wiper motors excellent candidates for applications that require reciprocating, low-to-medium speed actuation for millions of cycles.

For the structural material, plywood was selected, also for its availability and the relatively simple and inexpensive tools required to cut it into useable parts. Cabinet makers, wood workers, and many hobbyists have the tools and know-how to make all of the mechanical parts.

SYM

Given these materials and constraints, the SYM offers a simple, relatively low component count and low fabrication-precision

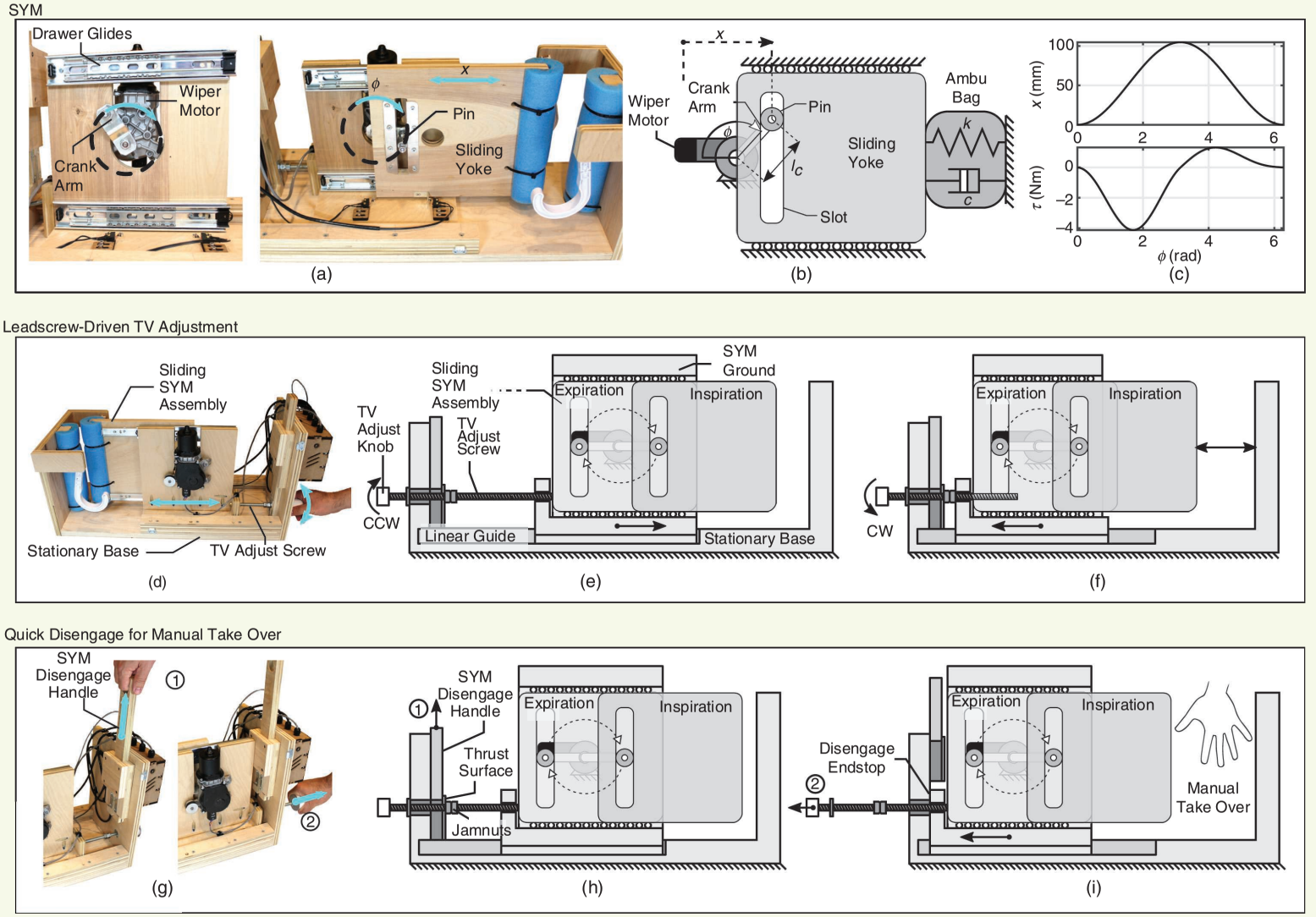


Figure 4. The VOV mechanical design: the (a) SYM implemented on the VOV (where the sliding yoke is removed on the left to show the wiper motor and crank arm); (b) lumped-parameter model of the SYM compressing an Ambu bag with airway compliance and resistance modeled as a spring and damper, respectively; (c) characteristic steady-state waveforms of crank angle ϕ versus compression distance x (top) and motor torque τ (bottom); (d) leadscrew-driven