
URGENT FIELD SAFETY NOTICE
fabian HFO, fabian +nCPAP evolution, and fabian Therapy evolution
Multiple Issues related to Software Anomalies
for Field Safety Corrective Actions FSCA-21-002 and FSCA-21-003

09 August 2021

Field Safety Notice (FSN) Ref: FSCA-21-002_FSCA-21-003-FSN-1

Attention: Users of the fabian HFO, fabian +nCPAP evolution, and fabian Therapy 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 Vyaire Medical, involving the following fabian HFO, fabian +nCPAP evolution, and fabian Therapy evolution ventilators.

Affected devices

Affected versions of fabian HFO, fabian +nCPAP evolution, and fabian Therapy evolution:

Device Name	Model Reference Number	Description	Affected Devices
fabian HFO	113001 112001 111001 111001.01	Neonatal and pediatric ventilator	Refer to Table 1 on page 8 for affected devices per issue
fabian +nCPAP evolution	122001 122012	Neonatal and pediatric ventilator	
fabian Therapy evolution	121001 121012	Neonatal and pediatric ventilator	

Description of the problems

This FSN covers multiple issues representing software anomalies identified after investigation by Acutronic. Table 1 on page 8 specifies which issue is addressed by which FSCA.

Issue 1: Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode – fabian HFO

Acutronic has received reports of short (0.5-3 second) interruptions in High Frequency Oscillation (HFO). When the amplitude is set to 53mbar or higher, the mean airway pressure drops to zero and a patient circuit tube occlusion alarm activates. During HFOV in the absence of high amplitude settings (lower than 53mbar) there are no alarms or indications activated. The ventilator continues to hold pressure during the HFO interruption. The HFOV mode resumes after the interruption in both scenarios. The ventilator continues to hold mean airway pressure during the HFO interruption. Mean airway pressure drops by 0.5 cmH₂O after the restart of the HFOV mode.

Potential Health Risk: Worst-case potential outcomes (harm) as a result of this failure mode include lung injury, hypoxia and/or bradycardia, potentially life-threatening in nature.

Issue 2: HFO-specific External Bias Flow setting menu incorrectly visible in all conventional (non-HFO) ventilation modes – fabian HFO

Problem Description: Acutronic has received reports that patients receiving nitric oxide (NO) therapy on a fabian HFO ventilator using external bias flow in HFO mode did not receive NO for a few minutes after switching from HFO mode to a conventional ventilation mode. Although external bias flow is valid only for HFO mode, the external bias flow settings are also present in conventional ventilation modes due to a software anomaly. The user may believe that external bias flow is available in all modes as the option is visible. When the clinician is administering NO using external bias flow in HFO mode and changes to a conventional ventilation mode, the NO gas flow is discontinued without a prompt to the user, with the user potentially unaware that NO delivery has stopped. The ventilator continues to provide otherwise set ventilation parameters without NO therapy.

Potential Health Risk: The potential outcome from this failure mode is hypoxia that is potentially life-threatening as a result of discontinuing the supply of nitric oxide without prompting the clinician.

Issue 3: No alarm on ETT disconnection – fabian HFO

Problem Description: Under certain Pmean and Amplitude settings, the HFO disconnect detection algorithm cannot detect an unintentional endotracheal tube (ETT) disconnection while the flow sensor remains connected, and anticipated alarm activation may not occur. During accidental ETT disconnection, the ventilator will not alarm to notify the clinician. The resistance of the flow sensor acting in conjunction with the Pmean and Amplitude servos will prevent the disconnect detection criteria from being met. The simplified description of the disconnect detection algorithm is that either measured Pmean or measured Amplitude drops below 50% of the set value and stays below that threshold for 5 seconds. Acutronic has established the Pmean and Amplitude settings where the HFO disconnect algorithm is ineffective to be as follows:

- When the set Pmean is approximately 20 cmH₂O or greater and the set Amplitude is approximately 3.5 times higher than the set Pmean or greater.
- When the set Pmean is approximately 10 cmH₂O or lower.

- Higher bias flow increases the likelihood of the HFO disconnect algorithm not triggering the alarm.

