

**URGENT FIELD SAFETY NOTICE**  
**fabian™ HFO Classic and fabian™ HFOi Ventilators**  
**SW V5.2.2 with Potential False “Patient Disconnect” Alarm**  
**for Field Safety Corrective Action FSCA-24-003**

2024-04-12

FSN Ref: FSCA-24-003-FSN-1

**Attention:** Distributors and end-users of the fabian™ HFO Classic and fabian™ HFOi 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”), a subsidiary of Vyair Medical, Inc., relating to the fabian™ HFO Classic and fabian™ HFOi ventilators listed below.

**Affected Devices**

The fabian™ HFO is intended for premature infants, new-borns as well as children weighing up to 30 kg. The fabian™ HFO is intended for “in-patient use” in hospitals, medically used rooms, and intra-hospital patient transport. The ventilators are respiratory assist devices intended to provide life sustaining ventilatory support to neonatal and pediatric patients experiencing respiratory failure.

**Table 1: Device Information**

Device / Model	Model Reference Number	UDI
fabian™ HFO Classic	112001	17640140860203
fabian™ HFOi	113001	17640140860043

Affected devices includes all fabian™ HFO Classic and fabian™ HFOi ventilators with Software Version (SW V) 5.2.2. installed.

**Table 2: Affected Fabian™ HFO Ventilators**

Device / Model	Model Reference Number	Description	Affected Serial Numbers (SN) / Software Version(s)
fabian™ HFO Classic	112001	Neonatal and pediatric ventilator	All SN updated to SW V5.2.2
fabian™ HFOi	113001	Neonatal and pediatric ventilator	All SN updated to SW V5.2.2

**Note:** The fabian™ +nCPAP evolution (122001), fabian™ Therapy evolution (121001), and fabian™ HFO Light ventilators (Models 111001 and 111001.01), are **NOT** affected.

## Description of the Issue

### Issue:

As part of FSCA-21-003, SW V5.2.2 changed the criteria for detecting a patient circuit disconnect during HFO ventilation with the intent to reduce the potential for patient safety-related risks.

While ventilating a patient in HFO mode with pressure amplitude (Pamp) > 1.5x mean pressure (Pmean) and with the breathing circuit properly connected, if the breath-by-breath leak monitor exceeds 40%, the ventilator triggers the disconnect alarm. When this condition occurs, the displayed volume and leak monitors reset to zero and the ventilator reduces the HFOV amplitude. This is a protection mechanism to prevent lung injury upon reconnection following a true disconnection. During this time, if the patient is not disconnected this results in a small increase in Pmean, and potentially large reduction in amplitude until the alarm is cleared.

### Potential Health Risk:

The potential health risk for a false disconnect alarm occurring that cannot be resolved is inadequate ventilation due to the oscillation being out of range, resulting in hypoxia, hypercapnia, hypoventilation and / or respiratory arrest.

## Mitigative Actions & Advice to End-Users

For fabian™ HFO ventilator models 112001 and 113001 that have not yet been updated to SW V5.2.2, Acutronic advises that the update not be performed.

For fabian™ HFO ventilator models 112001 and 113001 that have already been updated to SW V5.2.2, Acutronic advises users to reinstall SW V5.2.1 to avoid the potential for a false disconnect alarm when the ventilator is used in the HFOV mode on patients with the occurrence of a high leak. The benefit from reinstalling SW V5.2.1 for the fabian™ HFO ventilator models 112001 and 113001 outweighs the risks associated with the high occurrence of false disconnect alarms on ventilators running SW V5.2.2. Acutronic will make available SW V5.2.1 for fabian™ HFO along with the fabian™ HFO SW V5.2.1 Instructions for Use (IFU) with Addendum.

Reinstallation of SW V5.2.1 for the fabian™ HFO ventilator models 112001 and 113001 will revert the corrections implemented in SW V5.2.2. Table 3 provides an overview of the issues present in SW V5.2.1.

**Table 3: Issues Present in SW V5.2.1 for fabian™ HFO ventilator models 112001 and 113001**

Issue No.	Issue / Topic	SW V5.2.1	Affected Device / Model
1	Incorrect display of Bias Flow selection buttons	<p>Bias Flow selection buttons removed from the user interface in conventional ventilation (non-HFO) modes.</p> <p><b>Note:</b> Pop-up windows, introduced in SW V5.2.2, to provide additional information (e.g., about Bias Flow impact) to the user when switching from conventional ventilation to HFO ventilation or when switching from HFO ventilation to conventional ventilation will not be available.</p>	113001
2	Absence of alarm on endotracheal tube (ETT) disconnection	Update to the fabian™ HFO IFU, including new Warning.	112001 113001
3	Graphical User Interface (GUI) freeze	<p>Majority of root causes for GUI freeze resolved in SW V5.2.1.</p> <p><b>Note:</b> Correction, introduced in SW V5.2.2, to remedy GUI freeze related to trend data management design error will not be available.</p>	112001 113001
4	Pressure delivery is below specification with Infant Flow™ LP circuits	<p>Not addressed by SW V5.2.1.</p> <p><b>Note:</b> Correction, introduced in SW V5.2.2, to remedy the issue of pressure delivery below specification with Infant Flow™ LP generator circuits will not be available.</p>	112001 113001
N/A	Removal of support for Inspire™ and Medijet® nCPAP generators.	<p>Removal of support for Inspire™ and Medijet® nCPAP generators will be reverted.</p> <p>See the following section.</p>	112001 113001

**Upon reinstallation of SW V5.2.1 end-users must take the following steps to avoid possible patient harm if using Medijet® and Inspire™ nCPAP generators with their ventilator:**

All end-users should always exercise use of standard mitigative actions as referenced in the fabian™ SW V5.2.1 IFU.

