المملكة العربية السعودية
الهيئة العامة للغذاء والدواء

Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

**Safety Communication** رسالة سلامة

# Software Malfunction associated with Over-delivery of peak-inspiratory pressure

<table>
<tr><td>Device/ Product Description:</td><td colspan="3">Neonatal and pediatric ventilator</td></tr>
<tr><td rowspan="3">Affected product:</td><td>Device</td><td>REF. No.</td><td>Software Version(s)</td></tr>
<tr><td>Fabian HFO</td><td>111001<br>111001.01<br>112001<br>113001</td><td rowspan="2">5.0x (with VG function)<br>5.1.x (with VG function)</td></tr>
<tr><td>Fabian +nCPAP evolution</td><td>122001</td></tr>
<tr><td>Manufacturer:</td><td colspan="3">Acutronic Medical Systems AG</td></tr>
<tr><td>Problem:</td><td colspan="3">Specific Software versions can experience a malfunction associated with over-delivery of peak-inspiratory pressure with delayed or absent alarm during use of the Volume Guarantee (VG) function. This malfunction is associated with the breath-to-breath algorithm and causes a temporary elevation of peak-inspiratory pressure (PIP) above the set Pmax for no longer than 80ms that potentially leads to an increased risk of lung injury, hypoxia, barotrauma, and changes to intrathoracic pressure.</td></tr>
<tr><td>Recommendation /Actions:</td><td colspan="3">1. Review this notice and ensure that all affected personnel within your organization are aware of the contents.<br>2. All users of the fabian HFO and fabian +nCPAP evolution ventilators shall read and take into consideration the immediate mitigative actions below:<br><br>Discontinue use of, and/ or do not activate and use the optional Volume Guarantee function with the affected fabian HFO and +nCPAP evolution devices, until the Software update addressing the Volume Guarantee malfunction is installed.<br><br>This malfunction does not affect the general use of the ventilators and only impacts the use of the Volume Guarantee function. Other functions of</td></tr>
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| | *the ventilators are not affected. The ventilators may continue to be used for all ventilation modes of therapy, without using the Volume Guarantee function.*<br>*For infants with severe lung disease, alternative forms of lung protective ventilation may be considered.*<br><br>*The ongoing "Corrective action" related to the software version 5.1.0 is a mandatory software update to correct identified issues affecting previous software versions. Any devices that have not yet been updated to software version 5.1.0 must still be updated with the "Corrective Action" software. However, the VG function on these updated devices must not be used.*<br><br>3. Contact the Authorized Representative for required assistance.<br><br>For more information, please check the "FSCA"<br><br>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through:<br>NCMDR<br>Vigilance system<br>19999 unified call center |

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| **Devices/Products photo:** |  | |
| **Authorized Representative Details** | AR name: | Bio Standards |
| | Assigned Contact Person: | Ahmed Al Shareef |
| | Mobile/Phone: | 0502923399 |
| | Email: | info@bio-standards.com |