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A LOW-COST, OPEN-SOURCE SOLUTION TO THE COVID-19 VENTILATOR SHORTAGE

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ABSTRACT

Mechanical ventilators are beneficial in treating and managing various respiratory diseases, including interstitial pneumonia associated with Coronavirus infection (COVID-19). The unprecedented COVID-19 pandemic has led to the emergence of a worldwide need for more accessible and affordable mechanical ventilatory devices. This project, known as the Third Coast Ventilator, aims to create a low-cost, open-source solution to the ventilator shortage created by the COVID-19 pandemic; this device can additionally be implemented in developing countries with limited medical resources, where ventilators are often inaccessible. Using readily available components found within hospitals and local stores, our team designed a prototype that can be assembled and functional within an hour. Our testing demonstrated accurate tidal volume delivery while modulating commonly used ranges of inspiratory to expiratory ratios, air flow rates, and respiratory rates. These promising results are an important step toward our goal of creating a low-cost, open-source, globally accessible ventilator in areas where shortages exist.

Keywords: Respirator, device, shortage, ventilator, critical care, COVID-19

NOMENCLATURE

PEEP	Positive End Expiratory Pressure
PIP	Peak Inspiratory Pressure
ARDS	Acute Respiratory Distress Syndrome
FDA	Food & Drug Administration
Vt	Tidal Volume
LPM	Liters Per Minute (Flow Rate)
RR	Respiratory Rate

1. INTRODUCTION

Respirators, mechanical ventilators, and other machines that assist with breathing are used to treat respiratory diseases and have become a precious commodity in treating patients with COVID-19 infections [1]. As the pandemic unfolded, hospitals worldwide suffered shortages of these life-sustaining devices [2]. Ventilators perform the work of breathing for a patient, allowing the patient's lungs to recover from COVID-19. Severely ill patients may need respiratory assistance from mechanical ventilators when the virus infects the lower respiratory tract. The virus sets off a dysregulated immune response within the lungs, and this overwhelming inflammatory reaction impairs lung expansion and hinders the diffusion of oxygen through lung tissue into the blood [3]. This pathological process is commonly known as the "cytokine storm" which can lead to acute respiratory distress syndrome (ARDS), respiratory failure, and death [3]. Such patients require positive pressure ventilatory support with supplemental oxygen because as their respiratory muscles fatigue, blood oxygen levels decline [3]. The goal of extended ventilator support is to provide assisted breathing, allow time for the patient's immune system to eradicate the infection and for the dysregulated immune response within the lungs to subside, and finally for their lung tissue to recover from the damage.

There was a clear gap between ventilator supply and the demand created by the pandemic. Our team recognized an opportunity to address the pitfalls in current delivery models that hinder access to and utilization of mechanical ventilators. Inequities in ventilator distribution between developed and developing countries are largely driven by ventilator cost, and these disparities worsened during the COVID-19 pandemic [4].

The ventilator shortage following the initial spread of COVID-19 spurred several ventilator prototypes [5-7]. These efforts aimed to develop an affordable device that could rapidly augment hospitals' ventilation capacity; however, essential considerations such as availability of parts, ease of use, assembly, and affordability were only partially realized. We address these challenges with a ventilator design that accounts for variation in technological literacy and access to medical supplies.

Standard mechanical ventilation systems allow for accurate delivery of variable tidal volumes, manipulation of ventilation parameters such as peak pressures, and real-time monitoring. Traditional ventilators are effective but costly, with most costing over $20,000 per machine [8]. Furthermore, these machines are complex to manufacture, resulting in supply shortages when demand shocks such as COVID-19 disrupt the supply chain.

This paper describes the design of a pneumatic apparatus that can support the tidal volumes, respiratory rates, positive end-expiratory pressure (PEEP), peak inspiratory pressures (PIP), and inspiratory/expiratory ratios necessary to help patients requiring mechanical ventilation. Our device design is accessible and available via an open-source repository [9]. In addition, the total cost of components for our method is under $1,500, which is significantly less than standard ventilators currently on the market.

