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

5 October, 2020

FSN Ref: FSCA-20-001-FSN

Attention: Users of the fabian HFO and fabian +nCPAP evolution ventilators

Dear Customer,

The purpose of this communication is to inform you of a product Field Safety Corrective Action (FSCA) initiated by Acutronic Medical Systems AG (hereafter "Acutronic"), as part of Vyair Medical, involving the following fabian HFO and fabian +nCPAP evolution ventilators.

Details of affected devices

Affected software versions of fabian HFO and fabian +nCPAP evolution

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

Description of the problem

Malfunction of VG function for fabian HFO and fabian +nCPAP evolution

Acutronic has received reports of patient desaturation related to the following malfunction. The fabian HFO and fabian +nCPAP evolution ventilators with the above-mentioned software (SW) versions can experience a malfunction associated with over-delivery of peak-inspiratory pressure with delayed or absent alarm during use of the Volume Guarantee (VG) function. This malfunction is associated with the breath-to-breath algorithm and causes a temporary elevation of peak-inspiratory pressure (PIP) above the set Pmax for no longer than 80ms which potentially leads to an increased risk of lung injury, hypoxia, barotrauma, and changes to intrathoracic pressure.

Actions to be taken by the users

- Make sure that the content of the complete FSCA package, including this *FSN*, is forwarded immediately to any potential user of the fabian HFO and fabian +nCPAP evolution ventilators using the Volume Guarantee (VG) function.
- Check receipt of FSCA package, containing this *FSN*, *User Work Instructions TS-AA-027e*, *fabian Instruction (FI) Card*, *FSCA Response Form*.
- In case affected devices are transferred to another location or organization make sure the complete FSCA package is forwarded to the respective users accordingly.
- Make sure that all devices affected are identified according to the *User Work Instruction (TS-AA-027e)*.
- For identified devices, print out the *fabian Instruction (FI) Card*, make sure that it is available to all potential users, keep it together with the Instructions for Use (IfU) and retain it until further notice.
- All users of the fabian HFO and fabian +nCPAP evolution ventilators shall read and take into consideration the immediate mitigative actions below:

Discontinue use of, and / or do not activate and use the optional Volume Guarantee function with the affected fabian HFO and +nCPAP evolution devices, until the Software update addressing the Volume Guarantee malfunction is installed.

This malfunction does **not** affect the general use of the ventilators and only impacts the use of the Volume Guarantee function. Other functions of the ventilators are not affected. The ventilators may continue to be used for all ventilation modes of therapy, without using the Volume Guarantee function.

For infants with severe lung disease, alternative forms of lung protective ventilation may be considered.

The ongoing FSCA-18-004 related to the software version 5.1.0 is a mandatory software update to correct identified issues affecting previous software versions. Any devices that have not yet been updated to software version 5.1.0 must still be updated with the FSCA-18-004 software. However, the VG function on these updated devices

- Fully complete and return the signed *FSCA Response Form* to Acutronic directly as per the instructions on the form.

Contact Information

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

The undersigned confirms that this notice has been provided 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

Field Safety Corrective Action Response Form FSCA-20-001

Details of affected parts and products:

Affected Products

Model	REF No.	Software Version(s)
fabian HFO	112001	5.0.x (with VG function) 5.1.x (with VG function)
fabian HFO Light	111001	
fabian HFOi	113001	
fabian HFOi Light	111001.01	
fabian +nCPAP evolution	122001	

Refer to the **User Work Instruction (TS-AA-027e)** and the **fabian Information (FI) Card** for further information about how to identify affected devices and instructions to follow for this FSCA.

User Declaration

Number of affected devices (total)	
FOR EACH AFFECTED DEVICE PLEASE PROVIDE (if necessary, attach extra page)	
Device Serial Number	Software Version

Please verify the following by checking the box below.

