2023 Annual Conference & Exposition
Baltimore Convention Center, MD | June 25 - 28, 2023
The Harbor of Engineering
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Paper ID #39744

A democratized open-source platform for medical device troubleshooting

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Nathaniel Bechard

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Introduction

The COVID pandemic underscored the need for accessible respiratory technology in high- and low-resource settings. For critically ill patients in the US and worldwide, the mechanical ventilator supply was insufficient [1]–[3]. Indeed, the presence of more mechanical ventilators, in addition to therapeutic oxygen, skilled respiration staff, and ICU beds could have reduced the 6.8 million COVID related death toll. While governments and private companies attempted to meet the demand by maximizing the production of new ventilators, troubleshooting and repair of existing devices could have also ameliorated the available global supply [1], [2].

Our bioengineering curriculum addresses this skill of troubleshooting with an advanced senior laboratory course called Troubleshooting for Clinically Relevant Biomedical Course. The course is designed to teach students the troubleshooting process, allowing them to explore and repair instructor-made failures in mini-centrifuges, refrigerators, syringe pumps, suction pumps, microscopes and oxygen concentrators. In the course, students identify equipment operational principles, common failure modes, and preventative maintenance. Despite their relevance in recent times, ventilators have never been explored in the course due to the prohibitive cost and complexity associated with the device [4].

Ventilators are devices that physically push air in and out of lungs [5], [6]. The lungs and respiratory system are primarily responsible for delivering oxygen to the blood and removing carbon dioxide from the blood to maintain optimal cellular metabolism. The physical compliance of the lung tissue and chest wall comprised of structural features such as elastin fibers, the presence of surfactant to minimize the effects of surface tension and the appropriate dilation/constriction of the bronchiole airways enable the lungs to perform optimized oxygen delivery and carbon dioxide removal to fit the body’s metabolic needs. Conditions such as emphysema, asthma, pneumonia, chronic obstructive pulmonary disease (COPD), COVID and acute respiratory distress syndrome (ARDS) in which the optimal air flow and gas exchange are threatened require patients to rely on alternative systems for oxygen delivery through devices such as ventilators [7]. Respiratory rate, airway pressure, flow rate, amount of air breathed in (tidal volume), and total air delivered in one minute (minute volume) must all be customized for each patient based on anatomy and disease severity.

From a troubleshooting perspective, the ventilator requires background in a variety of disciplines and serves as an excellent case study. For example, mechanical engineering is needed to understand the production of air pressure and flow, while electrical engineering is needed to understand sensors and valve, motor or pump control. Computer engineering plays a role in converting sensor data reliably to digital control of the electrical components. Finally, biomedical engineering is required to integrate these aspects into a functional device. Human factors must also be considered when examining safety, consistency, user training and ease of use.

In this study, we describe the use of the PolyVent educational platform, an open-source ventilator, for courses such as the Troubleshooting for Clinically Relevant Biomedical Course. The accessible design and real-time data traces facilitate physiology and engineering-based learning. In addition, the modularity and open-source nature of the platform could motivate future design and innovation.

PolyVent Modules

The PolyVent consists of four major modules in a metal “tub” with a transparent cover. The device has a “cake dome” design - the machine can operate without the cover in place. The four major modules shown in **Figure 1** are:

1. Power Supply Module, which is protected by a plastic shield, and converts 110VAC to the 24VDC power used by the valves and both 5V and 3.3V power needed by the control module. The power module is below the Oxygen Mixing Module.
2. Oxygen Mixing Module, which takes in air and optionally Oxygen or Nitrogen at up to 50 psi and mixes them in a clear cylinder which is near 22 psig.
3. Control Module, which is a highly extensible card-and-slot system powered by an ESP32 microcontroller which runs the VentOS software.
4. Beathing Circuit Module, which reduces the mixed medical gases to clinically specified breathing pressure and open and closes the Patient Inflating Valve.

The Breathing Circuit Module is detailed in **Figures 1 and 2**.

