Ventilation Beyond Limits

ACUTRONIC

Addendum to the fabian™ Instructions for Use for SW V5.2.2

Applies to fabian™ HFO, fabian™ +nCPAP evolution, and fabian™ Therapy evolution

Acutronic Medical Systems AG is supplying this addendum to the fabian™ Instructions for Use (IFU) to provide users with supplemental information to support use of the fabian™ ventilators. This addendum is intended to augment the IFUs regarding three topics.

1. fabian™ Flow Sensor Calibration Requirements
2. Supported Exhalation Membrane Holders
3. Setting up PRICO (Predictive Intelligent Control of Oxygenation)

This addendum supplements the following IFUs.

Table 1

Product	IFU P/N and Revision
fabian™ HFO (113001; 112001; 111001; 111001.01)	113003.XX Date: 17AUG2023 and later
fabian™ Therapy (121001)	121003.XX Date: 17AUG2023 and later
fabian™ +nCPAP (122001)	122003.XX Date: 17AUG2023 and later

1. fabian™ Flow Sensor Calibration Requirements

The Instructions for Use provided with fabian™ ventilators includes instructions for users to install and calibrate the flow sensor prior to use of the fabian™ ventilators. For fabian™ ventilators installed with Software Version 5.2.2, the applicable Instructions for Use and the sections describing requirements for flow sensor calibration are shown in Table 2.

Table 2

Product	IFU P/N and Revision	Section (s)
fabian™ HFO (113001; 112001; 111001; 111001.01)	113003.XX Date: 17AUG2023	6.3 System Start-up 6.4 Device Check 7.1.1 Flow Sensor Calibration
fabian™ Therapy (121001)	121003.XX Date: 17AUG2023	N/A – flow sensor calibration not required
fabian™ +nCPAP (122001)	122003.XX Date: 17AUG2023	6.3 System Start-up 6.4 Device Check 7.1.1 Flow Sensor Calibration

The following Warning (green text) is added to supplement the existing Instructions for Use.

WARNING: Always install and calibrate the flow sensor in accordance with this Operators Manual before using the fabian™ ventilator. Failure to install and calibrate the flow sensor can result in incorrect volume monitoring and false alarms.

Users are reminded to refer to and follow the Flow Sensor Calibration Sections shown in Table 2 when any of the following conditions below are met.

The Flow Sensor Calibration needs to be performed each time:

- A new sensor is put in place.
- After device start-up
- After enabling a Flow sensor (*manual and automatic*)
- After patient range change (***NOTE***: The Flow sensor type must match the patient weight range selected)
- After reconnection of a flow sensor when resolving a disconnection alarm.

ACUTRONIC Medical Systems recommends cleaning the Flow Sensor once daily.

2. Supported Exhalation Membrane Holders

In accordance with the IFU, the exhalation membrane holder must be replaced after 30 sterilization cycles. Acutronic recommends that only the latest polycarbonate membrane holder REF 151520.01 (available since 2018) be used with the fabian™ family of ventilators.

Refer to Section 13.2 of the fabian™ HFO and fabian™ +nCPAP Instructions for Use for the current Exhalation Membrane Holder and Exhalation Membrane. The following text in green is provided to supplement Section 13.2 of the IFU.

WARNING: The metal membrane holder (P/N 151529) and grey membrane holder (P/N 7360), which were discontinued in 2019, should no longer be used. The calibration of the exhalation valve can be affected by the type of membrane holder in use and therefore users are advised not to mix different versions of this part and to use only membrane holder REF 151520.01.

3. Setting up PRICO

The following fabian™ Instructions for Use sections for Setting up PRICO are being revised to provide additional clarity for the use.

- fabian™ +nCPAP and fabian Therapy evolution IFUs: Section 13.4.2
- fabian™ HFO IFU: Section 13.5.2

The text in green is being added to supplement the IFU.

Interdependencies:

- "Min FiO_2" must be lower than "Max FiO_2".
- "SpO_2 low target" must be lower than the "SpO_2 high target".

1. Press the PRICO parameter on the touch screen to select.
   1.1. Adjust the parameter with the Rotary pulse knob. The value will be shown in the button.
   1.2. The bars depicting the range of the FiO_2 and the SpO_2 will be adjusted accordingly.
   1.3. The current SpO_2 and FiO_2 values are indicated with vertical Blue lines.
2. Press the Rotary pulse knob again to confirm the PRICO parameter value.
   2.1. SIQ (Signal quality) is depicted as the red to green vertical scale.
   2.2. The Red line on the SIQ scale indicates the SIQ alarm limit.

3. Before starting PRICO, set the FiO2 starting value.
   3.1. Return to the main screen.
   3.2. Set the O2 parameter. The O2 setting in the main screen will be used as the O2 value in event of an alarm disabling PRICO.

Note: If PRICO is automatically enabled due to clearing of the alarm, PRICO will start from the Back-up O2 value established on the main screen. When PRICO is in use the O2 setting should be checked routinely during care to ensure it is appropriate for the patient's current condition. When PRICO is switched off or disabled due to an alarm condition PRICO will restart at the current O2 setting. Refer to Instructions for Use sections 13.5.4 and 13.5.5 for disabling alarms and PRICO re-enabling conditions, respectively.

The "FiO_2" parameter in the main screen will be used as the Back-up "O_2" in case the PRICO is turned OFF.

The value can be adjusted also when PRICO is ON.