

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.

Drägerwerk AG & Co. KGaA
Moislinger Allee 53-55
23558 Lübeck, Germany
Postal address:
23542 Lübeck, Germany
Tel. +49 451 882-0
Fax +49 451 882-2080
info@draeger.com
www.draeger.com
VAT No. DE135082211

Bank information:
Commerzbank AG, Lübeck
IBAN: DE95 2304 0022 0014 6795 00
Swift Code: COBA DE FF 230
Sparkasse zu Lübeck
IBAN: DE15 2305 0101 0001 0711 17
Swift Code: NOLADE21SPL

Company headquarters: Lübeck
Commercial register:
Municipal Court Lübeck HRB 7903 HL
General Partner: Drägerwerk Verwaltungs
AG
Company headquarters: Lübeck
Commercial register:
Municipal Court Lübeck HRB 7395 HL

Chairman of the Supervisory
Board of
Drägerwerk AG & Co. KGaA and
Drägerwerk Verwaltungs AG:
Professor Dr. Nikolaus
Schweickart
Executive Board:
Stefan Dräger (Chairman)
Rainer Klug
Gert-Hartwig Lescow

Page 2 / 2

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