


## Safety Communication

## رسالة سلامة

### Power Board Failures due to Component Electrical Overstress

<b>Device/ Product Description:</b>	Neonatal and pediatric ventilator		
<b>Affected product:</b>	<b>Device</b>	<b>Ref. No.</b>	<b>Affected Serial Numbers</b>  See the attached (FSCA) below
	Fabian Therapy evolution	121001 121012	
	Fabian +nCPAP evolution	7050.IB 122001 7250.IB/122011 122012	
	Fabian HFO	111001 111001.01 112001 113001	
<b>Manufacturer:</b>	ACUTRONIC Medical Systems AG		
<b>Problem:</b>	<p>The power board can fail due to electrical overstress resulting from a short-circuit caused by insufficient soldering of one of the components on the board. The electrical overstress may produce a spark, a popping sound or a burnt smell. As a result, the ventilator can fail to start up prior to use, or shut down during patient use, in which case the ventilation to the patient will cease without an alarm to notify the clinical staff due to the power down condition. This could potentially lead to patient death or serious injury such as hypoxia, hypercapnia, respiratory and/or cardiac arrest.</p>		
<b>Recommendation /Actions:</b>	<ul style="list-style-type: none"> <li>• Make sure that this document is reached to the end-users.</li> <li>• Ensure that all devices affected are identified.</li> <li>• Follow the instructions as indicated in the attached Field Safety Corrective Action.</li> <li>• Contact the authorized representative for required corrective action.</li> </ul>		

	<p>For more information please click <a href="#">here</a>.</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:  <a href="#">NCMDR</a>  <a href="#">Vigilance system</a>            (19999 )unified call center</p>	
<p><b>Devices/Products photo:</b></p>		
<p><b>Authorized Representative Details</b></p>	<p>AR name:</p>	<p>Bio Standards</p>
	<p>Assigned Contact Person:</p>	<p>Eng. Wafaa Mohammad</p>
	<p>Mobile/Phone:</p>	<p>+966 505 301 778</p>
	<p>Email:</p>	<p><a href="mailto:info@bio-standards.com">info@bio-standards.com</a>  <a href="mailto:wmohammad@bio-standards.com">wmohammad@bio-standards.com</a></p>