TV-adjustment mechanism (enclosure removed for clarity); (e) counterclockwise rotation of the knob that advances the SYM toward the Ambu bag receptacle, increasing TV delivery per stroke; (f) clockwise rotation that retracts the SYM, reducing the TV delivery per stroke; (g) emergency mechanical disengage (enclosure removed for clarity); (h) pulling the disengage handle, which removes the leadscrew thrust surface; and (i) pulling the TV leadscrew backwards, which retracts the SYM subassembly, opening up the Ambu bag receptacle for manual removal/takeover. CW: clockwise; CCW: counterclockwise.

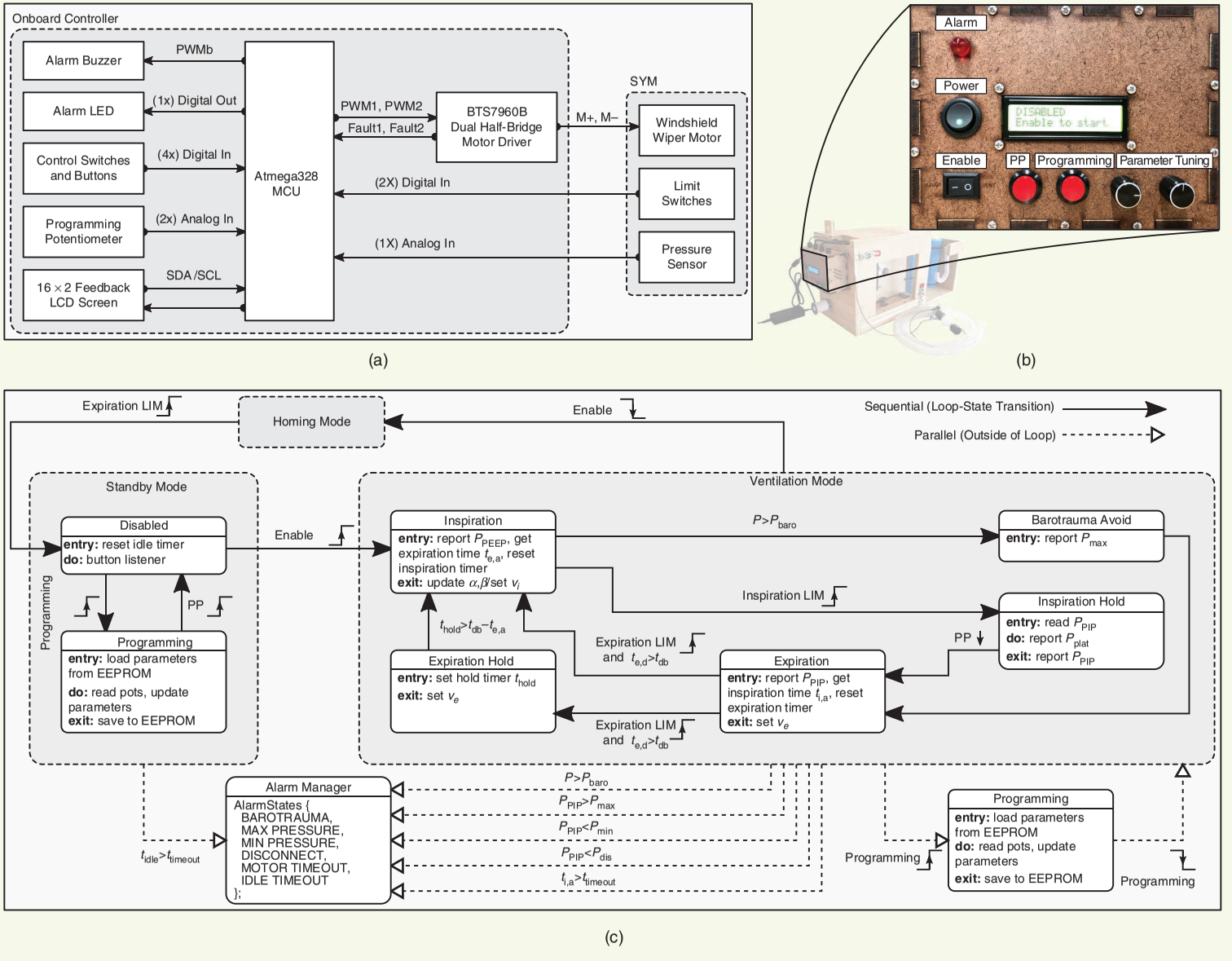


Figure 5. The integrated digital controller: (a) a block diagram of the electronics that comprise the (a) embedded controller, (b) a photo of the UI, and (c) a block diagram of the FSM implementation. MCU: microcontroller unit; EEPROM: electrically erasable programmable read-only memory; PWM: pulsewidth modulation; SDA/SCL: serial data/serial clock; PP: plateau pressure; LIM: limit switch.

