URGENT FIELD SAFETY NOTICE
for Field Safety Corrective Action FSCA-21-004
fabian™ HFOi Ventilator
Bias Flow selection buttons unavailable in the User Interface after incorrect selection of device configuration during software update

28 March 2022 FSN Ref: FSCA-21-004-FSN

Attention: Users of the fabian™ HFOi 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"), a wholly owned subsidiary of Vyaire Medical, Inc., involving the following fabian™ HFOi ventilators.

Details of affected devices

Potentially affected devices: fabian™ HFOi ventilators with software version older than 5.2.1.

Device	REF No.	Description	Serial Number Prefix	Potentially Affected Software Versions
fabian™ HFOi	113001	Neonatal and pediatric ventilator	AI	Software versions older than 5.2.1

Description of the problem: Bias Flow selection buttons unavailable in the User Interface following incorrect selection of device configuration during a software update
Acutronic has received reports that the Bias Flow selection buttons were inaccessible (missing) from the user interface on fabian™ HFOi ventilators. The fabian™ HFOi ventilator user interface includes an internal bias flow button (*bias flow intern*) and an external bias flow button (*bias flow extern*) (please refer to Figure 1). The Bias Flow selection buttons being unavailable has the potential consequence that the administration of inhaled Nitric Oxide to a patient will not be possible, as the external Bias Flow button is not available on the screen to select. The feature to select the Bias Flow mode (internal or external) only exists on fabian™ HFOi devices. Due to that, the Bias Flow selection buttons, in which the Bias Flow can be changed from internal to external and vice versa, is available only on the fabian™ HFOi model (REF 113001). The fabian™ HFO Classic model (REF 112001) is not affected by this issue as the fabian HFO Classic is designed for only external bias flow and does not provide an internal bias flow option.

Root Cause
Investigation determined that this issue **does not represent a fault in the software itself**. Investigation concluded that the issue occurs as a result of human error during the software update procedure, where an incorrect device configuration (based on the device serial number prefix) is selected for the fabian™ HFOi ventilator during a software upgrade. For example, the configuration for a fabian™ HFO Classic device is inadvertently selected when updating the software on a fabian HFOi device. This results in the Bias Flow selection buttons not being visible in the user interface of the HFOi device. The older installation instructions for software upgrades did not include a step to specifically verify the presence of the Bias Flow selection buttons after software installation.

Potential Health Risk

The clinician is unable to switch to external bias flow during HFO ventilation to administer Nitric Oxide to the patient, if needed. Ventilation at set parameters continues to the patient. Neonates requiring administration of iNO therapy may not tolerate a delay in treatment while the clinician sets up an alternative ventilator or attempts to deliver iNO through a different route of administration. In a worst-case scenario, this delay may lead to a potentially life-threatening scenario, such as hypoxia.

FSCA Implementation

Note: Any fabian™ HFOi (113001) ventilator that is already running software version 5.2.1 is not in scope of this FSCA. The 5.2.1 software installation instructions include a specific step to verify the presence of Bias Flow selection buttons in the user interface following the software update. Any fabian™ HFOi device not yet updated to software version 5.2.1 should be updated per FSCA-21-002 at the earliest opportunity. Completion of FSCA-21-002 for any fabian™ HFOi device also completes this FSCA (FSCA-21-004) for that device.

Reminder for FSCA-21-002: To fulfill the requirements of FSCA-21-002, upgrade *any* ventilator in the fabian™ portfolio with a software version older than 5.2.1 to software version 5.2.1 at the earliest opportunity.

Actions being taken by the manufacturer

- Acutronic has investigated and determined the root cause of the observed problem. Reinstallation or an update of the software restores the Bias Flow selection buttons to the fabian HFOi user interface and fully resolves the issue on affected devices. Acutronic recommends updating all fabian™ ventilators, including the fabian HFOi, to the 5.2.1 software according to the instructions given in the *Technical Bulletin TB-0036, Software Update Process fabian™ HFO Models*.

- Acutronic will send the FSCA package which includes: the *Field Safety Notice (FSN)* in English and in national language, *FSCA-21-004 Distributor Response Form*, and *FSCA-21-004 End User Response Form* to all affected distributors.

- Acutronic will also use the attached *FSCA-21-004 End User Response Form* to support acknowledgement of notification and confirmation of device inspection. Where available, Acutronic will use responses for FSCA-21-002 to support execution and completion of this corrective action. 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* and the *FSCA-21-004 End User Response Form*.

- Return the completed and signed *FSCA-21-004 Distributor Response Form* to Acutronic as per the instructions provided on the 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 *FSCA-21-004 End User Response Form* to those recipients and include contact information of those parties in the *FSCA-21-004 Distributor Response Form* for device tracking purposes and further support.

- Identify all fabian™ HFOi devices in your stock as well as those you distributed to end users.

- For any fabian™ HFOi device with software version older than 5.2.1, inspect the ventilator for the

presence of the Bias Flow selection buttons as described in the section "Actions to be taken by the end users" below. If the Bias Flow selection buttons are not present at inspection, update the ventilator software to version 5.2.1 urgently according to the instructions given in the *Technical Bulletin TB-0036, Software Update Process fabian™ HFO Models*. Return all completion records to Acutronic using the email address **GMB-AMS-FSCAresponsecentre@vyaire.com**.