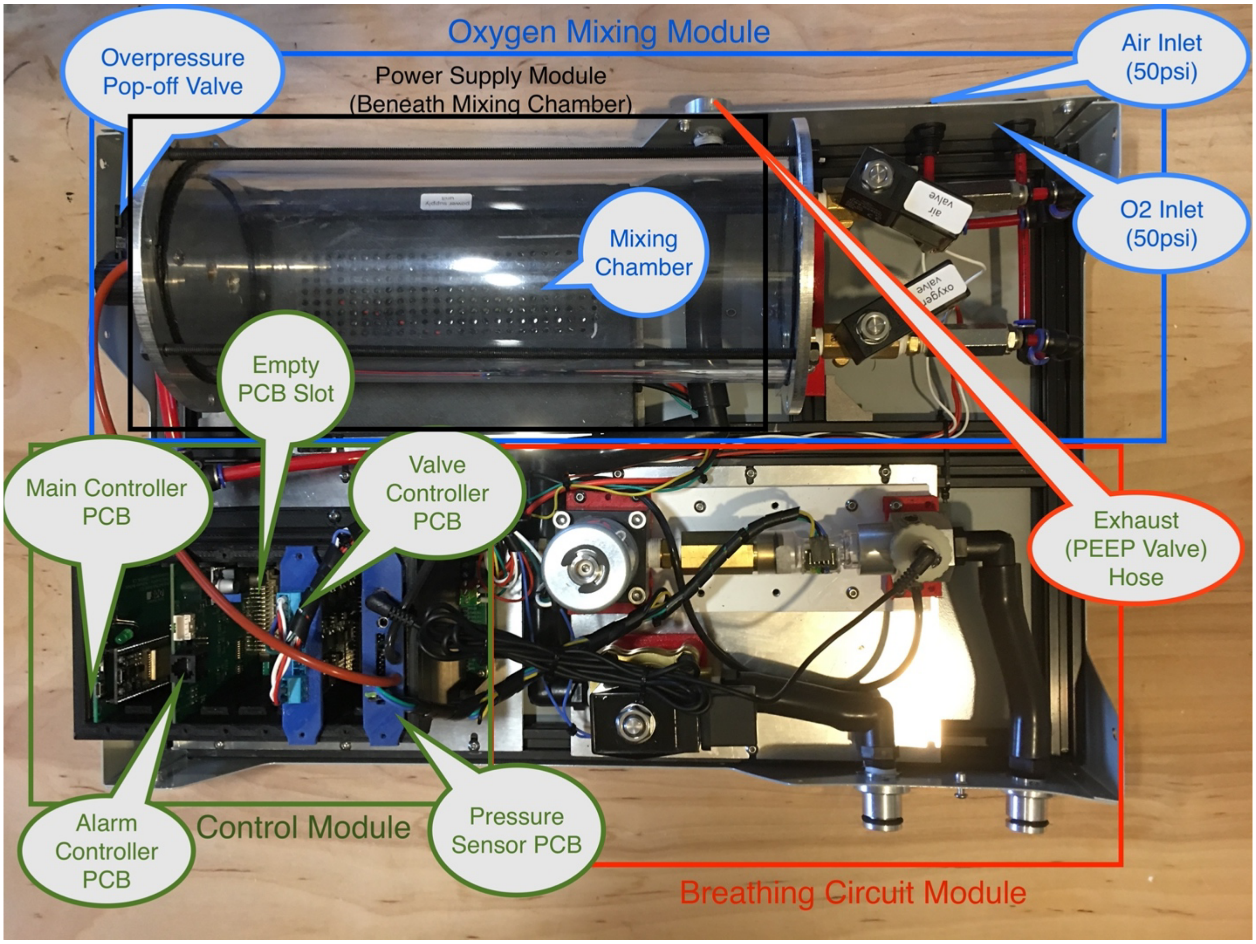


Figure 1: Major Modules of the PolyVent (without device cover). The PolyVent consists of the oxygen mixing (highlighted in blue), breathing circuit (highlighted in red) and control (highlighted in green) modules (clockwise from the top). PEEP: Positive end-expiratory pressure; PCB: Printed circuit board; O2: oxygen.

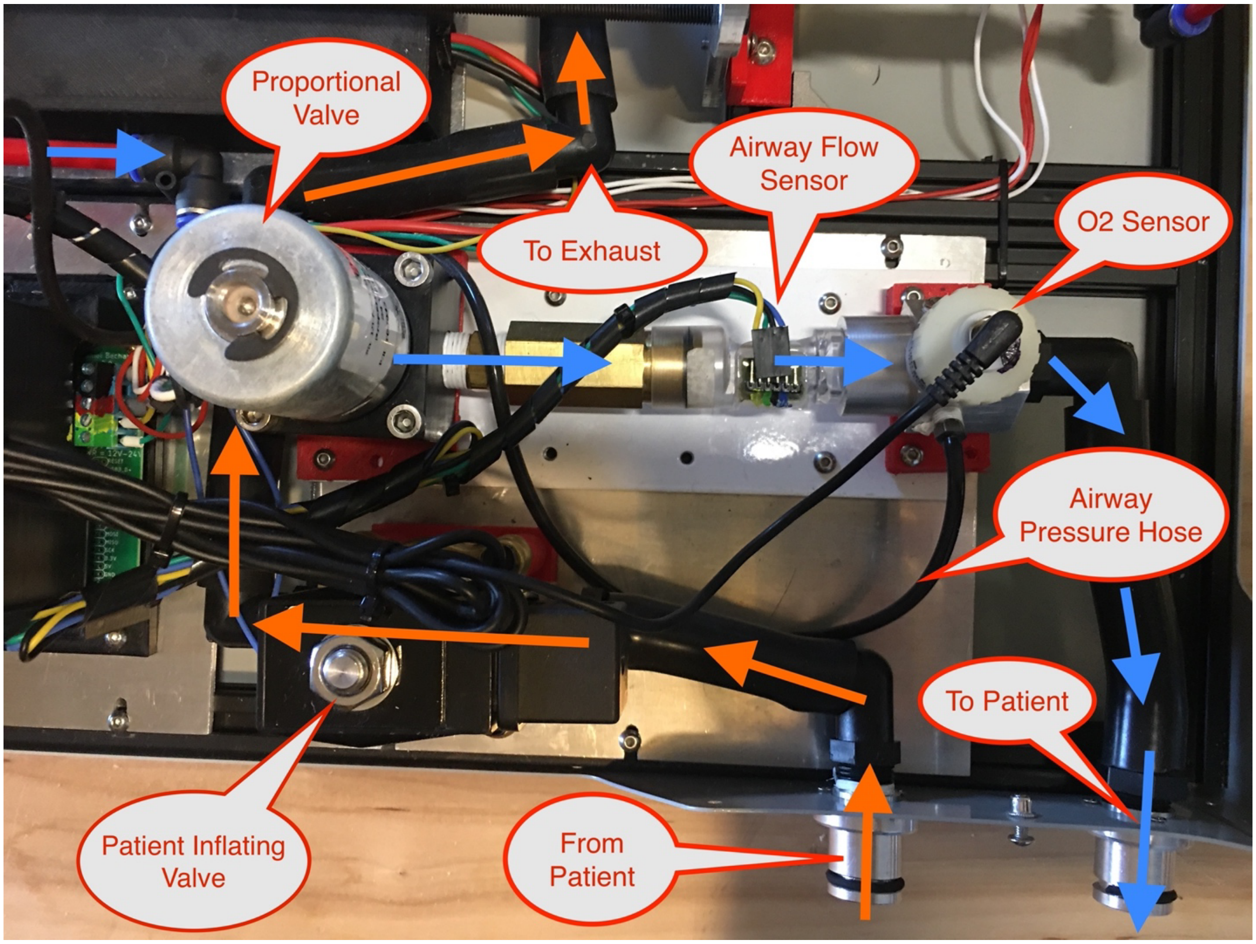


Figure 2: Detail of Breathing Circuit Module and Airway Path. Blue arrows represent gas pathway to the patient (inhalation) while orange arrows represent gas pathway from the patient (exhalation). O2: oxygen.