2. MATERIALS AND METHODS

The current iteration of this device consists of a modified off-the-shelf electrical microcontroller (Arduino) and 17 patient-interfacing parts, 15 of which are FDA-approved and readily available at most hospitals (Image 1).

Some electromechanical components, such as buttons, display screens, and solenoid valves, are common, but must be acquired from outside the hospital setting. After acquiring all necessary components, users can assemble a ventilator using instructions provided online from our website [10]. The Arduino code is also available on our website and must be loaded into the microcontroller in order for the ventilator to function.

Non-corrugated air tubing is connected to valves with hose clamps. Corrugated ventilator tubing slips on fittings without external hardware, consistent with existing ventilator designs. Jumper cables and a breadboard are needed to connect the solenoid valves and control switches to the Arduino..

After assembly, the device must be connected to power and a pressure source (compressed air, oxygen, or a mixture of the two). Once connected to power, the device turns on and displays a menu to control respiratory rate and relative time spent in inspiration for a given breath cycle (I:E ratio).

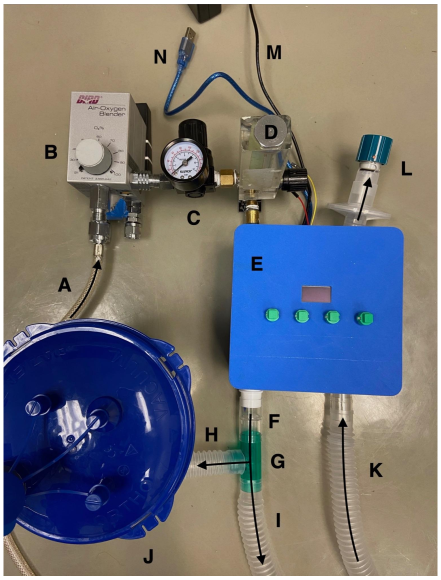

IMAGE 1: OVERVIEW OF VENTILATOR APPARATUS WITH ARROWS SHOWING THE FLOW OF AIR (A-INPUT TUBING, B-OPTIONAL GAS MIXER, C-PRESSURE REGULATOR, D-ROTAMETER, E-OPTIONAL 3D PRINTED COMPONENT HOUSING, F-PLASTIC FEMALE-FEMALE CONNECTOR, G-PLASTIC T SHAPED MALE END CONNECTOR, H-PLASTIC TUBING TO PIP CANISTER, I-PLASTIC INHALATION TUBING, J-WATER BUCKET (PIP CANISTER), K-PLASTIC EXHALATION TUBING, L-PEEP VALVE, M/N-POWER SOURCE WIRING)

The inspiratory limb of the flow circuit consists of all components in Image 1 from Component A through Component I, extending from the pressure source to the patient. During the inspiratory phase, a solenoid valve along this limb opens to allow air flow towards the patient. The peak inspiratory pressure (PIP) is regulated by a column of water placed parallel to the inspiratory limb that vents excessive pressure, protecting the lungs. The expiratory limb consists of Components K and L in Image 1, extending from the patient to the ambient air. The inspiratory solenoid closes during the expiratory phase and the expiratory solenoid opens, allowing the patient to expire through the expiratory limb. At the end of the expiratory limb, a positive end-expiratory pressure (PEEP) valve is present to allow expiration of air exceeding a set pressure. PEEP valves ensure that the lungs remain partially inflated after expiration, and are important in the treatment of ARDS.

Respiratory therapists and ICU physicians were consulted to ensure that this device could meet the needs of most COVID-19 patients. Critical technical considerations included supporting a range of tidal volumes, respiratory rates, I:E ratios, PEEP, and PIP to treat patients with varying respiratory needs.

3. RESULTS AND DISCUSSION

The device has been tested and validated using a calibrated ventilator analyzer, which measures various parameters such as flow rate, volume, pressure, and oxygen concentration. This testing has shown that the device can perform under the wide range of conditions required of an ICU ventilator for COVID-19 patients, with only minor error between calculated and administered tidal volumes.