- I have received the FSCA package, including the *Field Safety Notice (FSCA-20-001-FSN)*, the *FSCA Response Form*, *User Work Instruction TS-AA-027e*, and the *fabian Instruction (FI) Card*, and understood the content and will follow and implement the instructions accordingly.
- I confirm that all users of the affected devices were and will be informed about the FSCA immediately and the FSCA package provided.
- I have identified all affected devices and have entered them on or attached them to this response form.
- I have printed out the *fabian Instruction (FI) Card* for affected devices and ensured it is or will be made available to all potential users, is kept together with the Instructions for Use, and will be retained until further notice.

- I confirm that affected devices were transferred to another location/organization and the complete FSCA package was forwarded to the respective users accordingly.
 ❖ List contact details of recipients _____

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

PLEASE SEND THIS RESPONSE FORM TO THE FOLLOWING ADDRESS:

Contact Information

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

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FI Card-20-001.DE

HFO / +nCPAP evolution - FSCA-20-001

Funktion „Volumengarantie“ (VG) nicht verwenden



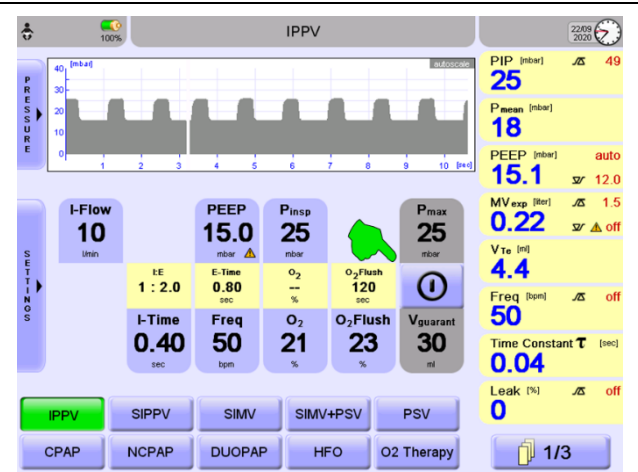
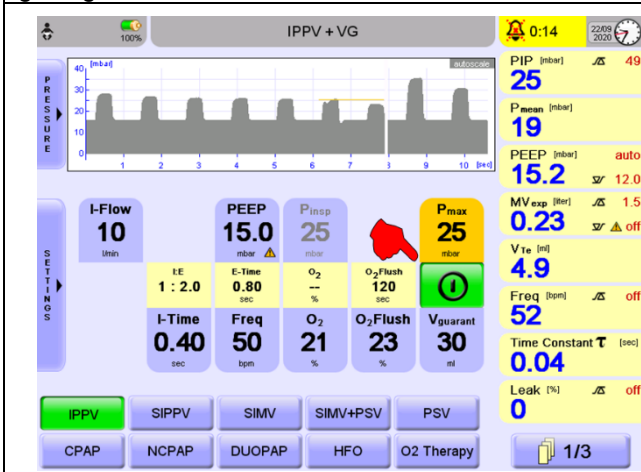
Beenden Sie die Verwendung der optionalen Funktion „Volumengarantie“ mit einem betroffenen Beatmungsgerät fabian HFO und +nCPAP evolution und/oder aktivieren und verwenden Sie diese Funktion nicht, bis das Software-Update installiert wurde, das die Fehlfunktion der Volumengarantie behebt.

Diese Fehlfunktion beeinflusst **nicht** die generelle Verwendbarkeit der Beatmungsgeräte und betrifft nur die Anwendung der Funktion „Volumengarantie“. Die anderen Funktionen der Beatmungsgeräte sind nicht beeinträchtigt. Die Beatmungsgeräte können weiterhin in allen Beatmungs-Modi genutzt werden, ohne die Funktion „Volumengarantie“ anzuwenden. Bei Säuglingen mit schwerer Lungenerkrankung sollten andere Formen der lungenschonenden Beatmung erwogen werden.

fabian HFO: Funktion „Volumengarantie“ (VG) abschalten

Wenn die in der unten stehenden Abbildung gezeigte Schaltfläche grün ist, ist die VG-Funktion aktiviert. Bitte deaktivieren Sie die Funktion, indem Sie auf die gezeigte Schaltfläche drücken.

