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To whom it may concern

Use of Dräger Ventilators with Oxygen 93

April 7, 2020

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 the possibility 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 may lead to situations which require ventilators to be operated in environments were 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% (±3%).

If a Dräger ventilator, which is only specified for 100%, is used with oxygen 93 instead, it 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 and at his own (liability) risk.

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**.

If the above listed ventilators, which are not specified for oxygen 93, are nonetheless 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. FiO2 alarms will only occur when the FiO2 setting is above 90% or in cases of strong fluctuations of the oxygen concentrations of the supply gas.

Safety information

If **Evita-Family ventilators, Savina-Family ventilators, Carina or Oxylog 3000plus** are operated on oxygen 93 as an off-label use contrary to the applicable IFUs, 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 delivery at 100% is generally only necessary for extreme clinical situations. In case that a patient needs very high oxygen concentrations, the ventilator must be supplied with oxygen at 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.

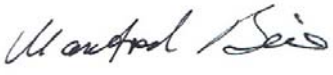
- The device check must be performed with the same oxygen type as used during operation.

- 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 specfied accuracy limits documented in the instructions for use.

With kind regards,



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