

Dräger Medical AG & Co. KG, Moislinger Allee 53-55, D-23558 Lübeck

December 2005

To Customers and Users of

Dräger Neonatal Respirator Babylog 8000plus (Babylog 8000 with SW 5.n only)

Important Safety Notice!

Possible disconnection alarm failure with very low PEEP

Dear Sirs,

Within the frame work of our world wide post market surveillance activities, we have been made aware of an incident that occurred in France involving the Babylog 8000plus (Babylog 8000 with SW 5.n). Using a PEEP equivalent to 0 mbar, the Babylog 8000 failed to generate an alarm when unintended disconnection of the patient occurred between flow sensor and endotracheal tube.

Our investigations have revealed that with very low PEEP settings, a disconnection of the patient system is not reliably detected or alarmed. In such cases, the slight differences from the ambient pressure do not allow reliable detection based on pressure monitoring. This problem affects only the Babylog 8000 with SW 5.n!

Although we consider it extremely unlikely that the device would behave in such a way, we feel it necessary to inform you of the situation and make you aware of the following requirement:

When using the Babylog 8000 (with SW 5.n) and PEEP settings below 2.5 mbar, an additional method of patient monitoring (e.g. respiration, SpO2) must be employed so that a patient disconnection and/or its direct consequences are reliably detected and appropriately alarmed. Please advise all affected users in your company of this action!

As a further technical measure, Dräger Medical is currently developing a modification to the control, which, if a PEEP of less than 2.5 mbar is set, will deliberately enable this range. In the meantime, we stress the need to employ an additional method of patient monitoring. This solution is expected to be available in March 2006.

With regard to the update for your device(s), our service organisation will contact you shortly to agree an appointment for the conversion to be carried out free of charge.

We apologise for any inconvenience caused but feel this action is a necessary, preventive measure for increasing patient safety. Please do not hesitate to contact your usual contact person at DrägerService if you have any further questions.

Yours sincerely

Dräger Medical AG & Co. KG
General Manager of Intensive Care Business Unit



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