The tidal volume (mL) delivered by the ventilator can be accurately predicted within 10% error for an input of desired flow rate (liters/min), respiratory rate (breaths/min), and I/E ratio (Figures 1, 2, 3, 4). The ventilator is capable of delivering tidal volumes of clinical relevance. Tidal volumes were calculated as a function of flow rate, respiratory rate, and I/E ratio as shown in Equation 1 below:

$$V_t = \frac{(1000)(LPM)}{RR} \times \frac{I}{I+E} \qquad (1)$$

where Vt = Tidal Volume, LPM = Flow Rate; RR = Respiratory Rate; I = Inspiratory Time, and E = Expiratory Time.

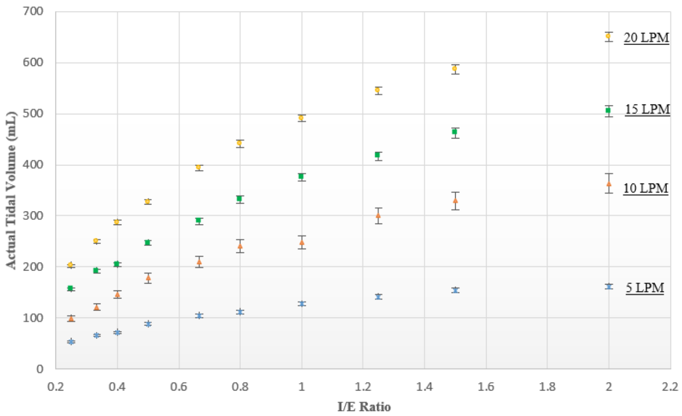

FIGURE 1: ACTUAL (MEASURED) TIDAL VOLUMES WITH RESPECT TO CHANGES IN I/E RATIO. RESPIRATORY RATE = 20 BREATHS/MIN. STAR MARKERS (BLUE) = 5 LPM; TRIANGLE MARKERS (ORANGE) = 10 LPM; SQUARE MARKERS (GREEN) = 15 LPM; CIRCLE MARKERS (YELLOW) = 20 LPM. ERROR BARS REPRESENT THE ABSOLUTE ERROR (IN ML) BETWEEN ACTUAL AND CALCULATED TIDAL VOLUMES FOR EACH FLOW RATE: 5, 10, 15, 20 LPM.

The device has also been tested using a mechanical lung at various levels of resistance and compliance to simulate a wide range of clinical lung states, from healthy lungs to the acute respiratory distress syndrome (ARDS) lungs that might be seen in a COVID-19 patient. The ventilator has been subjected to a 24-hour continuous use test with consistent performance.

Tidal volumes have been calculated at flow rates from 5 liters per minute to 50 liters per minute, at respiratory rates from 10 breaths per minute to 30 breaths per minute, and at positive end-expiratory pressures (PEEP) of 1.5 to 20 cm H2O. In addition, I:E ratios ranging from 1:4 to 2:1 have been tested and produced values that have been replicated in multiple tests.

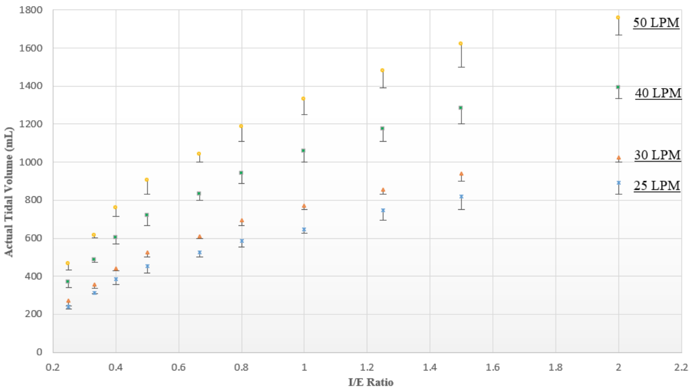

FIGURE 2: ACTUAL (MEASURED) TIDAL VOLUMES WITH RESPECT TO CHANGES IN I/E RATIO USING *HIGH FLOW* ROTAMETER. RESPIRATORY RATE = 20 BREATHS/MIN. STAR MARKERS (BLUE) = 25 LPM; TRIANGLE MARKERS (ORANGE) = 30 LPM; SQUARE MARKERS (GREEN) = 40 LPM; CIRCLE MARKERS (YELLOW) = 50 LPM. ERROR BARS REPRESENT THE ABSOLUTE ERROR (IN ML) BETWEEN ACTUAL AND CALCULATED TIDAL VOLUMES FOR EACH FLOW RATE: 25, 30, 40, 50 LPM.

