

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To our customers and users of the Fabius with
Auxiliary Common Gas Outlet (ACGO)

Add. device label – ext. fresh-gas outlet / aux. common gas outlet

September 2018

Dear Madam/Sir,

We would like to follow up on the Safety Notice issued by Dräger in October 2017, which addressed that the external fresh-gas outlet / auxiliary common gas outlet on anaesthesia workstations had – in some cases – not been used in accordance to the instructions for use. Therefore, Dräger illustrated the functional principle of rebreathing systems and again highlighted guidelines for the safe use of the external fresh-gas outlet / auxiliary common gas outlet of Fabius anaesthesia machines which are already given in the instructions for use.

Moreover, we already indicated our intention to create a separate device label as an additional reminder to check the setting of the fresh-gas path when starting a mechanical ventilation or ManSpont, (i.e. when using the COSY rebreathing system) in our initial writing.



You will find this new label and a supplement to the Instruction for Use enclosed to this letter. The label consists of a graphical and a textual part/description and it is designed to fit to the ventilator control panel next to the keys for selecting the ventilation modes. There is one label for each variant of the external fresh-gas outlet:

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Swift-Code: NOLADE21SPL

Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7903 HL
General partner: Drägerwerk Verwaltungs AG
Registered office: Lübeck
Commercial register:
Local court Lübeck HRB 7395 HL

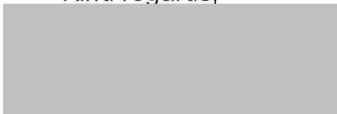
Chairman of the Supervisory Board
for Drägerwerk AG & Co. KGaA
and Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive Board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

	Variant External fresh-gas outlet	External fresh-gas outlet with an additional switch
<i>Description in the IfU</i>	When an automatic ventilation mode (Volume Control, Pressure Control, Pressure Support, SIMV/PS) or the ManSpont ventilation mode is used,connect the short fresh-gas hose to the external fresh-gas outlet.	...set the switch on the external fresh-gas outlet to the COSY position.
<i>Label</i>		

Please select the label that fits your device configuration and the correct language and stick both onto the ventilator control panel as per the instructions on the sticker board.

In case of questions, please do not hesitate to contact your local Dräger contact.

Kind regards,



Alexander Herden

Product Management Life Support Systems
Anesthesiology

Attachment

- Labels for both variants of the ext. fresh-gas outlet
- Supplement to the Instructions for Use