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Our reference

COVID-19-Ox93 – Respiratory Care

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To whom it may

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Use of Dräger ventilators with Oxygen 93

Dear customer, dear health care professional,

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 to supply Dräger ventilators with oxygen 93% generated by oxygen concentrators instead of oxygen 100%. Dräger ventilators are generally specified to be operated with a high-pressure oxygen source with a concentration of at least 99,5% (Oxygen 100).

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 operating Dräger ventilators with Oxygen 93%.

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.

According to the instructions for use Dräger ventilators must be operated with the supply of oxygen with an oxygen concentration of 100%.

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Any use of the device outside of the intended use specified in the instructions for use (e.g. ICU) 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, the COVID-19 pandemic leads to situations which requires ventilators to be operated in environments where the specified oxygen supply may not be available. The benefit to ventilate the patient with a ventilator supplied with oxygen 93% has to be weighed against the risk of the off-label usage of the ventilator. 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 ventilators operated with Oxygen 93

WARNING: Dräger as the manufacturer cannot and may not market or promote or sign-off such off-label use. 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.

Oxygen 93 is generated by oxygen concentrators and has a lower percentage with a typical concentration of 93% ($\pm 3\%$). Oxygen 93 can be supplied to a common high-pressure central gas supply system.

In case that a Dräger ventilator, which is only specified for 100%, is used with oxygen 93 will not achieve all specifications provided in the instructions for use, or accuracies required by international Standards. Consequently, these ventilators have not been approved by authorities for use with oxygen 93. Using these ventilators with oxygen 93 would therefore be regarded as an off-label use carried out by the user under his sole responsibility.

Classification of Dräger ventilators:

1. The following Dräger ventilators are not specified for Oxygen 93%:
Evita-Family ventilators, Savina-Family ventilators, Carina and Oxylog 3000plus ventilators.
2. The emergency ventilator **Oxylog VE300** is specified for both, oxygen 100% and oxygen 93%.

In case that above listed ventilators, which are not specified for oxygen 93, are used with oxygen 93 typically the following deviations from the specified behavior of the device can occur:

1. Real inspiratory O₂ concentration lower than the setting

As a consequence of the lower oxygen content of oxygen 93, the oxygen concentration of the inspiratory breathing gas will be lower than the setting. The deviation will be highest at O₂ concentration > 80% and decrease with lower settings and will be zero at 21%.

Due to the described deviation the achieved inspiratory oxygen concentration (FiO₂) is outside the specification according to the related IFUs and therefore not in compliance with international standards.

2. Influence of displayed measured inspiratory O₂ concentration FiO₂

Usually oxygen sensors of the ventilators will be calibrated with an oxygen concentration of 100%. As a result, the calibration of oxygen measurement with oxygen 93 is incorrect. The measured FiO₂ will be higher compared to the real oxygen concentration of the inspiratory breathing gas. At high FiO₂ the deviation is higher (up to +10%) and low for smaller values of FiO₂.

The achieved measurement accuracy for FiO₂ is outside the specification according to the related IFUs and not in compliance with international standards.

3. Additional FiO₂ monitoring Alarms

The alarm limits for the alarms “FiO₂ high” and “FiO₂ low” are automatically connected to the set FiO₂. Because the delivered FiO₂ and the measured FiO₂ deviate in the same direction (due to the calibration with oxygen 93) additional alarms are not expected.

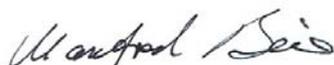
Only in case of strong fluctuations of the oxygen concentration of the supply gas or FiO₂ settings above 90% FiO₂-alarms can occur.

Safety information

If **Evita-Family ventilators, Savina-Family ventilators, Carina or Oxylog 3000plus** are operated on Oxygen 93 the following safety information must be followed:

- The users must be informed and must be aware of the effects and possible problems arising from the lower oxygen concentration of oxygen 93.
- Oxygen 100 is only necessary for extreme clinical situations. In case that a patient needs very high oxygen concentrations the ventilator must be supplied with Oxygen 100.
- FiO₂ should be set at maximum 90%, otherwise alarms from FiO₂ monitoring can occur.
- Due to the operating principle of oxygen concentrators oxygen 93 can fluctuate in the range of 93% ±3%. The supplying system must be designed to supply at minimum 90% Oxygen.
- The device check must be performed with the same oxygen type like during operation.
- Due to calibration with oxygen 93 instead of oxygen 100 the delivered FiO₂ can be lower by up to 11%. This must be considered when setting FiO₂.
- In case that the oxygen concentration of the O₂-supply strongly fluctuates alarms can occur. If FiO₂ monitoring is switched off an external FiO₂ monitor must be used.
- Due to the changed gas composition inspiratory and expiratory measured values (e.g. flow, volume, minute volume, resistance and compliance or CO₂ values) can exceed the specified accuracy limits documented in the instructions for use.

With kind regards,



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