

Kingdom of Saudi Arabia عند المملكة الصربية السعودية عند المحادث المملكة الصامة للضفاء والدواء المعلقة المامة المعلقة المعلقة العامة المعلقة العامة المعلقة العامة العامة

Medical Device Sector Surveillance & Biometrics Executive Department قطاع الأجهزة والمنتجات الطبية الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication

رسالة سلامة

Device failure may lead to alarm malfunction

Device/ Product Description:	Stellar 100 and 150 Portable Ventilators		
Affected product:	Product Numbers 24156, 24164, 24147, 24162. Serial number range 20160123307 to 22171057208 Manufacturing date between April 2016 and June 2017		
Manufacturer:	ResMed Limited.		
Problem:	The alarm buzzer is not working properly due to a combination of software and a component failure. If the device is used on a ventilator dependent patient, an alarm or failure condition may present a risk of injury or even death.		
Recommendation /Actions:	1- Review this notice and ensure that all affected personnel within your organization are aware of the contents. 2- Make sure to follow the instructions for use provided in the user's guide 3- Contact the Authorized Representative for required corrective action. 4- For more information, click Here. 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		

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Devices/Products photo:	Transco	
Authorized Representative	AR name:	Bio Standards
Details	Assigned Contact Person:	Ahmed Al Shareef
	Mobile/Phone:	0545459900
	Email:	info@bio-standards.com

SFDA

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