threshold to replicate the squeezing motion of the human hand. The SYM is a reciprocating motion mechanism that converts rotary motion into linear motion, as illustrated in Figure 4(a) and (b). The SYM transmission couples the pin on a rotating crank arm directly to a sliding yoke with a slot that engages the pin. The linear travel of the sliding yoke in this design is constrained by ball-bearing drawer glides, which can be sourced from office supplies stores, hardware stores, and offices.

A dynamic analysis of the SYM, detailed in the Supplementary File, reveals that a maximum motor torque of 4.1 N · m is required to ventilate a worst-case lung [$C_{stat} = 10$ mL/hPa and airway resistance of $R_{dyn} = 50$ hPa/(L/s)] at the highest ventilator settings (BPM = 55, TV = 800 mL). Representative displacement and torque curves at these settings are displayed in Figure 4(c). This requirement is well within the torque capabilities of standard windshield wiper motors, which typically have nominal working torque ratings of 10 N·m and above.

Gross TV Adjustment

During normal ventilation, the SYM moves the yoke back and forth with a fixed amplitude defined by the crank arm length, as presented in Figure 4(a) and (b). To adjust the TV, the entire SYM subassembly can be manually adjusted, relative to the bag, to modulate the amount of Ambu bag compression during a single stroke, as illustrated in Figure 4(e)–(g). This is enabled through a sliding linear stage on the base plate that couples the SYM assembly to the back plate with a lead screw fashioned from a 3/8"–16 × 7" carriage bolt. The operator can twist the handle counterclockwise to advance the SYM assembly to increase the TV delivered per stroke [Figure 4(f)] or twist the handle clockwise to reduce it [Figure 4(g)]. The pitch of the lead screw (1/16" lead) is low enough that the SYM assembly is not back-drivable and does not move from its set position. The travel of the TV-adjustment mechanism enables the overall delivered TV to span 0–800 mL, as per our functional requirements.

Electronics and Control

The VOV features an embedded controller and UI, mounted to the rear of the device, that enable the physician to digitally configure and monitor critical ventilator and patient parameters.

Integrated Electronics

A block diagram of the electronics that comprise the embedded controller is presented in Figure 5(a). The entire ventilator system (motor, sensors, and onboard controller) is powered by a 12-Vdc, 5-A, ISO 60601-compliant power supply. The Arduino Uno MCU (or equivalent) is responsible for executing the integrated controller, processing sensor/UI data, and issuing motor commands. Various

