Dräger

Drägerwerk AG & Co. KGaA, D-23542 Lübeck

To the customers and users of the paediatric ventilation hoses VentStar Oxylog3000F (P) 190

May 2016

Important safety notice!!!

Disposable paediatric ventilation circuit VentStar Oxylog3000F (P) 190 for Oxylog 3000 and Oxylog 3000 plus
Affected date of manufacture up to 03-2016, part number 5704964
Potential for rebreathing with reduced oxygen concentration

Dear Madam/Sir,

During the course of routine internal testing, we detected isolated leakages at the check valve (one way valve of the inspiration branch) of the above mentioned disposable paediatric ventilation circuit. Affected circuits with this fault were potentially distributed to customers.

All other ventilation circuits for the Oxylog family of devices are not affected.

Leakage at the check valve can result in patient's exhaled gas entering into the breathing circuit, which could lead to the rebreathing of the exhaled gas with reduced oxygen concentration for the patient. This leakage is not detected during the ventilator operational readiness check! To date, we have not received any complaints associated with this issue.

Further detailed investigations have shown that the check valve functions properly with no leak observed at positive end-expiratory pressures above 5 mbar / cmH2O. The problem only occurs at PEEP values below 5 mbar / cmH2O.

We urgently recommend that you immediately inspect any stock and dispose of any product (part number 5704964) with a date of manufacture up to and including 03-2016. Free of charge replacement product can be obtained by completing and returning the attached "Customer Reply and Order Card".

You can see the date of manufacture on the packaging label.

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If it is absolutely necessary to use affected ventilation circuits prior to receiving replacements, we recommend only using the circuits at a PEEP setting of >5 mbar / cmH2O, provided that a PEEP setting of >5 mbar / cmH2O is appropriate from a medical point of view. Additionally, we recommend for this use case the use of external CO2 monitoring by means of a paediatric cuvette and CO2 mainstream sensor.

We regret any inconvenience this has caused, but consider it necessary as a preventive measure to increase patient safety.

Thank you for your cooperation and support.

Sincerely,

Arno Wolters
Head of Product Management
Drägerwerk AG & Co. KGaA

Attachment:

- Customer Reply and Order Card