



Dräger Medical GmbH, 23542 Lübeck

**To our customers and users  
of the Infinity® Acute Care System (IACS) Monitoring Solution  
in neonatal areas, only**

November 2013

**Important Safety Notice!**

**Infinity® Acute Care System (IACS) in Neonatal Mode:  
No Life-threatening SpO2 desat alarm if low SpO2 alarm was paused  
Software versions VG2.0.3 and higher are affected only**

Dear Madam or Sir,

Within our product surveillance activities we were informed about a laboratory test in which a low SpO2 (yellow) medium grade alarm was provoked and subsequently paused by the user by using the alarm pause function. In this test the SpO2 value was further decreased to reach the set alarm limit for the high grade life threatening SpO2 alarm. Other than expected, the IACS did not generate the SpO2 (red) high grade life threatening SpO2 low alarm on the cockpit and did not on the central station; only the M540 showed the red signal. The correct SpO2 value is indicated on all devices.

Dräger is not aware of any occurrence during use on patient.

Dräger was able to reproduce the reported behavior and determined the root cause to be a software issue with software versions VG2.03 or higher. This IACS behavior happens only in Neonatal Mode. Pediatric or Adult Mode does not have this latching alarm feature for SpO2 desaturation, thereof the problem cannot occur with these modes.

Dräger is in process to develop a new software version to fix this defect. It is planned that this software will be available in March 2014. Your sales and service representative will contact you and carry out the update free of charge on IACSs used in your neonatal care area.

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Seite 2 / 2

Until the fix is implanted in your systems, we highly recommend not to pause the yellow SpO2 low alarm, without adequate patient surveillance as the high grade life threatening alarm will not be initiated for that alarm situation on the cockpit.

Please distribute this Safety Information to users in your neonatal care units to make them aware of the device behavior and this risk mitigation measure.

We apologize for any inconvenience this action may cause and appreciate your patience and cooperation.

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



President  
Key Application Field Monitoring & IT