

Addendum to the fabian™ HFO Instructions for Use for SW V5.2.1

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

1. Supported Exhalation Membrane Holders
2. Setting up PRICO (Predictive Intelligent Control of Oxygenation)

This addendum supplements the following IFUs.

Table 1

Product	IFU P/N
fabian™ HFO (113001; 112001)	113003.XX

1. [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 12.2 of the fabian™ HFO Instructions for Use for the current Exhalation Membrane Holder and Exhalation Membrane. The following text in green is provided to supplement Section 12.2 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.

2. [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™ HFO IFU: Section 12.5.2

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

Interdependencies:

- “Min FiO₂” must be lower than “Max FiO₂”.
 - “SpO₂ low target” must be lower than the “SpO₂ 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 Green bars depicting the range of the FiO₂ and the SpO₂ will be adjusted accordingly.
 - 1.3. The current SpO₂ and FiO₂ 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 12.5.4 and 12.5.5 for disabling alarms and PRICO re-enabling conditions, respectively.



The “FiO₂” parameter in the main screen will be used as the Back-up “O₂” in case the PRICO is turned OFF.

The value can be adjusted also when PRICO is ON.