
URGENT FIELD SAFETY NOTICE
fabian HFO and fabian +nCPAP evolution Volume Guarantee function
for Field Safety Corrective Action FSCA-20-001

18 February 2021

FSN Ref: FSCA-20-001-FSN-2

Attention: Distributors and users of the fabian HFO and fabian +nCPAP evolution ventilators

Dear Customer,

The purpose of this communication is to inform you that a software upgrade (software version 5.1.2) is now available to remedy the malfunction of the Volume Guarantee (VG) function on fabian HFO and fabian +nCPAP evolution ventilators as communicated in the original Urgent Field Safety Notice (FSN) FSCA-20-001-FSN dated 05 October 2020.

The software release 5.1.2 includes a new version of the Instructions for Use with updated information regarding the VG function.

Details of affected devices

Affected software versions of fabian HFO and fabian +nCPAP evolution

Device	REF No.	Description	Software Version(s)
fabian HFO	111001	Neonatal and pediatric ventilator	5.0.x (with VG function) 5.1.x (with VG function)
	111001.01		
	112001		
	113001		
fabian +nCPAP evolution	122001	Neonatal and pediatric ventilator	

Once the new software upgrade (fabian Software Release Package 5.1.2) is installed you can use the VG function thereafter as described in the updated IFU.

Note: Devices that fall outside the scope of FSCA-20-001 but have not yet had FSCA-18-004 implemented can be upgraded directly to the new software version 5.1.2. Distributors should refer to the technical bulletin *Technical Bulletin TB-0033 Release of Software Version 5.1.2* for further information about the upgrade strategy.

Next Steps

You will be contacted by your Acutronic Distribution partner / authorized technical service engineer, who will inform you about the new software via an *End User Release Note* and will make the necessary arrangements to install the software on your affected device(s).

Actions to be taken by distributors / authorized technical service partners

- **Create client account.** To download the Software Release Package 5.1.2 and the accompanying Instructions for Use, you need to create an account for access to the client FSCA download area. Even if you already have an account, you will need to re-register. Please refer to the **Technical Bulletin TB-0033 Release of Software Version 5.1.2** for further information.
- Download the Instructions for Use for the affected device(s).
- Download the relevant Software Release Package 5.1.2 from the Acutronic client website as described in the technical bulletin **Technical Bulletin TB-0033 Release of Software Version 5.1.2**. Choices are **fabian HFO**, **fabian Therapy evolution**, and **fabian +nCPAP evolution**.
- Check the contents of the download. Software Release Package 5.1.2 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-20-001 Completion Data & Verification Record form
- Inform immediately the end users of the fabian HFO and fabian +nCPAP evolution ventilators in scope of this FSCA about the fabian Software Release 5.1.2 by sending them this *FSN*, the *End User Release Note* and the relevant update of the *Instructions for Use* for Software Release 5.1.2.
- 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-20-001 Completion Data & Verification Record form for each device successfully upgraded to version 5.1.2, and return it using the following email address:

GMB-AMS-FSCAresponsecentre@vyaire.com

Actions to be taken by the end users

- Make sure that this *FSN*, the *End User Release Note* and the *Instructions for Use* for Software Release 5.1.2 is forwarded immediately to any potential user of the fabian HFO and fabian +nCPAP evolution ventilators in 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 Vyaire Distribution / authorized technical service partner or Acutronic/Vyaire Sales Representative, as appropriate.

Contact Information

For questions, concerns or any events that reasonably suggest being 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,



Abir Roy
QA Manager, Post Market Surveillance / FSCA Coordinator
Fabrik im Schiffli
CH-8816 Hirzel
Switzerland
Phone: +41 447297098
Email: abir.roy@vyaire.com