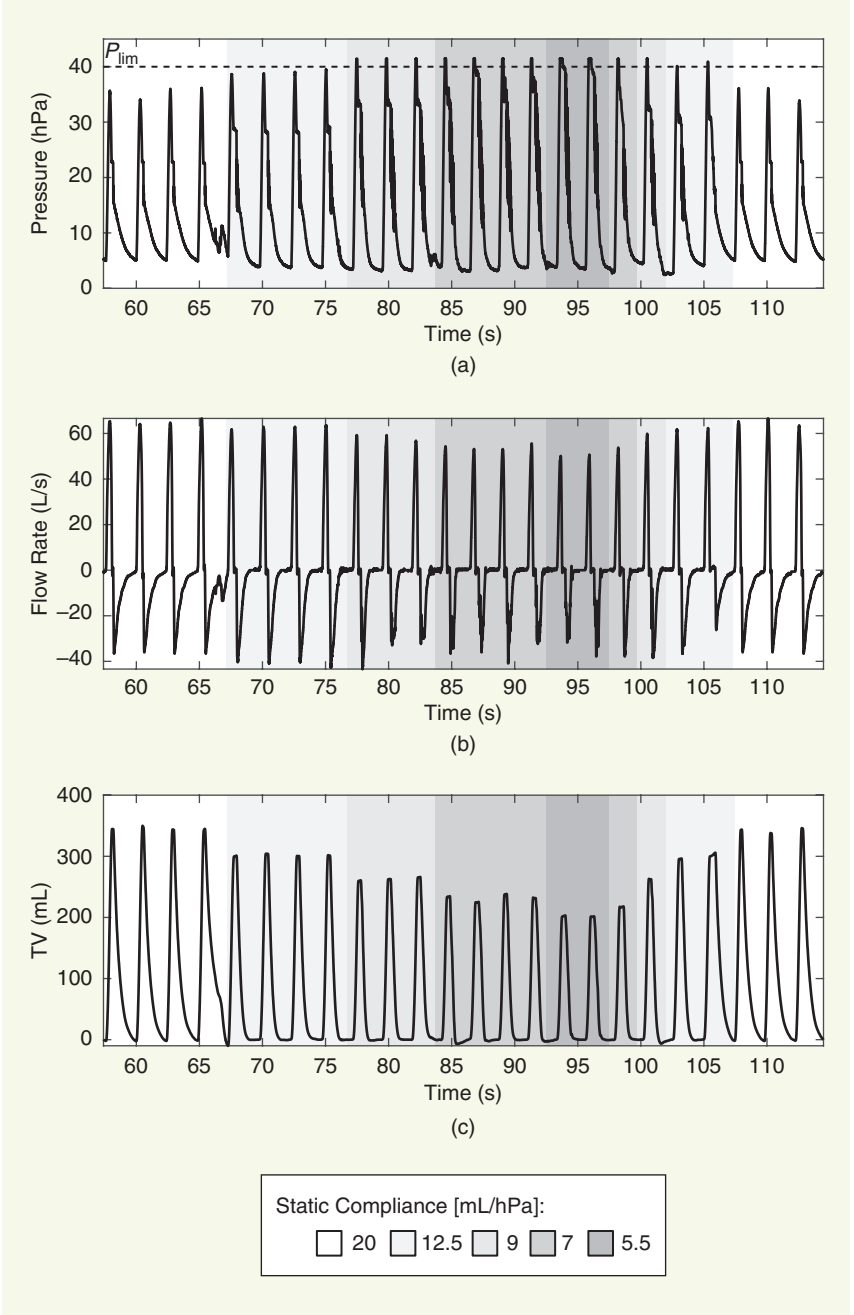


Figure 6. The automatic TV modulation to limit P_{PIP} (where shaded gradients indicate the artificially induced lung compliance): (a) airway pressure versus time, (b) flow rate versus time, and (c) TV versus time.

UI features (potentiometers, buttons, switches, and an LCD screen) allow the physician to interact with the ventilator and monitor the status of both the ventilator and the patient, as illustrated in Figure 5(b).

Control Architecture

The controller is implemented in the form of a finite-state machine (FSM), illustrated in Figure 5(c). An alarm manager object keeps track of various alarm conditions outside of the loop and reports them to the user through a combination of a flashing LED, ringing buzzer, and message displayed on the UI LCD. We also note that new settings may be programmed while the ventilator is actively ventilating, without breaking the main loop, enabling the physician to modify ventilation parameters during operation based on feedback from the pressure-sensing, single-limb circuit. Patient safety was of paramount importance in every design decision of the VOV, particularly in regards to barotrauma avoidance. The VOV implements active barotrauma avoidance by modulating the TV if the inspiratory pressure exceeds predefined thresholds, as displayed experimentally in Figure 6. This is detailed in the Supplementary File, as are numerous other control-based and mechanical-based safety solutions.

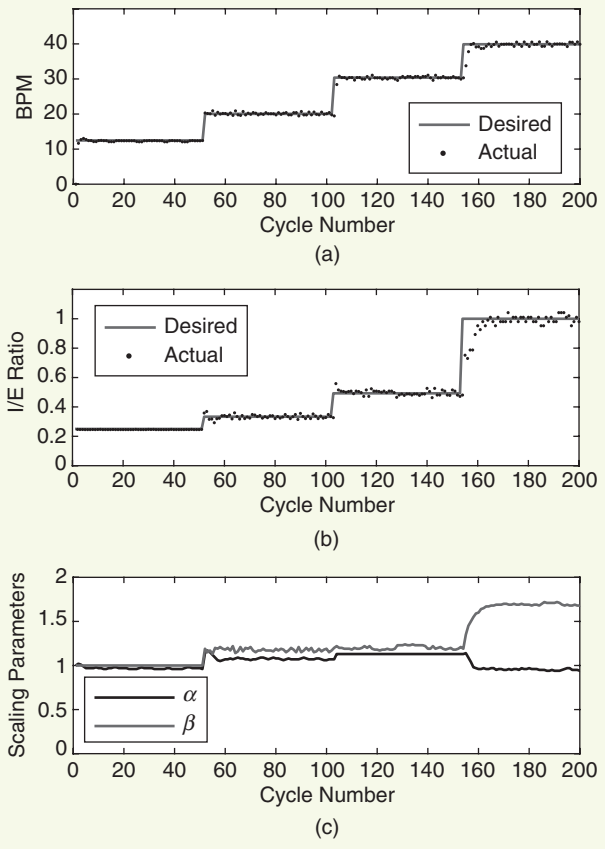


Figure 7. The end-cycle proportional timing controller for various BPM and I/E settings: block diagram of the (a) BPM versus cycle number (commanded and actual), (b) I/E ratio versus cycle number (commanded and actual), and (c) speed scaling parameters α and β versus cycle number.

