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

31 July 2023 FSN Ref: FSCA-21-002_FSCA-21-003-FSN-5

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 provide a status update on the phased deployment of 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*.

In March 2023, we communicated plans for a phased deployment of Software 5.2.2. Phase 1 and 2 of the software deployment were successfully completed in March 2023 and May 2023, respectively. As planned, we are initiating deployment of Software 5.2.2 to remaining markets (Phase 3) starting 31 July 2023. We will delay deployment in a limited number of markets pending availability of translations of the IFUs. These markets will be addressed in Phase 4. Individual markets will be notified as Software 5.2.2 and revised IFUs become available for release.

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 – Complete
2nd Phase	May 2023 – Complete
3rd Phase	July 2023 – Initiated for all markets except those placed in Phase 4
4th Phase	No later than December 2023

Markets in Phase 4: Croatia, Estonia, Greece, Hungary, Latvia, Lithuania, and Russia.

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 SW V5.2.1.	Further software enhancements to address remaining causes of GUI freeze. Resolved in SW V5.2.2.	111001 111001.01 112001 113001	122001	121001
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

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
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,

[redacted]
Senior Manager, Quality Assurance
Fabrik im Schiffli
CH-8816 Hirzel
Switzerland

Update to Field Safety Corrective Actions
FSCA-21-002 and FSCA-21-003
FSCA End User Response Form
fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution
Use of Medijet® and Inspire™ nCPAP generators

Affected Products (according to FSN *FSCA-21-002_FSCA-21-003-FSN-5*)

Affected fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators used in conjunction with Medijet® and Inspire™ nCPAP generators:

Device Group Name	Model Reference Number	Description	Affected Devices
fabian™ HFO	113001 112001 111001 111001.01	Neonatal and pediatric ventilator	All devices with the listed model numbers are affected. Refer to Table 1 in the Field Safety Notice (FSN) FSCA-21-002_FSCA-21-003-FSN-5 for affected devices per issue
fabian™ +nCPAP evolution	122001		
fabian™ Therapy evolution	121001		

User Declaration

Please answer all the questions by checking the appropriate boxes

1. Have you received the full FSCA package, comprising the Field Safety Notice (FSCA-21-002_FSCA-21-003-FSN-5) and the FSCA End User Response Form? If NO, please elaborate:	YES ☐	NO ☐
2. Have you read the Field Safety Notice (FSCA-21-002_FSCA-21-003-FSN-5) and understood the content and will you follow and implement the instructions accordingly? If NO, please elaborate:	YES ☐	NO ☐
3. Were all users of the fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators informed immediately about the FSCA and the FSCA package provided? If NO, please elaborate:	YES ☐	NO ☐
4. Were fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators transferred to another location/organization?	YES ☐	NO ☐
5. If devices were transferred to another location, was the complete FSCA package forwarded to the respective users accordingly? If NO, please elaborate:	YES ☐	NO ☐
List contact details of recipients:		

If you answered NO to questions 1, 2, 3 or 5 above, please contact your service partner urgently for clarification.

User Details			
Contact person (name)			
Hospital (address)			
Country			
email address			
Date		Signature	

PLEASE SEND THIS RESPONSE FORM FOR THIS MANDATORY FIELD SAFETY CORRECTIVE ACTION TO THE FOLLOWING ADDRESS:
GMB-AMS-FSCAresponsecentre@vyaire.com

Contact Information
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

[redacted]
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