

Safety Communication

رسالة سلامة

Usage of Draeger Anesthesia Devices for Long-term Ventilation

Device/ Product Description:	Ventilators
Manufacturer:	Draeger
Problem:	<p>The pandemic has created a high demand for mechanical ventilation that may exceed the number of available ICU ventilators in hospitals treating patients with the disease. Draeger states that it has received requests for information regarding use of Draeger anesthesia devices for long-term ventilation as an alternative ventilator when existing devices are fully utilized and there is no other ventilator option. Against these special circumstances, Draeger believes it is their responsibility to provide some insights both (1) on the legal and regulatory perspective as well as (2) on some known limitations of Draeger anesthesia devices for long-term ventilation.</p>
Recommendation /Actions:	<p>Any use of the device outside of the intended use specified in the instructions for use (e.g. long-term ventilation) constitutes off-label use.</p> <ul style="list-style-type: none"> If a device is used off-label, the user recognizes that it is not the intended use of the device and does so in his own responsibility and at his own (liability) risk. However, in a situation in which a patient requires long-term mechanical ventilation but cannot be ventilated due to a lack of intensive care ventilators, the benefit of being able to ventilate such a patient with a Dräger anesthesia devices has to be weighed against the risk of the off-label usage of a Dräger anesthesia device. This risk benefit assessment and the resulting decision has to be made by the responsible health care professional based on the circumstances of the particular case. <p>If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>

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