


Safety Communication

رسالة سلامة

Multiple Issues related to Software Anomalies

Device/ Product Description:	Neonatal and pediatric ventilator	
Manufacturer:	Acutronic Medical Systems AG	
Affected devices:	Device Name	Reference Number
	fabian HFO	113001 ; 112001 ; 111001 ; 111001.01
	fabian +nCPAP evolution	122001 ; 122012
	fabian Therapy evolution	121001 ; 121012
Problem:	<p>Multiple issues representing software anomalies that might result in harms to the patients:</p> <ul style="list-style-type: none"> Issue 1: Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode – fabian HFO Issue 2: HFO-specific External Bias Flow setting menu incorrectly visible in all conventional (non-HFO) ventilation modes – fabian HFO Issue 3: No alarm on ETT disconnection – fabian HFO Issue 4: Global Alarms Off function becomes enabled during ventilation – fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO Issue 5: Graphical User Interface (GUI) freeze / Application error and potential shut down – fabian HFO Issue 6: Pressure delivery below specification with Infant Flow LP circuits – Fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO 	
Recommendation /Actions:	<ul style="list-style-type: none"> Make sure that this document is reached to the end-users. Go through the links here to find out all the details and instructions. Contact the authorized representative for the required support. 	

	<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>Image:</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>0502923399</p>
	<p>Email:</p>	<p>info@bio-standards.com</p>