# VentFree™ Respiratory Muscle Stimulator receives FDA Emergency Use Authorization for Use During COVID-19 Pandemic

**Ohio manufacturer Valtronic partners to accelerate delivery to hospitals nationwide**

CRESTWOOD, KY, 6th May 2020 –Liberate Medical today announced that it has received Federal Drug Administration (FDA) Emergency Use Authorization for its VentFree™ Respiratory Muscle Stimulator, intended to be used to reduce disuse atrophy of the abdominal wall muscles, which may reduce the number of days adult patients require mechanical ventilation, including those patients with COVID-19.

Reducing the time patients spend on mechanical ventilation may reduce the risks of prolonged mechanical ventilation, which include hospital acquired infections, deteriorated quality of life and death. Fewer days on ventilation may also increase the availability of ventilators during the COVID-19 pandemic.

Liberate Medical has been working with Valtronic in Ohio to accelerate production and distribution in order to meet demand. Valtronic is a contract manufacturer who produces the boards and assembles the VentFree™.

"The responsiveness and flexibility of Valtronic is key in such extraordinary situations", said Angus J McLachlan. "They very quickly organized the supply of all necessary parts and adapted their organization to meet our needs".

"It is crucial to join efforts to face this situation", said Rainer Platz, CEO of the Valtronic Group. "At Valtronic we have the expertise and manufacturing capacity to support the ramp-ups needs for life-saving medical devices. We are ready and determined to provide all the help we can to manage this unprecedented crisis".

Two pilot randomized controlled trials, recently completed in Europe and Australia, indicated that compared with placebo stimulation, the VentFree may reduce ventilation duration and ICU length of stay. Last year VentFree™ received FDA Breakthrough Device Designation and CE marking in the European Union.

"We are grateful to the FDA for recognizing the potential of VentFree and feel privileged to have the opportunity to help patients on mechanical ventilation during the COVID-19 pandemic," said Angus McLachlan PhD, co-founder and CEO of Liberate Medical.

Invasive mechanical ventilation commonly weakens the breathing muscles, increasing the need for further ventilator support. Current methods of respiratory muscle training cannot be used

when patients are sedated or delirious, which is common among critically ill patients. The VentFree uses proprietary non-invasive neuromuscular electrical stimulation to contract the abdominal wall muscles in synchrony with exhalation during mechanical ventilation. These features enable treatment to begin from the early phase of mechanical ventilation, while patients are sedated or delirious, and continue until the patient is successfully weaned from mechanical ventilation.

**About Emergency Use Authorization of VentFree**

VentFree has neither been cleared or approved for the indication for use by health care providers to treat adult patients by reducing disuse atrophy of the abdominal wall muscles, which may reduce the number of days of ventilator support in patients who require mechanical ventilation in healthcare settings during the COVID-19 pandemic.

VentFree has been authorized for the above emergency use by FDA under an Emergency Use Authorization.

VentFree has been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**About Liberate Medical**

Liberate Medical is a clinical / commercial stage medical device company that develops neuromuscular electrical stimulation technology to improve the quality and reduce the cost of care for patients with pulmonary disorders. For more information please visit https://liberatemedical.com.

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**About Valtronic**

Valtronic is a full-service contract manufacturer dedicated to medical devices. Worldwide companies rely on our 35+ years of experience to develop, industrialize and manufacture innovative Class I, II & III medical devices, including active implants. Our expertise includes turnkey devices, microelectronic assembly and miniaturization. Headquartered in Switzerland, our company spreads over three continents with manufacturing sites in Switzerland, the United States and Morocco and employs more than 350 employees worldwide.
For more information please visit: www.valtronic.com

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