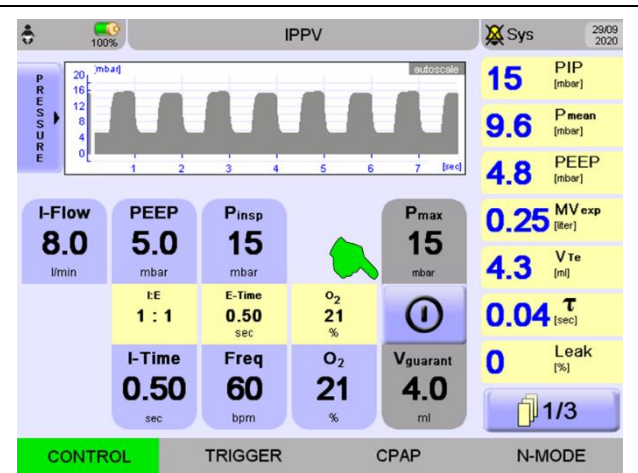
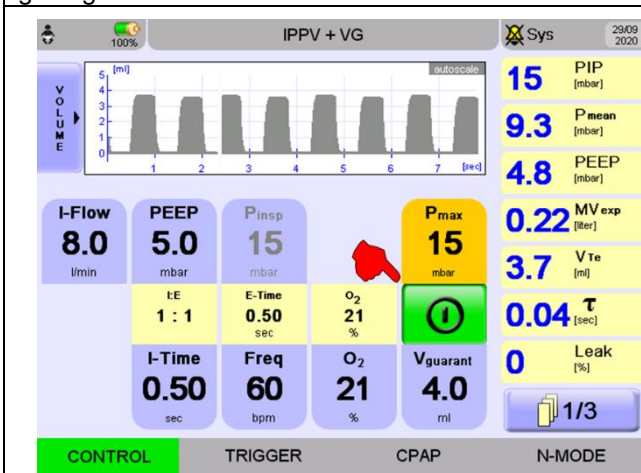
Wenn die in der unten stehenden Abbildung gezeigte Schaltfläche nicht grün ist, ist die VG-Funktion deaktiviert. Aktivieren Sie die Funktion nicht.



fabian +nCPAP evolution: Funktion „Volumengarantie“ (VG) abschalten

Wenn die in der unten stehenden Abbildung gezeigte Schaltfläche grün ist, ist die VG-Funktion aktiviert. Bitte deaktivieren Sie die Funktion, indem Sie auf die gezeigte Schaltfläche drücken.

Wenn die in der unten stehenden Abbildung gezeigte Schaltfläche nicht grün ist, ist die VG-Funktion deaktiviert. Aktivieren Sie die Funktion nicht.



HINWEIS: Die VG-Fehlfunktion wird durch die Installation eines Software-Upgrades (derzeit in Entwicklung) auf Ihrem Gerät behoben. Die VG-Funktion kann danach verwendet werden. Sobald die neue Software verfügbar ist, wird Ihr Acutronic/Vyaire-Vertriebspartner Sie informieren. Bezüglich der Installation des Software-Updates wenden Sie sich bitte an Ihren Acutronic/Vyaire-Vertriebspartner, einen autorisierten technischen Servicetechniker oder Ihren Handelsvertreter.

FI Card-20-001.EN

HFO / +nCPAP evolution - FSCA-20-001

Do not use the Volume Guarantee (VG) function



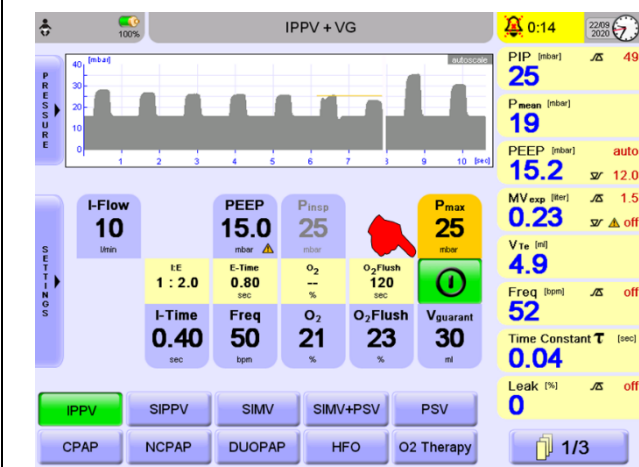
Discontinue use of, and / or do not activate and use the optional Volume Guarantee function with the affected fabian HFO and +nCPAP evolution devices, until the Software update addressing the Volume Guarantee malfunction is installed.