These are specific conditions under which this malfunction would occur. Note that situations where the device does not generate an alarm on disconnections are dependent on various settings and on the way the system is configured. Due to this variability of end-user system configurations and settings, these specific settings may not apply to your system. These specific settings that lead to the ineffective disconnect algorithm are rarely used in clinical practice. The Minute Volume alarm or the Pmean alarm would be activated if the user sets the alarm limits as close as possible to the set mean air way pressure, and it is only in very extreme settings that there would not be an activated alarm. In most cases under commonly used settings, the Minute Volume or Pmean alarm would alert the user during a potential disconnect.

Potential Health Risk: The potential outcome from this failure mode of no alarm on disconnection of the ETT is hypoxia as a result of hypoventilation, potentially life-threatening.

Issue 4: Global Alarms Off function becomes enabled during ventilation – fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO

Problem Description: The feature of global alarms off was implemented by design only for service mode work or for demonstration purposes, so that the ventilator could be worked on or showcased without the acoustic alarms being active during this specific use. The global alarms off function is not intended to be enabled during patient use. Internal testing has established that it is possible to enable the global alarms off function during ventilation. When the alarms become disabled, the alarm off sign (crossed alarm icon) becomes visible on the user interface and replaces the normal alarm icon. Upon start-up, alarms must be checked and recalibrated in order to disable this feature and prepare the device for patient use.

Potential Health Risk: The potential outcome from this failure mode of alarms being disabled during ventilation is hypoxia and/or hypercapnia, lung injury and/or airway injury, potentially life-threatening.

This issue will be addressed in software revision 5.2.1 so that it will no longer be possible to enable the global alarms off function when the device is connected to a patient.

Issue 5: Graphical User Interface (GUI) freeze / Application error and potential shut-down – fabian HFO

Problem Description: Acutronic has received reports of graphical user interface (GUI) freeze conditions resulting in the monitored values not being visible. There have been no reports of any patient harm. When the GUI freeze condition occurs, the screen and rotary knob become frozen/unresponsive and/or the device displays an “application error.exe, unit must shut down” pop-up window. When this issue occurs during use, the fabian device may cease ventilation to the patient. In the instance where ventilation ceases, ventilation remains suspended until the ventilator is re-started. When the GUI freeze condition occurs, a high priority watch-dog alarm is activated. For a GUI freeze to occur, one of the following situations must exist:

- During use of the fabian HFO when either etCO₂ OR SpO₂ module is enabled, OR
- When the device is running for 49 days, OR
- When trend data management communication system is enabled.

Potential Health Risk: The potential outcome from this failure mode, in the worst-case scenario of the ventilator suspending ventilation while in use on a patient, is hypoxia and/or hypercapnia and potentially life-threatening.

Issue 6: Pressure delivery below specification with Infant Flow LP circuits - fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO

Problem Description: Acutronic has received a report of incorrect pressure delivery (under-delivery) on fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO ventilators. For the inaccurate pressure delivery to occur, the ventilator must be set to non-invasive ventilation (NIV) mode and used with Infant Flow LP generator circuits attached. The clinician will set a pressure value, however there is a discrepancy between the delivered value (lower than set) and the monitored value (higher than set). There is no display or alarm notifying the clinician of the discrepancies. The discrepancies may mislead the clinician to adjust the set pressure, potentially causing a patient injury without being able to correlate this to a device malfunction. Tests performed by Acutronic determined that the actual delivery of pressure is below target specification of " $\pm [0.5 \text{ mbar} + 3\% \text{ of the set pressure}]$."

Potential Health Risk: The potential outcome from this failure mode of incorrect pressure delivery may include hypoxia and/or hypercapnia, lung injury, potentially life-threatening.

Acutronic has not received any reports of patient injury related to this failure. However, without extensive pre-use testing, the clinician would not be aware that the device is delivering incorrect pressure; there are no alarms or visual prompts to alert the clinician of the failure. In the case of a patient deterioration, an external monitor will alert the clinician and prompt response. However, the clinician will not be able to correlate that deterioration to the ventilator because the monitored values and the ventilator logs will continue to display an inaccurate pressure.

Advice to users

Until the appropriate FSCA software to remedy your device is available, users are advised to take the following steps to avoid possible patient harm.

➤ **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 (SpO₂, etCO₂, Respiration Rate and hemodynamics).



WARNING (from the *Instructions for Use*): Only use this ventilator in combination with an external monitoring device (*for example*: SpO₂).

➤ **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 Instructions for Use.
- 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 original 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 and the FSCA package, while remedies are deployed.