Mandatory: If you install software version 5.2.1 to address this potential issue, provide documented evidence regarding implementation of FSCA-21-002 by returning the fully completed and signed *Completion Data & Verification Record* for FSCA-21-002. Acutronic will use the *Completion Data & Verification Record* to confirm the actions required to complete FSCA-21-002 and FSCA-21-004 are complete.

Note: Any fabian™ ventilator that has a software version older than 5.2.1, including any fabian™ HFOi where inspection showed that the Bias Flow selection buttons are present, must be updated to software version 5.2.1 under implementation of FSCA-21-002.

Actions to be taken by the end users

- Check receipt of the FSCA package, containing this *FSN* and *FSCA-21-004 End User Response Form.*
- Make sure that the complete content of the FSCA package, including this *FSN,* is forwarded immediately to any potential user of the fabian™ HFOi ventilators.
- In case any fabian™ HFOi devices are transferred to another location or organization, make sure to forward the complete FSCA package to the respective users accordingly.
- Determine whether your fabian™ HFOi device already has software version 5.2.1 installed. If your fabian™ HFOi device already has software version 5.2.1 installed, no further action is required for such devices. If you have no devices with software version older than 5.2.1, enter 0 (zero) in the first row of the User Declaration on the *FSCA-21-004 End User Response Form* and return the completed and signed form to **GMB-AMS-FSCAresponsecentre@vyaire.com**.
- For all fabian™ HFOi devices with a software version older than 5.2.1, you need to inspect the ventilator to determine whether the Bias Flow selection buttons are available or not and record the result on the *FSCA-21-004 End User Response Form*. To confirm your fabian™ HFOi is configured correctly, follow these instructions:

  1. Switch on the fabian™ HFOi device and check whether it powers up normally and there are no error messages.

  2. Enter the HFO mode setup screen and view the extended settings.

     If the fabian™ HFOi has been configured correctly during installation, you will observe the screen as shown below, with buttons accessible for external or internal Bias Flow as highlighted (sample screen shows English user interface).

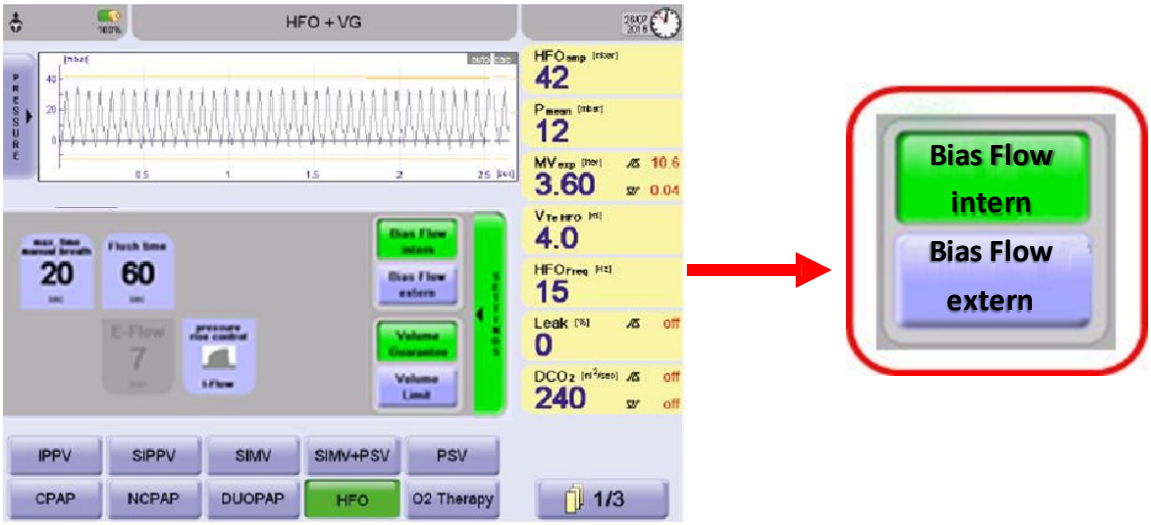

Figure 1: Bias Flow Selection Buttons

3. If you have confirmed that the device has been correctly configured and the internal and external Bias Flow selection buttons are visible in the user interface, record this on the *FSCA-21-004 End User Response Form*. You can continue to use the device as usual according to the Instructions for Use. *Note: Acutronic recommends that software 5.2.1 is installed at the user's earliest convenience to address FSCA 21-002.*

4. If your fabian™ HFOi device has been incorrectly configured and the external or internal Bias Flow selection buttons are not visible/accessible, record this on the *FSCA-21-004 End User Response Form* and please contact your Acutronic/Vyaire service representative urgently to perform a software update to 5.2.1.

- **Mandatory**:

  Fully complete, sign and return the included *FSCA-21-004 End User Response Form* to Acutronic directly using the email address GMB-AMS-FSCAresponsecentre@vyaire.com 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,

…