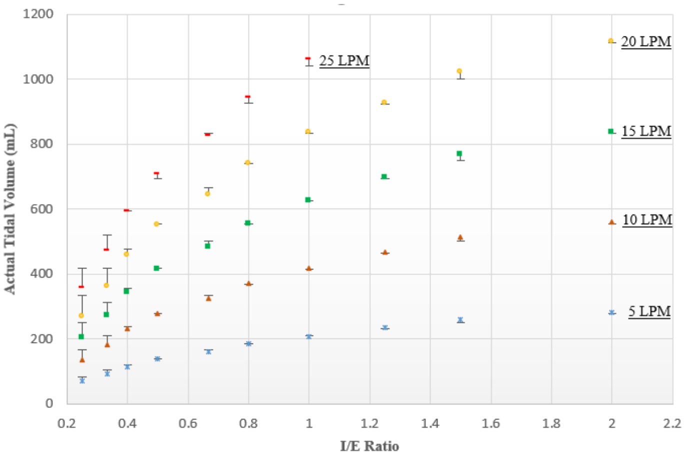

FIGURE 3: ACTUAL (MEASURED) TIDAL VOLUMES WITH RESPECT TO CHANGES IN I/E RATIO USING *HIGH FLOW* ROTAMETER. RESPIRATORY RATE = 12 BREATHS/MIN. STAR MARKERS (BLUE) = 5 LPM; TRIANGLE MARKERS (ORANGE) = 10 LPM; SQUARE MARKERS (GREEN) = 15 LPM; CIRCLE MARKERS (YELLOW) = 20 LPM; DASH MARKERS (RED) = 25 LPM. ERROR BARS REPRESENT THE ABSOLUTE ERROR (IN ML) BETWEEN ACTUAL AND CALCULATED TIDAL VOLUMES FOR EACH FLOW RATE: 5, 10, 15, 20, 25 LPM.

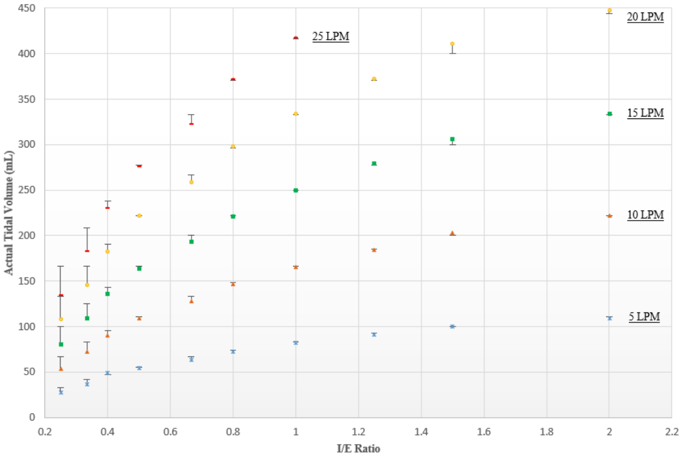

FIGURE 4: ACTUAL (MEASURED) TIDAL VOLUMES WITH RESPECT TO CHANGES IN I/E RATIO USING *HIGH FLOW* ROTAMETER. RESPIRATORY RATE = 30 BREATHS/MIN. STAR MARKERS (BLUE) = 5 LPM; TRIANGLE MARKERS (ORANGE) = 10 LPM; SQUARE MARKERS (GREEN) = 15 LPM; CIRCLE MARKERS (YELLOW) = 20 LPM; DASH MARKERS (RED) = 25 LPM. ERROR BARS REPRESENT THE ABSOLUTE ERROR (IN ML) BETWEEN ACTUAL AND CALCULATED TIDAL VOLUMES FOR EACH FLOW RATE: 5, 10, 15, 20, 25 LPM.

