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To whom it may concern

Our reference
COVID-19 – PM Anesthesiology

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COVID-19: Usage of Dräger anaesthesia devices for long-term ventilation

Dear customers, dear health care professionals,

The World Health Organization (WHO) declared COVID-19 a pandemic on March 11th, 2020 with over 118,000 cases of the coronavirus illness reported in over 110 countries worldwide. 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 anaesthesia devices 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 anaesthesia devices 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 anaesthesia device is described in the relevant instructions for use. Although the wording of the intended use may vary in between the devices the content is very similar: The devices are specified for a usage during surgical or diagnostic interventions 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 anaesthesia devices has to be weighed against the risk of the off-label usage of a Dräger anaesthesia device. 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 Anaesthesia Devices regarding Use in long-term Ventilation

WARNING: The following information list is based on our currently available knowledge as of the date of this letter. It does only apply to Dräger Anaesthesia Devices still being marketed. It is most likely not complete and exhaustive. If you detect important points which are missing, please let us know.

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

- Anaesthesia devices have a different working principle and different user interface (e.g. different operating modes) than intensive care ventilators. Therefore **medical personnel using the device must be well trained and familiar with the unique performance characteristics of the devices.**

- Before connecting a patient the user must be able to check the proper device status, ensure that all accessories (e.g. ventilation hoses, bacteria filter, gas sampling line, manual breathing bag, water traps) are properly connected and that the device is able to generate gas flow and pressure at the patient connector. With the exception of Australia and New Zealand the connectors for manual breathing bag and ventilation hoses have the same diameter. Therefore the risk of incorrectly connected patient hoses is given. A false connection (e.g. bag hose connected to inspiratory port) would make the ventilation of the patient impossible. Therefore **particularly for connecting a patient properly to an anaesthesia device** the user requires **device knowledge and clinical experience** with anaesthesia devices. Directly before connecting the patient the user has to check if the device is able to deliver pressure to the patient connector and that by unblocking the patient connector the pressure can be released and gas is flowing out (see e.g. website of European Patient Safety Foundation: https://www.eupsf.org/safety-alert-wrong-tube-connections)

- The instructions for use states a manual **resuscitator must always be available at the device** which enables back-up ventilation of the patient in case of problems or malfunctions with the

device. Particularly for users with limited knowledge in anaesthesia devices, it is particularly important that **in case of irregularities** or unexpected system behaviour impairing patient therapy the patient has to be disconnected from the anaesthesia device and ventilated with an operator powered **resuscitator.**

- The user has to understand **the mode Man/Spon (Manual or Spontaneous Ventilation)** which is a unique ventilation mode that is not available in most intensive care ventilators. This mode might be live-saving in case of a failure of automatic ventilation and absence of the resuscitator. The influence of the **APL-valve has to be understood as well.** Users with no anaesthesia background may expect that it also limits airway pressure during mechanical ventilation. **The APL-valve has no influence in mechanical ventilation**. It is only active in Man/Spon. In case of a ventilator failure Man/Spon becomes automatically active and the fresh gas flow will make the airway pressure rising up to the APL-setting. Therefore also **in mechanical ventilation the APL-valve has always to be set to a value suitable for the patient.** When setting the APL-valve to the desired PEEP level (or alternatively SPONT which equals zero) it is prevented that in case of a ventilator failure excessive airway pressures are generated to the patient. For the system test the APL-valve must be set to a relatively high value, therefore the user has to actively reduce this value also for mechanical ventilation.

- The user interface of Dräger anaesthesia devices cannot be protected against non-authorized users. Therefore the **operating organisation must ensure that non-authorized users cannot approach the device** to avoid that settings are changed or therapy is stopped (no alarm is generated when device is switched to standby).

- The alarm and safety concept of Dräger anaesthesia is designed for a permanent presence of the user within a distance of up to four meters. This facilitates fast recognition and response in the event of an alarm or in the event of any malfunction. Thus the alarm volume has always to be set sufficiently loud, particularly in noisy environments. The alarm distribution via serial interface is not designed in a redundant (fail-safe) way. Therefore a remote supervision (e.g. via central station) is not sufficient. 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.

- For enabling the device to generate the necessary alarms **all alarm limits have to be set patient specific** and may have to be adapted over time to the changing clinical situations. Particularly important in this topics are the alarm limits for the minute volume (lower and upper limit) and the expiratory CO2 (lower and upper limit) to be able to generate alarms when hypo- or hyperventilation occurs.

- Please be aware that in Dräger anaesthesia devices alarm notifications stop automatically when the alarm situation that caused the alarm is not valid any longer. In general the alarm concept of ICU ventilators is completely different in this respect. Therefore it is recommended to **check periodically the alarm history / alarm log of the anaesthesia device** to check if any alarms have been generated in absence of the user.

