URGENT FIELD SAFETY NOTICE
fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution
Update
for Field Safety Corrective Actions FSCA-21-002 and FSCA-21-003
Use of Medijet® and Inspire™ nCPAP generators

17 October 2022 Field Safety Notice (FSN) Ref: FSCA-21-002_FSCA-21-003-FSN-3

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

Dear Customer**,**

This communication is an update to the previously communicated Field Safety Notices (FSN) *FSCA-21-002_FSCA-21-003-FSN-1* and *FSCA-21-002_FSCA-21-003-FSN-2*.

This FSN update is to inform you about a modification to the scope of the Field Safety Corrective Actions FSCA-21-002 and FSCA-21-003. Field Safety Notice *FSCA-21-002_FSCA-21-003-FSN-1* notified users about potential incorrect airway pressure delivery on fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution ventilators when used with Infant Flow™ LP nCPAP generators. Acutronic / Vyaire Medical has subsequently determined similar inaccuracies in airway pressure delivery when fabian™ devices are used with Medijet® and Inspire™ nCPAP generators in Non-Invasive Ventilation (NIV) and DuoPAP modes.

Identified issues, potential risks and mitigations for affected devices

The potential software anomalies identified, their potential harm, and mitigations to be taken by the user are described in the following Table 1. *In addition to the specific mitigations to be taken by the user as stated in the table, all users should exercise use of standard mitigative actions as referenced in the fabian™ Instructions for Use (IFU). Refer to the section "*Standard mitigative actions that always apply*" below in this document.*

Table 1: Identified issues, potential risks and mitigations for affected devices

	Issue 1	Issue 2	Issue 3
Issue Description	While in Non-Invasive Ventilation (NIV) mode, when used with the Inspire™ generator, over-delivery of pressure can occur.	While in DuoPAP mode, target pressure might not be reached within a clinically relevant inspiratory time when used with the Inspire™ generator.	While using the Medijet® generator with fabian™ ventilators in NIV mode, incorrect airway pressure delivery can occur.
Circumstances Necessary for Issue to Occur	Use of the Inspire generator on fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution devices while in NIV mode.	Use of the Inspire generator on fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution devices while in DuoPAP mode.	While using the Medijet® generator with fabian™ ventilators in NIV mode, incorrect airway pressure delivery occurs.
Resulting outcome if issue occurs	Monitored Mean Airway Pressure (MAP) values differ from the set value and the delivered value. The monitored and the delivered value are higher than set.	As a result, the patient is under-ventilated.	Monitored Mean Airway Pressure (MAP) values differ from the set value and delivered value. The monitored value is higher than set, and the delivered value is lower than set.
Potential Risks Due to Issue	In worst-case events, Lung Injury, Hyperventilation and/or Hypocapnia.	In worst-case events, Lung Injury, Hypoxia, and/or Hypercapnia.	In worst-case events, Lung Injury, Hypoxia, and/or Hypercapnia.
Affected fabian™ HFO (product number)	113001, 112001, 111001, 111001.01	113001, 112001, 111001, 111001.01	113001, 112001, 111001, 111001.01
Affected fabian™ +nCPAP evolution (product number)	122001	122001	122001
Affected fabian™ Therapy evolution (product number)	121001	121001	121001
Corrective Action / Software Update Version	With the release of software version 5.2.2 under FSCA-21-003, • Inspire™ generators will no longer be supported for use with fabian™ devices. • Full, validated support of Infant Flow™ LP generators only.	With the release of software version 5.2.2 under FSCA-21-003, • Inspire™ generators will no longer be supported for use with fabian™ devices. • Full, validated support of Infant Flow™ LP generators only.	With the release of software version 5.2.2 under FSCA-21-003, • Medijet® nCPAP generators will no longer be supported for use with fabian™ devices. • Full, validated support of Infant Flow™ LP generators only.
Mitigations to be taken by the user until software version 5.2.2 is released and installed	• Refer to the section “Standard mitigative actions that always apply” below.	• A low PIP alarm can be set to alert the clinician when target pressure is not reached in DuoPAP mode. • Refer to the section “Standard mitigative actions that always apply” below.	• Refer to the section “Standard mitigative actions that always apply” below.

Advice to users

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 Field Safety Notice *FSCA-21-002_FSCA-21-003-FSN-1*. Acutronic / Vyaire will no longer support the use of Medijet® and Inspire™ nCPAP generators following the 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. Software version 5.2.2 is scheduled for release in December 2022.

Until software version 5.2.2 is available, users must take the following steps to avoid possible patient harm if using Medijet® and Inspire™ nCPAP generators with their ventilators in the interim.

➢ Standard mitigative actions that always apply

All users should always exercise use of standard mitigative actions as referenced in the fabian™ IFU.