Mitigative actions specific to each issue

➤ **Issue 1: Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode – fabian HFO**

- 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.
- In certain settings, HFO interruption is called to attention via the tube occlusion alarm and an immediate response to the high priority alarm will reduce risk of harm. If the amplitude is set to 53mbar or higher, the mean airway pressure drops to zero, and the SW triggers a tube occlusion alarm, which would alert the clinical staff to the issue. The HFOV mode resumes after the interruption.

➤ **Issue 2: HFO-specific External Bias Flow setting menu incorrectly visible in all conventional (non-HFO) ventilation modes – fabian HFO**

- External bias flow should ONLY be used in HFO mode.
- When switching from HFO to conventional mode, turn off external bias flow, remove flow sensor from patient circuit and reconfigure the circuit. (For circuit diagrams showing NO system usage, see section 5.1.4.1 for HFO mode, and section 5.1.4.2 for conventional ventilation modes).
- Measured iNO, detected via the sample line, should have appropriate alarms.

➤ **Issue 3: No alarm on ETT disconnection – fabian HFO**



WARNING:

During High-Frequency Oscillatory ventilation (HFOV) therapy, a disconnect between the flow sensor and the endotracheal (ET) tube may not lead to a disconnection alarm from the ventilator under certain conditions.

The disconnection alarm is triggered by a drop in mean airway pressure (MAP).

The high resistance of the flow sensor can prevent a drop in MAP after disconnection. In some cases, the pressure drop is not sufficient to trigger the disconnection alarm.

It is strongly recommended to keep the MAP high and MAP low alarm settings as close as possible to the set MAP.

Always use an advanced external patient monitoring system to continuously monitor the patient's physiological parameters, such as Oxygen Saturation (SpO₂), Transcutaneous CO₂ (tcCO₂), and Transcutaneous Oxygen (tcO₂) monitoring to alert the clinical staff reliably to an alarm situation.

Acutronic is incorporating this warning into the fabian HFO Instructions for Use for software version 5.2.1.

- If the alarm limits for the Minute Volume alarm or the Pmean alarm are set conservatively, the Minute Volume alarm or the Pmean alarm would be triggered in case of a patient disconnect. An alarm would not be activated only in case of extreme settings. In most cases under commonly used settings, the Minute Volume or Pmean alarm would alert the user during a potential disconnect. Therefore, it is strongly recommended to set the alarm limits for Minute Volume alarm or the Pmean alarm as close as possible to the set mean airway pressure.

➤ **Issue 4: Global Alarms Off function becomes enabled during ventilation – fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO**

- NEVER use the Global Alarms Off function when a patient is connected to the device.
- Before connecting the ventilator to the patient, ALWAYS make sure all the alarms are set appropriately and are active.

➤ **Issue 5: Graphical User Interface (GUI) freeze when using etCO₂ module – fabian HFO with etCO₂ module**

- Reboot the device to clear the issue.
- Do not enable the etCO₂ or SpO₂ module (do not connect the module to the ventilator real panel).

Refer to Chapter 7.3.3 of the fabian HFO Instructions for Use for further information.

➤ **Issue 6: Pressure delivery below specification with Infant Flow LP circuits - fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO**

- When using LP generators, and according to the standard practice of care, make sure that the ventilator is used only as part of a continuous patient monitoring system. In the event of a ventilator malfunction, clinical detection of changes in patient condition would be indicated, including audible and visual alarms, as part of the continuous monitoring of patient values (SpO₂, etCO₂, Respiration Rate and hemodynamics).
- Mitigation for CPAP: consider titrating up based on assessing work of breathing

Summary of identified issues, their potential harm and mitigations

The potential software defects identified, their potential harm, and mitigations to be taken by the user are summarized in Table 1 below. Table 1 also indicates which software version remedies each issue. *In addition to the specific mitigations to be taken by the user as stated in Table 1, all users should exercise use of standard mitigative actions as referenced in the fabian Instructions for Use (IFU). Refer to “Standard mitigative actions that always apply” on page 4 of this FSN.*

Table 1: Summary of identified issues, potential risks and mitigations for affected devices