End-Cycle Proportional Timing Control Methodology

Windshield wiper motors run in open loop, so to achieve accurate respiratory-rate timing, we have implemented an end-cycle proportional timing controller. We sense the position of the motor at the two most important points in the respiratory cycle (full inspiration and full expiration) with a pair of limit switches, dead-reckon between these two points, and adjust speeds on the next cycle as necessary to meet these respiratory timing requirements, based on the error between the desired and actual inspiration/expiration times. The specific hardware implementation of the end-cycle proportional timing methodology is available in the Supplementary File. This proportional timing update capability is demonstrated experimentally in Figure 7, where the BPM and I/E ratio were increased every 50 cycles (12 BPM at 1:4 I/E, 20 BPM at 1:3 I/E, 30 BPM at 1:2 I/E, and 40 BPM at 1:1 I/E) while the VOV was actively ventilating a test lung apparatus with a built-in compliance of 20 mL/hPa. As can be observed, the VOV is quick to converge to the new settings (within 30% of the desired setting after a single breath cycle) and with negligible steady-state error.

In Vivo and In Vitro Testing

In preparation for the FDA EUA submission, the VOV was experimentally validated using a combination of in vitro validation in a calibrated mechanical test lung and live animal testing using an anesthetized swine model.

In Vivo Swine Study

Two live animal studies were performed in which the VOV provided continuous ventilation to an anesthetized swine for four hours. In the first study, as mentioned in the "VOV Development Process" section, there was insufficient gas exchange due to the length of the ET tubing. For a more detailed discussion of this, see "Insights from First In Vitro Swine Study" in the Supplementary File. In the second swine study, we corrected the problem with a pressure-sensing, single-limb circuit [Figure 8(a)]. The swine was ventilated continuously for four hours (with average settings of 20 BPM and an I/E ratio of 1:2) as per our approved IACUC protocol. Throughout the course of the second experiment, the swine remained hemodynamically normal, with adequate oxygenation, ventilation, and a normal pH. Subsequent histology results revealed well-preserved alveolar structural integrity with no evidence of barotrauma or atelectasis [Figure 8(b) and (c)] [25].

It is likely that humidification would be useful in the future long-term (e.g., weeks) use of this ventilator with human patients. We successfully accomplished

