

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:	<p>The alarm buzzer is not working properly due to a combination of software and a component failure.</p> <p>If the device is used on a ventilator dependent patient, an alarm or failure condition may present a risk of injury or even death.</p>	
Recommendation /Actions:	<ol style="list-style-type: none"> 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. <p>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</p>	

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

