Dräger

Urgent Medical Device Recall

Oxylog 3000 Plus, Model 5704811 and Oxylog 3000 System, Model 2M86955

Failure of Ventilation Function with "Poti Unplugged" Error Message

December 8, 2016

Attention: Risk Manager
Cc: Director of Biomedical Engineering, Department of Anesthesia and Respiratory Care

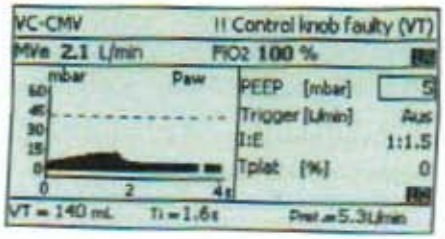
Dear Madam/Sir,

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 controllers (adjustment potentiometers) 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. There were no injuries reported in any of these situations.

Our investigations indicated that the error condition was caused by an oxide layer in the controller. These oxide layers may accumulate over a longer period of time as a result of various factors, i.e.; if the controllers are moved rarely or never. A verified remedy is the rotating of the controllers, which removes the oxide layer. This recommendation was described in the previous Medical Device Recall Notification.

However, this particular error condition was still reported from the field after the issuance of the Recall Notification. The remedy of rotating the controllers is still considered effective, however, to reduce the impact of this special error condition Draegerwerk AG & CO. KGAA has developed revised software (version 1.06 for Oxylog 3000 Plus, Model 5704811 and version 1.23 for Oxylog 3000 System, Model 2M86955) that reduces the impact of the error condition.

With the revised software, if a "Control knob faulty" condition occurs **the device will continue to ventilate with the last valid settings** and post the corresponding alarm. For example, in case of a faulty Tidal Volume (VT) potentiometer, the device will display the last VT setting in the lower left corner and post a Control knob faulty (VT) alarm message. Please refer to the below illustration:



As reflected in the amended Instructions for Use (IFU) you are advised to check patient's condition and the ventilation.

Our records indicate that at least one of the referenced devices was shipped to your facility. You will be contacted by a DrägerService Representative to schedule a time to perform the software update. The software update will be provided free of charge.

For the Director of Biomedical Engineering, Head of Anesthesia Department and Respiratory Care Department at your site using the Oxylog 3000 Plus, Model 5704811 and Oxylog 3000 System, Model 2M86955 with complete and return the attached **Acknowledgement Form** to Draeger Medical Canada Inc. via email at canada.complaints@draeger.com within the next 3 business days as an acknowledgement of:

- Receipt of this Recall and
- Understanding of the information contained within this Letter

Please share the information in this Recall with your staff. Please ensure that all personnel who operate the Oxylog 3000 Plus, Model 5704811 and Oxylog 3000 System, Model 2M86955 are aware of this Recall.

Any adverse events or complaints experienced with use of this product should be reported to Draeger Medical Canada Inc.. The Medical Device Bureau of Health Canada has been informed of the recall.

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 Zovinar Boghossian at (905) 212-6530. For questions regarding the operation and/or servicing of your Draegerwerk AG& CO. KGAA the Oxylog 3000 Plus, Model 5704811 and Oxylog 3000 System, Model 2M86955, please contact DrägerService Technical Support at 1-800-543-5047 (press 4 at the prompt).

Sincerely,

Zovinar Boghossian
Country, Quality & Regulatory Affairs Manager
Draeger Medical Canada Inc,

Draeger Medical Canada, Inc.
2425 Skymark Ave., Unit 1
Mississauga, L4W 4Y6
Tel: (905) 212-6530
Fax: (905) 763-1890

Oxylog 3000 Plus, Model 5704811 and Oxylog 3000 System, Model 2M86955 Acknowledgement

RETURN Via Email To: canada.complaints@draeger.com

Please read this acknowledgment and complete all information below.

I certify that I have been informed of the Medical Device Recall related to **the Oxylog 3000 Plus and Oxylog 3000 System.**

Product Serial Number: _____

Account Name: _____

Name of BioMed/Representive of Department: _____

Street Address: _____

City: _____

Country, Postal Code: _____

Signature: _____

Date: _____

Complete if appropriate:

☐ This **Oxylog 3000 Plus and Oxylog 3000 System** been transferred to another facility

Facility Name: _____

Street Address: _____

City: _____

Country, Postal Code: _____

Please return this acknowledgement to Draeger Medical Canada Inc. within 3 business days.

Draeger Medical Canada, Inc.
2425 Skymark Ave., Unit 1
Mississauga, L4W 4Y6
Tel: (905) 212-6530
Fax: (905) 763-1890