URGENT FIELD SAFETY NOTICE
fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution
Multiple Issues related to Software Anomalies
for Field Safety Corrective Action FSCA-21-003

16 March 2023 FSN Ref: FSCA-21-002_FSCA-21-003-FSN-4

Attention: Distributors and end users of the fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators.

Dear Customer**,**

The purpose of this communication is to inform you that fabian™ Software (SW) Version 5.2.2 and revised Instructions for Use (IFU) associated with FSCA-21-003, as communicated in the original Field Safety Notice (FSN) *FSCA-21-002_FSCA-21-003-FSN-1*, are now available for the fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators **in limited regions**.

In January 2023, we communicated a delay to the global deployment of Software Version 5.2.2 to July 2023 due to supply chain challenges with the Infant Flow™ LP components. One of the design changes included in this software version is correction of airway pressure inaccuracies that can occur when using variable flow generators. SW Version 5.2.2 is designed to work exclusively with the Vyaire Medical Inc.'s Infant Flow™ LP nCPAP generators. No other nCPAP generators are supported with SW Version 5.2.2. Therefore, it is critical that healthcare providers and facilities have adequate supplies of Infant Flow™ LP nCPAP generator circuits to deliver life-sustaining treatment.

As we continue to work to resolve the Infant Flow™ LP supply chain issues, we are implementing a phased deployment of Software Version 5.2.2. This phased deployment allows us to make SW Version 5.2.2 available where possible in limited regions, while simultaneously ensuring fabian™ therapy remains available to healthcare providers for treatment of patients requiring it. We continue to monitor and manage the availability and supply of Infant Flow™ LP nCPAP components, and deployments will follow as supplies become available.

Acutronic Medical Systems AG will deploy Software Version 5.2.2 according to the following schedule:

Phased Deployment - Software Version 5.2.2	**Planned Availability**
1st Phase	March 2023
2nd Phase	May 2023
3rd Phase	July 2023

Markets will be notified individually as and when the software is deployed to them.

As supplies of Infant Flow™ LP nCPAP components improve, Acutronic/Vyaire Medical Inc. will contact you regarding access to the software (see "Actions to be taken by distributors / authorized technical service partners" later in this document).

Until software version 5.2.2 is deployed to your market, all users must continue to observe all instructions and mitigations contained in previously communicated Field Safety Notices *FSCA-21-002_FSCA-21-003-FSN-1* and *FSCA-21-002_FSCA-21-003-FSN-3* to allow continued safe and effective use of fabian ventilators in the interim.

Overview of main content changes in software version 5.2.2 to address affected devices

Affected versions of fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution per issue are listed below (*FSN Issue # as referenced in the FSN *FSCA-21-002_FSCA-21-003-FSN-1*. Issues 1 and 4 were completely addressed in Software Version 5.2.1 / FSCA-21-002).

Please refer to the *End User Release Note* for full details of the software changes introduced in Software Version 5.2.2.

Overview of Main Changes in Software Version 5.2.2

Issue #*	Issue / Topic	SW 5.2.1 (FSCA-21-002)	SW 5.2.2 (FSCA-21-003)	Affected fabian™ devices		
				HFO	+nCPAP evolution	Therapy evolution
1	HFO only - Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode	Resolved in SW V5.2.1.	N/A	112001 113001	Not affected	Not affected
2	HFO only - incorrect display of Bias Flow selection buttons	Bias Flow selection buttons removed from the user interface in conventional ventilation (non-HFO) modes.	Pop-up windows introduced 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 V5.2.2.	113001	Not affected	Not affected
3	HFO only – absence of alarm on endotracheal tube (ETT) disconnection	Update to the fabian™ HFO Instructions for Use, including new Warning (Refer to *FSCA-21-002_FSCA-21-003-FSN-1).*	Enhancements in the software to improve patient disconnection detection alarm, thereby further increasing the clinician's awareness of ETT disconnect detection in HFO mode. Resolved in SW V5.2.2.	112001 113001	Not affected	Not affected
4	Global Alarms Off function becomes enabled during ventilation	Resolved in SW V5.2.1.	N/A	111001 111001.01 112001 113001	122001	121001
5	Graphical User Interface (GUI) freeze	Majority of root causes for GUI freeze resolved in	Further software enhancements to address remaining	111001 111001.01 112001 113001	122001	121001