The PolyVent uses simple off-the shelf on-off solenoid valves to accept air and O_2 or N_2 at up to 50 psi, reducing this pressure to 22 psi above ambient air pressure. A proportional valve in the breathing circuit then reduces the pressure further to the programmed peak inspiratory pressure (PIP). This is accomplished by sensing both pressure and flow in the airway directly read by a sensor card in the control module. An O_2 sensor is used to ensure the programmed FiO_2 is reached. A Patient Inflating Valve (PIV) closes the airway during expiration. The expired air from the patient is ducted to the rear of the machine, where a positive end-expiratory pressure (PEEP) valve may be installed to provide PEEP. The valves all operate at a safe 24V, gated by power transistors on a card in the control module.

Benefits of the PolyVent Platform for Educational Applications

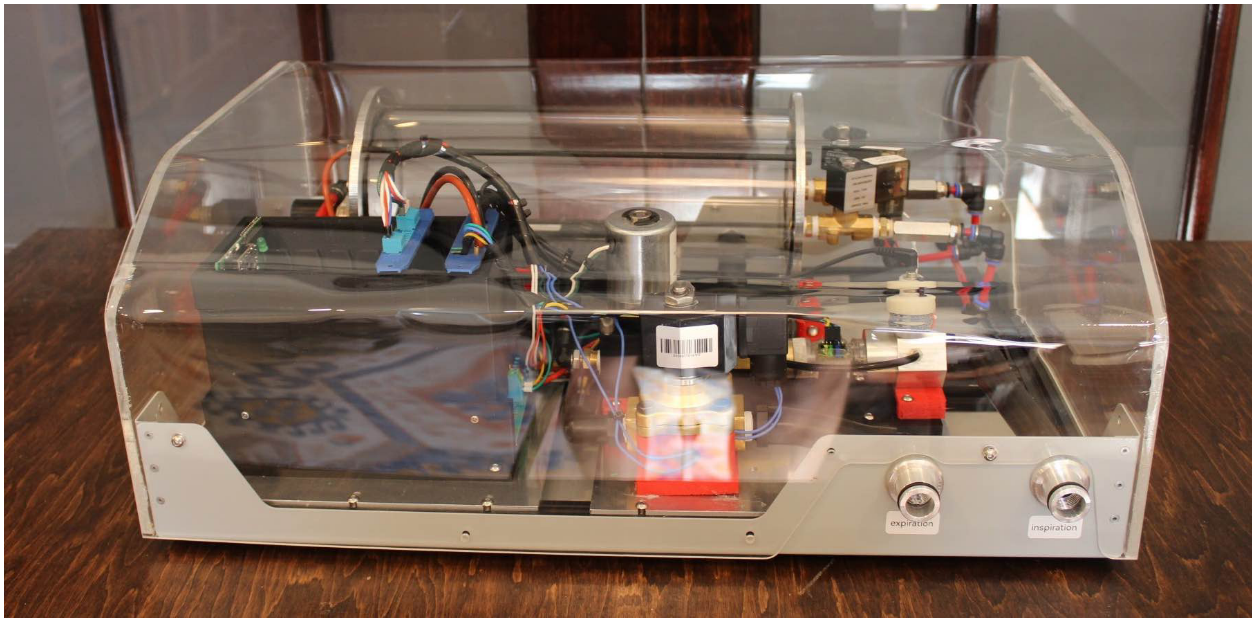


Figure 3: The PolyVent Educational Platform with the transparent cover in place.

The PolyVent Educational Platform is a positive pressure ventilator (**Figure 3**) designed to offer classroom experiences as educational modules. Intentional educational design features of the device include:

1. *Free and open design*. The design is licensed with reciprocal open-source licenses that allow anyone to legally duplicate, repair, modify, and extend the design, as long as they do not attempt to monopolize it.
2. *Large footprint to facilitate identification and repair.* Due to the space constraints of clinical facilities, devices can be small and difficult to repair. The PolyVent was designed with a spacious "footprint" so that components are easy to identify, assemble, repair and replace.
3. *Transparent cover to facilitate mechanical part viewing and environmental protection.* Rather than an opaque cover which hides the internals, the PolyVent has a transparent cover which allows the interior to be viewed even before the cover is removed. The cover is a "cake dome" design that can be removed and the PolyVent can be operated in the classroom without the cover to allow about eight students to simultaneously view it as it operates.
4. *Microelectronic modularity to enable future additions.* The microelectronics are all in one module which uses a classic "card based" architecture, common in electrical

engineering-based design (**Figure 4**). This allows new features to be designed and added to the PolyVent, potentially by students, by designing new printed circuit boards (PCBs).

