


Safety Communication

رسالة سلامة

Occasional restart of the devices

Device/ Product Description:	Ventilator
Affected product:	Evita V500 Babylog VN500 Evita V300 (With SW2.60 and lower with installed CO2 measurement option.)
Manufacturer:	Draeger Medical Systems Inc
Problem:	Technical error has occurred in connection with the ventilators due to an error in the software. It was reported that the ventilation unit restarted which resulted in an interruption of ventilation and loss of PEEP for approx. 8 seconds. This could possibly result in a deterioration of the patient's condition.
Recommendation /Actions:	<ul style="list-style-type: none"> • Make sure that this document is reached to the end-users. • Ensure that all devices affected are identified. • The behavior mentioned above can be effectively prevented by not activating the integrated CO2 measurement. If necessary, external CO2 monitoring can be used. • Contact the authorized representative for required support. <p>For more information, please click here.</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: NCMDR Vigilance system (19999)unified call center</p>

<p>Image:</p>		
<p>Authorized Representative Details</p>	<p>AR name:</p>	<p>Draeger Arabia Co. Ltd.</p>
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