

Drägerwerk AG & Co. KGaA, 23542 Lübeck

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

December 2016

Important safety information!!!

**Oxylog 3000, Oxylog 3000 plus
Failure of ventilation function with "Control knob faulty" error message**

Dear Madam/Sir,

In December 2015 we informed you about an error condition observed in the market with products of the Oxylog 3000 family, where the loss of contact of one of the control knobs generates an error message (previously referred to as "Poti unplugged"). In these cases, acoustical and visual alarms are triggered, the breathing system releases pressure and the ventilation function stops operating. Personal injury was not reported in any of these situations.

Our investigations indicate that the error condition is caused by an oxide layer in the potentiometer. These oxide layers may accumulate over a longer period of time if various factor collude i.e. if the knobs are moved rarely or never. A verified remedy is repeated twisting of the knobs that removes the oxide layer. This recommendation was described in the previous Safety Notice.

However, this particular error condition was still reported from the field after the Safety Notice. The remedy of twisting the knob is still considered effective. Nonetheless, to reduce the impact of this special error condition Dräger has developed a new software that reduces the impact of the error condition.

Software version 1.06 will now be introduced for Oxylog 3000plus, version 1.23 for Oxylog 3000, respectively.

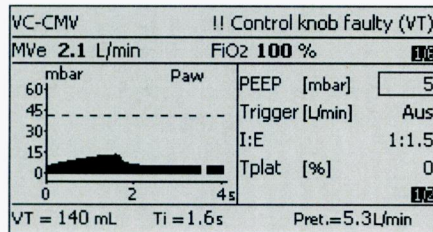
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Whenever a “Control knob faulty” condition will occur with a device being equipped **with the new software the device will continue to ventilate with the last valid settings**, display for example the values for tidal volume in case of a defective potentiometer for VT and post the corresponding alarm (see Picture below)



As reflected in the amended IfU you are advised to check patient's condition and the ventilation.

Your local Dräger Service representative or our service partner will contact you to schedule a time to perform the software update.

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

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

We thank you for your support.

With best regards,

Michael Großmann
Head of Product Management
Life Support Systems – Respiratory Care

Drägerwerk AG & Co. KGaA