- The **devices are designed to be tested each 24 hours** to ensure readiness for operation. If the device test is not done, the readiness of operation is not tested, furthermore particularly the flow measurement may become inaccurate. Unlike many ICU ventilators, the flow measurement of the anaesthesia device cannot be calibrated during operation. The accuracy of gas measurement should not be affected as the gas measurement modules perform a zeroing independently of the system test. For performing the system test the patient must be disconnected from the anaesthesia device and for this time sufficient ventilation of the patient (e.g. via the resuscitator) has to be ensured. As the system test takes up to eight minutes (depending on device type), assistance of an experienced user is required for this step. If a system test each 24 hours is not feasible due to clinical reasons, we recommend to perform the test **at least each 72 hours** to reduce the likelihood of device malfunctions.

- As the Dräger anaesthesia devices are not designed for long time usage. The **overall status of the device and its accessories has to be checked on regular base** (at least each 12 hours, ideally more frequently). In particular the following situations have to be prevented: Exhausted CO2-absorber, full water trap, standing water in breathing hoses and excessive condensation at filter that may lead to increased resistance.

- One significant difference between intensive care ventilators anaesthesia devices is, that anaesthesia ventilators are based on a rebreathing system and adjustable fresh gas flows. This requires the use of a CO2 absorber to prevent high CO2 levels in the circuit. It is important to

examine the CO2 absorber and change it when it is exhausted. An exhausted absorber can be detected by the measurement of increasing inspiratory CO2 or the changed colour of the Dräger CO2 absorber (see instructions for use of anaesthesia device and CO2-absorber for more information). The **activation of an inspiratory CO2-high alarm limit** helps to directly inform the user about an exhausted absorber.

- The breathing bag of most Dräger anaesthesia devices act as a reservoir during mechanical ventilation. The exhaled breathing gas is captured in the breathing bag. Therefore the breathing bag moves during mechanical ventilation. The filling level of the breathing bag should be constantly sufficient.

- In general **leakages are not compensated** by Dräger anaesthesia devices. This has to be considered by the user, especially during all Volume Controlled ventilation modes. Depending on the device type the PEEP level might not be maintained. In fresh gas deficit situations (leakage higher than fresh gas flow) ventilation will be affected and immediate reaction of the operator is required (reduce leakage, increase FG-flow). As an alternative a disconnection of the manual breathing bag to use ambient air prevents a fresh gas low situation and increases the availability of ventilation. In this case the resulting inspiratory oxygen concentration will be in between the set fresh gas oxygen concentration and the 21% of the ambient air. If the fresh gas flow is high, less ambient air is entrained and the inspiratory oxygen concentration will increase.

- In order to prevent that anaesthetic agents are used in a situation in which it might harm the patient or the environment of the patient, it is recommended to **disconnect all vaporizers/ agent dosing modules** from the anaesthesia device and to store them in the operation theatre. This is particularly important as already smallest concentrations of volatile agents may trigger malign hyperthermia (e.g. at the clinical personnel). If usage of anaesthetic agents is intended, please see the additional information about sedation with volatile agents in the Attachment 1.

- The rebreathing of exhaled patient gases furthermore leads to another difference to ICU ventilators. The oxygen concentration of the inhaled gas (measured as “FiO2”) may differ to the set oxygen concentration in the fresh gas as the result from mixing fresh gas with rebreathed gas of the patient. Therefore **special attention must be given to the FiO2 values and the FiO2 low alarm**. The difference in between fresh gas oxygen concentration and FiO2 values

can be reduced to a minimum by increasing the fresh gas flow to at least 150% of the minute volume.

- In contrast to many ICU ventilators, the gas measurement of anaesthesia devices is a side stream monitoring. Therefore the gas measurement values and waveforms have a delay of several seconds.

- To avoid that the rebreathing of the patient creates excessive additional humidity in the system, a **fresh gas flow of at least 150% of the minute volume of the patient is required.** A low fresh gas flow will increase the amount of rebreathed gas and therefore may lead to the following situations:

    - condensation in breathing system and hoses, which may accumulate to a point where it impairs the therapy
    - CO2-absorber has to be exchanged more frequently
    - high difference between the set fresh gas oxygen concentration and the measured inspiratory oxygen concentration

- In addition a high fresh gas flow increases the robustness of the ventilation. When the fresh gas flow is too low the manual breathing bag (reservoir for the patient gas) may collapse in leakage situation and this would impair the ventilation. Particularly spontaneous breathing patients might require very high tidal volumes which they inhale from the manual breathing bag. The **usage of a very large breathing bag (e.g. Dräger 3 litre breathing bag) is recommended** to avoid that the spontaneous breath of the patient is limited by the size of the breathing bag.

- **Regarding the infection prevention the hospital guidelines have to be followed.** This includes the reprocessing of the device after the usage on infectious patients (particularly the device surfaces) but also the adequate usage of bacteria filters. **Only mechanical filters are suitable in long-term ventilation** as with electrostatic filters the filtering performance is reduced when they become too humid. More information regarding infection prevention in the context of COVID-19 are given in the Dräger 2019-nCoV infection prevention customer letters for anaesthesia and intensive care.

