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

2024-04-15 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 Vyaire Medical, Inc., relating to the fabian™ HFO Classic and fabian™ HFOi ventilators listed below.

Affected Devices

The fabian™ HFO is intended for premature infants, newborns 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 users to install SW V5.2.1. Further, users are advised not to install SW V5.2.2 on these ventilator models.

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 and the associated potential health risk. 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 remove some of the corrections implemented in SW V5.2.2. Table 3 provides an overview of the corrections that are present in SW V5.2.2 and will not be available with reinstallation of SW V5.2.1.

Table 3: Items not Corrected 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	SW V5.2.1 removes the Bias Flow selection buttons from the user interface in conventional ventilation (non-HFO) modes. The additional pop-up window, 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 present in SW V5.2.1.	113001
2	Absence of alarm on endotracheal tube (ETT) disconnection	The fabian™ HFO IFU for SW V5.2.1 includes a Warning to keep an alternative mode of ventilation present and to use an external monitoring device. SW V5.2.1 does not include any changes to the software for the ETT disconnection detection.	112001 113001
3	Graphical User Interface (GUI) freeze	Majority of root causes for GUI freeze resolved in SW V5.2.1. SW V5.2.1 will not include corrections to remedy GUI freeze related to trend data management.	112001 113001
4	Pressure delivery is not within specification for the Infant Flow™ LP, Inspire™, and Medijet® nCPAP generators.	Corrections introduced in SW V5.2.2, to remedy the issue of pressure delivery outside of specification will not be available in SW V5.2.1. See the following section.	112001 113001

Upon reinstallation of SW V5.2.1, end-users must take the following steps to avoid possible patient harm if the Infant Flow™ LP, Medijet®, or Inspire™ nCPAP generators are used with their fabian™ HFO ventilators (models 112001 and 113001):

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

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_2, $etCO_2$, Respiration Rate and hemodynamics).

WARNING (from the *Instructions for Use*)**:** Only use this ventilator in combination with an external monitoring device (*for example*: SpO_2).

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 with Addendum 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 except the ETT disconnect detection issue (issue 2). The subsequent update will address the ETT disconnect detection issue and associated alarm.
- Acutronic expects SW V5.2.3 to be available by end of Q3 calendar year 2024. Additional information regarding the availability of the subsequent revision to address the ETT disconnect detection issue 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 the completed and signed FSCA Distributor Response Form to Acutronic as per the provided instructions.
- Should any of the user facilities have distributed the fabian™ HFO Classic and HFOi ventilators (models 112001 and 113001) 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 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 ventilators (models 112001 and 113001).
- Install SW V5.2.1 on all fabian™ HFO Classic and HFOi ventilators, where SW V5.2.2 was previously installed, in a timely manner and return all execution records to the manufacturer via the contact information provided below.

  Note: *The fabian™ +nCPAP evolution (122001), fabian™ Therapy evolution (121001), and fabian™ HFO Light ventilators (models 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 Form, and End-User Response Form.
- Should any of the user facilities have distributed the fabian™ HFO Classic and HFOi ventilators (models 112001 and 113001) 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 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 ventilators (models 112001 and 113001).
- For ventilators where SW V5.2.2 has already been installed, reinstall SW V5.2.1 for all fabian™ HFO Classic and HFOi ventilators 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** no later than **2024-05-15**, 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.**

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

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

Sincerely,

Electronically signed by: Abraham Agboli
Reason: I approve this document
Date: Apr 15, 2024 20:24 GMT+2

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