**Standard of care: Always keep alternative means of ventilation, such as manual resuscitation devices or another appropriate ventilator immediately available as a back-up means of ventilation in case of ventilator failure.**



**WARNING** (from the *Instructions for Use*): in case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death.

The ventilator must only be used as part of a continuous patient monitoring system. In the event of a ventilator failure where ventilation to the patient ceases, clinical detection of changes in patient condition would be indicated, including audible and visual alarms, as part of the continuous monitoring of patient values (SpO<sub>2</sub>, etCO<sub>2</sub>, Respiration Rate and hemodynamics).



**WARNING** (from the *Instructions for Use*): Only use this ventilator in combination with an external monitoring device (*for example*: SpO<sub>2</sub>).

**To avoid possible patient injury from hypoxia or hypoventilation related to potential software anomalies listed above:**

- Make sure that all alarms are adapted to the patient situation.
- If available, consider the use of an alternative mechanical ventilator system, especially in circumstances where a short interruption in mechanical ventilation or a loss of positive pressure could pose an inordinate risk of hypoxemia.
- For every patient, assure that an alternate means of providing positive pressure ventilation with supplemental oxygen is immediately available, as outlined in the IFU.
- Always utilize independent adjunctive devices that continuously monitor the adequacy of ventilation and oxygenation (e.g., pulse oximetry, capnometry) and be sure that alarms are appropriately enabled.
- Ensure that every patient being ventilated with an affected fabian™ ventilator is appropriately monitored by caregivers who are trained in ventilator assessment and management.

Please assure that all caregivers are familiar with the SW V5.2.1 IFU with Addendum and this Field Safety Notification (FSN). If clinicians operate fabian™ products in accordance with the IFU and follow established monitoring guidelines, the likelihood that a patient could suffer an injury from the described failure modes is exceedingly small. Since the benefit to patients of continued availability of fabian™ products outweighs the patient risk of injury from the potential issues, Acutronic supports continued clinical use of these products, respecting all constraints and information provided in this FSN.

**Actions to be Taken by Manufacturer**

- Acutronic has determined the root cause of the failure and will be providing a SW update. The update will occur in two stages. The first update to SW V5.2.3 will address the issues that were resolved with SW V5.2.2 and the subsequent update will address the remaining issue of false disconnect alarm.
- Acutronic expects SW V5.2.3 to be available by end of calendar year Q3 2024. Additional information regarding the availability of the subsequent revision will be communicated at release of SW V5.2.3.
- Acutronic will send the FSCA package, containing this FSN in English and in national languages, the SW V5.2.1 IFU with Addendum, the Distributor Response Form, and the End-User Response Form.
- Acutronic will make available SW V5.2.1 for fabian™ HFO ventilators via FTP.
- Acutronic will collect and follow-up on all response forms and the execution and completion of this FSCA.

**Actions to be Taken by Distributors / Authorized Technical Service Partners**

- Notify immediately all affected end-users by providing them with the FSCA package, containing this FSN in English and in national languages, the SW V5.2.1 IFU with Addendum, the Distributor Response, and End-User Response Form.
- Return of the completed and signed FSCA Distributor Response Form to Acutronic as per the provided instructions.
- Should any of the user facilities have distributed any of the affected devices to other persons or facilities, promptly forward a copy of this FSCA package to those recipients and include contact information of those parties in the FSCA Distributor Response Form for device tracking purposes and further support.
- Immediately stop upgrading to SW V5.2.2 for the fabian™ HFO Classic and HFOi devices.
- Execute the software downgrade to SW V5.2.1 for all fabian™ HFO Classic and HFOi currently on SW V5.2.2, in a timely manner and return all execution records to the manufacturer via the contact information provided below.

**Note:** The fabian™ +ncPAP evolution, fabian™ Therapy evolution, and two models of the fabian™ HFO, 111001 and 111001.01, are not affected and should be updated to and/or retained at SW V5.2.2.

**Actions to be taken by End-Users**

- Confirm receipt and thoroughly review the contents of the FSCA package, containing this FSN in English and in national languages, the SW V5.2.1 IFU with Addendum, the Distributor Response, and End-User Response Form.
- Should any of the user facilities have distributed any of the affected devices to other persons or facilities, promptly forward a copy of this FSCA package to those recipients and include contact information of those parties in the FSCA Distributor Response Form for device tracking purposes and further support.
- Immediately stop upgrading to SW V5.2.2 for the fabian™ HFO Classic and HFOi devices.
- For ventilators where SW V5.2.2 has already been installed, re-install SW V5.2.1 for all fabian™ HFO Classic and HFOi currently on SW V5.2.2, in a timely manner and return all execution records to the manufacturer.
- Fully complete and return the signed End-User Response Form to [GMB-AMS-FSCAresponsecentre@vyaire.com](mailto:GMB-AMS-FSCAresponsecentre@vyaire.com) no later than **May 12, 2024**, or within 30 days from receipt.

**Contact Information**

**For Distributors and End-Users:** For responses, feedback, 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](mailto:GMB-AMS-FSCAresponsecentre@vyaire.com).

**For Regulatory Agencies / Competent Authorities:** For all correspondence related to this FSCA, please email: [GMB-CH-AMS-Safety@vyaire.com](mailto:GMB-CH-AMS-Safety@vyaire.com).

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

Sincerely,

—  
  
Abraham Agboli  
Senior Manager, Quality Assurance  
Fabrik im Schiffli  
CH-8816 Hirzel  
Switzerland