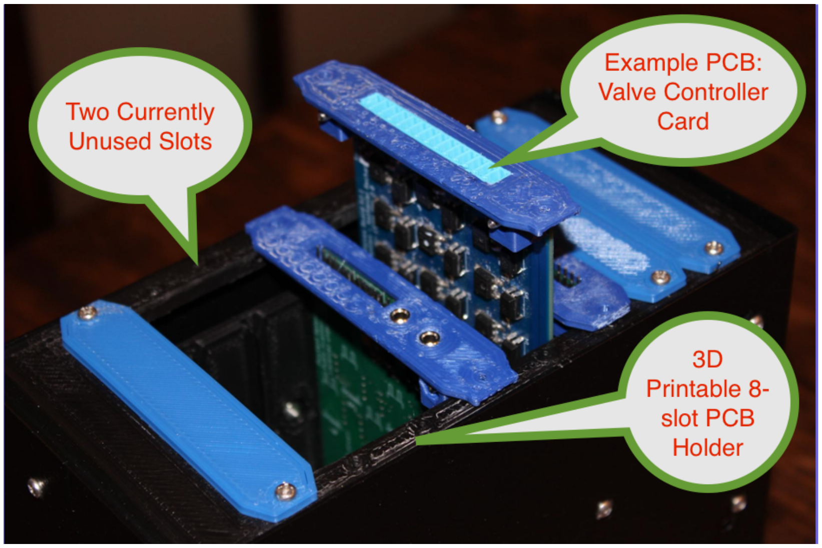


Figure 4: The control module, showing extensibility by adding PCBs.

5. *Real-time data viewing.* The instrumentation producing a dynamic real-time graph of breath pressure, flow, and volume is provided by a separate WiFi enabled device (the VentMon), allowing easy projection on a large monitor to an entire class [8].
6. *Use of accessible parts.* Many of the components, such as the air connectors, are off-the-shelf components purchasable in any country from vendors such as Amazon and McMaster-Carr. The parts are individually labeled with stickers.
7. *Mechanical component modularity.* The PolyVent mechanical airway components are designed as separate modules, each being kept in their own GitLab repositories. These modules are mounted in the frame with standard 20mm x -20mm extruded aluminum section, making it easy to replace, repair, or redesign a module.
8. *Isolation of functions for energy-challenged settings.* The PolyVent uses pressurized air (and oxygen or nitrogen if desired) as an independent source of power, separating that function from the mechanical control of the air production. This approach was inspired by the SmithVent made by Smith College [9]. It is particularly appropriate for low- and middle-income countries, since it represents an energy store that can survive temporary blackouts, allowing the battery backup to be relatively small to power the PolyVent. However, this design makes the ventilator itself relatively small and removes some components. It has the disadvantage that not being integrated, and it requires a separate compressor unit.

The VentOS Free Software

The PolyVent device is controlled by an inexpensive ESP32 microcontroller. The VentOS software for this application is freely available in a GitLab repository where any student or researcher may read, study, and change it [10]. This software is uploaded with PlatformIO, a common system for cross-compilation for embedded microcontrollers. The architecture of the VentOS system itself is a so-called “super loop” or “simple loop” architecture within the Arduino framework. These factors, namely the reprogrammability and open-source nature, improve the accessibility to students of Computer Science, Computer Engineering, and Electrical Engineering. The ability to conceive of a programming-based change, execute it and observe its impact on the hardware in real time has the potential to improve the student learning experience. Improved retention and engagement were both observed when students used real-time microcomputer-based laboratory tools to learn motion concepts [11]. Moreover, many ventilation modes which are still an active area of research and the activity of the VentOS repository suggest that there are several opportunities for undergraduate exercises as well as genuine research enabled by this software [10], [12], [13].

VentMon and Real-time Breath Tracings for Learning

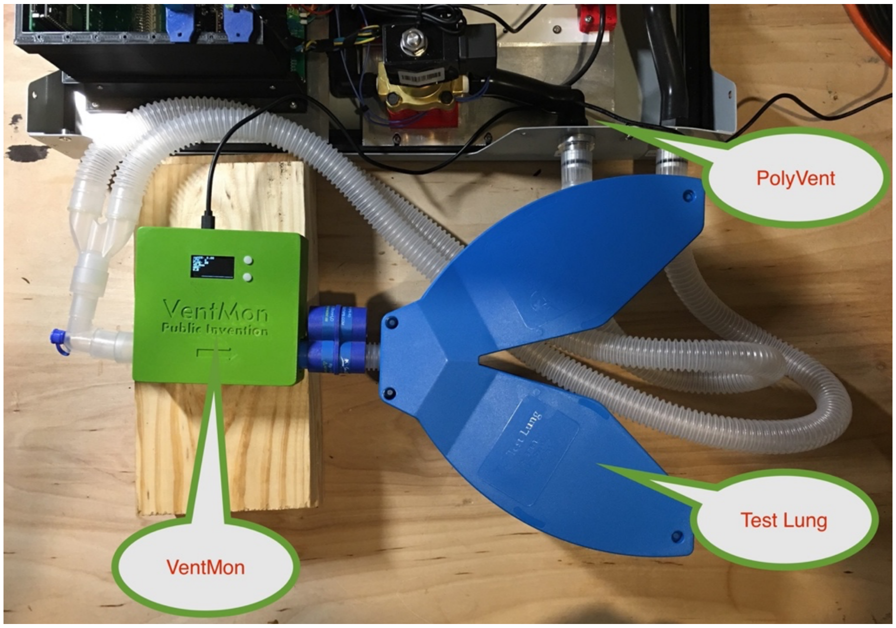
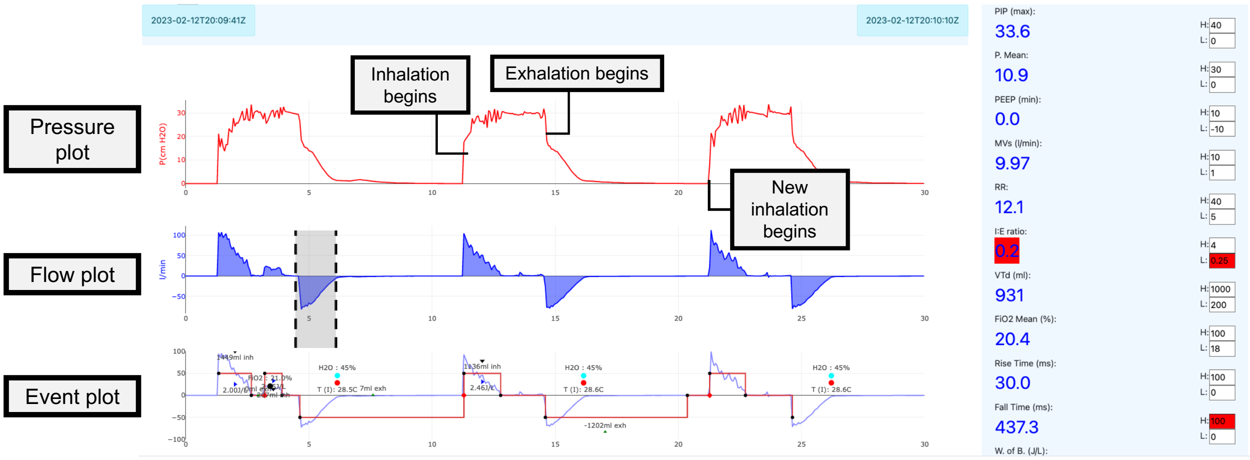