This malfunction does not affect the general use of the ventilators and only impacts the use of the Volume Guarantee function. Other functions of the ventilators are not affected. The ventilators may continue to be used for all ventilation modes of therapy, without using the Volume Guarantee function.

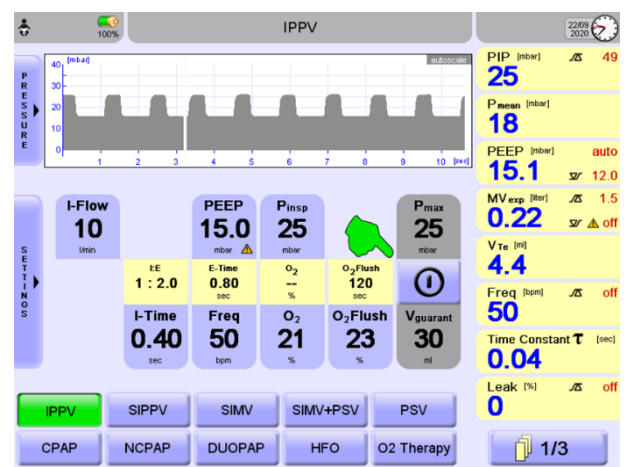
For infants with severe lung disease, alternative forms of lung protective ventilation may be considered.

fabian HFO: switch off Volume Guarantee (VG) function

When the softkey indicated below is green, the VG function is activated. Please deactivate it by pushing the indicated softkey below.

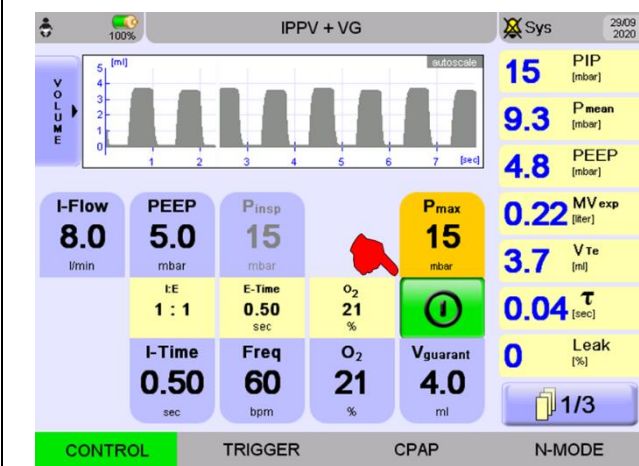


If the indicated softkey below is not green, the VG function is deactivated. Do not activate.

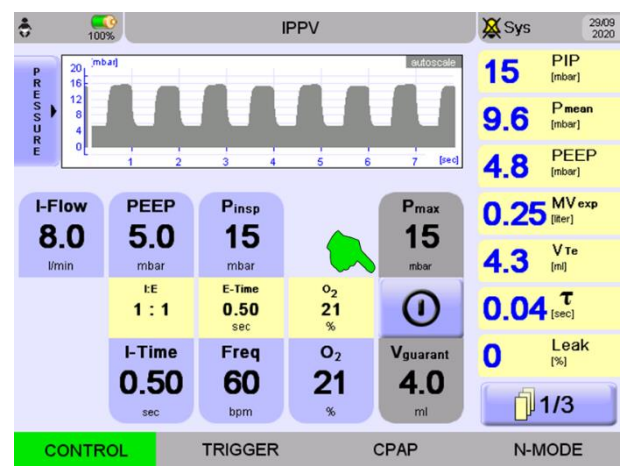


fabian +nCPAP evolution: switch off Volume Guarantee (VG) function

When the softkey indicated below is green, the VG function is activated. Please deactivate it by pushing the indicated softkey.



