URGENT FIELD SAFETY NOTICE
fabian HFO and fabian +nCPAP evolution Volume Guarantee function for Field Safety Corrective Action FSCA-20-001

5 October 2020 FSN Ref: FSCA-20-001-FSN

Attention: Users of the fabian HFO and fabian +nCPAP evolution ventilators

Dear Customer,

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by Acutronic Medical Systems AG (hereafter "Acutronic"), as part of Vyaire Medical, involving the following fabian HFO and fabian +nCPAP evolution ventilators.

Details of affected devices

Affected software versions of fabian HFO and fabian +nCPAP evolution

Device	REF No.	Description	Software Version(s)
fabian HFO	111001 111001.01 112001 113001	Neonatal and pediatric ventilator	5.0.x (with VG function) 5.1.x (with VG function)
fabian +nCPAP evolution	122001	Neonatal and pediatric ventilator	

Description of the problem

Malfunction of VG function for fabian HFO and fabian +nCPAP evolution
Acutronic has received reports of patient desaturation related to the following malfunction. The fabian HFO and fabian +nCPAP evolution ventilators with the above-mentioned software (SW) 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 which potentially leads to an increased risk of lung injury, hypoxia, barotrauma, and changes to intrathoracic pressure.

Actions to be taken by the users

- Make sure that the content of the complete FSCA package, including this *FSN,* is forwarded immediately to any potential user of the fabian HFO and fabian +nCPAP evolution ventilators using the Volume Guarantee (VG) function.
- Check receipt of FSCA package, containing this *FSN, User Work Instructions TS-AA-027e, fabian Instruction* (FI) *Card, FSCA Response Form.*
- In case affected devices are transferred to another location or organization make sure the complete FSCA package is forwarded to the respective users accordingly.
- Make sure that all devices affected are identified according to the *User Work Instruction (TS-AA-027e.)*
- For identified devices, print out the *fabian Instruction* (FI) *Card,* make sure that it is available to all potential users, keep it together with the Instructions for Use (IfU) and retain it until further notice.
- All users of the fabian HFO and fabian +nCPAP evolution ventilators shall read and take into consideration the immediate mitigative actions below:

> **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.**
>
> This malfunction does **not** affect the general use of the ventilators and only impacts the use of the Volume Guarantee function. Other functions of the ventilators are not affected. The ventilators may continue to be used for all ventilation modes of therapy, without using the Volume Guarantee function.
>
> For infants with severe lung disease, alternative forms of lung protective ventilation may be considered.
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> The ongoing FSCA-18-004 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 FSCA-18-004 software. However, the VG function on these updated devices must not be used.

- Fully complete and return the signed *FSCA Response Form* to Acutronic directly as per the instructions on the form.

Contact Information

For questions, concerns or any events that reasonably suggest being related to the subject of this FSCA OR to related Forms, please email **GMB-AMS-FSCAresponsecentre@vyaire.com**

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agencies.

Sincerely,

Abir Roy
QA Manager, Post Market Surveillance / FSCA Coordinator
Fabrik im Schiffli
CH-8816 Hirzel
Switzerland
Phone: +41 447297098
Email: abir.roy@vyaire.com