

**To all customers of the ZEUS IE  
anesthesia workstation**

May 2014

**Important Safety Notice!!!**

**ZEUS IE with integrated patient monitoring ,  
software version 1.03**

Dear Madam/Sir,

Within the framework of our international market surveillance activities, we have become aware of an incident in which no SpO<sub>2</sub>-low alarm was given despite a SpO<sub>2</sub> value measured below the SpO<sub>2</sub>-low alarm threshold. There was no injury reported.

During the course of the investigation a software error was discovered. The integrated Patient monitoring system of the Zeus IE is designed to generate an audible and visual alarm, when the measured value falls below the alarm threshold set for the SpO<sub>2</sub> low alarm by the clinician. If the measured value continues to fall, the device is designed to continue to generate a SpO<sub>2</sub> low alarm. But if the measured value drops below the SpO<sub>2</sub> low alarm threshold by more than 10 percent, the audible and visual alarm for SpO<sub>2</sub> low will stop. If the value measured rises again, the alarm will be generated again as soon as the measured value is ten percent or less below the SpO<sub>2</sub>-low alarm threshold.

During the reported situation, the patient's actual SpO<sub>2</sub> values were more than 10 percent below the set SpO<sub>2</sub> threshold right from the beginning of the measurements and no SpO<sub>2</sub> low alarm was generated. The initial alarm would only be generated if the measured SpO<sub>2</sub> value is not more than 10 percent below the set SpO<sub>2</sub> low alarm threshold.

However, all displayed measurements of values and SpO<sub>2</sub> curves are performing as designed at any time.

Dräger Medical GmbH  
Moislinger Allee 53-55  
23558 Lübeck, Deutschland  
Postanschrift:  
23542 Lübeck, Deutschland  
Tel. +49 451 882-0  
Fax +49 451 882-2080  
info@draeger.com  
www.draeger.com  
UID-Nr. DE813745277

Bankverbindungen:  
Commerzbank AG, Lübeck  
Konto-Nr. 014 679 500  
BLZ 230 400 22  
IBAN DE95 2304 0022 0014 6795 00  
SWIFT-Code COBADEFF230

Sparkasse zu Lübeck  
Konto-Nr. 1 071 117  
BLZ 230 501 01  
IBAN DE15 2305 0101 0001 0711 17  
SWIFT-Code NOLADE21SPL

Sitz der Gesellschaft: Lübeck  
Handelsregister:  
Amtsgericht Lübeck HRB 4358 HL

Vorsitzender des Aufsichtsrats:  
Professor Dr. Nikolaus Schweickart

Geschäftsführer:  
Stefan Dräger (Vorsitzender)  
Dr. Herbert Fehrecke  
Andreas Frahm  
Gert-Hartwig Lescow  
Anton Schrofner

The situation was corrected in software version 1.04; only devices with software version 1.03 are affected.

Zeus *IE* workstations without the “integrated patient monitoring” option are not affected, Your local Dräger Service representative or our service partner will contact you to schedule a time to perform the software update.

Until the software update is implemented, you may continue to use your Zeus *IE* workstations. We suggest that you take the following precautionary measures:

- Inform all users within your organization of the potential missing SpO<sub>2</sub> low alarm;
- Observe continuously the displayed SpO<sub>2</sub> measurements and curves in case of falling SpO<sub>2</sub> values measured particularly following a SpO<sub>2</sub> low alarm; and
- if possible consider different parameters for evaluation of the patient status.

Dräger is committed to customer satisfaction and patient safety. We apologize for any inconvenience this action may cause and appreciate your patience and cooperation. The competent authorities have been notified of this action

If you have any further questions, please contact your local Dräger representative.

With kind regards



Vice President  
Anesthesiology  
Product & Application Management