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Ventilator-sharing device. Credit: Vent Multiplexor LLC

Vent Multiplexor's ventilator-sharing device wins FDA nod for emergency use

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April 20, 2020

The U.S. FDA has granted emergency use authorization (EUA) to New Haven, Conn., startup Vent Multiplexor LLC (http://www.cortellis.com/intelligence/qsearch/"Vent Multiplexor") for its emergency rescue co-ventilation device. Developed in collaboration with Yale New Haven Hospital, the Vent Multiplexor enables individualized mechanical ventilation of two adults on a single ventilator – lessening demand for more critical care machines in the ongoing COVID-19 outbreak.

Fears of a serious ventilator shortfall have grown amid unprecedented demand for the life-sustaining equipment due to novel coronavirus. In a recent research note, William Blair analysts predicted the need for additional units could top 150,000.

To address the shortage, the U.S. Public Health Service issued an open letter (https://www.hhs.gov/sites/default/files/optimizing-ventilator-use-during-covid19-pandemic.pdf) on optimizing ventilator use during the pandemic, including the use of the T-connector to co-ventilate more than one patient when the number of patients needing ventilation exceeded the supply of available ventilators. Subsequently, Vent Multiplexor asked the FDA to include its dual connector among ventilator products eligible for EUA.

Conceived by two Yale students

The brainchild of two Yale students, physics major Timothy Foldy-Porto and medical student Brian Bietler, the Vent Multiplexor utilizes two small valves in the inspiratory limb of the respiratory circuit to adjust the flow and tidal volumes delivered to each patient. 3D-printed Venturi tubes are used to measure relative outputs, a feature of lung compliance, which measures the lung's ability to stretch and expand.

The April 17 EUA came just days after Yale New Haven Hospital doctors used the device simultaneously to ventilate two adult patients with different disease states, lung sizes and tidal volume requirements while correctly measuring lung compliance of each patient in real time.

"While we continue to hope for lower-than-predicted volumes of COVID-19 patients, we continue our planning for worst case projections," said Jonathon Siner, medical director-Medical Intensive Care Unit for Yale New Haven Hospital and associate professor of pulmonary, critical care and sleep medicine at Yale School of Medicine, who led the device's deployment. "The Vent Multiplexor will help us to maintain critical care capacity during the pandemic and make a real impact in the MICU."

Rigorous preclinical testing

The emergency deployment and EUA followed extensive preclinical testing using critical care ventilators, as well as TSI Instruments Ltd.'s Certifier FA Plus, the calibrator Yale New Haven Hospital System uses to validate a ventilator's accuracy prior to use on patients.

"Yale New Haven Hospital is proud to have collaborated with Vent Multiplexor LLC and other groups on the development and successful trial of new technologies," said Thomas Balcezak, Yale New Haven Hospital's chief clinical officer and executive vice president. "We are committed to doing everything in our power to bring urgently needed new technologies and treatments to the community to fight against COVID-19."

As part of the collaboration with Yale New Haven Hospital, Vent Multiplexor has agreed to provide the device to the hospital at cost and license the technology for both internal use and further development.

'Ramping up production'

Now with FDA authorization secured, Vent Multiplexor is focusing on "quickly ramping up production" and working with partners around the world where potential shortages of mechanical ventilators could worsen the current health crisis, said Todd Higgins, Vent Multiplexor's president.

The tool is produced using a combination of 3D-printed components, as well as components from partner vendors. "We anticipate being able to rapidly produce thousands of affordably priced Vent Multiplexors for hospitals, health systems and countries" to help sustain critically ill patients during the COVID-19 pandemic, Higgins told *BioWorld*.

He said the company is in direct communication with hospitals, and is exploring distribution agreements and partnerships in the U.S. and elsewhere. Beyond that, "we are exploring discussions with ventilator manufacturers for possible integration of the technology as part of a build in/authorized after-market emergency capability for their devices," Higgins said.

Following their initial work on the prototype, Foldy-Porto and Bietler teamed with Peter Kahn, a Yale New Haven Hospital physician and medical director of Vent Multiplex, and Higgins, a veteran corporate and intellectual property lawyer, to speed the product's development, preclinical testing, EUA and further commercialization. The company has applied for two U.S. patients covering its technology, related to the individual regulation of tidal volumes, inspiratory pressures, fraction of inspired oxygen and respiratory rate during dual patient ventilation.

Other companies are also looking at innovative ways to address the shortage of ventilators. Earlier this month, Shanghai Asclepius Meditec Co. Ltd. reported it had developed (https://www.bioworld.com/articles/434406-asclepius-meditec-develops-hydrogen-oxygen-nebulizer-to-tackle-covid-19) a hydrogen-oxygen nebulizer that can produce three liters of mixed gas by using water electrolysis. The AMS-H-03 can be employed alone or in combination using a trident joint, and can also be used in tandem with oxygen pipelines and invasive and noninvasive ventilators. It runs continuously for up to 24 hours.