

**To the customers and users of
heated Dräger breathing circuits**

May 2020

Important safety notice!!!

Combinations of breathing circuits with humidifiers

Product affected:

Only heated Dräger breathing circuits are affected

Dear Sir or Madam,

As part of our global product monitoring, Dräger has become aware of a case in which a VentStar Helix heated breathing circuit was used together with a Fisher & Paykel MR810 humidifier. This product combination is not approved. The humidifier used did not detect previously unexplained damage to the heating wire of the VentStar Helix Heated. This led to the ignition of the breathing gas and the affected patient suffered burns.

If Dräger breathing circuits are used with humidifiers other than the Fisher & Paykel MR850 humidifier indicated in our instructions for use, patients and/or users can be injured if an error occurs.

The Fisher & Paykel MR850 humidifier has control functions that would have disconnected the power supply and generated an alarm if the above error had occurred.

Make sure that all heated Dräger breathing circuits are only used together with the Fisher & Paykel MR850 humidifier indicated in the instructions for use

Please inform all relevant users in your hospital.

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

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Drägerwerk Verwaltungs AG:
Stefan Lauer
Executive board:
Stefan Dräger (chairman)
Rainer Klug
Gert-Hartwig Lescow
Dr. Reiner Piske
Anton Schrofner

With many thanks in advance for your support.

Yours faithfully,

A handwritten signature in blue ink, appearing to read 'M. Kämer', is placed over a light gray rectangular background.

Markus Kämer
Senior Product Manager
BU Hospital Consumables & Accessories
Drägerwerk AG & Co. KGaA

A handwritten signature in blue ink, appearing to read 'Oliver Möller', is placed over a light gray rectangular background.

Oliver Möller
Deputy Safety Officer for Medical Devices
Post Market Surveillance
Drägerwerk AG & Co. KGaA