Intensive Care Medicine

LETTER TO THE EDITOR **Un-edited accepted proof**

Rapidly Scalable Mechanical Ventilator for the COVID-19 Pandemic

Albert H. Kwon, MD[1#], Alexander H Slocum, Jr, MD PhD[2#], MIT E-Vent Team [3,4], Dirk Varelmann, MD[5], Christoph G. S. Nabzdyk, MD[6]

1. Department of Anesthesiology, Westchester Medical Center, New York Medical College, Valhalla, NY
2. Department of Plastic and Reconstructive Surgery, Medical College of Wisconsin, Wauwatosa, WI
3. Department of Mechanical Engineering, Massachusetts Institute of Technology, Cambridge, MA
4. Computer Science and Artificial Intelligence Laboratory, Massachusetts Institute of Technology, Cambridge, MA
5. Department of Anesthesiology, Perioperative and Pain Medicine, Brigham and Women's Hospital, Boston, MA
6. Department of Anesthesiology and Perioperative Medicine, Mayo Clinic, Rochester, MN

# These authors contributed equally.

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Introduction
The SARS-CoV-2 pandemic is straining healthcare systems worldwide and a global ventilator shortage is fueling the dire situation. As a response, the MIT E-Vent Team (S1) manufactured a scalable ventilator prototype for mass production and demonstrated basic clinical feasibility.

Methods
MIT E-Vent engineering information and capabilities, but also missing safety features are provided on the MIT E-Vent website (https://e-vent.mit.edu/) and in the attachments (Fig 1a, S2). Pressure-based alarms were implemented including in the "Spiro Wave" device that is based on the MIT E-vent and was just authorized for emergency use by the US FDA. In brief, the MIT E-Vent houses a manual resuscitator, an external compression mechanism, and a control system for adjusting tidal volumes, inspiration to expiration ratio, and respiratory rate (Fig 1a, S3, S4). The MIT E-Vent is equipped with a pressure relief and a positive end-expiratory pressure (PEEP) valve. It delivers unassisted (Fig 1b) and assisted (not shown) volume control ventilation (VCV). As a proof of concept, a pig was ventilated with MIT E-Vent or a standard mechanical ventilator (SMV) at distinct settings and arterial blood gases, ventilator waveforms and flow-volume loops were obtained.

Results
The MIT E-Vent performed similar to a SMV at identical respiratory settings. After 36 hours of usage including at high demand settings (TV 600cc, RR 30, PEEP 20) no signs of device failure were noted (S5).

Tidal Volume Delivery
MIT E-Vent waveforms showed a smooth tidal volume delivery (Fig 1b). It revealed similar flow-volume loops when compared to manual ventilation using a manual resuscitator (Fig 1c).

Gas Exchange
MIT E-Vent settings were changed to achieve 'low' and 'high' minute ventilation, and 'low' and 'high' FiO2 states as reflected in the ABGs (Fig 1d, 1e).

Discussion
The MIT E-Vent provides (un-)assisted VCV, variable MV and PEEP with airway pressures profiles comparable to a SMV. The MIT E-Vent is not equipped to provide pressure control ventilation (PCV), which may make it unsuitable for awake and the most complex ARDS patients. However, this device is meant as a bridging tool when a conventional ventilator is not available, serve as 'destination ventilator device' in the absence of any alternatives or may help free up SMV in certain cases.

The MIT E-Vent team was determined to equip the MIT E-Vent with comprehensive safety features including oxygen and flow sensors, but due to widespread hardware supply shortages, this became impossible. Omitting these safety features was deemed necessary to provide a rapidly scalable prototype. Consequently, increased clinical monitoring is required to provide adequate safety during the use of the MIT E-Vent (S2). Despite these limitations, the MIT-E Vent offers basic mechanical ventilation for selected patients during this extreme ventilator shortage.

The MIT E-Vent Team invites the global community to improve and distribute a version of this scalable, low-cost ventilator during this COVID-19 pandemic.

Conclusion
Oxygenation and ventilation capabilities of a scalable, low-cost ventilator were demonstrated. MIT E-Vent engineering documentation was made public to rapidly implement MIT E-Vent into the clinical care of patients requiring invasive mechanical ventilation.

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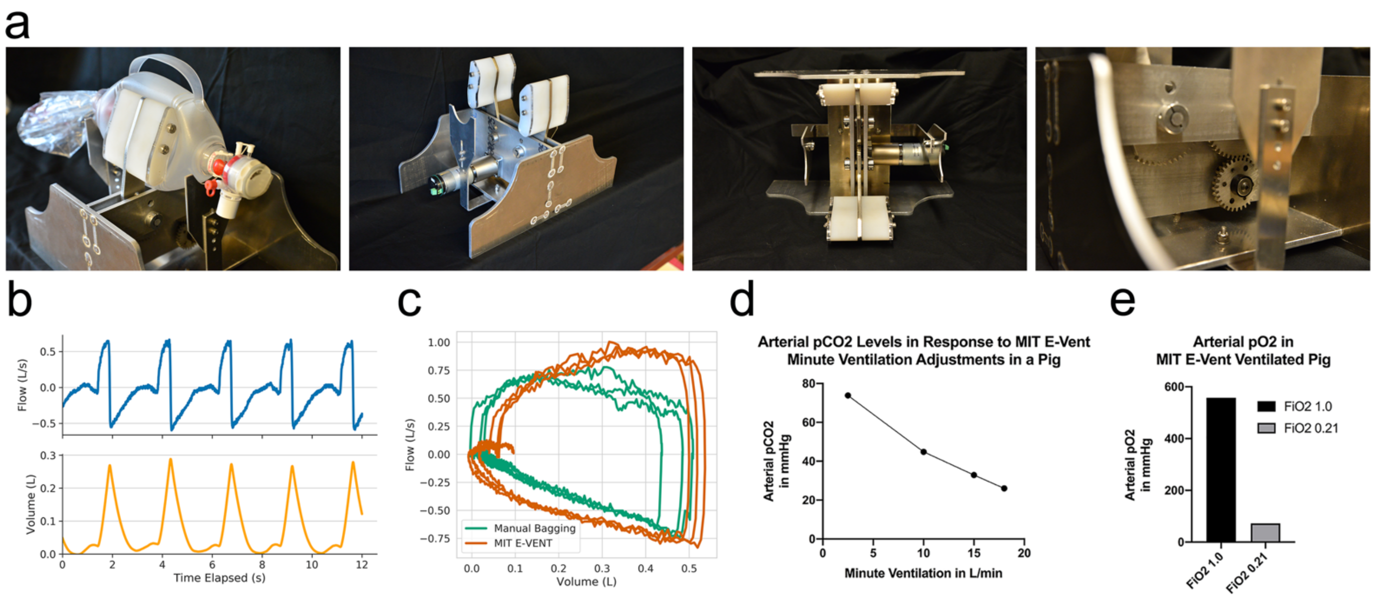
Conflict of Interest
On behalf of all authors, the corresponding author states that there is no conflict of interest.



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