Figure 5: Detail of Breathing Circuit Module and Airway Path

Following the modularity best practices pioneered by the open-source software community, the PolyVent separates instrumentation into a separate device, the VentMon, which is an independent spirometer [14]–[16]. The VentMon spirometer is placed in-line in the breathing circuit between the PolyVent and the test lung and is WiFi enabled (**Figure 5**). When brought to a new classroom, the WiFi network SSID and password are entered through the serial port with, for example, the Arduino IDE serial monitor. Thereafter, the VentMon uses WiFi to transmit data in the Public Invention Respiration Data Standard (PIRDS) format to a public data lake, which all browsers can point to [17]. This enables classrooms to display the browser using a projection system to the entire class, and even remote students, to view real-time breath traces (**Figure 6**) as they are produced by the VentMon based on the PolyVent operation.



PIP (max): 33.6 H: 40 L: 0
P. Mean: 10.9 H: 30 L: 0
PEEP (min): 0.0 H: 10 L: -10
MVs (l/min): 9.97 H: 10 L: 1
RR: 12.1 H: 40 L: 5
I:E ratio: 0.2 H: 4 L: 0.25
VTd (ml): 931 H: 1000 L: 200
FiO2 Mean (%): 20.4 H: 100 L: 18
Rise Time (ms): 30.0 H: 100 L: 0
Fall Time (ms): 437.3 H: 100 L: 0
W. of B. (J/L):

Figure 6: Sample breath traces of the PolyVent produces with the VentMon. PIP = Peak Inspiratory Pressure; P. Mean = Average Pressure; PEEP = Positive End-Expiratory Pressure; MV = Minute Volume; RR = Respiratory Rate; I:E Ratio = Inspiratory to Expiratory Ratio; VTd = Tidal Volume; FiO2 = Fraction of Inspired Oxygen; H, L refer to high and low parameter value warning limits, respectively. In the Event Plot, upside triangle refers to breath volume, H2O to humidity and T (I) = temperature. The gray shaded region with dashed lines refers to negative flow or expiration.

The clinical parameters computed from the breath traces on the right-hand side of the VentMon display can serve to motivate potential classroom exercises centered around pulmonology, physics, and engineering. In **Figure 6**, the pressure and flow graphs on the left are related by basic physical laws of importance to mechanical engineering. At a basic level, volume is the integration of flow over time, made visible in the Event Plot. Addressing more physiological concerns, basic lung compliance is the change in volume divided by the change in pressure, and varies as the lungs fill and with disease condition. A plastic test lung can serve as a useful simulation of an actual patient lung function. The changeable diameter of the small hole leading into the test lung can model different airway resistances, defined as the airway pressure difference driving airflow divided by the volumetric airflow. The event graph at the bottom shows, for example, that volume is the integration of flow over time (**Figure 6**). Periodic measurements, such as temperature and humidity are placed here as well (**Figure 6**). The sensitivity of the breath traces unlocks a number of possible physiological exercises. For example, changing resistance of the test lung produces clearly visible breath trace differences corresponding to Chronic Obstructive Pulmonary Disease (COPD). Likewise, adding weight to the test lung is a partial simulation of reduced lung compliance, as seen in many disease conditions, including COVID-19 [9].

The Internet-of-Things (IoT) visualization approach is paired with controlling the PolyVent with special commands over the serial port using the Public Invention Respiratory Control Standard (PIRCS) [18]. Future work includes the development of a physical GUI device which allows a PolyVent to be controlled by a gloved clinician like traditional medical ICU ventilators.

A Classroom Experience

In Fall 2022, the PolyVent platform was used for an extra-credit classroom exercise for the senior Troubleshooting for Clinically Relevant Biomedical laboratory course. The platform was arranged such that all students could view the interiors of the platform. Prior to the troubleshooting exercises, a brief introduction to ventilators and pulmonology was provided. The components of the device were identified and discussed. Students were asked to walk through the airflow path of the device. The real-time breath graph was projected onto a large screen easily visible to all students.

Five troubleshooting exercises had been prepared ahead of time with the goal of students identifying common failure points within a 5-10 minute window per failure using observation of physical parts and breath traces. Failures included disconnections, intentionally placed previously manufactured defective components, for example, and were created in the absence of the students. Detail on failures, symptoms and student observations is summarized in **Table 1** below.

