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

2024-07-18 **FSN Ref: FSCA-24-003-FSN-2**

Attention: Distributors and end-users of the fabian™ HFO ventilators

Dear Customer,

The purpose of this communication is to inform you that software (SW) version 5.2.3 and revised Instructions for Use (IFU) are now available for the fabian™ HFO ventilators. All fabian™ HFO ventilators (model numbers 112001 and 113001) should immediately be updated to SW version 5.2.3 moving forward.

Note: fabian™ therapy evolution (121001), fabian™ +nCPAP (122001), and fabian™ HFO Light and HFO Classic Light (model numbers 111001 and 111001.01) are not affected by the reported issue.

Table 1: Overview of main contents change in SW 5.2.3 for fabian™ HFO ventilators (model numbers 112001 and 113001)

Issue #	Issue Description	Changes in SW version 5.2.3	fabian™ HFO devices	
			HFO Classic (112001)	HFOi (113001)
1	Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode	No changes. Resolved in SW version 5.2.1.	Applicable	Applicable
2	Incorrect display of Bias Flow selection buttons	Introduction of pop-up windows 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. Resolved in SW version 5.2.3.	N/A	Applicable

Issue #	Issue Description	Changes in SW version 5.2.3	fabian™ HFO devices	
			HFO Classic (112001)	HFOi (113001)
		Note: Bias Flow section buttons removed from the user interface in conventional ventilation (non-HFO) modes in SW version 5.2.1.		
3	Absence of alarm on endotracheal tube disconnection	Reset default changed to ensure that the High Leak alarm is not reset to Off. Resolved in SW version 5.2.3.	Applicable	Applicable
4	Global Alarms Off function becomes enabled during ventilation	Resolved in SW version 5.2.1.	Applicable	Applicable
5	Graphical User Interface (GUI) freeze	Final software enhancements to address remaining causes of GUI freeze. Resolved in SW version 5.2.3.	Applicable	Applicable
6	Pressure delivery is below specification with Infant Flow™ LP circuits	Correction in the software to remedy the issue of pressure delivery below specification with Infant Flow™ LP generator circuits. Resolved in SW version 5.2.3.	Applicable	Applicable

Support strategy for nCPAP generators

With the release of fabian™ HFO SW version 5.2.3 under FSCA-24-003, Acutronic / Vyaire is remedying the issue of incorrect pressure delivery of the fabian™ HFO ventilators when used with Infant Flow™ LP generators.

Acutronic / Vyaire will no longer support the use of Medijet® and Inspire™ nCPAP generators following this release of fabian™ SW version 5.2.3. Therefore, Infant Flow™ LP generators will be the only nCPAP generators supported by Acutronic / Vyaire following the release of SW version 5.2.3. Acutronic / Vyaire has included the following warning in the updated IFU for SW version 5.2.3 reflecting the revised support strategy for nCPAP generators used with fabian™ ventilators:

WARNING:

With Software v. 5.2.3 the device is only validated with Infant Flow™ LP for the delivery of nCPAP as per the approved accessories list in section 13.1. Do NOT use any other nCPAP generators than Infant Flow™ LP. The use of sets other than Infant Flow™ LP may lead to malfunctioning of the device and result in injuries and serious health consequences for the patient. The malfunctioning, such as inaccurate ventilation parameters, inaccurate indications, wrong alarms or the like, may not always be noticeable during the operation of the device. Non-approved sets should NOT be used, their use will NOT be recognized or supported by the manufacturer. If a system malfunctions with non-approved sets, the user is entirely and solely responsible and liable for any and all issues associated with the system malfunction and any consequences thereof, unless the user will prove that the use of non-approved sets did not cause the issues or that the consequences did not result from the use of non-approved items.

Always perform a leakage test before the use of the Infant Flow™ LP system and consult the Infant Flow™ LP Instructions For Use (IFU) for correct connectivity with the fabian HFO ventilator. !

SW version 5.2.3 is a mandatory software update for fabian™ HFO ventilators (model numbers 112001 and 113001) to fulfill the requirements of FSCA-24-003 and must be completed at the earliest opportunity.

Once the new software update (fabian™ Software Release Package 5.2.3) is installed, you should use the device according to the updated IFU provided by the distributor or service partner.

Note: fabian™ HFO devices, including fabian™ HFO Light and HFO Classic Light (model numbers 111001 and 111001.01), that have not yet had FSCA-18-004, FSCA-20-001, FSCA-21-002, or FSCA-21-003 implemented can be updated directly to SW version 5.2.3. Distributors should refer to the technical bulletin, Technical Bulletin TB-0060, Release of Software Version 5.2.3, for further information about the software update strategy.

Note: For fabian™ HFO Light and HFO Classic Light (model numbers 111001 and 111001.01) already upgraded to SW version 5.2.2 under FSCA-21-003, no further action is required.

Actions to be taken by Distributors / Authorized Technical Service Partners

1. Review the contents of the FSCA package comprising of this FSN and the Distributor / End-User Response Form.
2. Complete and return the signed Distributor / End-User Response Form to GMB-AMS-FSCAresponsecentre@vyaire.com within **30 days** from receipt to confirm and acknowledge understanding of the FSCA package.
3. Inform immediately the end-users of the fabian™ HFO ventilators about the fabian™ software release 5.2.3 for fabian™ HFO by sending them this FSN, the release notes, and the relevant IFU for fabian™ HFO SW version 5.2.3.
4. Download the software release package 5.2.3.
   *Note: Designated individuals within each distributor will receive an email message from Vyaire FTP with the title **Important Message – Fabian 5.2.3 – Package Download Link**, which will contain links to download the software package, IFUs, and the Technical Bulletin TB-0060, Release of Software Version 5.2.3, from Vyaire Medical Inc.'s secure FTP server. The Technical Bulletin provides information on how to download and install*

the software package.

5. Install the software upgrade according to the upgrade instructions.
6. Perform calibration and testing according to the test instructions.
7. Complete and return a fabian™ Field Safety Corrective Action - FSCA-24-003 Completion Data & Verification Record form for each device successfully upgraded to SW version 5.2.3, and return it using the following email address: **GMB-AMS-FSCAresponsecentre@vyaire.com**.

Actions to be taken by End-Users

1. Review the contents of the FSCA package comprising of this FSN and the Distributor / End-User Response Form.
2. Disseminate this FSN package within your healthcare facility to any potential users of the fabian™ HFO ventilators.
3. If devices have been further distributed, forward the FSCA package to the respective parties.
4. Complete and return the signed Distributor / End-User Response Form to **GMB-AMS-FSCAresponsecentre@vyaire.com** within **30 days** from receipt to confirm and acknowledge understanding of the FSCA package.
5. Ensure that all potential users are adequately trained according to local training protocols.
6. Contact your Acutronic / Vyaire Distribution / authorized technical service partner to coordinate SW installation.
7. Notify Vyaire of any devices that are no longer in service via the Distributor / End-user Response Form.

Contact Information

For Distributors and End-Users: 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**.

For Competent Authorities / Regulatory Agencies: 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 Competent Authorities / Regulatory Agencies.

Sincerely,

Abraham Agboli
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Switzerland