To whom it may concern

Our reference
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COVID-19: Use of Babylog Neonatal Ventilators in pediatric patients

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 ventilators worldwide. Customers and health care professionals approached us, to obtain information about the possibility to use Babylog Neonatal Ventilators in bigger pediatric patients, possibly also small adult patients when existing devices are fully utilized and there is no other ventilator option.

Due to these exceptional circumstances, we believe it is our responsibility to provide some insights both (I) on the legal and regulatory perspective as well as (II) related to the use of Dräger Babylog ventilator products.

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 the Dräger Babylog VN500, VN600 and VN800 ventilators is described in the corresponding instruction for use (IfU) of the product. The ventilators are intended for the ventilation of premature and term neonates and pediatric patient.
The list of accessories approved for the Babylog VN500, VN600 and VN800 contains 2 breathing circuits, which are approved for use in neonatal and pediatric patients up to a tidal volume of 100ml. The following list shows the patient circuits, which are approved up to 100ml tidal volume:

MP02650 VentStar Helix dual beheizt (N) plus
MP02608 VentStar Helix beheizt (N) plus

When using the Babylogs in pediatric patients both intended use statements (device and patient circuit) need to be considered.

Any use of the product outside of the intended use specified in the instructions for use constitutes off-label use.

If a product is used off-label, the user recognizes that it is not the intended use of the product and does so in his responsibility and at his own (liability) risk.
However, in a situation in which a user requires a ventilator to ventilate a bigger pediatric patient, the benefit of being able to ventilate the patient need to be weighed against the risk of the off-label usage of the device and breathing circuit. This risk-benefit assessment and the resulting decision must be made by the responsible health care professional based on the circumstances of the individual case.

II. Known Limitations of using a Babylog VN500, VN600 and VN800 ventilator in bigger pediatric Patients

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 products 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 products. 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.

Dräger Babylog VN500, VN600 and VN800 ventilators are equipped with 11mm diameter nozzles for connection of neonatal breathing circuits. These ventilators are not equipped with an expiratory flow monitoring, but with a proximal flow monitoring sensor in between the Y-piece and the ETT connector.
Due to the reduced diameter of connection nozzles, the hoses of the patient circuit, Y-piece and proximal flow sensor, all these parts create a resistance, which is fulfilling international standards and is uncritical for neonatal and pediatric patients up to the limitations defined in the IfU of the respective patient circuit.
However, if used with higher tidal and minute volumes in bigger patients, the resistance of the mentioned components will cause a pressure drop over the patient circuit, which will cause higher work of breathing in patients, who are breathing spontaneously.
In patients mandatorily ventilated, the higher resistance might cause prolonged times for in- and expiration. If higher respiration rates are needed these needed longer in- and expiratory times can cause air trapping and intrinsic PEEP if an insufficient expiratory time is set (according to the set respiration rate).

If the Babylogs are used in bigger pediatric patients, please closely monitor:

- The flow curve during in- and expiration (return to zero line before next in-/expiration)
- The trend of the mean airway pressure
- Minute Volume by use of minute volume alarm limits

Please consider that the PEEP monitoring of the ventilator is unable to detect a higher intrinsic PEEP.

Dräger Babylog VN500, VN600 and VN800 are offering only pressure-controlled ventilation modes with and without Volume Guarantee. If Volume Guarantee is activated, the inspiration pressure is automatically regulated to meet a set tidal volume. In this mode tidal volumes of up to 300ml can be adjusted.
The proximal flow sensor of the Babylog is designed for use in neonates and small pediatric patients. Therefore, the diameter of this flow sensor is small. In case of excessive mucus during coughing, the proximal flow sensor might be partially or completely occluded, or the operation of the flow sensor might be disturbed. In this case appropriate alarms will be generated by the ventilators. In bigger patients a more frequent exchange of a soiled and disturbed proximal flow sensor might be necessary.

In order to reduce the total resistance of the breathing circuit, the proximal flow sensor can be removed. Please consider that in this case any kind of synchronized ventilation and no flow and volume monitoring is possible any more. Also, ventilation with Volume Guarantee will not be possible without the flow sensor. The ventilator will provide a pressure controlled, time cycled ventilation in this case. External monitoring must be used.

If you have any further questions or need any support, please contact Dräger's local service support or sales representative.

Kind Regards,

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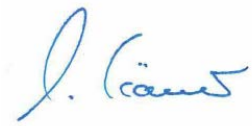

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