If this button is not green, the VG function is deactivated. Do not activate.



NOTE: The VG malfunction will be fixed by installing a software update (currently in development) on your device. The VG function may be used thereafter. Once the new software is available, your Vyair Distribution partner will inform you via End User Release Note. Regarding the installation of the software update, please refer to your Acutronic/Vyair Distribution partner, authorized technical service engineer or your sales representative.

FSCA-20-001
 User Work Instruction
Volume Guarantee function
fabian HFO and fabian +nCPAP evolution



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Document No: TS-AA-27 Volume Guarantee function		Date: 2020-10-5
Unit: fabian		Our Ref: FSCA-20-001
Software: 5.0.X, 5.1.X	Hardware: fabian HFO, fabian +nCPAP evolution	
Description: FSCA-20-001 fabian HFO and fabian +nCPAP evolution Volume Guarantee (VG) function		
<input checked="" type="checkbox"/> Mandatory	<input type="checkbox"/> Where necessary	<input type="checkbox"/> As Information
Revision 1.0: Creation		

1. How to identify affected devices (FSCA-20-001)

1.1 How can you determine whether your devices are affected?

Turn on the device. On the main screen, press 2x



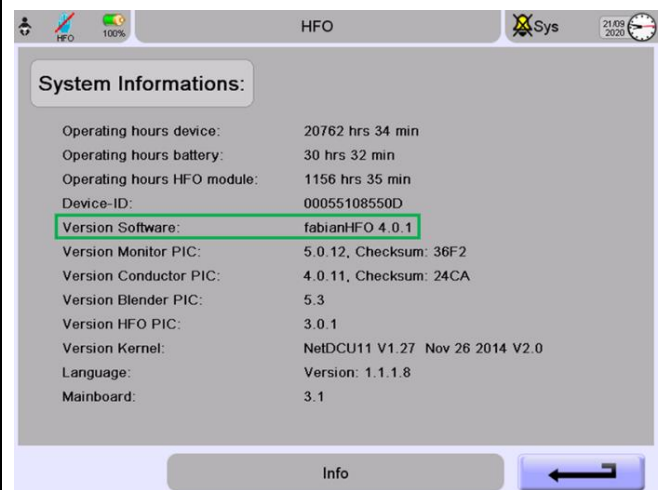
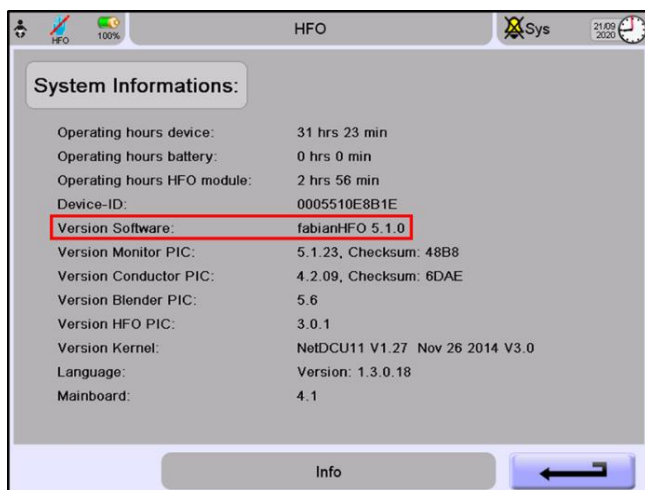
press the “Info” button