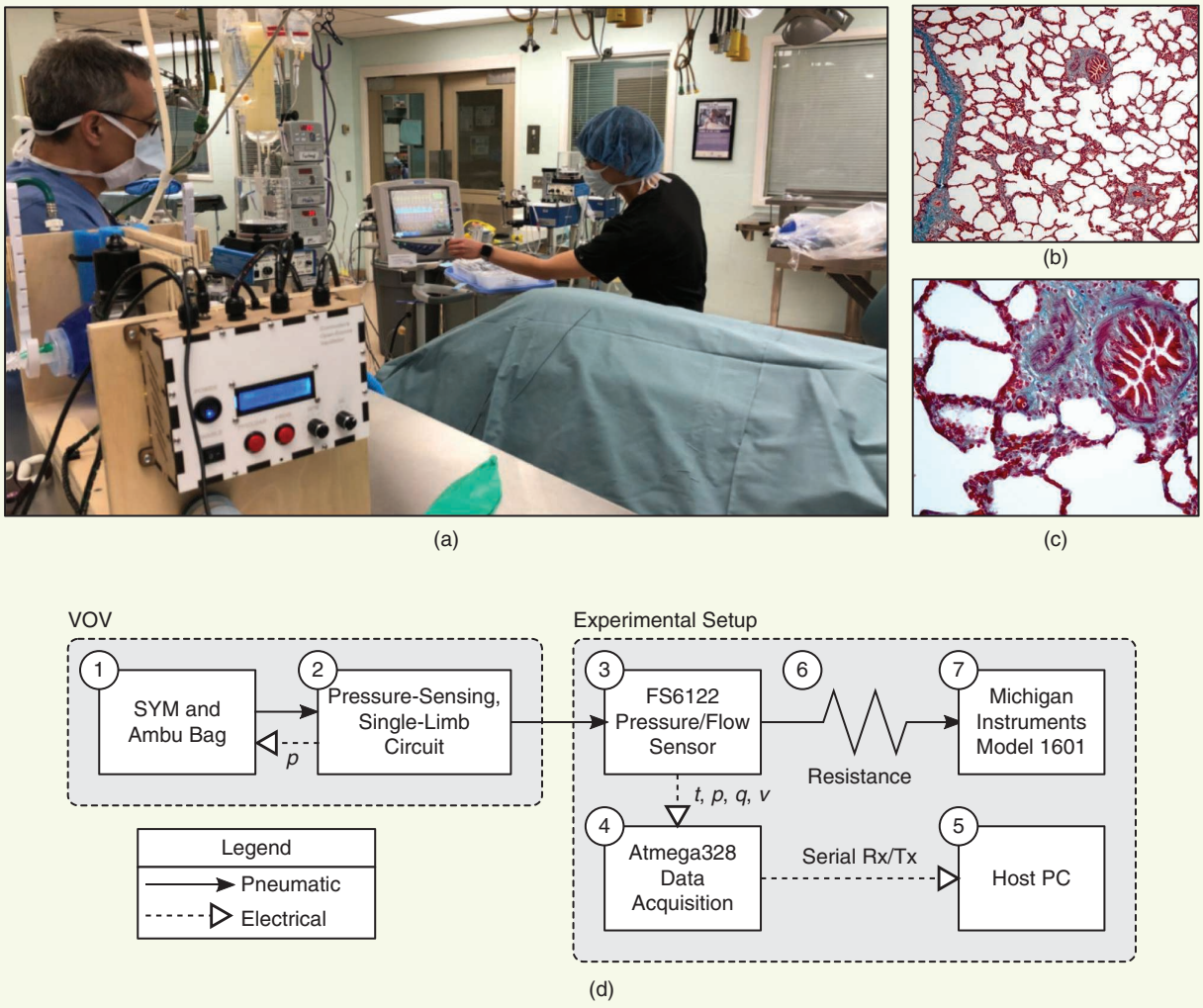


Figure 8. The in vivo and in vitro experimental setups. (a) The experimental setup for the live swine study; histological analysis of alveolar structure (Gomori trichrome) at (b) 5× and (c) 20× magnification reveals the maintenance of alveolar and airway structural integrity without evidence of barotrauma or atelectasis. (d) A block diagram of the in vitro experimental setup for parameter variability study. (e) A photograph of the in vitro experimental setup, with labels corresponding to those in (d). Rx/Tx: receiver/transmitter.

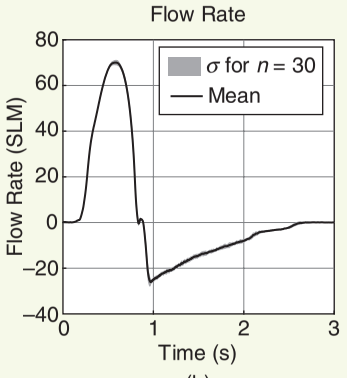
Ventilator/Lung Settings

Settings	Value
C_{stat} (mL/hPa)	50
R_{dyn} (hPa/L/s)	5
TV (mL)	500
BPM	20
I:E Ratio	1:2
P_{PEEP} (hPa)	5

Performance Parameters

Parameter	$\sigma \pm \mu$	Max Dev
q_{max} (L/s)	70.5±1	6.06%
V_{max} (mL)	504±2.52	2.15%
P_{max} (hPa)	14.3±0.15	5.64%
P_{PEEP} (hPa)	5.1±0.06	5.2%

(a)



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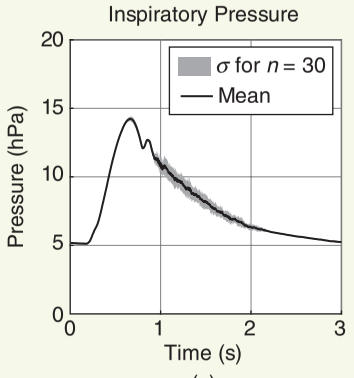
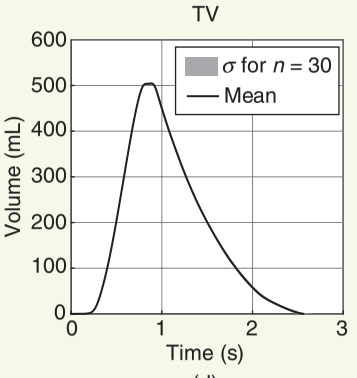


