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Vent Multiplexor Successfully Deployed at Yale New Haven Hospital for Crisis Care Co-Ventilation During COVID-19 Pandemic

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- **Revolutionary device developed by Vent Multiplexor LLC in collaboration with Yale New Haven Hospital is the first device ever produced to provide temporary dual patient rescue mechanical ventilation with individualized patient care until an additional ventilator is available to resume single mechanical ventilation.**
- **Emergency Use Authorization for Vent Multiplexor During COVID-19 Pandemic Under Review with FDA; Immediate Distribution Planned for Emergency Use at Hospitals Around the World Facing Ventilator Shortages.**

NEW HAVEN, Conn., April 13, 2020 /PRNewswire/ -- **Vent Multiplexor, LLC** (www.ventmultiplexor.com) announced today the successful emergency deployment of the ***Vent Multiplexor*** emergency rescue device at Yale-New Haven Hospital. The pioneer emergency deployment of the ***Vent Multiplexor***, a patent-pending co-ventilation device developed in collaboration with YNHH to provide individualized emergency crisis care for two adult patients requiring ventilation when limited to a single mechanical ventilator, successfully co-ventilated two critically ill COVID-19 patients with different disease states, different lung sizes, and different tidal volume requirements, all while accurately measuring lung compliance of both patients in real time, a dramatic advancement in life saving co-ventilation technology that may help reduce the clinical need for critical care mechanical ventilators during an emergency.

Dr. Peter Kahn, MD, Medical Director for Vent Multiplexor LLC, hailed the successful results from the April 7, 2020 emergency deployment of the ***Vent Multiplexor*** at Yale-New Haven Hospital, calling it "a critical breakthrough in emergency crisis care during the COVID-19 pandemic." Dr. Kahn explained, "We stand

committed to supporting the entire medical community as we urgently look for ways to quickly develop and deploy novel solutions that are desperately needed to overcome the challenges of delivering emergency crisis care during the pandemic, including the unprecedented challenge of delivering individualized patient care using co-ventilation strategies during temporary ventilator shortages." Dr. Kahn continued, "We must do everything possible to deliver life-saving crisis rescue care; having an affordable, state of the art approach, to individualized patient care during emergency co-ventilation will give us yet another critical weapon in the fight to save lives."

The crisis care deployment of the ***Vent Multiplexor***, which was initially developed by two of the co-founders of Vent Multiplexor LLC, Brian Beitler and Tim Foldy-Porto, came after days of around-the-clock pre-clinical testing. Among other things, the ***Vent Multiplexor*** and associated clinical protocols underwent rigorous testing on critical care ventilators at Yale-New Haven Hospital, as well as on the TSI Inc. Certifier FA Plus, which is the calibration device used by YNHHS to validate ventilator accuracy prior to deployment for

patient care. The ***Vent Multiplexor*** performed precisely as intended***, making it the first ever*** device developed and deployed to independently control the delivery of tidal volumes when two patients are sharing a single mechanical ventilator—a crucial component in the clinical management of patients with Acute Respiratory Distress Syndrome, which is frequently the case in ventilated patients critically ill with COVID-19.

As part of the collaboration with YNHH, Vent Multiplexor LLC agreed to produce the ***Vent Multiplexor*** for YNHH at cost and license the technology for internal use and development by YNHH. Todd Higgins, President of Vent Multiplexor LLC, commented, "We believe the ***Vent Multiplexor*** will offer a significant and immediate contribution to emerging crisis care during the COVID-19 epidemic and look forward to our continued collaboration with YNHH as well as local governments, non-profit organizations, and ventilator manufacturers around the world, as we work with the FDA to secure emergency use authorization." Mr. Higgins added that the entire mission behind the ***Vent Multiplexor*** has been the disciplined execution of a four-week crisis plan to rapidly develop affordable ventilation technology

capable of being deployed at scale now, to help alleviate ventilator shortages until more ventilators become available. "We are pleased with the progress but remain intensely focused on getting the ***Vent Multiplexor*** immediately into the hands of hospitals across the country, as well as in other parts of the world where they are facing even more terrifying resource constraints, as they fight to save lives during the COVID-19 epidemic with a limited number of ventilators on hand." The ***Vent Multiplexor*** is manufactured using 3-D printing technology and requires almost no production lead time. Once authorized by the FDA, Vent Multiplexor LLC anticipates tens of thousands of units can be made available for almost immediate distribution as needed for emergency crisis care use during the COVID-19 pandemic.

Additional Information on the *Vent Multiplexor*

The ***Vent Multiplexor*** is a patent-pending co-ventilation device developed in Connecticut by Vent Multiplexor LLC, in collaboration with YNHH, as an emergency rescue device intended to provide individualized temporary rescue mechanical ventilation until an

additional ventilator is available to resume single mechanical ventilation or as soon as respiratory recovery is attained in either patient. The ***Vent Multiplexor*** has the potential to help reduce the clinical need for ventilators during the COVID-19 pandemic, as it permits the emergency sharing of ventilators between two patients who are not equally matched by delivering individualized tidal volumes, while also providing critical validation data on the quality of patient matching using existing "T-connector" and similar ventilator splitting technologies, a potentially revolutionary paradigm shift in the delivery of pandemic emergency respiratory care.

On March 31, 2020, the US Public Health Service released an open letter from the Assistant Secretary for Health and the U.S. Surgeon General for "Optimizing Ventilator Use during the COVID-19 Pandemic." The open letter includes the following statement from the FDA: "The FDA does not object to the creation and use of the T-connector that meets specifications described in the instructions provided to us for use in placing more than one patient on mechanical ventilation when the number of patients who need invasive mechanical ventilation exceeds

the supply of available ventilators and the usual medical standards of care has been changed to crisis care in the interest of preserving life. The FDA's no objection applies during the duration of the declared COVID–19 emergency."

On April 1, 2020, in accordance with the Emergency Use Authorization ("EUA") for the emergency use of medical devices, including alternative products used as medical devices, during the COVID-19 pandemic, issued by the United States Food and Drug Administration ("FDA") for the emergency use of ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories, Vent Multiplexor LLC requested the addition of the Vent Multiplexor on the list of authorized products included on Appendix B of the EUA. On April 2, 2020, The FDA confirmed that the EUA request for the Vent Multiplexor appears to meet a minimum threshold of acceptability for further review and has been submitted to the Office of Health Technology 1 (OHT 1: Ophthalmic, Anesthesia, Respiratory, ENT & Dental

Devices).

The FDA is working closely with Vent Multiplexor LLC to expedite completion of the EUA review so that the ***Vent Multiplexor*** can be authorized for immediate distribution. For more information on the ***Vent Multiplexor***, please contact Vent Multiplexor LLC at information@ventmultiplexor.com.

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