Addendum to the Instructions for Use (valid for all fabian IFU versions up to and including SW V5.2.1)

For fabian HFO, fabian +nCPAP evolution, and fabian Therapy evolution

Acutronic has identified software issues that are being addressed via Field Safety Corrective Action FSCA-21-002 and FSCA-21-003. Please refer to the Field Safety Notice (FSN) FSCA-21-002_FSCA-21-003-FSN-1 for full details of the issues.

Until the appropriate FSCA software (SW V5.2.2) to fully remedy your device is available, take the mitigative actions below. Keep this Addendum together with the device and the original IFU until further notice.

Issue #	Issue	Circumstances necessary for issue to occur	Outcome	Potential Risks due to Issue	Impacted fabian Model	Mitigative Actions
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 pressure during HFO interruption. Mean airway pressure drops by 0.5cmH20.	Hypoxia (transient, temporary)	HFO	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.
		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		
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	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.

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3	No alarm generated on ETT disconnection	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	HFO	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 in most cases under commonly used settings. Therefore, set the alarm limits for Minute Volume alarm or the Pmean alarm as close as possible to the set mean airway pressure.
	⚠ ***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.					
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	HFO +nCPAP evolution Therapy evolution	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.
5	Pressure delivery is below specification with Infant Flow LP circuits	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.	HFO +nCPAP evolution Therapy evolution	Reboot the device to clear the issue. Do not enable the $etCO_2$ or SpO_2 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 #	Issue	Circumstances necessary for issue to occur	Outcome	Potential Risks due to Issue	Impacted fabian Model	Mitigative Actions
6	Graphical User Interface (GUI) freeze	**Pre-4th edition device** MUST be in use along with 1 of the following conditions: Enabling of the etCO2 or SpO2 sensor operation Ventilator run time of 49 days Trend Data (storage, retrieval and management)	Cease in ventilation during use. A high priority watch-dog alarm activates.	In worst case events, Hypoxia or hypercapnia, potentially life-threatening.	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. Mitigation for CPAP: consider titrating up based on assessing work of breathing.
		4th edition or newer device MUST be in use along with 1 of the following conditions: Enabling of the etCO2 or SpO2 sensor operation. Ventilator run time of 49 days Trend Data (storage, retrieval and management)	Monitored values cannot be visualized. Ventilation continues at the previously inputted settings. A high priority watch-dog alarm activates.	Indirect harm; non-clinically significant procedural delay (due to troubleshooting)	HFO	