

Somnetics gains FDA authorization to supply vital non-invasive ventilators in the fight against COVID-19.

In response to anticipated ventilator shortages across the nation, Somnetics repurposes its Transcend CPAPs to provide non-invasive ventilators.

MINNEAPOLIS (May 11, 2020) — Somnetics International, Inc., a Minneapolis, MN-based CPAP manufacturer, announced today the company has received authorization from the FDA for the immediate distribution of BiPAP machines and respiratory circuits to medical facilities for use in the fight against COVID-19 under the Emergency Use Authorization (EUA) issued by the FDA.

The Minnesota-based CPAP manufacturer is supporting local and regional medical communities with an emergency supply of EUA BiPAP devices purchased by the state of Minnesota and South Dakota medical facilities. The company is prepared to supply the healthcare system nationwide as it works to quickly produce as many BiPAP machines as possible. To help healthcare providers prepare for the anticipated demand for mechanical ventilation devices, Somnetics is committed to providing the EUA BiPAP devices to medical facilities for significantly less than comparable BiPAP machines currently offered in the market.

“We believe it’s our responsibility to do everything we can to support the medical community with the vital medical supplies they need during this time of crisis, and we are diverting production to this effort,” says Clarence Johnson, CEO of Somnetics. “It’s our honor, as well as our obligation, to provide this support to medical care providers fighting on the front line to manage this public health crisis.”

As the healthcare system battles a surge of COVID-19 patients, experts predict there will be a shortage of critically needed mechanical ventilators. Although ventilator manufacturers have increased production of these devices, they are not expected to meet the surging demand.

Somnetics has responded to these concerns by repurposing its Transcend CPAP machines into EUA BiPAP machines to assist patients that have trouble breathing as a result of the COVID-19 virus. The Somnetics team of engineers has also designed a new breathing circuit for use with its EUA BiPAP device to help control aerosolization of virus particles to help protect healthcare workers.

Medical experts have recently recommended less reliance on invasive ventilation for the treatment of COVID-19 patients, as some physicians have expressed concerns that hospitals have been too quick to adopt this treatment. Some physicians have suggested, instead, using a phased approach to treatment with the use of non-invasive ventilators, such as those provided by Somnetics.

The FDA issued the EUA, dated March 24th, 2020, authorizing the emergency use of continuous positive airway pressure machines (CPAPs) — like those Somnetics has repurposed— in healthcare settings to treat patients during the COVID-19 pandemic. While the FDA has not granted traditional clearance or approval for the Somnetics BiPAP machines, it has

authorized the use of these devices by medical facilities for the duration of the EUA for ventilators during the COVID-19 pandemic.

The US already has over 1.3 million confirmed COVID-19 cases, which have resulted in about 79,000 deaths so far. Those numbers are expected to peak in the coming weeks, which will put a strain on the already stretched healthcare community. Ventilators are essential in the fight against COVID-19, a respiratory illness that affects the lungs and can cause severe breathing issues in patients.

About Somnetics International, Inc.

Somnetics International, Inc. is a privately held medical device company based in Minneapolis, Minn. It is an emerging leader in customer-driven design, development and production of respiratory medical devices to treat sleep apnea and related issues. Somnetics' mission is focused on integrating technology, customer input and employee creativity to provide innovative, high quality products that improve quality of life for people with respiratory disorders. Its leading CPAP machine, Transcend, received the 2011 Medtrade Innovation Award, the 2012 Medtrade Spring Provider's Choice Award, and the 2012 Best Practices Award for Product Differentiation in the Sleep Disordered Breathing market from Frost & Sullivan. Somnetics received FDA market clearance for the Transcend 365 CPAP machine in November 2018 and CE Mark in May 2018.

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