7th of December 2018

Urgent Field Safety Notice – FSCA 18-004

Attention: Distributors and end-users of fabian Therapy evolution, fabian +nCPAP evolution and fabian HFO ventilators (herein after fabian product family).

Details on affected products:

Name	Serial number (SN) prefix
fabian HFO	AH / AK / AI / AL / 20
fabian +nCPAP evolution	AN
fabian Therapy evolution	AT

Dear Valued Customer:

The purpose of this letter is to advise users that Acutronic Medical Systems AG is issuing a Field Safety Corrective Action (FSCA) for its fabian product family.

Acutronic Medical Systems takes seriously all product complaints and consistent with its quality management system and processes, reviews all customer complaints, internal stress tests and service record trends and initiates investigations as warranted. Issues with fabian ventilators were identified through those investigations as well as post-market surveillance data.

Description of the problem:

Detailed information on the discovered issues can be found in the current document. Restrictions of use and additional warnings for end-users can be found in fabian Instructions Card (FI Card).

The FI Card together with an Ethernet port blocker will be dispatched to all the distributors and end-users of affected products. The concerned issues require additional attention by all users to ensure patient safety when using fabian ventilator devices. The FI Card and the Ethernet port blocker is an immediate and temporary mitigation to avoid possible risk of harm to the patient during use of the fabian product family and will be replaced by final corrective actions announced to our users as per separate communication.

If clinicians follow established monitoring guidelines, operate fabian products in accordance with the Instructions for Use and carefully observe the additional instructions outlined in the attached FI Card, the likelihood that a patient could suffer an injury from any of these rare failure modes is exceedingly small. Since the benefit to patients of continued availability of fabian products far outweighs the small risk of injury from these temporary operational issues, Acutronic supports continued clinical use of these products while remedies are deployed.

Actions to be taken by the end-users:

- All users are required to read and take into considerations the constraints listed the content of this FSN and FI Card.
- Disconnect immediately the device from any Ethernet connection. Install the port blocker within the Ethernet port (RJ45 port).
- Place the FI Card close to/attached to the affected fabian devices upon receipt
- Keep the FI Card visible until final corrective actions are implemented
- Make sure that the content of this FSN is forwarded to any potential user of the fabian ventilators.
- It is essential to maintain using fabian ventilators according to the communicated additional instructions (in supplement to the prevailing IFU).

Actions being taken by the manufacturer:

- Acutronic has determined the root cause of these design failures and will be providing a software (SW) update.
- Acutronic expects the SW update to be available in the first quarter 2019.
- Acutronic will send the FSCA package which will include: FSN letter in English and in national language, FI Card, Response Form for distributors, Response Form for end-users and RJ45 port blocker to all affected distributors.
- Acutronic will update the Instructions for Use (IFU) for affected devices and will distribute to all business partner/distributors together with the SW update.
- Acutronic will collect and follow up on all response forms and the execution and completion of this corrective action.

Actions to be taken by the distributors:

- Notify immediately all affected end-users.
- Return of the completed and signed Distributors Response Forms to Acutronic Medical Systems as per the provided instructions.
- Should any of the user facilities have distributed any of the affected products and/or parts to other persons or facilities, promptly forward a copy of this FSN, and End-users Response Form to those recipients and include contact information of those parties in the Distributors Response Form to Acutronic for device tracking purposes and further support.
- Execute the software update, once informed of its availability, in a timely manner and return all execution records to the manufacturer.

Identified issues and their potential harm:

Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Risk of harm to patient if FI Card is not followed
A Graphical User Interface (GUI) freeze/crash could occur when the device is connected to an Ethernet network. It could also cause loss of ventilation with alarming during patient use.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia
In case of an error in our device's alarm system, there may be no or no sufficient notification to the user of an alarming condition.	Affected	Affected	Affected	severe hypoxemia / hypercapnia, possible death
While using volume guarantee option, a disconnection of the patient circuit may not generate a patient disconnect alarm.	Affected	Affected	Not affected	severe hypoxemia / hypercapnia, possible death
When saving, loading or manipulating trends a system failure or application error could occur causing loss of ventilation with alarming.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia
Switching between languages could result in a GUI freeze/crash causing loss of ventilation with alarming.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia
In SIMV breath delivery while using volume limit mode, the ventilator may deliver incorrect ventilation skipping expected mandatory breaths.	Affected	Affected	Not affected	transient, moderate hypoxemia / hypercapnia
Pressure might not be immediately released when high peak inspiratory pressure (PIP) alarm is triggered (when high PIP alarms are set less than 12 mbar above the set PIP) as pressure release is not tied to it. Pressure relief occurs 12 mbar above the set PIP and pressure is released till ZEEP.	Affected	Affected	Affected	moderate hypotension, barotrauma
User bypass of the flow sensor and O_2 sensor calibration could result in incorrect ventilation.	Affected	Affected	Affected	transient, moderate hypoxemia / hypercapnia.
In dual limb CPAP ventilation, the ventilator may deliver a lower number of burst breaths than what is set.	Affected	Affected	Not affected	transient, moderate hypoxemia / hypercapnia.

For all events that reasonably suggest being related to the subject of this FSN please report to Acutronic without delay including all available information that is relevant and could be important for further investigation of those cases.

Should you need further information or support on this matter please contact Acutronic immediately by e-mail to **GMB-AMS-FSCAresponsecentre@vyaire.com** or by telephone at: **+41 44 729 70 99** or your local distributor and your cause will be paid further attention by the appropriate parties.

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

Signature
Richard Brown
VP, RA Vyaire Medical