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-21-002

30 November 2021 FSN Ref: FSCA-21-002_FSCA-21-003-FSN-2

Attention: Distributors and 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 a software upgrade (software version 5.2.1) and revised Instructions for Use associated with FSCA-21-002, 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.

Details of affected devices

Affected versions of fabian HFO, fabian +nCPAP evolution, and fabian Therapy evolution
(*Issue # as referenced in the FSN FSCA-21-002_FSCA-21-003-FSN-1)

Issue #*	Issue	Affected devices		
		fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution
1	Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode	112001 113001	Not affected	Not affected
2	Presence of incorrect display of external bias flow	113001	Not affected	Not affected
3	Presence of no alarm on endotracheal tube (ETT) disconnection	112001 113001	Not affected	Not affected
4	Global Alarms Off function becomes enabled during ventilation	112001, 113001	122001	121001
5	Graphical User Interface (GUI) freeze	111001 111001.01 112001 113001	122001	121001
6	Pressure delivery is below specification with Infant Flow LP circuits - fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO	111001 111001.01 112001 113001	122001	121001

NOTE: Corrections to the Field Safety Notice FSCA-21-002_FSCA-21-003-FSN-1 regarding affected devices:

- The scope (devices affected) for Issue 5 was incomplete in FSN FSCA-21-002_FSCA-21-003-FSN-1. Issue 5 affects all fabian devices (fabian HFO, +nCPAP evolution, and Therapy evolution). Refer to the following table for the corrections.

Page #	Incorrect text	Correct Text
3	Issue 5: Graphical User Interface (GUI) freeze / Application error and potential shut-down – fabian HFO	Issue 5: Graphical User Interface (GUI) freeze / Application error and potential shut-down – fabian HFO, fabian +nCPAP, and fabian Therapy evolution
7	Issue 5: Graphical User Interface (GUI) freeze when using etCO2 module – fabian HFO with etCO2 module	Issue 5: Graphical User Interface (GUI) freeze / Application error and potential shut-down – fabian HFO, fabian +nCPAP, and fabian Therapy evolution

- The devices with reference numbers 121012 and 122012 that were listed on FSN FSCA-21-002_FSCA-21-003-FSN-1 are not in the scope of this FSCA and will be addressed separately.

Once the new software update (fabian Software Release Package 5.2.1) is installed, you should use the device according to the updated Instructions for Use provided by the distributor or service partner.

Note: fabian devices that have not yet had FSCA-18-004 or FSCA-20-001 implemented can be updated directly to the new software version 5.2.1. Distributors should refer to the technical bulletin *Technical Bulletin TB-0035 Release of Software Version 5.2.1* 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

- Log into your client account on the Acutronic client website as described in the ***Technical Bulletin TB-0035 Release of Software Version 5.2.1.*** (If you do not have an account, you need to register.)
- Download the Instructions for Use for the affected device(s) from the client FSCA download area.
- Download the relevant Software Release Package 5.2.1 from the Acutronic client server as described in the technical bulletin ***Technical Bulletin TB-0035 Release of Software Version 5.2.1***. Choices are **fabian HFO**, **fabian Therapy evolution**, and **fabian +nCPAP evolution.**
- Check the contents of the download. Software Release Package 5.2.1 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-21-002 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 5.2.1 by sending them this *FSN*, the *End User Release Note* and the relevant update of the *Instructions for Use* for Software Release 5.2.1.
- 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-21-002 Completion Data & Verification Record form for each device successfully upgraded to version 5.2.1, 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 *Instructions for Use* for Software Release 5.2.1 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 questions, concerns or any event that reasonably suggests is related to the subject of this FSCA, please email **GMB-AMS-FSCAresponsecentre@vyaire.com**.

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

Sincerely,

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