- Two different solutions for the usage of mechanical filters can be recommended:
    - Solution 1 – Passive humidification
        - Use of a combined element: Heat and Moisture Exchanger (HME) / mechanical breathing system filter (e.g. *Dräger TwinStar HEPA*)
        - Location: Only at the patient connector (Y-piece)
    - Solution 2 – Active humidification
        - In combination with active humidification use two mechanical filters without HME (e.g**.** *Dräger SafeStar filter series*).
        - Location: At the inspiratory AND the expiratory port of the anaesthesia device
        - Please consider the following information in regards to active humidification in combination with anaesthesia devices.

  If possible from a clinical perspective HME / mechanical breathing system filters at the Y-piece (solution 1) should be used with Dräger anaesthesia devices.

- The usage of **active humidification** is not approved with Dräger anaesthesia devices. Should nevertheless an active humidifier be used in this exceptional situation it has to be avoided that rebreathed humid gas creates excessive condensation in the breathing system of the anaesthesia device. Breathing circuits require **a water trap in the expiratory limb**. Dual heated breathing circuits must not be used with Dräger anaesthesia devices. Also, the usage of filters or even HME/filters at the Y-piece must be avoided to prevent excessive breathing resistance due to clogged filters resp. HME/filters during active humidification. When using a filter at the expiratory port the resistance can potentially exceed values demanded by the standard (ISO 80601-2-13:2011). Close monitoring of the respective ventilation, e.g. particularly narrow limits for the minute volume low alarm, and vital parameters are compulsory. Additionally a filter must be used on the inspiratory port of the anaesthesia device. As mentioned before, only mechanic filters shall be used. **A high fresh gas flow of at least 150% of the minute volume contributes to avoid excessive condensation in the breathing system as well as at the filter at the inspiratory port.** Reprocessing of the anaesthesia device after each patient is

essential and shall follow the recommendations for anaesthesia devices contaminated with SARS CoV-2.

- The water trap at the gas measurement module of Dräger anaesthesia devices protects the gas measurement module against humidity. **To ensure system functionality the water trap has to be emptied or exchanged before it becomes full**. The required frequency of doing this depends on the humidity of the sample gas. For usage of the Dräger anaesthesia device with high fresh gas flows and a combined HME-filter we expect that the filling level has to be checked each 12 hours.

- Modes that are not known by the user (e.g. Ext. Fresh Gas Outlet or Pause) shall not be used. Furthermore **several modes may behave differently than in intensive care ventilators**. Details are listed in the Attachment 1.

- Modes, measurement values, settings, manoeuvres etc. that are possibly used with ICU ventilators might not be available in the anaesthesia devices.

- Nebulisation of drugs or aerosol therapy are not approved with anaesthesia devices. If aerosol or other drugs are given to the airways this may cause malfunctions (e.g. incorrect measurement of the gas analyser).

If you have any questions or remarks to this topic, please do not hesitate to contact your local Dräger representative. As mentioned feedback is highly appreciated to enable us to share new information about this topic with medical caregivers worldwide.

With kind regards,

Ines Thams	Ralf Heesch	Moritz Rahlf-Luong
Risk Manager	System Engineer	Product Management Anaesthesiology

Attachements:
Attachement 1 - Comments to particular modes of operation

Attachment 1- Comments to particular modes of operation:

- **Volume Control and VC-Autoflow:** In most ICU ventilators the upper airway pressure alarm limit “Paw-high” is not only used for generating the airway pressure high alarm but also used for limiting the maximum pressure generated by the therapy device. In Dräger anaesthesia devices the alarm limit is only used for generating the alarm but does not limit the pressure. For the pressure limitation the setting **“Pmax”** is used which also has to be set specific to the patient and the clinical situation.

- **Pressure Support:** When the patient triggers breaths with a lower frequency than the set minimum frequency (RRmin), the anaesthesia device remains in the mode Pressure Support and non-triggered breaths are given additionally to the spontaneous triggered breaths to achieve the set minimum frequency. In addition the alarm “Apnea Ventilation” is generated. In many of the Dräger anaesthesia devices the alarm can be configured to low or medium priority. As in long-term ventilation the user might not be directly in front of the device the medium alarm priority is recommended. Dräger anaesthesia devices have no dedicated apnea-time and apnea back-up ventilation mode like it is available in most ICU ventilators.

- **Non Invasive Ventilation (NIV):** Dräger anaesthesia devices do not offer a dedicated NIV-mode. Therefore the user has to pay particular attention to leakages when doing mask ventilation.

- **Sedation with volatile agents:** If the long-term ventilation is combined with a sedation of the patient with anaesthetic agents, the direct environment of the patient has to be protected against surplus of anaesthetic agent. Typically in the operating theatre an active scavenging takes care that the surplus of fresh gas is evacuated. In environments of use without an active scavenging an ejector may protect the direct environment of the patient against increased concentrations of anaesthetic agents (already smallest concentrations of anaesthetic agent may trigger malign hyperthermia). In the devices Fabius, Primus/Apollo and Zeus IE also the usage of activated char coal filters might be an alternative. Please check your respective regulations, e.g. employment protection requirements. The usage of low flow anaesthesia to reduce anaesthetic agent polluting the OR environment requires deep knowledge of the rebreathing function and will lead over time to difficulties with water condensation in the system. In this case a permanent supervision by an experienced anaesthesia user is mandatory.