Dräger

Drägerwerk AG & Co. KGaA, 23542 Lübeck

To the customers and users of the emergency breathing devices Oxylog 3000, Oxylog 3000 plus and Oxylog 2000 plus

November 2015

Important safety information!!!

Oxylog 3000, Oxylog 3000 plus and Oxylog 2000 plus
Failure of ventilation function with "Poti unplugged" error message

Dear Madam/Sir,

As part of our product monitoring we have become aware of situations where the error message "Poti unplugged" was generated. In these cases, an acoustic and visual alarm is generated, the breathing system release pressure and the ventilation function stops operating. Personal injury was not reported in any of these situations.

Our investigations showed that the error message is caused by increased electrical contact resistance of the controllers (adjustment potentiometers). The increased resistance is the result of an oxide layer on the controllers, which accumulates over a longer period of time. This oxide layer can only accumulate if the controllers are moved rarely or never. Our product monitoring has shown that some users rarely use the FiO2 controller or do not use it at all.

As a preventive measure, we therefore highly recommend to move all controllers once when the device is switched off; at least 10 times to the left and right stop (minimum and maximum value). This measure suffices to clean the resistance taper of the controllers sufficiently.

In particular with the error "Device malfunction – Poti unplugged", this method can also be used to put the device back into operation.

This letter includes a **supplement to your instructions for use**.

This supplement expands the test for operational readiness in such a way that all controllers must be operated once every time the device is put into operation.

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May we remind you that the Oxylog must only be used after verifying its operational readiness. Please include this supplement with your instructions for use and inform all affected users in your hospital.

We regret any inconvenience this information may cause but consider it necessary as a preventive measure to increase patient and user safety.

We thank you for your support.

With best regards,

[redacted]

Drägerwerk AG & Co. KGaA

Annex:

- Supplement instructions for use