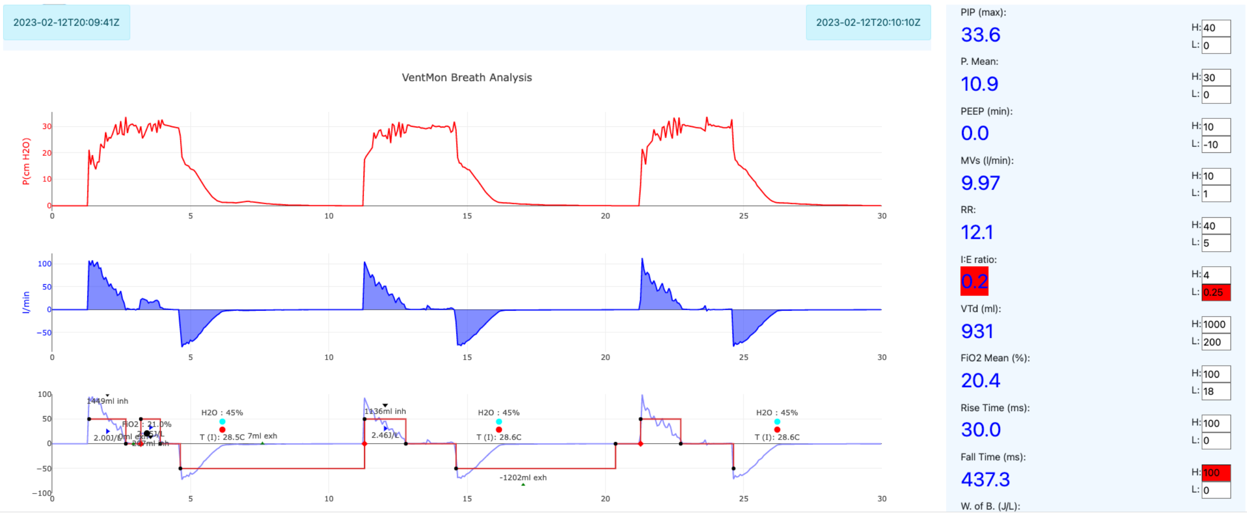
Table 1: Summary of Troubleshooting Exercises

Failure Point	Detail	Symptoms	Observations
Emergency pop-off valve	Adjustment of emergency pop-off valve on air and oxygen mixing chamber to open at approximately 5 psi, a pressure insufficient to reach the PIP in the test lung	Audible leak, in ability to achieve pressure	Students deduced problem quickly due to audible leak.
Defective air line	Installation of intentionally defective air line with slit preventing programmed pressure of 30cm H2O from being obtained	Audible leak, inability to achieve pressure	Students deduced problem quickly due to audible leak.
Restricted exhalation	Machine was set to 30cm H2O, the least restrictive test lung setting and 10 breaths per minute. A ball bearing was placed in the exhalation path resulting in a slow and "soft" exhalation. (See **Figures 7** and **8**.)	Breath traces not exhibiting "crisp" edges during deflation	Challenging exercise that required class discussion to identify physical failure point.
Partial O-ring in inhalation port - leaking breathing circuit	Partial (cut with a knife) O-ring was installed on inhalation port resulting in leaking breathing circuit with a slow and inaudible leak and backward flow.	Backward flow across flow sensor via breath traces	Somewhat challenging exercise that required prompting students to traces and possible causes.
Compressor turned off	Compressor was turned off which resulted in no effects in the beginning due to existing pressure in the mixing chamber. After 2 minutes, the inspiratory pressure began to fall with each breath cycle.	Breath traces showing dropping inspiratory pressure	One student observed the changes in the breath traces after a few minutes had passed.

In each case, students were able to discover the problem, sometimes with prompting and guidance. Each failure encouraged the discussion of physiological processes that normally occur or are affected during a disease condition. The visual breath traces were an essential tool in helping troubleshoot the device failure and simulate effects of failure on patient. It should be noted that diseased conditions were not simulated in this exercise although such an activity could be beneficial for a physiological course.

Figures 7 and 8 below demonstrate what the students saw in the third exercise described above. In this exercise, a ball bearing nearly the diameter of the airway was placed in the expiration path (retrievable with an included magnet.) **Figure 7** shows the pressure and flow over 30 seconds of the unobstructed airway, and **Figure 8** shows the obstructed airway. In the exercise, the students had gained experience seeing several traces like **Figure 7**. When viewed side-by-side, the impact of the obstruction was more evident with slight pressure bumps caused by the ball bearing rattling around in the airway. The ball bearing slows the expiration and causes a precipitous change in the "fall time" of the pressure. In fact, the pressure never reached zero in the 10 seconds of each breath. The students, however, did not see these plots side-by-side, but observed **Figure 8** only. Eventually, they clearly understood that the expiration was slowed somehow. A discussion ensued about whether this could be in the test lung/patient as a disease condition, or somewhere else in the airway. After an assurance that the test lung itself had not been modified, they were able to deduce the approximate location of the problem (although they could not see the ball bearing.)

Other exercises made similar use of the visual breath traces. Several students seemed comfortable relating these changes to either changes in the machine or changes in the test lung/disease condition.