Issue #	Issue	Circumstances Necessary for Issue to Occur	Outcome	Potential Risks due to Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Corrective Action / Software Update Version	Mitigations to be taken by the user
1	Interruption of High Frequency Oscillation (HFO) in HFO Ventilation mode	HFO mode during use.	HFOV restarts itself after the interruption. The ventilator continues to hold mean airway pressure during HFO interruption. Mean airway pressure drops by 0.5 cmH ₂ O after HFOV mode restarts.	Lung injury, hypoxia and/or bradycardia	Affected: All 112001 113001	Not affected	Not affected	FSCA-21-002: Software update V5.2.1	All users should exercise use of standard mitigative actions as referenced in the fabian IFU. Refer to "Standard mitigative actions that always apply" on page 4.
		HFOV mode during use with amplitude of 53mbar or higher.	Results in the mean airway pressure dropping to zero, and the SW triggers a tube occlusion alarm.	Lung injury, hypoxia, bradycardia, life-threatening					

Issue #	Issue	Circumstances Necessary for Issue to Occur	Outcome	Potential Risks due to Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Corrective Action / Software Update Version	Mitigations to be taken by the user
2	Presence of incorrect display of external bias flow	Issue occurs when switching from conventional mode to External Bias Flow delivery.	Discontinuation of the supply of inhaled nitric oxide without prompting the clinician.	Hypoxia, life-threatening	Affected: All 113001	Not affected	Not affected	<p>This issue will be addressed over two software releases:</p> <p>FSCA-21-002: Software update V5.2.1: Bias Flow selection will be removed from the user interface in conventional ventilation (non-HFO) modes.</p> <p>and</p> <p>FSCA-21-003: Software update V5.2.2: Pop-up windows will be introduced when the user changes from / to HFO mode, to inform the user about bias flow impact.</p>	<ul style="list-style-type: none"> • External bias flow should ONLY be used in HFO mode. • When switching from HFO to conventional mode, turn off external bias flow, remove flow sensor from patient circuit and reconfigure the circuit. (See Chapters 5.1.4.1 (HFO mode) and 5.1.4.2 (conventional mode) in the fabian HFO IFU.) • Ensure activation of appropriate alarms when measured iNO is detected via the sample line. • Refer to “Standard mitigative actions that always apply” on page 4.

Issue #	Issue	Circumstances Necessary for Issue to Occur	Outcome	Potential Risks due to Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Corrective Action / Software Update Version	Mitigations to be taken by the user
3	Presence of no alarm on ETT disconnection	<ul style="list-style-type: none"> When the set Pmean is approximately 20 cmH₂O or greater and the set Amplitude is approximately 3.5 times higher than the set Pmean or greater. When the set Pmean is approximately 10 cmH₂O or lower. 	Discontinuation of ventilation to the patient due to disconnect. No alarm activation.	Hypoxia, hypoventilation, potentially life-threatening	Affected: All 112001, 113001	Not affected	Not affected	<p>FSCA-21-002: Update to the fabian HFO Instructions for Use.</p> <p>FSCA-21-003: Software update V5.2.2</p>	<ul style="list-style-type: none"> The Minute Volume alarm or the Pmean alarm limits should be set as close as possible to the mean airway pressure. Refer to <i>WARNING</i> on page 6. This warning will be incorporated into the fabian HFO IFU for software version 5.2.1. Refer to "Standard mitigative actions that always apply" on page 4.
4	Global Alarms Off function becomes enabled during ventilation	The alarm silence and the home buttons must be pressed simultaneously for three seconds.	Absence of activation of audible alarms in the presence of an adverse event possible. The alarm off sign (crossed alarm sign) becomes visible on the user interface and replaces the normal alarm sign.	Hypoxia, hypercapnia, lung injury, airway injury, potentially life-threatening	Affected: All 112001, 113001	Affected: All 122001, 122012	Affected: All 121001, 121012	FSCA-21-002: Software update V5.2.1	<ul style="list-style-type: none"> NEVER enable Global Alarms Off function when connected to a patient. Intended for service mode, training, or demonstration purposes only. Refer to "Standard mitigative actions that always apply" on page 4.