Standard of care: Always keep alternative means of ventilation, such as manual resuscitation devices or another appropriate ventilator immediately available as a back-up means of ventilation in case of ventilator failure.

WARNING (from the *Instructions for Use*)**:** in case of ventilator failure, the lack of immediate access to appropriate alternative means of ventilation can result in patient death.

The ventilator must only be used as part of a continuous patient monitoring system. In the event of a ventilator failure where ventilation to the patient ceases, clinical detection of changes in patient condition would be indicated, including audible and visual alarms, as part of the continuous monitoring of patient values (SpO_2, $etCO_2$, Respiration Rate and hemodynamics).

WARNING (from the *Instructions for Use*)**:** Only use this ventilator in combination with an external monitoring device (*for example*: SpO_2).

➢ To avoid possible patient injury from hypoxia or hypoventilation related to potential software anomalies listed above:

- If available, consider the use of an alternative mechanical ventilator system, especially in circumstances where a short interruption in mechanical ventilation or a loss of positive pressure could pose an inordinate risk of hypoxemia.

- For every patient, assure that an alternate means of providing positive pressure ventilation with supplemental oxygen is immediately available, as outlined in the IFU.

- Always utilize independent adjunctive devices that continuously monitor the adequacy of ventilation and oxygenation (e.g. pulse oximetry, capnometry) and be sure that alarms are appropriately enabled.

- Ensure that every patient being ventilated with an affected fabian™ ventilator is appropriately monitored by caregivers who are trained in ventilator assessment and management.

Please assure that all caregivers are familiar with the current Instructions for Use and with the information in this FSN. If clinicians operate fabian™ products in accordance with the Instructions for Use and follow established monitoring guidelines, the likelihood that a patient could suffer an injury from the described failure modes is exceedingly small. Since the benefit to patients of continued availability of fabian™ products outweighs the patient risk of injury from the potential issues, Acutronic supports continued clinical use of these products, respecting all constraints and information provided in this FSN update, until the release of software version 5.2.2.

Actions being taken by the manufacturer

- **With the release of software version 5.2.2** (implementation of FSCA-21-003), Acutronic / Vyaire will support only Infant Flow™ LP nCPAP generators:
  - Infant Flow™ LP will be the only generator supported by Acutronic / Vyaire for the delivery of nCPAP for fabian™ ventilators.
  - One fully validated system under the full control of Acutronic / Vyaire will ensure the highest patient safety and performance.
- Acutronic expects the FSCA-21-003 software (version 5.2.2) to be available in December 2022. Availability of the software update will be notified by an FSN update.
- Acutronic will send the FSCA update package which will include this *FSN* and the *FSCA End User Response Form* to all affected distributors (initially in English to all recipients, national language translations to follow)
- Acutronic will update the IFU for affected devices and will distribute it to all business partners/distributors together with the SW update when available.
- Acutronic will collate and follow up on the *End User Response Forms* and the execution and completion of this corrective action.

Actions to be taken by the distributors

- Notify immediately all affected end-users by providing them with this *FSN* and the *FSCA End User Response Form*.
- Should any of the user facilities have distributed any of the affected products and/or parts to other persons or facilities, promptly forward a copy of this *FSN* and the *FSCA End User Response Form* to those recipients and inform Acutronic via email to **GMB-AMS-FSCAresponsecentre@vyaire.com.**

Actions to be taken by the end-users

- Check receipt of the FSCA package, containing this *FSN* and the *FSCA End User Response Form*.
- Make sure that this *FSN* and the *FSCA End User Response Form* are forwarded immediately to any potential user of all affected

fabian™ HFO, fabian™ +nCPAP evolution and fabian™ Therapy evolution ventilators.

- All users of the affected devices shall read and take into consideration all instructions, advice and information provided in this *FSN*.
- In case affected devices are transferred to another location or organization make sure the complete FSCA package is forwarded to the respective users accordingly.
- It is essential to use affected devices in accordance with the additional instructions (supplemental to the prevailing IFU) given in this *FSN*.
- Keep a copy of this *FSN* together with the device and the IFU and retain it until software version 5.2.2 is available and has been installed on the device.
- Fully complete and return the signed *FSCA End User Response Form* to your Acutronic / Vyaire authorized technical service representative as per the instructions on the form.

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 communicated to the appropriate Regulatory Agencies.

Sincerely,

Abir Roy
QA Manager, Post Market Surveillance / FSCA Coordinator
Fabrik im Schiffli
CH-8816 Hirzel
Switzerland

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Affected Products (according to FSN *FSCA-21-002_FSCA-21-003-FSN-3*)

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-3 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-3) 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-3) 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:
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