



LETTER TO PROVIDERS OF MECHANICAL VENTILATION

Draeger recognizes that the need for ventilators, ventilator accessories, and other respiratory devices may outpace the supply available to health care facilities during the Coronavirus Disease 2019 (COVID-19) outbreak.

On March 22, 2020, the FDA issued a guidance document intended to help increase availability of ventilators and their accessories as well as other respiratory devices during the COVID-19 pandemic. This guidance document can be found at: <https://www.fda.gov/medical-devices/letters-health-care-providers/ventilator-supply-mitigation-strategies-letter-health-care-providers>

This Letter provides recommendations for health care providers and facilities, based on the recently issued guidance, regarding the use of devices with patients who develop respiratory compromise from COVID-19 or other respiratory disorders. The FDA's recommendations are intended to augment, not replace, specific controls and procedures developed by health care organizations and the [Centers for Disease Control and Prevention](https://www.cdc.gov) (CDC).

Draeger continues to work with all worldwide health authorities during this crisis, and want to disseminate factual information to healthcare providers to support the patients under their care.

We have received many inquiries regarding social media postings and publications that discuss the use of one ventilator to be used on multiple patients. Any such use would be considered "off-label application". The intended use of Draeger ventilators is as a single patient item to ensure safe and reliable management of the respiratory failure patient that requires mechanical ventilation. Draeger has not tested or validated for use any scenario using one ventilator on multiple patients. Further, this concept is not one of the recommendations in the FDA guidance document and such use would seem to be contrary to the CDC's recommendations for proper isolation procedures for treatment of COVID-19 infected patients.

We recognize that there are principles of disaster medicine that identify normal business operations, crisis mode operations where the national strategic stockpile would be utilized, and catastrophic operational conditions where physicians and hospital administration may be required to take extraordinary measures to save lives when faced with limited resources. The concept of "Crisis Standard of Care" can be found at: <https://www.ncbi.nlm.nih.gov/books/NBK32749/>

Access to the national disaster stockpile is accomplished through the individual state health departments who in turn coordinate with the federal government. Training for these devices can be found at <https://www.aarc.org/resources/clinical-resources/strategic-national-stockpile-ventilator-training-program/>

In cases where hospitals are forced into catastrophic operating conditions, Draeger suggests hospitals have a prepared plan in advance which includes input from all disciplines such as medical advisors, administration, legal counsel, Respiratory Care, and ethics teams in place for such measures that is based on best clinical practices and evidence-based guidelines to guide decision making during difficult situations such as rationing mechanical ventilation equipment and supplies.

If you have any questions, please feel free to contact:

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Sincerely,

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