Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Ventilating ICU patients using Flow-i, Flow-c and Flow-e anesthesia machines

Device/ Product Description:	Anesthesia machines
Manufacturer:	Getinge
Problem:	In view of the situation with the coronavirus, Novel Coronavirus (2019-nCoV), and the possibility to repurpose Flow-i, Flow-c and Flow-e anesthesia machines for use in the ICU as a ventilator only, the manufacturer would like to draw your attention to important information in the following three sections: 1. General information and warnings 2. Preparations for use 3. Key system differences (between Flow anesthesia machines and ICU ventilators) • Rebreathing • Manual and automatic ventilation (MAN/AUTO) and APL • O2 flush • Sampling line and watertrap • AGSS (Anesthesia Gas Scavenging System) • Emergency ventilation • Alarms and monitoring • System checkout
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. • 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. • Check the letter from the manufacturer for more information here. MAQUET Inc.pdf.pdf

	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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