(c)



(d)

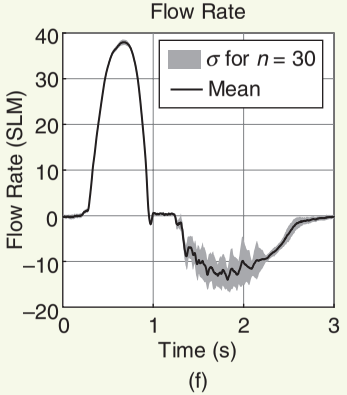
Ventilator/Lung Settings

Settings	Value
C_{stat} (mL/hPa)	10
R_{dyn} (hPa/L/s)	50
TV (mL)	300
BPM	20
I:E Ratio	1:2
P_{PEEP} (hPa)	10

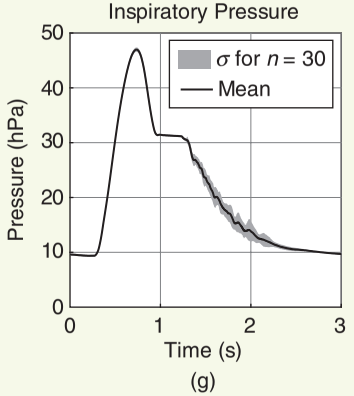
Performance Parameters

Parameter	$\sigma \pm \mu$	Max Dev
q_{max} (L/s)	38.2±0.6	4.79%
V_{max} (mL)	300±2.28	3.26%
P_{max} (hPa)	47±0.37	3.46%
P_{PEEP} (hPa)	9.29±0.2	8.13%

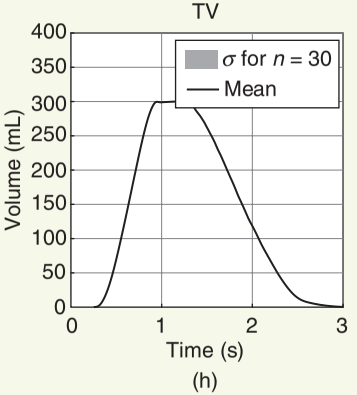
(e)



(f)



(g)



(h)

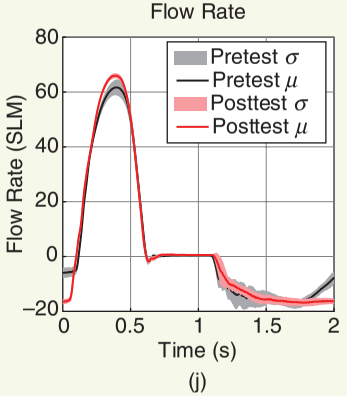
Ventilator/Lung Settings

Settings	Value
C_{stat} (mL/hPa)	10
R_{dyn} (hPa/L/s)	50
TV (mL)	350
BPM	30
I:E Ratio	1:2
P_{PEEP} (hPa)	5

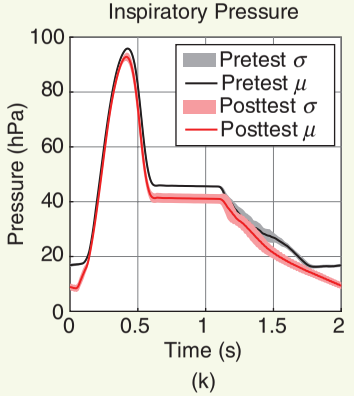
Performance Parameters

Parameter	$\sigma \pm \mu$ (Pre)	$\sigma \pm \mu$ (Post)
q_{max} (L/s)	62.1±2.8	66.4±0.9
V_{max} (mL)	344±13.9	353±5.6
P_{max} (hPa)	95.9±0.3	93.1±1.5
P_{PEEP} (hPa)	15.5±0.3	7.9±1.1

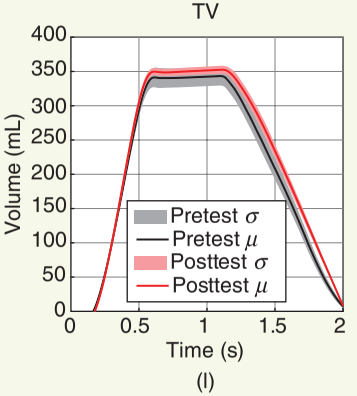
(i)



(j)



(k)



(l)

Figure 9. The parameter variability testing per ISO 80601: (a)–(d) performance data and characteristic waveforms for a compliant, low-resistance airway; (e)–(h) performance data and characteristic waveforms for a stiff, high-resistance airway; and (i)–(l) performance data and characteristic waveforms at worst-case, near-maximum settings over a 24-h period, where black denotes characteristic performance prior to the 24-h period and red denotes characteristic performance after the 24-h period. Max Dev: maximum deviation.

this in our first animal study with a standard, off-the-shelf nebulizer (Aquapak, 760 mL) hooked up to the Ambu bag input. It was determined by our veterinary staff that this was not needed for our second animal study because the duration was hours rather than days or weeks.