Check the Software version available on the fabian HFO or fabian +nCPAP evolution device

e.g: affected software version

e.g: not affected software version

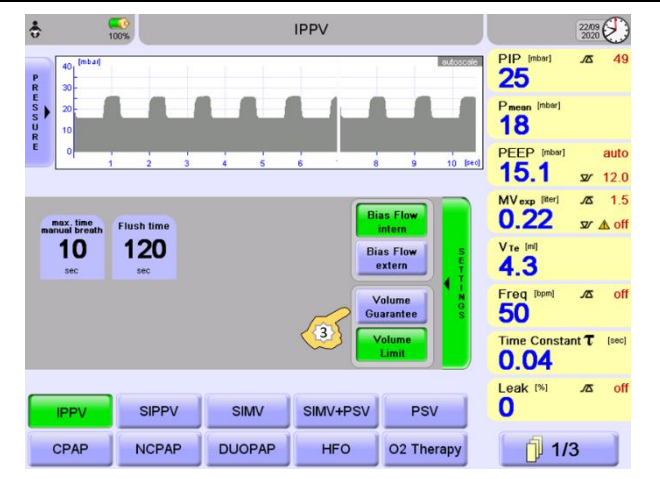
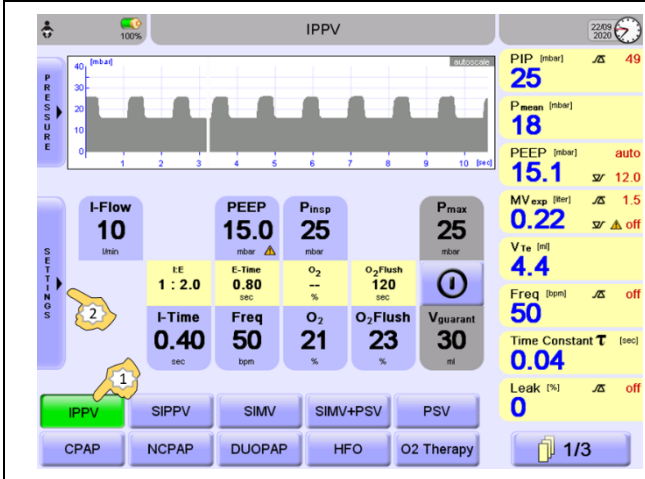


1.2 How to check whether the VG function is available on your device

1.2.1 fabian HFO: check whether the VG function is available on your device

1. switch to IPPV mode
2. press an the “SETTINGS” button

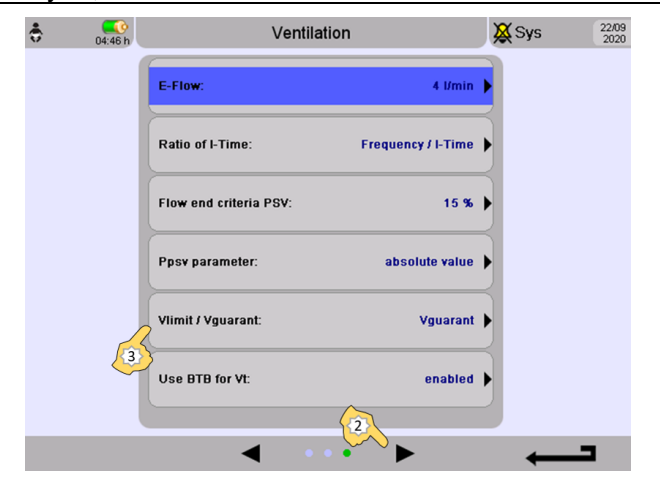
3. check whether the Volume Guarantee (VG) button is available. If yes, the VG option is available.



