Safety Communication رسالة سلامة

COVID-19 - Requests for information regarding the off-label use of GE Healthcare anesthesia devices for ICU ventilation

Device/ Product Description:	Anesthesia devices
Manufacturer:	GE Healthcare
Problem:	Responding to numerous requests for information regarding whether existing anesthesia devices could temporarily be used to supplement ventilator capacity. However, the use of these devices as ICU ventilators has not been verified or validated. And regulatory authorities (e.g., FDA, Health Canada, TGA, EU competent authorities) have not cleared or approved these anesthesia devices as safe and effective for use as ICU ventilators. GE states that the use of an anesthesia machine as an ICU ventilator is considered off-label use (not formally cleared or approved by any regulators), and GE does not promote or recommend the use of anesthesia devices as ICU ventilators in any normal circumstances. GE states that it understands the extreme circumstances driving this request and the need to weigh the relative risks and benefits to support patients during the pandemic. While an anesthesia device has a ventilator within it, the overall device is not the same as an ICU ventilator, and it is critical to understand the differences to minimize risks to patients.
Recommendation /Actions:	• Use of the device in an off-label manner is the sole responsibility of the device owner and is done at his/her own (liability) risk. • GE Healthcare anesthesia machines are life supporting/life sustaining devices. There is a risk of serious injury or death if the devices are not used by properly trained clinicians, continuously monitored, and used in accordance with the instructions for use. • For more information, Please check the letter for GE's full analysis here.

	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	
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