

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

## Interrupted gas measurement in Zeus IE anaesthesia devices

March 2019

Dear valued customer,

During our global post market surveillance activities cases have been reported where the gas measurement of Zeus IE anaesthesia workstations became inactive. Our analyses revealed that the deactivations were caused by a too strict supervision of the sample gas pumps which are used in the gas measurement modules. As the characteristic of the pumps changes with their usage time, the supervision system deactivates the gas measurement and a corresponding alarm message appears. Consequently, the probability of a gas measurement deactivation is correlated with the total usage time of the sample gas pumps.

Long-term tests clearly indicate that the gas measurement is reliable for approximately 7 months assuming an average runtime of 84 hours per week. From that point on the probability of a deactivation increases beyond our initial estimations.

Please be aware, that the pump is not only running during times when the Zeus IE is used on patients. Depending on certain settings it is also running during times when it is not used:

- during Standby (if within the "operating time" configurable in the "basic settings" of each Zeus IE)
- during Standby when "Startup dialog" is opened (which is e.g. the case after an automatically started system test)

Our quality promise obliges Dräger to take a preventive action in this matter, to keep the performance levels within expectations.

Therefore, we are going to introduce a mandatory exchange interval of 6 months for the affected pumps until a final solution can be provided. Furthermore, your local Dräger representative will provide you with additional information on how to change the relevant settings ("operating time" and times for automatically started system test) to avoid unnecessary runtime. These steps are required to maintain an acceptable performance level.

The adjustment of the settings does not restrict the readiness of the Zeus IE. It will still be ready for use at any time of the day.

The preventive exchange of pumps ensures that even if the devices were to be used daily 24 hours during the 6 month interval the probability of a gas measurement deactivation would still result in an acceptable risk

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according to all relevant standards and regulations, but it would deviate from our initial product assessment. In case the gas measurement is deactivated during operation, the gas measurement of the Zeus IE will become inoperable and the Zeus IE will generate a corresponding alarm message .

According to our information, you have Zeus IE devices in your facility which are potentially affected. The exchange of pumps and the adjustment of the settings will be provided by Dräger free of charge. Your local Dräger representative will contact you to arrange an appointment.

We apologise for the inconvenience caused by this issue and by the implementation of the measures outlined above.

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

With kind regards,



Moritz Rahlf-Luong

Product Management Anaesthesia