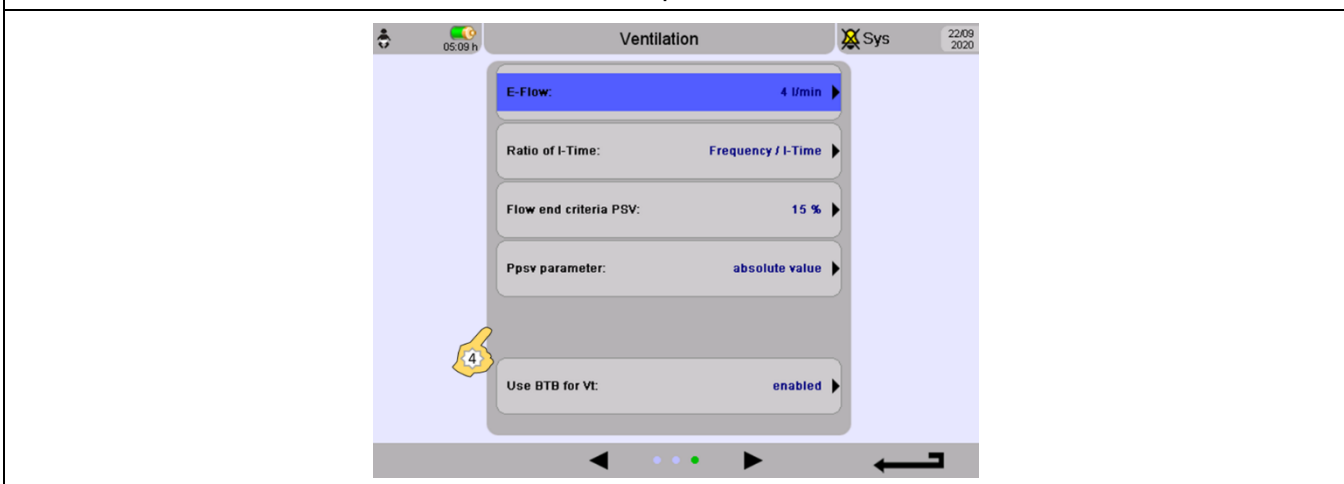
1.2.2 fabian +nCPAP evolution: check whether the VG function is available on your device

1. press the “Ventilation” button

2. press 2x the “▶” button
3. check whether the *Vguarant* field is available. If yes, the VG function is available



4. If not, the VG option is not available.



2. How to identify your device is affected or not

1. fabian HFO



fabian HFO: overview/identification FSCA-20-001 affected software version(s)

Model	VG option installed?	SW V5.0.X	SW V5.1.X	SW V4.X.X	Affected?
fabian HFO	Yes	Yes	-	-	Yes
	Yes	-	Yes	-	Yes
	Yes	-	-	Yes	No
	No	Yes	-	-	No
	No	-	Yes	-	No
	No	-	-	Yes	No

2. fabian HFO Light



fabian HFO Light: overview/identification FSCA-20-001 affected software version(s)

Model	VG option installed?	SW V5.0.X	SW V5.1.X	SW V4.X.X	Affected?
fabian HFO Light	Yes	Yes	-	-	Yes
	Yes	-	Yes	-	Yes
	Yes	-	-	Yes	No
	No	Yes	-	-	No
	No	-	Yes	-	No
	No	-	-	Yes	No

3. fabian HFOi



fabian HFOi: overview/identification FSCA-20-001 affected software version(s)					
Model	VG option installed?	SW V5.0.X	SW V5.1.X	SW V4.X.X	Affected?
fabian HFOi	Yes	Yes	-	-	Yes
	Yes	-	Yes	-	Yes
	Yes	-	-	Yes	No
	No	Yes	-	-	No
	No	-	Yes	-	No
	No	-	-	Yes	No

4. fabian HFOi Light

Same front design as HFOi, but serial number starts with AL. for example: AL-XXXXX



fabian HFOi Light: overview/identification FSCA-20-001 affected software version(s)

Model	VG option installed?	SW V5.0.X	SW V5.1.X	SW V4.X.X	Affected?
fabian HFOi Light	Yes	Yes	-	-	Yes
	Yes	-	Yes	-	Yes
	Yes	-	-	Yes	No
	No	Yes	-	-	No
	No	-	Yes	-	No
	No	-	-	Yes	No

5. fabian +nCPAP evolution



fabian +nCPAP evolution: overview/identification FSCA-20-001 affected software version(s)

Model	VG option installed?	SW V5.0.X	SW V5.1.X	SW V4.X.X	Affected?
fabian +nCPAP evolution	Yes	Yes	-	-	Yes
	Yes	-	Yes	-	Yes
	Yes	-	-	Yes	No
	No	Yes	-	-	No
	No	-	Yes	-	No
	No	-	-	Yes	No

3. What to do if your devices are affected

1. Print out the fabian Instruction Card (FI Card-20-001) that was provided to you by the Distributor as part of the *FSCA-20-001 package*.
The fabian Instruction Card describes how to determine if the Volume Guarantee function is active and how to deactivate it. Keep this document together with the IFU of the affected devices.
2. Make sure that all potential users of the affected devices read and understand the contents of the fabian Instruction Card (FI Card-20-001).

