

Dräger Medical AG & Co. KG, 23542 Lübeck

To all customers and users of  
the Dräger anaesthesia workstation system  
"Zeus Infinity Empowered"

Management or administrative department (medical technology)

July 2010

## Important Safety Notice!

**Internal device monitoring switches to "Safety Settings"  
Memory reset urgently needs to be performed by DrägerService  
Affected product: Zeus Infinity Empowered units installed since October 2009  
(only "Infinity Empowered" Zeus systems are affected!)**

Dear Madam/Sir,

Within the framework of our worldwide product surveillance activities, we have been informed about isolated cases in which the integrated Zeus IE monitoring software has resulted in the device switching to "Safety Settings". We were recently notified that this switching/safety function occurred in three devices in one hospital on one day. No patient/nobody was injured.

The cause analysis that was immediately initiated revealed a memory problem in the processor of the Cockpit C500. Due to a faulty software component in the operating system, more and more memory space is continually used up as the device is operated. After approximately 850 hours of operation, this can result in the failure of individual display elements on the screen. The internal device monitoring of safety-relevant displays and parameters detects this display problem and reacts by posting an alarm message on the screen, sounding an audible alarm/emergency alarm, and switching to "emergency mode" as described in the Instructions for Use (O2 emergency flow, shutdown of anaesthetic gas, check ventilation).

The investigation also showed that a "memory reset" urgently needs to be carried out by DrägerService as an initial short-term remedial measure, even if the activation of the emergency mode does not cause any direct risk to the patient.

The memory reset must be performed by DrägerService due to the fact that the memory problem cannot be resolved simply by switching the Zeus IE off and then on again!

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The measure to correct the identified faulty software component is already at the verification/validation stage and will be available in the near future.

We would like to apologize for any inconvenience this measure may cause, and thank you in advance for your assistance.

The competent authorities have been informed about this corrective measure.

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

With kind regards  
Dräger Medical AG & Co. KG  
Vice President Quality & Regulatory Affairs

