

Urgent Medical Device Recall

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

December 21, 2015

Risk Manager
Cc: Director of Clinical Engineering

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 releases 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 can accumulate over a period of time. This oxide layer can only accumulate if the controllers are rarely adjusted.

As a preventive measure, we therefore highly recommend that you perform the following as soon as possible: With the device switched off, rotate all controllers at least 10 times to the left and right stop (minimum and maximum value). This measure has shown to sufficiently clean any oxide layer that may have accumulated on the contacts of the controllers.

Additionally, with the error "Device malfunction – Poti unplugged", performing the above can resolve the condition and allow the unit to put back into operation after successfully passing the device check.

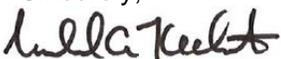
Our records indicate that at least one of the referenced devices was shipped to your facility. Enclosed with this letter is a **supplement to the Oxylog series Instructions for Use (IFU)**. This supplement expands the test for operational readiness in such a way that all controllers must be operated once every time the device is put into operation. We also remind you that the Oxylog must only be used after verifying its operational readiness.

Please include a copy of this supplement (Draeger Part Number 9055466) with your Oxylog Instructions for Use and inform all affected users in your facility. If you require additional copies, please contact Draeger Customer Support at 1-800-543-5047 (press 4 at the prompt) to order additional quantities. Additional quantities will be provided free of charge.

We apologize for any inconvenience this action may cause, but believe these measures to be essential in the interests of patient safety. If you have any questions regarding this letter please contact Michael Kelhart at 1-800-543-5047 (press 1 at the prompt, then 2, then 32349). For questions regarding the operation and/or servicing of your Dräger Oxylog ventilator please contact DrägerService Technical Support at 1-800-543-5047 (press 4 at the prompt).

The US Food and Drug Administration has been advised of this action.

Sincerely,



Michael A. Kelhart
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