

# Technical Bulletin

Important Information – Please Read and Keep



## Subject: TB-0035 Release of Software Version 5.2.1

Date: 30/11/2021

Originator: Acutronic Medical Systems AG as part of Vyairé

Distribution: International Distributors – fabian™ Ventilator System

## Release of Software Version 5.2.1

### Addressing the Requirements of FSCA 21-002

(bulletin ref. TB-0035)

Dear Valued Business Partner,

Acutronic Medical Systems AG, as part of Vyairé Medical, is pleased to advise that fabian™ software package 5.2.1 is now released to the market and available to be downloaded from the Acutronic client server (<https://www.acutronic-medical.ch/en/login>) by our authorized distributors for the fabian™ product portfolio. If you do not already have access please complete the registration process.

Software version 5.2.1 is compatible with all versions of fabian™ HFO, fabian™ +nCPAP evolution and fabian™ Therapy evolution devices and is a mandatory software update addressing the requirements of FSCA 21-002.

#### Changes which are included in software release 5.2.1

1. Correction of HFO interrupt issue (FSN issue no.1).
2. HFOi Only – Internal/External Bias flow buttons are now accessible only in HFO mode (FSN issue no.2).
3. Global Alarms Off is no longer accessible during normal operation of the device (FSN issue no.4)
4. GUI freeze triggered by SPO2, ETCO2 and 49 days extended use are now addressed (FSN issue no. 5)
5. In event of a factory reset SPO2 Lower alarm limit will be defaulted to 90%,
6. Correction of a number of Japanese translation issues.

#### FSCA-21-002 – Immediate mandatory action to be taken

The fabian™ software package 5.2.1 addresses a number of the software anomalies, as indicated above, which have been called out in Acutronic field safety notice FSCA-21-002/003.

Installation of fabian™ software package 5.2.1 and provision of the updated IFU is a mandatory action and **MUST** be completed and reported for ALL affected fabian™ devices at the earliest opportunity.

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A completion data & verification record document to record the completion is included in the software update package which **MUST** be completed in full for each device and returned to [gmb-ams-fscaresponsecentre@vyaire.com](mailto:gmb-ams-fscaresponsecentre@vyaire.com) as physical evidence of completion.

**Note:** If you are performing the earlier Power PCB FSCA 21-001 in parallel with FSCA 21-002 please also record the relevant details (including PCB part number and serial number) on the same completion data and verification record.

Additional documentation provided within the software package provides full detail on the changes within the software and the process to follow for installation of software and subsequent calibration and testing.

This is a mandatory action; all devices **MUST** be completed by April 2022.

Note: ALL devices which are affected by earlier fabian™ software field safety corrections (20-001 and 18-004), but which have not been completed, may be directly updated using software package 5.2.1.2 but may require installation of more PIC components. Please refer to the software installation instructions for more detail.

Should you have any questions in relation to FSCA-21-002 or earlier FSCAs please reach out the FSCA response centre [gmb-ams-fscaresponsecentre@vyaire.com](mailto:gmb-ams-fscaresponsecentre@vyaire.com) for clarification.

## **Support:**

**Should you require any technical assistance while performing this software update please reach out to your regional technical support contacts as normal.**

Europe, Middle East, Africa and Canada:

Email: [support.cc.eu@vyaire.com](mailto:support.cc.eu@vyaire.com)

Hotline: +49-931-4972-393

Asia Pacific, Japan, ANZ:

Email: [gmb-apac-ventilation-support@vyaire.com](mailto:gmb-apac-ventilation-support@vyaire.com)

Latin America:

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