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To whom it may concern

Our reference
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COVID-19: Usage of Dräger Oxylog Emergency Ventilators for long-term ventilation

Dear customers, dear health care professionals,

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11th, 2020. The pandemic has created a high demand for mechanical ventilation that may exceed the number of available ICU ventilators in hospitals treating patients with the disease. In the last few days many customers and health care professionals approached us, to obtain information about possibly using Dräger Oxylog emergency and transport ventilators for long-term ventilation as an alternative ventilator when existing devices are fully utilized and there is no other ventilator option.

Against these special circumstances, we believe it is our responsibility to provide some insights both (i) on the legal and regulatory perspective as well as (ii) on some known limitations of Dräger Oxylog emergency and transport ventilators for long-term ventilation.

I. Legal and Regulatory Perspective

WARNING: The following information on the legal and regulatory perspective is limited to the laws in force in the European Union (EU) as of the date of this letter and provides only general guidance. Please contact your legal counsel for guidance on your particular case.

The intended use of each Dräger Oxylog emergency and transport ventilator is described in the dedicated instructions for use. Although the wording of the intended use may vary in between the devices Oxylog 1000, Oxylog 2000, Oxylog 2000plus, Oxylog 3000, Oxylog 3000plus and Oxylog VE300 the content is very similar: The devices are specified for ventilating patients in prehospital and intrahospital emergencies and transport conditions under constant supervision of users.

Any use of the device outside of the intended use specified in the instructions for use (e.g. long-term ventilation) constitutes off-label use.

If a device is used off-label, the user recognizes that it is not the intended use of the device and does so in his own responsibility and at his own (liability) risk. However, in a situation in which a patient requires long-term mechanical ventilation but cannot be ventilated due to a lack of intensive care ventilators, the benefit of being able to ventilate such a patient with a Dräger Oxylog emergency and transport ventilator has to be weighed against the risk of the off-label usage of the Oxylog. This risk benefit assessment and the resulting decision has to be made by the responsible health care professional based on the circumstances of the particular case.

II. Known Limitations of Dräger emergency ventilators Oxylog regarding use in long-term Ventilation

WARNING: Dräger as the manufacturer cannot and may not market or promote or sign-off such off-label use of different types of Dräger Oxylog emergency and transport ventilators. The following information is therefore provided only to provide a better basis for the decision of the responsible health care professional. If a device is used off-label, the user does so in his own responsibility and at his own (liability) risk.

- Oxylog emergency and transport ventilators have a limited performance and a different user interface compared to intensive care ventilators. Therefore **medical personnel using the device must be trained and familiar with the specific characteristics of the devices.**

- Before connecting a patient the user must be able **to check the devices with the system test** and ensure that all accessories (e.g. ventilation hoses, filters) are properly connected.

- The alarm and safety concept of Dräger Oxylog devices is designed for a **permanent presence of the user**. This facilitates fast recognition and response in the event of an alarm or in the event of any malfunction. In case of situations in which a user is not within direct proximity of the device it has to be ensured that
    - the **alarm volume is set to maximum (100%)** to increase the probability that potentially live threatening situations are recognized in time.
    - if available the **built-in ventilation monitoring is activated**, e.g. monitoring of the expired volume.
      Due to missing further monitoring parameters which are state of the art for intensive care ventilators the user **should always consider using additional monitoring**, e.g. CO2 or SpO2. Monitoring of a patient's condition can range from direct observation to electronic monitoring by means of medical devices.
    - a **bag valve mask resuscitator must always be available at the device** which enables back-up ventilation of the patient in case of problems or malfunctions.

- Dräger Oxylog devices which are powered by batteries allow ventilation for few hours only. For longer ventilation periods those devices **must continuously be connected to an AC/DC power supply**.

- Dräger Oxylog devices are mixing ambient air and O2 when using FiO2 settings <100%. Therefore use only **100% O2 setting in contaminated environments** to protect patients, user and devices from contamination. For a maximum safety of equipment, users and patients it is recommended to **use additional Breathing System Filters (BSF)** between the breathing hose and the tube of the patient.

- Patients undergoing long-term ventilation need humidification of the breathing gas to protect the lung from drying-out. Active humidification is not approved with Dräger Oxylog emergency and transport ventilators. **Passive humidification with a Heat and Moisture Exchanger (HME) is recommended and approved**. In the latter case the HME correction should be set to 'On' for Oxylog 3000plus and Oxylog VE300 to provide accurate tidal volumes.

If you have any questions or remarks to this topic, please do not hesitate to contact your local Dräger representative.

With kind regards,

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Risk Manager	Life Cycle Manager	Product Management Respiratory Care