PIP (max):
33.6
H: 40
L: 0

P. Mean:
10.9
H: 30
L: 0

PEEP (min):
0.0
H: 10
L: -10

MVs (l/min):
9.97
H: 10
L: 1

RR:
12.1
H: 40
L: 5

I:E ratio:
0.2
H: 4
L: 0.25

VTd (ml):
931
H: 1000
L: 200

FiO2 Mean (%):
20.4
H: 100
L: 18

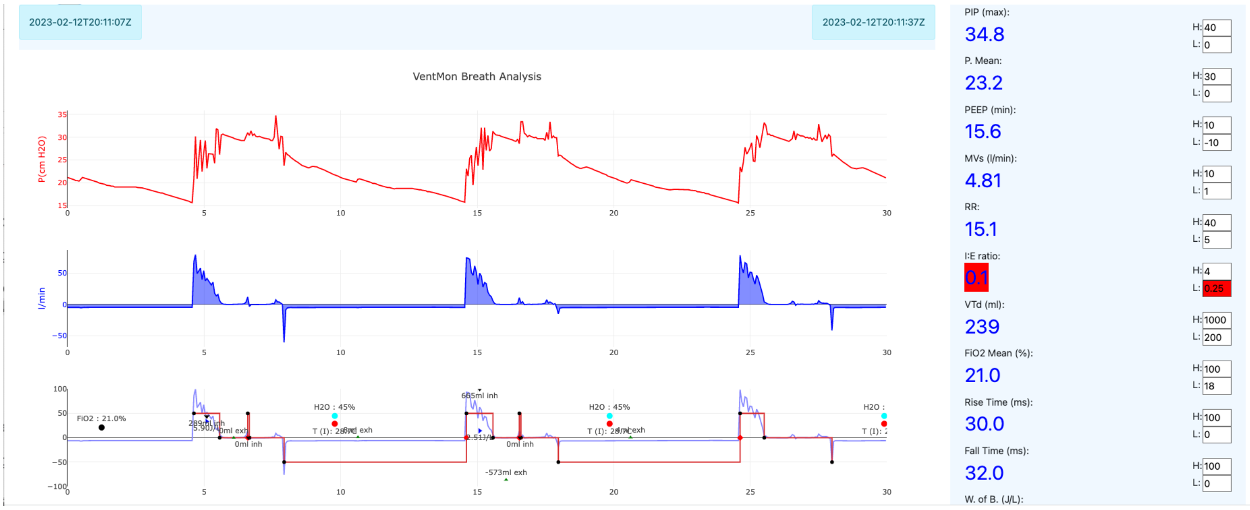
Rise Time (ms):
30.0
H: 100
L: 0

Fall Time (ms):
437.3
H: 100
L: 0

W. of B. (J/L):

Figure 7: Sample breath trace at 30cmH2O, 6 bpm, unobstructed airway.

In Figure 8 below, the exhalation flow is slower, as evidenced by the shape of the blue region in the negative flow area (below the center line.) When unobstructed, the pressure drops within half a second to near zero; in the obstructed flow, it slowly moves from 20 psi to 16 psi. Immediately when the exhalation begins, the force of the air is strong enough to make the ball bearing rattle in the airway, as can be seen at seconds 7.5, 17.5, and 22.5 in the pressure trace.



2023-02-12T20:11:07Z

2023-02-12T20:11:37Z

PIP (max): 34.8 H: 40 L: 0

P. Mean: 23.2 H: 30 L: 0

PEEP (min): 15.6 H: 10 L: -10

MVs (l/min): 4.81 H: 10 L: 1

RR: 15.1 H: 40 L: 5

I:E ratio: 0.1 H: 4 L: 0.25

VTd (ml): 239 H: 1000 L: 200

FiO2 Mean (%): 21.0 H: 100 L: 18

Rise Time (ms): 30.0 H: 100 L: 0

Fall Time (ms): 32.0 H: 100 L: 0

W. of B. (J/L):

Figure 8: Sample breath trace at 30cmH2O, 6 pm, with an obstructed expiration airway.

Following the in-class exercise, 12 students completed an anonymous survey addressing the value of the platform. Most students believed the mechanical design (50%) and physiological aspects in the traces (33%) were of greatest interest (electronic design – 8.3%, open-source aspect – 8.3%, programming – 0%). Additional results are summarized in **Figure 9** below.