In Vitro Parameter Variation/Durability Study

In addition to live animal tests, we also conducted a series of performance characterization and durability experiments on a mechanical test lung, pursuant to testing standards set forth in ISO 80601-2–80:2018(E), "Particular Requirements for Basic Safety and Essential Performance of Ventilatory Support Equipment for Ventilatory Insufficiency" [26]. The tests were performed using a calibrated test lung (Model 1601, Michigan Instruments) with adjustable compliance and linear resistance, which was generously loaned to the project by Volunteer State Community College, Gallatin, Tennessee. A Siargo FS6122 pressure/flow sensor was used to capture pressure, flow rate, and TV waveform data at a sampling rate of 200 samples/s. The TV was calculated by numerically integrating the flow rate data. Data were postprocessed and statistically analyzed in MATLAB. The experimental setup is presented in Figure 8(e) and (f).

The characteristic flow rate, airway pressure, and TV waveforms from these experiments are displayed in Figure 9. For the purpose of brevity, we observe that cyclic variability is very low across short (seconds) and long (hours) time scales and is well within acceptable limits as per ISO 80601-2–80:2018(E). The details of these experiments are presented in the Supplementary File.

Conclusions

The COVID-19 pandemic has crippled health-care infrastructures across the globe due to the insufficient supplies of protective, diagnostic, and therapeutic equipment. Most notably, shortages of clinically approved ventilators have led to many preventable deaths. This shortage has motivated engineering communities to quickly mobilize and develop alternative solutions that could provide a last resort for patients who face triage. As part of this effort, the VOV was developed by a team of engineers, roboticists, and clinicians to provide an alternative to patients who otherwise may not have access to traditional, clinical mechanical ventilators. Manufactured from inexpensive and easy-to-source components, the VOV and its open source design could serve as a viable option for resource-constrained communities who are severely impacted by COVID-19 or similar respiratory viruses that may present in the future. By distributing the design files found in the Supplementary File to members of the local community, we have manufactured 100 ventilators ready for immediate deployment in Nashville and middle Tennessee, and we envision a similar deployment model being used in other communities with access to our design files and to basic woodworking/electronics materials and fabrication equipment. While the VOV is not intended to replace clinically approved ventilators, it is capable of carrying out many critical therapeutic functions necessary to support COVID-19 patients, as substantiated through extensive in vivo and in vitro testing [specifically designed according to testing standards set forth in ISO 80601-2–80:2018(E), which is an FDA-recognized standard for evaluating ventilation equipment submitted for emergency use]. It is thus ready to save lives in emergency events where the demand for ventilators outstrips supply.

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Joshua Gafford, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: joshua.b.gafford@vanderbilt.edu.

Kevin Galloway, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: kevin.c.galloway@vanderbilt.edu.

Scott Webster, Virtuoso Surgical, Nashville, Tennessee, 37205, USA. Email: scott.webster@vanderbilt.edu.

Max Emerson, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: maxwell.emerson@vanderbilt.edu.

Katherine Riojas, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: katy.riojas@vanderbilt.edu.

Dominick Ropella, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: dominick.ropella@vanderbilt.edu.

Andrew Tumen, Vanderbilt University Medical Center, Nashville, Tennessee, 37212, USA. Email: tumenaz@vumc365.mail.onmicrosoft.com.

Fabien Maldonado, Vanderbilt University Medical Center, Nashville, Tennessee, 37212, USA. Email: fabien.maldonado@vumc.org.

Matthew Bacchetta, Vanderbilt University Medical Center, Nashville, Tennessee, 37212, USA. Email: matthew.bacchetta@vumc.org.

Eric Barth, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: eric.j.barth@vanderbilt.edu.

S. Duke Herrell, Vanderbilt University Medical Center, Nashville, Tennessee, 37212, USA. Email: duke.herrell@vanderbilt.edu.

Robert J. Webster III, Department of Mechanical Engineering, Vanderbilt University, Nashville, Tennessee, 37212, USA. Email: robert.webster@vanderbilt.edu.