Issue #	Issue	Circumstances Necessary for Issue to Occur	Outcome	Potential Risks due to Issue	fabian HFO	fabian +nCPAP evolution	fabian Therapy evolution	Corrective Action / Software Update Version	Mitigations to be taken by the user
5	Graphical User Interface (GUI) freeze	<p>The fabian HFO MUST be in use along with one of the following conditions:</p> <ul style="list-style-type: none"> • Enabling of the etCO₂ or SpO₂ sensor operation. • Ventilator run time of 49 days • Trend Data enabled (storage, retrieval and management) 	<ul style="list-style-type: none"> • Cease in ventilation during use. • A high priority watch-dog alarm activates. 	In worst case events, hypoxia or hypercapnia, potentially life-threatening.	Affected: All 113001, 112001, 111001, 111001.01	Affected: All 122001, 122012	Affected: All 121001, 121012	<p>FSCA-21-002: Software update V5.2.1 will address all issues except Trend Data.</p> <p>FSCA-21-003: Software update will address Trend Data issue.</p>	<ul style="list-style-type: none"> • Rebooting the device will clear the failure. • Do not enable the etCO₂ or SpO₂ module (do not connect to the ventilator real panel). • Refer to Chapter 7.3.3 of the fabian HFO Instructions for Use.
6	Pressure delivery is below specification with Infant Flow LP circuits - fabian Therapy evolution, fabian +nCPAP evolution, and fabian HFO	Use of Infant Flow LP circuits with fabian therapy evolution, fabian +nCPAP evolution, and fabian HFO.	Monitored MAP value is higher than the set and delivered value without a display or alarm	Hypoxia and/or hypercapnia, Lung injury, potentially life-threatening.	Affected: All 113001, 112001, 111001, 111001.01	Affected: All 122001, 122012	Affected: All 121001, 121012	FSCA-21-003: Software update V5.2.2	<ul style="list-style-type: none"> • Ensure patient is connected to an external monitoring device when using the fabian ventilator with the Infant Flow LP generators. • Mitigation for CPAP: consider titrating up based on assessing work of breathing • Refer to "Standard mitigative actions that always apply" on page 4.

Service action required

All the above anomalies will be addressed with FSCA-21-002 (SW release 5.2.1) or FSCA-21-003 (SW release 5.2.2.). To understand availability of this software correction, please work closely with your distributor, authorized technical service engineer or your sales representative. The FSCA-21-002 software release is expected in September 2021. The FSCA-21-003 software release is expected in April 2022.

Actions being taken by the manufacturer

- Acutronic has determined the root cause of these design failures and will be providing software updates.
- Acutronic expects the **FSCA-21-002** software (version 5.2.1) to be available in September 2021.
- Acutronic expects the **FSCA-21-003** software (version 5.2.2) to be available in April 2022.
- Acutronic will send the FSCA package which will include: *FSN* in English and in national language, *FSCA Distributor Response Form*, *Addendum to the Instructions for Use*, and *FSCA End User Response Form* to all affected distributors.
- Acutronic will update the Instructions for Use (IFU) for affected devices and will distribute to all business partners/distributors together with the SW update.
- Acutronic will collect and follow up on all 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 the FSCA package, containing this *FSN*, *Addendum to the Instructions for Use*, and *FSCA End User Response Form*.
- Return of the completed and signed *FSCA Distributor Response Form* to Acutronic as per the provided instructions.
- 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*, *Addendum to the Instructions for Use*, and *FSCA End User Response Form* to those recipients and include contact information of those parties in the *FSCA Distributor Response Form* for device tracking purposes and further support.
- Execute the software updates for FSCA-21-002 and FSCA-21-003 according to Table 1 on page 8 once informed of their availability, in a timely manner and return all execution records to the manufacturer. Availability of the software updates will be notified by an update to this *FSN*.

Actions to be taken by the end-users

- Make sure that the content of the complete FSCA package, including this *FSN*, is forwarded immediately to any potential user of all affected fabian HFO, fabian +nCPAP evolution and fabian Therapy evolution ventilators as indicated in Table 1 above.
- Check receipt of FSCA package, containing this *FSN*, *Addendum to the Instructions for Use*, and the *FSCA End User Response Form*.
- 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.
- Make sure that all affected devices are identified by serial number and location.

- It is essential to use the devices in accordance with all communicated additional instructions (supplemental to the prevailing Instructions for Use).
- For affected devices, print out the *Addendum to the Instructions for Use*, make sure that they are available to all potential users and all users have read and understood the contents, keep them together with the device and the Instructions for Use (IfU) and retain them until further notice.
- 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 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 notified to the appropriate Regulatory Agencies.

Sincerely,