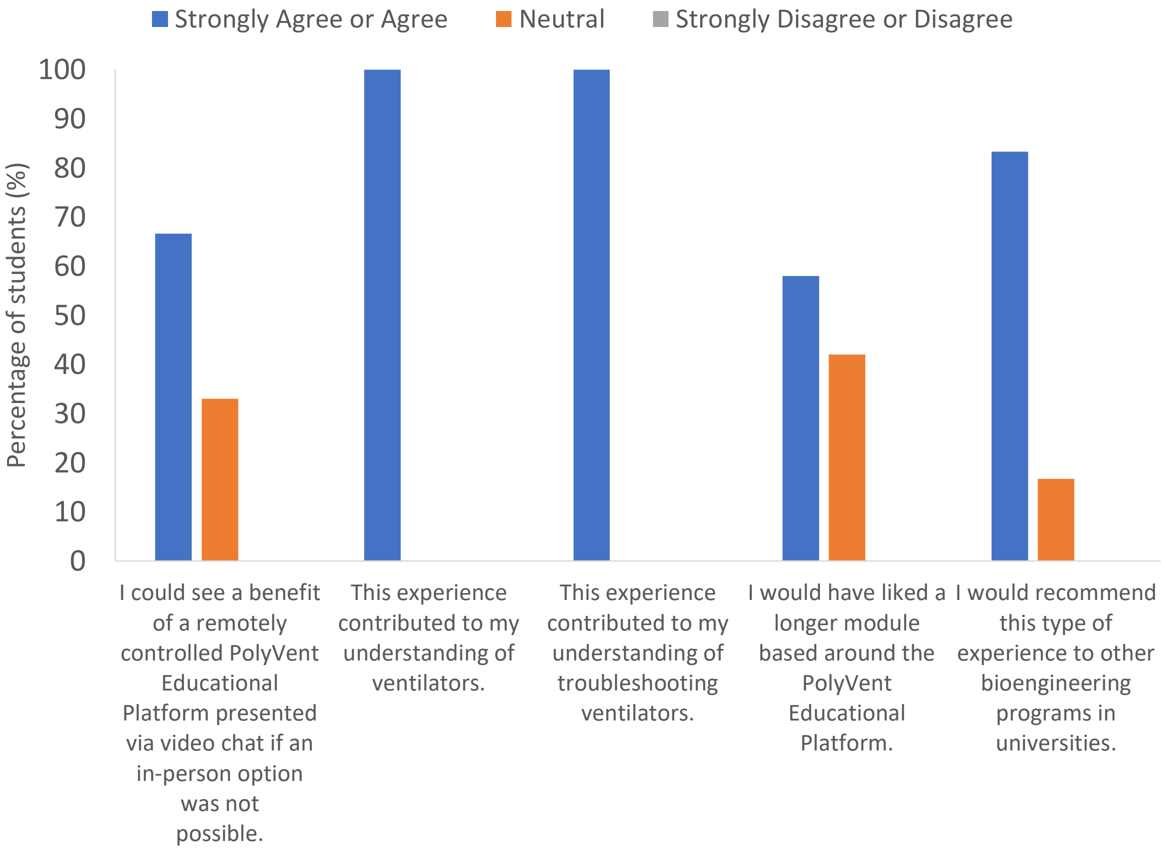


Figure 9: Post Exercise Student Summary. Results representative of 12 student surveys following exercise.

Overall 100% of students agreed or strongly agreed on the contribution of the PolyVent platform exercise to their understanding of ventilators and ventilator troubleshooting. About 58.3% of the students agreed or strongly agreed on a preference for a longer module (41.7% were neutral) while 88.3% agreed or strongly agreed to recommending this type of experience for other bioengineering university programs. It should be noted that this exercise was held on a Friday evening after classes which may have affected the responses about exercise length. About 66% of students agreed or strongly agreed on the benefit of a remotely controlled PolyVent platform while 33% of students were neutral. When asked how the experience of the PolyVent Educational Platform could be improved, students suggested more detail on the code and device feedback functions, visual schematics/diagrams, and air flow detail. Additionally, discussion on design criteria and part selection and preventative strategies especially for LMICs was also suggested.

These results allude to the widely reported benefits of experiential learning [19]–[22]. More specifically, the real-world nature of the device and the ability to tweak mechanical aspects to simulate device and physiological failures and observe the visual tracings real-time, *i.e.* the ability to interact with the device live. Kolb's four stages of learning in the experiential learning cycle can be seen in the activities described: concrete experience, reflective observation, abstract conceptualization and active experimentation [19]. Students directly experiencing the effects of a "broken" ventilator, reflecting on what could have been responsible, relating that knowledge to previous iterations and learnings of physiology and finally trying a new approach. The improved access to interior device hardware and coding aided in the experience and active experimentation. Such experimentation experiences can be limited by fragile expensive parts, proprietary coding and design legally or mechanically frustrating repeated opening.

More Advanced Project/Capstone Project Ideas

Beyond modules which can be accomplished in a laboratory class setting of two to three hours, the PolyVent can also provide inspiration for larger projects, for courses such as Capstone Engineering Design not specific to bioengineering but open to many disciplines. Ideas for research or advanced undergraduate projects include:

- Designing a PCB to drive an air heater and/or humidifier and creating a supportive software extension
- Designing a nebulizer for drug delivery
- Programming new ventilation modes
- Designing a hardware module to support acoustic ventilation
- Programming the system to become a small animal veterinarian ventilator
- Designing a software control, and possibly a new hardware, to explore percussive ventilation[3]

- Replacing the air pressure reservoir approach with a low-inertia turbine
- Developing a clinical GUI
- Developing an alarm device
- Computing pressure-volume loops from the breath traces
- Preparing the PolyVent for use in an LMIC by designing robust filtering and battery backup

Legal Licensing and Purchasing

The PolyVent hardware is licensed with the most open reciprocal or share-alike licenses available. The licenses give anyone the right to make modifications, as long as they do not attempt to preclude others from building on their own modifications. Documentation, hardware designs, software, and graphical art and scientific papers are part of the complete PolyVent communal publication. Each is covered by a different license, specifically the CERN Open Hardware License (OHL) Version 2 - Strongly Reciprocal for hardware, the GNU Affero Public License for Software, and various Creative Commons licenses for documentation and academic work [23], [24].

Public Invention, a US 501c3 non-profit public charity, maintained a curated list of over 100 open source ventilators started during the COVID-19 pandemic [25]. Of all of these, the PolyVent is the most open and transparent functional ventilator still being actively developed. Currently, the ventilator can be purchased from Public Invention for $4000USD. The PolyVent is not available free of charge currently due to parts and testing, however, it is free-of-proprietary intellectual property and licensing.

Limitations

While promising in its initial implementation in a troubleshooting course, the PolyVent survey results are representative of a single course limited to 12 students and their associated demographics. Moreover, an assessment of actual learning or retention was not completed. The benefits of such an approach should be further studied with a simultaneous course offering without the hardware/software machine to more conclusively report on possible effects.

Conclusion

The PolyVent is a free-libre open-source hardware and software machine designed specifically to support a variety of biomedical engineering and engineering educational experiences in general. The platform offers the unique benefits of cheap cost and technically complex functionalities with an accessible interior and real-time remotely accessible data traces aiding in device troubleshooting and physiological function and dysfunction diagnosis. Moreover, the modular and open-source design can be used as a springboard for innovative design ideas in engineering disciplines. By increasing the accessibility of highly motivating, complex life-saving devices such as ventilators into the classroom, students have the opportunity to not only improve their troubleshooting skills and extend the life of existing medical equipment but innovate on existing designs for extended access and improved function.

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