Drägerwerk AG & Co. KGaA, 23542 Lübeck

To whom it may concern

Our reference
COVID-19-Carina – PM Respiratory Care

Phone
+49 451 882-0

Fax

E-mail
jan.evers@draeger.com

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COVID-19: Usage of Carina sub-acute Care Ventilators in ICUs

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 Carina sub-acute Care ventilators as an alternative ventilator when alternative 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 Carina sub-acute care ventilators for usage on ICUs.

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 the Dräger Carina ventilator is intended for the treatment of sub-acute care patients in hospitals or medical rooms for non-invasive and invasive ventilation with a tidal volume with at least 100mL.

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, 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 Carina sub-acute care ventilator has to be weighed against the risk of the off-label usage of the Carina. 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 Carina acute-care ventilator in comparison to intensive care ventilators

WARNING: Dräger as the manufacturer cannot and must not market or promote or sign-off such off-label use of Carina sub-acute Care 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.

- Carina 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 built-in monitoring of Carina facilities monitor the following parameters:

- Airway pressure
- Inspiratory minute volume
- Applied minute volume (without leakage compensation)
- Apnea alarm time
- Disconnection time

- Mean airway pressure
- Respiratory rate
- Leakage minute volume

- In comparison to intensive care ventilators according to ISO80601-2-12 the monitoring of the following parameters is not available in Carina as built-in monitoring:

  - monitoring of the **expired minute volume or tidal-volume**
  - monitoring of the **inspiratory oxygen concentration FiO2**
  - the user has to ensure that the **built-in ventilation monitoring is activated.**
    Due to the missing monitoring of **expired volume** and **FiO2** the user **should always consider using additional monitoring**, e.g for FiO2, 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 Carina can be powered via internal batteries which allow ventilation for 60 minutes only. For longer ventilation periods those devices **must continuously be connected to mains voltage.**

- 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** can be performed via the usage of the breathing circuit 84 18 655 and an active humidifier according to the instructions for use of Carina. **Passive humidification with an Heat and Moisture Exchanger (HME) also can be used.**

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

Manfred Beier
Risk Manager

Gert Hauswald
Life Cycle Manager

Jan Evers
Product Management
Respiratory Care