Hirzel, 15th of November 2016

Medical Device Urgent Field Safety Corrective Action

Products:
fabian HFO (Art. No. 7200, 7200.i, 7201)
fabian evolution (Art. No. 7250, 7250.N)

Manufacturer:
ACUTRONIC Medical Systems AG
Fabrik im Schiffli
CH-8816 Hirzel

Reason for the Medical Device Urgent Field Safety Corrective Action
ACUTRONIC received a customer complaint. In conjunction with the enabling of the SpO2 option, there are rare cases where the freezing of SPI interface can lead to a situation where the GUI freezes and ventilation stops. The ventilator will alarm with both an alarm sound and a blinking red alarm LED.

Risk to Patient
The ventilation stop may lead to hypoventilation, lung collapse, O2 undersupply and requires the user to switch to another means of ventilation.

Immediate preventive action by device users
For this case we have identified that the freezing of the SPI interface is prevented by disabling the SpO2 option, disconnection of SpO2 module and restarting the device.

Corrective action by manufacturer
We will therefore issue a Software bug fix within 5 weeks. We will inform in due time when this new bug fix will be issued. Until further notice please refrain from using the SpO2 option.

We apologize for any inconveniences caused by this and thank you for your patience, cooperation and support during this period. If you have any questions regarding this letter, please contact your local ACUTRONIC Medical Systems partner.

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