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قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector
National Center for Medical Devices Reporting

رسالة سلامة
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية
Title	Fabian™ HFO, Software V5.2.2 with potential false “Patient disconnect” alarm	العنوان
Medical Device Description	fabian HFO, fabian +nCPAP evolution, fabian Therapy evolution, fabian HFOi	اسم ووصف الجهاز/المستلزم الطبي
Manufacturer	Acutronic Medical Systems	اسم المصنع
Authorized Representative	Bio Standards	الممثل المعتمد
Medical Devices Marketing Authorization (MDMA)	MDMA-1-2018-2086	إذن التسويق
Potential /Associated risks	The potential health risk for a false disconnect alarm occurring that cannot be resolved is inadequate ventilation due to the oscillation being out of range, resulting in hypoxia, hypercapnia, hypoventilation and / or respiratory arrest.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul style="list-style-type: none"> For fabian™ HFO ventilator models 112001 and 113001 that have not yet been updated to SW V5.2.2, Acutronic advises users to install SW V5.2.1. Further, users are advised not to install SW V5.2.2 on these ventilator models. For fabian™ HFO ventilator models 112001 and 113001 that have already been updated to SW V5.2.2, Acutronic advises users to reinstall SW V5.2.1 to avoid the potential for a false disconnect alarm when the ventilator is used in the HFOV mode on patients with the occurrence of a high leak and the associated potential health risk. Acutronic will make available SW V5.2.1 for fabian™ HFO along with the fabian™ HFO SW V5.2.1 Instructions for Use (IFU) with Addendum. Reinstallation of SW V5.2.1 for the fabian™ HFO ventilator models 112001 and 113001 will remove some of the corrections implemented in SW V5.2.2. Table 3 provides an overview of the corrections that are present in SW V5.2.2 and will not be available with reinstallation of SW V5.2.1. 	التوصيات
For Reporting	  	للإبلاغ