

GE Healthcare Life Care Solutions Datex-Ohmeda, Inc.

March 27, 2020

Topic: COVID-19 - Requests for information regarding the off-label use of ventilating multiple patients with one ICU ventilator

Dear valued customer,

The pandemic situation related to COVID-19 is leading to significant concern around the world regarding the availability of ICU ventilators to meet potential needs. We are responding to inquiries for information regarding whether an ICU ventilator could be used to ventilate multiple patients.

On March 26, 2020, the Society of Critical Care Medicine (SCCM), American Association for Respiratory Care (AARC), American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (ASPF), American Association of Critical-Care Nurses (AACN), and American College of Chest Physicians (CHEST) (Joint Society Statement) published a consensus statement (<u>https://www.asahq.org/about-asa/newsroom/news-releases/2020/03/joint-statement-on-multiple-patients-per-ventilator</u>) indicating that they: "advise clinicians that sharing mechanical ventilators should not be attempted because it cannot be done safely with current equipment."

GE Healthcare ICU ventilators are designed and intended to be used on one patient at a time. The use of one GE Healthcare ICU ventilator to simultaneously ventilate multiple patients has not been tested for safety and performance. This use is off label and has not been cleared or approved by any regulatory body. We understand the extreme circumstances driving this request, but based on this and the Joint Society Statement referenced above, GE Healthcare does not support the use of ventilators on multiple patients. Regardless of whether FDA issues an Emergency Use Authorization for a manufacturer of an accessory that enables this capability, clinician discretion should be used for implementing this capability.

GE Healthcare is doing everything we can to address the ventilator shortage. Please reach out to your local GE Healthcare representative if we can help in any other way.

Sincerely,

Matti E. Lehtonen General Manager, Anesthesia and Respiratory Care GE Healthcare