Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية الادارة التنفيذية للرقابة والقياسات الحيوية

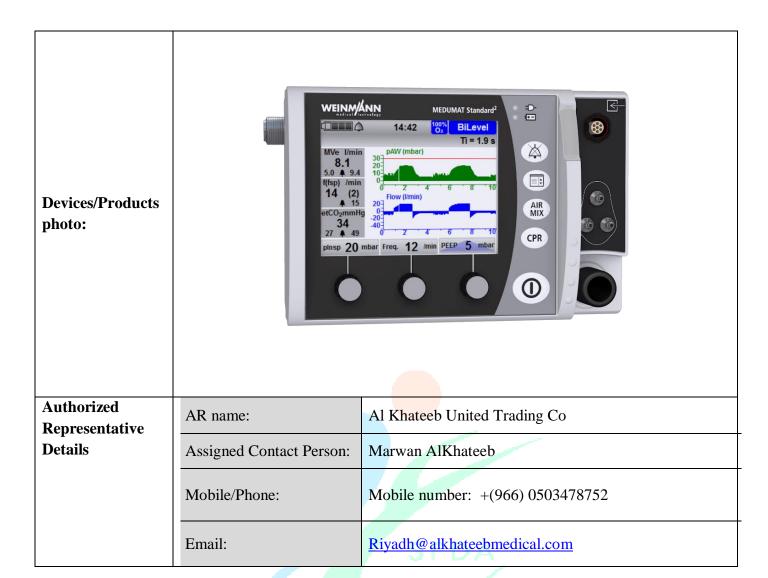
Safety Communication

رسالة سلامة

Medumat Standard² Cannot be Switched-On in Battery Mode

Device/ Product Description:	MEDUMAT Standard ² emergency and transport ventilator
Affected product:	All device serial numbers since product launch are affected.
Manufacturer:	WEINMANN Emergency Medical Technology GmbH + Co. KG.
Problem:	In very rare cases it might happen that MEDUMAT Standard ² cannot be switched on in battery mode (with no mains power supply connected). This means that, after the power button is pressed, the screen will remain dark and the device will not start. This can lead to a delay to therapy.
Recommendation /Actions:	 Update MEDUMAT Standard² to the new software version 4.15. Add the supplied insert to the instructions for use. Observe the safety information and the information relating to the modified function check on the insert. For more information, please check the "FSCA" 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

SG-2008-261-H 31/08/2020



SG-2008-261-H 31/08/2020