Issue #*	Issue / Topic	SW 5.2.1 (FSCA-21-002)	SW 5.2.2 (FSCA-21-003)	Affected fabian™ devices		
				HFO	+nCPAP evolution	Therapy evolution
		SW V5.2.1.	causes of GUI freeze. Resolved in SW V5.2.2.			
6	Pressure delivery is below specification with Infant Flow™ LP circuits	Not addressed by SW V5.2.1	Correction in the software to remedy the issue of pressure delivery below specification with Infant Flow™ LP generator circuits. Resolved in SW V5.2.2.	111001 111001.01 112001 113001	122001	121001
N/A	Removal of support for Inspire™ and Medijet® nCPAP generators. Notified under FSN Update *FSCA-21-002_FSCA-21-003-FSN-3.*	N/A	**Inspire™ and Medijet® nCPAP generator circuits will no longer be supported for use with fabian™ devices.** See following section.	111001 111001.01 112001 113001	122001	121001

Support strategy for nCPAP generators

With the release of fabian™ Software Version 5.2.2 under FSCA-21-003, Acutronic / Vyaire is remedying the issue of incorrect pressure delivery of the fabian™ ventilators when used with Infant Flow™ LP generators, as described in the FSN *FSCA-21-002_FSCA-21-003-FSN-1*.

Acutronic / Vyaire will no longer support the use of Medijet® and Inspire™ nCPAP generators following this release of fabian™ Software Version 5.2.2. Therefore, Infant Flow™ LP generators will be the only nCPAP generators supported by Acutronic / Vyaire following the release of Software Version 5.2.2. Acutronic / Vyaire has included the following warning in the updated IFU for Software Version 5.2.2 reflecting the revised support strategy for nCPAP generators used with fabian™ ventilators:

WARNING
With Software v. 5.2.2 the device is only validated with Infant Flow™ LP for the delivery of nCPAP as per the approved accessories list in the section “Accessories List” in the IFU. 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 IFU for correct connectivity with the fabian™ HFO ventilator.

Software Version 5.2.2 is a mandatory software update to fulfill the requirements of FSCA-21-003 and must be completed at the earliest opportunity.

Once the new software update (fabian™ Software Release Package 5.2.2) is installed, you should use the device according to the updated IFU provided by the distributor or service partner.

Note: fabian™ devices that have not yet had FSCA-18-004, FSCA-20-001 or FSCA-21-002 implemented can be updated directly to the new Software Version 5.2.2. Distributors should refer to the technical bulletin *Technical Bulletin TB-0040 Release of Software Version 5.2.2* for further information about the software update strategy.

Next Steps

The Acutronic distribution partner / authorized technical service engineer will inform end users about the new software via an *End User Release Note* and make the necessary arrangements to install the software on the affected device(s).

Actions to be taken by distributors / authorized technical service partners

- **When SW Version 5.2.2 is available in your market**, designated individuals within each distributor will receive an email message from Vyaire FTP with the title **Important Message – Fabian 5.2.2 – Package Download Link**, which will contain links to download the software package, IFUs and the ***Technical Bulletin TB-0040 Release of Software Version 5.2.2*** from Vyaire Medical Inc.'s secure FTP server. The Technical Bulletin provides information on how to download and install the software package.
- Download the Software Release Package 5.2.2.
- Check the contents of the download. Software Release Package 5.2.2 contains the following:
  - Release Note
    - *Technical Release Note*
    - *End User Release Note*
  - PIC package for programmers
  - USB package
  - Software update description
  - Test instructions
  - *fabian™ Field Safety Corrective Action - FSCA-21-003 Completion Data & Verification Record form*
- Inform immediately the end users of the fabian™ HFO, fabian™ +nCPAP evolution™, and fabian™ Therapy evolution ventilators in scope of this FSCA about the fabian™ Software Release 5.2.2 by sending them this FSN, the *End User Release Note* and the relevant update of the IFU for Software Release 5.2.2.
- Install the software upgrade according to the upgrade instructions.
- Perform calibration and testing according to the test instructions.
- Fill out a *fabian™ Field Safety Corrective Action - FSCA-21-003 Completion Data & Verification Record form* for each device successfully upgraded to version 5.2.2, and return it using the following email address: **GMB-AMS-FSCAresponsecentre@vyaire.com**

Actions to be taken by the end users

- Make sure that across the healthcare facility, this FSN, the *End User Release Note* and the IFU for Software Release 5.2.2 are made available immediately to any potential user of the fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators in the scope of this FSCA.
- Make sure that all potential users are adequately trained according to local training protocols.
- If you have any questions regarding installation of the software, please refer to your Acutronic / Vyaire Distribution / authorized technical service partner or Acutronic / Vyaire Sales Representative, as appropriate.

Contact information

For end users and distributors: 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,

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