Dräger

Drägerwerk AG & Co. KGaA, 23542 Lübeck

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

October 2017

Important safety notice!!!
Cycled Gas in Rebreathing Anesthesia Systems may become hypoxic

Dear Madam/Sir,

As part of our continued market and product monitoring we have become aware of information suggesting that the use of the Auxiliary Common Gas Outlet (ACGO) at anesthesia workstations of different manufacturers was not performed as described in the instructions for use of the relevant manufacturer, and not according to published safety guidelines (pre-use checklist) from various anesthesia societies. This is reflected in general Safety Alerts published by the MHRA* and ECRI** as well as by post market surveillance data for our own products. As the issue is not solely related to certain device models or manufacturers it must be considered a problem of more general nature as explained hereinafter.

The majority of anesthesia workstations are so-called "rebreathing systems". A certain volume of breathing gas will be circulated in the breathing system during any ventilation mode where the patient is connected to the internal breathing system. The exhaled patient gas is partially fed back into the breathing system, making it necessary to remove the expired CO2 via a soda lime absorber. If the oxygen metabolized by the patient and the CO2 absorbed by the soda lime are not replaced by the fresh-gas flow, the total gas volume in the rebreathing system will decrease with every breath therefore creating a hypoxic gas mixture over time.

Reasons for inadequate fresh-gas flow may be multiple. It can be simply related to the fact that the fresh-gas flow has been set too low, i.e. below the patient's uptake. Another scenario is a leakage inside the system causing fresh gas to escape into the atmosphere. Moreover, a hypoxic gas mixture may occur if the fresh gas does not reach the breathing system because it is channeled to an ACGO.
In the portfolio of Dräger, the Fabius family anesthesia machines do offer a two-step approach to switch over from ACGO mode to mechanical ventilation (refer to advise No. 5 on following page): Switching ON the mechanical ventilation AND toggling the mechanic switch for the fresh-gas path to COSY position (or reconnect the fresh gas inlet hose to the COSY if the device is fitted with the screw-on version without switch). In case the second step will be missed, the ventilator will start moving even so the fresh gas is still channeled through the ACGO. Therefore, we would like to underline the importance of following the measures described in this Safety Notice.

* MDA/2011/108, topic: ACGO at GE Healthcare devices, published December 1st, 2011
** H0360: "Anesthesia Units with ACGO – Incorrect ACGO switch setting may lead to patient harm", published January 19th, 2017

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The **ultimate measure** to prevent hypoxia is **monitoring the fractional inspired oxygen concentration (FiO2)** which has to include an adequate setting of the alarm limit. Every scenario that may lead to an inadequate level of inspired FiO2 will be detected by FiO2 monitoring. This statement is valid for all rebreathing anesthetic machines and thus, is essential part of safety guidelines issued by occupational societies such as "AAGBI Safety Guidelines: Recommendation for standards of monitoring during anesthesia and recovery, 2015" created by the "Association of Anaesthetists of Great Britain and Ireland" (AAGBI). The Dräger Fabius family devices offer internal monitoring of FiO2. The alarm for "FiO2 low" is of high priority, it can't be turned OFF, and the lowest possible value to adjust is at 18 Vol-%.

Please pay attention to the following and instruct your staff accordingly:

1. **Do not use the ACGO functionality of your Fabius device unless you are trained on this feature and have full understanding of its working principle! Before starting a procedure, verify that the manual switch for the fresh-gas path is in the correct position for the intended ventilation method!** The switch lever is marked with engraved position indicators and channels the fresh-gas either to the external outlet (symbol) or to the compact breathing system "COSY" for automatic ventilation. (If your device incorporates the screw-on version without switch reconnect the fresh gas hose to the COSY.)

2. **If you use the Fabius-internal FiO2 monitoring, please make sure that the limit for the FiO2 low alarm is set to an appropriate level** giving you a sufficient response time for intervention when the threshold is exceeded. The factory setting of 20 Vol-% may be inadequate for particular patients!

3. **If you use an external system for FiO2 monitoring instead, make sure that it facilitates the same features as described in the previous clause!** In particular, the "FiO2 low" alarm must not be deactivated, shall be of reasonable priority, and has to be set to an adequate limit.
   Remark: A reasonable capnography trace just tells you that patient's CO2 removal works – it is not reliable as a single indicator for proper oxygenation.

4. **The position where the patient gas sampling is taken from has to be adapted whenever a switch-over from automatic ventilation to use of the ACGO or vice versa is being performed**!

5. Switch the Fabius to "Stand-By", when using the ACGO- Mode. When using the rebreathing system and mechanical ventilation (or Man/Spont), switch the Fabius ON again, and toggle the switch for the fresh-gas path to "COSY" position (or switch the fresh gas inlet hose, respectively).

By following these guidelines, which are completely in line with what is mentioned in your relevant instructions for use, we hope you further enjoy the advantages of your Fabius anesthesia Workstation. In case of questions, please do not hesitate to contact your local Dräger contact.
In order to further highlight the importance of the issues mentioned above, Dräger is investigating the feasibility to create an additional device label as a reminder to check the setting of the fresh gas path when starting to use the rebreathing system.