

To our customers of  
**Dräger Zeus IE / Zeus C500 with  
optional external Fresh Gas outlet  
running on SW2.02**

June 2021

## Important Safety Notice

Missing gas supply failure alarms

### **Only the following products are affected:**

Zeus IE (MK04000) and Zeus RS C500 (MK3000), only devices with SW2.02  
AND the optional external Fresh Gas Outlet (ext. FG-Outlet) are affected.

Dear Sir or Madam,

During our global market surveillance activities, we have become aware of a case in which the red "Oxygen supply fail" alarm was not generated when the O<sub>2</sub> supply pressure dropped below 180 kPa while the Zeus IE was operated in ext. FG-Outlet mode. The investigation identified an error in SW2.02 as the root cause.

According to our software specification a blue alarm message "Oxygen supply low" or "Oxygen cylinder low" plus a single alarm tone will be generated if the supply pressure of your central supply drops below 260 kPa or your back-up cylinder pressure is low.

**If the Zeus IE or Zeus RS C500 is operated in ex. FG-Outlet mode and the central oxygen gas supply pressure decreases below 180 kPa or fails completely, the blue alarm will remain and will not be replaced by the specified "Oxygen supply fail" alarm (and if applicable also by the "Oxygen cylinder empty"-alarm). The device will still automatically switch to 100% AIR as specified to continue ventilation. As a consequence, a lack of O<sub>2</sub> supply might remain unnoticed and the oxygenation of the connected patient might be restricted. As of today, no injury has been reported to Dräger in this context.**

**This software failure also suppresses the respective alarms: "N<sub>2</sub>O supply fail", "Air supply fail", "N<sub>2</sub>O cylinder empty" and "Air cylinder empty".**

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Stefan Lauer  
Executive Board:  
Stefan Dräger (chairman)  
Rainer Klug  
Gert-Hartwig Lescow  
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The **software failure only affects the mode ext. FG-Outlet**. All other ventilation modes are not affected.

**Actions to be taken:**

Dräger has started to develop a software correction. Until the software correction is available, the identified risk must be mitigated by:

Downgrading the Zeus IE / Zeus RS C500 with ext. FG-Outlet to SW2.01

**or**

Deactivating the ext. FG-Outlet.

Your local Dräger representative will contact you to discuss the preferred option and schedule a service.

Since the above-mentioned blue alarm will be posted in any case and information about sufficient supply pressures is visible via LED lights under the device screen and on the configurable information fields displayed on the screen, the devices can be used until either software downgrade is completed or ext. FG-Outlet is deactivated. It is recommended to always check carefully the displayed alarms.

Please ensure that all users of the above-mentioned products and other persons within your organization are made aware of this Important Safety Notice. If you have provided the products to third parties, please forward a copy of this information.

Please keep this information available to all users at least until the mitigation measure has been completed.

The responsible authorities have been notified of this action.

**Identification of the affected medical devices:**

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According to our records you have received a Zeus IE with SW2.02 manufactured by Drägerwerk AG & Co. KGaA that is affected by this issue or your Zeus IE/ Zeus RS C500 has been upgraded to SW2.02.

**Contact:**

If you have any questions, please do not hesitate to contact your local Dräger representative.

We apologize for any inconvenience caused by this matter.

We thank you for your support.

With kind regards



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