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To whom it may concern

Unser Zeichen

Ambient air _02--KM

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Filtration Efficiency of Ambient Air Filters for Savina, Savina 300, Carina, Gas supply unit GS500 for V-series and Oxylog 2nd Update

Dear Sir or Madam,

The following information relates to ventilation devices from Dräger using ambient air for the patient breathing gas.

Savina, Savina 300, Carina and Gas supply unit GS500 for V-series:

Due to the use of turbine technology the Dräger ventilators Savina, Savina 300, Carina and GS500 for V-series protect the patients and the device itself against possible infections coming from ambient air using gas inlet filters.

The following filters are used:

- Savina and Savina 300,
GS500 for V-series : micro filter with part no. 6737545
- Carina: micro filter with part no. 5703105

Both fulfill very high requirements for medical use. The Savina / Carina / GS500 micro filters have been designed to efficiently filter particles with a size from 0,1 to 0,3 µm, e.g. SARS-CoV-2 infected particles.

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In this size range the Savina / Carina / GS500 micro filters with an efficiency of E12/H13 fulfill very high requirements for medical use. For further information refer to the table below.

Particles size	Filter class	Minimum efficiency
greater than 0,4 µm	H13	99,95%
with a size of 0,2 µm	E12	99,5%
smaller than 0,09 µm	H13	99,95%

Replacement interval:

The replacement interval for gas inlet filters remains as specified by the according instructions for use:

- Savina and Savina 300, GS500 for V-series: 12 months
- Carina: 6 months

V-series ventilator with gas supply unit GS500:

V-series ventilators are the following devices:

Evita V800, Evita V600, Evita Infinity V500, Evita V300, Babylog VN800, Babylog VN600 and Babylog VN500. All of the named devices have the option gas supply unit GS500.

In order to ensure a continuous compressed air supply, the device can be equipped with the GS500 gas supply unit. If the device is connected to the central gas supply system, the gas supply unit guarantees the device is supplied with compressed air in case the central supply fails. In case of a continuous operation with GS500 is done, the service life of the blower unit inside of the GS500 can be limited.

Oxylog family ventilators:

Devices of the Oxylog family provide a dust filter for ambient air only. To protect the device against possible infections in contaminated environment the FiO2 setting must be set to 100% (as requested for this case in the Instructions for Use). For protection of equipment, users and patients it is recommended to use a Breathing System Filter (BSF) at the y-piece.

Recommendation:

For a maximum protection of equipment, users and patients it is recommended to use additional Breathing System Filter (BSF) at the y-piece as common clinical practice.

Additional Remark:

Based on the individual situation, the hospital management responsible for infection control and epidemiology has the task to decide on the required measures. The measures described above are intended for devices used in the recommended manner. In justified cases of doubt we recommend the safe disposal of contaminated components.

This letter does not replace the reading of the respective Instruction for Use.

Kind regards,

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