Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

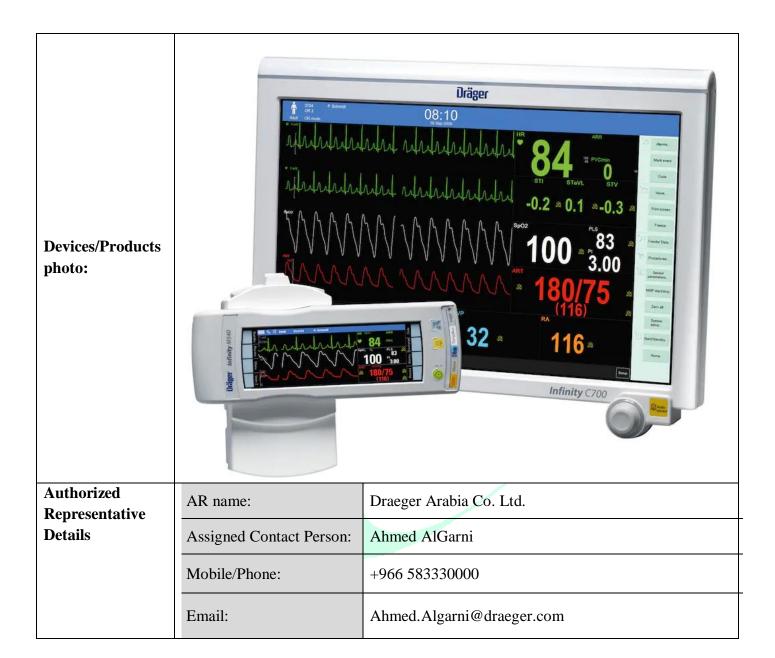| **Safety Communication**	رسالة سلامة

Software issues for the Infinity Acute Care System (IACS) and Standalone Infinity M540 patient monitor

Device/ Product Description:	• The Infinity Acute Care System (IACS). • Standalone Infinity M540 patient monitor.
Affected product:	Software version VG7.1
Manufacturer:	Draeger Medical Systems
Problem:	1- The Infinity M540 patient monitor may randomly reboot due to an error to correctly transmit and read the header data of files in the memory of the device. 2- The IACS Cockpit may lose the ability to send commands to the M540 patient monitor. 3- The IACS patient monitor may exhibit a loss of configuration of the patient and system profile due to disconnection from the internal database after power up of the Cockpit.
Recommendation /Actions:	Drager will provide the affected customers with an updated software version VG 7.1.1 to resolve these product issues. For more information, please check " NCMDR " If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center

Devices/Products photo:		
Authorized Representative Details	AR name:	Draeger Arabia Co. Ltd.
	Assigned Contact Person:	Ahmed AlGarni
	Mobile/Phone:	+966 583330000
	Email:	Ahmed.Algarni@draeger.com