3.1 Technical Specifications

Parameter	**Operating Range**
Tidal Volume	200 - 1000 mL
I:E Ratio	1:4 - 2:1
Fraction of inspired O2 (FiO2)	0.21 - 1
Respiratory Rate	10 - 30 per minute
Inlet Pressure Max	500 psi (35 bar)
Peak Inspiratory Pressure (PIP)	0 - 30 cm H2O
Positive End Expiratory Pressure (PEEP)	1.5 - 20 cm H2O

TABLE 1: OPERATING LIMITS OF VENTILATOR

3.2 Competitive Advantage

Competitor Advantages	**Comparison**	**Third Coast Ventilator Advantages**
Plug-and-play design	Stanford OpVent	Storage box optional
Stable and reliable electrical connections		No custom PCB required
Bag valve masks are easy to obtain	MIT E-Vent	No moving parts
Minimal number of components		More predictable operating pressures
Breathing assist	GlasVent	Custom I:E ratio
Manual fall-back		FiO2 modification

TABLE 2: COMPETITIVE ANALYSIS BETWEEN THIRD COAST VENTILATOR AND OPVENT (STANFORD UNIVERSITY), E-VENT (MIT), AND GLASVENT (UNIVERSITY OF GLASGOW)

Our design has advantages and drawbacks compared to other pandemic ventilator designs (Table 2). A team at the Massachusetts Institute of Technology (MIT) attempted to address the global ventilator shortage by developing an emergency ventilation system that squeezes a bag valve mask (Ambu bag) with a custom-built automatic actuator [5]. It is relatively inexpensive, and bag valve masks are a common hospital commodity. A team at the University of Glasgow developed a similar bag valve mask actuator called GlasVent, though it also incorporates a manual operation mode as a fail-safe. GlasVent also includes a breathing assist mode for lightly sedated patients [6]. Both of these designs have the key advantage of not requiring a pressurized gas source to operate, but closed-loop pressure monitoring is necessary to actuate bag valve masks of various compliances and capacities.

These systems utilize some existing hospital equipment, but the foundations of these designs are pre-built, custom bag valve mask actuators. Our ventilator, in contrast, has no custom parts and therefore does not add a step to the supply chain. Instead, users acquire off-the-shelf items that can be assembled with an instruction manual. The bill of materials, blueprint, assembly manual, and operation manual for the ventilator are open-source, all of which enhance accessibility.

Our design also differs from Op-Vent, an emergency ventilator developed by a team at Stanford University [7]. While Op-Vent is also a solenoid-based platform, its electronics rely on a printed circuit board and an included microcontroller. This provides electronic stability over a breadboard and jumper wires, but makes the design less accessible. In contrast, our ventilator utilizes an Arduino microcontroller, standard electrical jumper wires, and a simple breadboard. These products are relatively inexpensive and readily accessible in hardware or electronic stores. Finally, our pneumatic apparatus requires fewer parts than Op-Vent does, making for a more straightforward design that is easier to acquire and assemble.

3.3 Limitations

The primary limitation of this device is its lack of alarms and flow sensors, which provide real-time feedback for fine adjustments and optimal ventilation. The next generation of this ventilator has these features and is currently undergoing testing. The use of a breadboard offers maximal accessibility, but we acknowledge physical circuit instability as a point of failure. This could be solved by soldering or having a “plug and play” premade device, such as some of the competitors listed above. These potential developments must be balanced against accessibility and are less of a priority moving forward than safety features. Currently, the design requires an outlet to be powered, but future designs will implement battery backup to allow patients to be transported between rooms without interfering with device functionality.

4. CONCLUSION

The COVID-19 pandemic uncovered the global need for low-cost, accessible respiratory support in critically ill patients. This ventilator uniquely addresses the problem through an open-source solution that utilizes readily accessible parts and has been tested and proven to deliver accurate tidal volumes with critical physiologic controls. The next generation of this device is currently in development.

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