

Safety Communication

رسالة سلامة

Intermittent failures in the field during ventilation

Device/ Product Description:	Ventilators			
Brand:	Bellavista			
Affected product:	Commercial Name	Catalogue number	Hardware Generation	Serial Number (SN) Prefix
	bellavista 1000 ventillator	301.100.000	G2/3/4/5/6	MB 1000100 and higher
	bellavista 1000 US ventillator	301.100.030		
	bellavista 1000 NEO ventillator	301.100.060		
	bellavista 1000e 17.3" ventillator	301.100.100		
	bellavista 1000 set ventillator	301.100.200		
	bellavista 950 ventillator	950.100.000		
Manufacturer:	Vyair Medical, Inc – Imtmedical ag			
Problem:	<p>The mentioned devices can experience the following intermittent failures in the field during ventilation:</p> <ul style="list-style-type: none"> • Lack of acoustic high priority alarm (continuous alarm tone) under specific conditions, which may cause a delay in immediate action, required to avert a life-threatening situation. • Presence of a no alarm condition during a disconnect under specific use conditions which may cause a system leakage and potential for Louis and ventilation therapy without activation of a disconnection alarm. • Presence of a failsafe state under specific use conditions, which may cause a device ventilator response by suspending ventilation to the patient. 			
Recommendation /Actions:	<ul style="list-style-type: none"> • Review this notice and ensure that affected personnel are aware of the contents. 			

- all users of the mentioned devices shall read and take into consideration the immediate mitigated measures provided in attachment A in the attached file below.
- inspect the inventory to identify the affected devices of the above mentioned serial number range
- Contact the authorized representative for required correction.

For more information, Please click [here](#).

If you think you had a problem with your device or a device your patient uses, please do not hesitate to report the problem to SFDA through:

[NCMDR](#)
[Vigilance system](#)

19999 unified call center

Devices/Products photo:



Authorized Representative Details

AR name:	Bio Standards
Assigned Contact Person:	Yaser AlYami
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