Following the instructions in the fabian Instruction Card (FI Card-20-001), discontinue use of, and / or do not activate and use the optional Volume Guarantee function with the affected fabian HFO and +nCPAP evolution devices, until the Software update addressing the Volume Guarantee malfunction is installed.

This malfunction does **not** affect the general use of the ventilators and only impacts the use of the Volume Guarantee function. Other functions of the ventilators are not affected. The ventilators may continue to be used for all ventilation modes of therapy, without using the Volume Guarantee function.

For infants with severe lung disease, alternative forms of lung protective ventilation may be considered.

The ongoing FSCA-18-004 related to the software version 5.1.0 is a mandatory software update to correct identified issues affecting previous software versions. Any devices that have not yet been updated to software version 5.1.0 must still be updated with the FSCA-18-004 software. However, the VG function on these updated devices must not be used.

NOTE: The VG malfunction will be fixed by installing a software upgrade (currently in development) on your device. The VG function may be used thereafter. Once the new software is available, your Acutronic/Vyaire Distribution partner will inform you via End User Release Note. Regarding the installation of the software update, please refer to your Acutronic/Vyaire Distribution partner, authorized technical service engineer or your sales representative.

**Distributor’s Field Safety Corrective Action Response Form
FSCA-20-001**

Affected Products (according to FSN)

Device Model	REF No.	Software Versions
fabian HFO	112001	5.0.x (with VG function) 5.1.x (with VG function)
fabian HFO Light	111001	
fabian HFOi	113001	
fabian HFOi Light	111001.01	
fabian +nCPAP evolution	122001	

Distributor Self-declaration

Number of affected devices on the market		
Number of affected devices in stock		
FOR EACH AFFECTED DEVICE PLEASE PROVIDE (if necessary, attach extra page)		
Device Serial Number	Software Version	User facility name and address

Mark applicable check boxes below.

- All affected devices and users were identified.
- The FSCA package, incl. the *Field Safety Notice (FSCA-20-001-FSN)*, *User Work Instructions (TS-AA-027e)*, *fabian Instruction (FI) Card* and *FSCA Response Form* has been distributed to all identified affected users.
- The FSCA package, incl. the *Field Safety Notice (FSCA-20-001-FSN)*, *User Work Instructions (TS-AA-027e)*, *fabian Instruction (FI) Card* and *FSCA Response Form* has **not** been distributed to all identified affected users.

❖ Provide rationale below:

Target Response Rate set by Acutronic Medical Systems AG:

100%

Dateiname: Filename:	Distributor Response Form FSCA 20-001
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By signing this form, I certify the following (mark applicable check boxes)

I have read and understood the content of the Field Safety Notice (FSCA-20-001-FSN) and confirm that I understand all instructions noted within the Field Safety Notice (FSN).

All users were informed about this FSCA and the FSCA package provided.

Users were informed via:

Mail E-mail Other: _____

I confirm that affected devices were transferred to another location/organization and the complete FSCA package was forwarded to those recipients.

❖ List contact details of recipients _____

I was not able to fulfil the requirements specified in the FSN.

❖ Rationale _____

I do not have fabian ventilators in stock nor on the market.

I am not a fabian ventilator distributor, therefore I am not affected by this FSCA and no further actions are required.

❖ Rationale _____

Distributor (company name)			
Address of Distributor			
Email address			
Telephone number			
Name of person completing form (Please Print)			
Function of person completing form			
Signature of person completing form		Date	

**THIS FORM MUST BE RETURNED TO THE FOLLOWING ADDRESS.
ONLY FULLY COMPLETED AND SIGNED FORMS WILL BE ACCEPTED:**

GMB-AMS-FSCAresponsecentre@vyaire.com

Dateiname: Filename:	Distributor Response Form FSCA 20-001
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