

WEINMANN Emergency Medical Technology GmbH + Co. KG
PO Box 57 01 53 • 22770 Hamburg • GERMANY

To operators of WEINMANN ventilators

Hamburg, March 31, 2020

Use of WEINMANN MEDUMAT and MEDUVENT emergency and transport ventilators for long-term ventilation in the context of the COVID-19/SARS-CoV-2 pandemic

Dear Sir or Madam,

Due to the current pandemic situation and the associated shortage of intensive care ventilators, we are receiving an increased number of inquiries regarding the use of our MEDUMAT and MEDUVENT emergency and transport ventilators for long-term ventilation.

Please note that **only MEDUMAT Transport is approved for use lasting up to 30 days.**

According to the intended use in the instructions for use, MEDUMAT Standard², MEDUVENT Standard, MEDUMAT Standard/Standard a and MEDUMAT Easy CPR ventilators are only approved for emergency and transport ventilation up to a maximum of 24 hours.

Use of MEDUMAT Standard², MEDUVENT Standard, MEDUMAT Standard, MEDUMAT Standard a and MEDUMAT Easy CPR ventilators for long-term ventilation is therefore deemed “off-label use”.

Warning: If a device is used outside the intended purpose, the user acknowledges that this is not the intended use of the device and assumes responsibility and the (liability) risk for doing this.

This letter is to provide you with some information, including the limitations of the devices with regard to their use for long-term ventilation, so that, in a situation where an alternative ventilator may not be available, you can carry out a risk-benefit analysis that is as comprehensive as possible regarding the use of the above-mentioned devices. This risk-benefit assessment and the resulting decision must be carried out on a case-by-case basis by the responsible medical staff.

Page 1 of 3

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Certified QM System meeting
EC directive 93/42/EEC, Annex II
(EN ISO 9001/EN ISO 13485)

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To do so, please observe the following instructions:

- Due to regular endurance tests conducted with our devices, we assume that the devices and components are technically suitable for use > 24 hours.
- All of our devices meet the accuracy requirements for monitoring pressure and volume as per EN DIN 794-3 for emergency and transportation ventilators, but not the requirement according to the intensive care ventilation standard. Refer to the instructions for use for the respective tolerances and measurement accuracies. Only MEDUMAT Transport is able to perform inspiratory oxygen concentration measurements.
- The alarm and safety concept of WEINMANN MEDUMAT/MEDUVENT ventilators necessitates the constant presence of a user. No nurse call function is provided. For this reason, always set the alarm limits on a patient-specific basis and set the alarm volume to 100% (where possible).
- Always use an SpO₂ and etCO₂ monitoring device (external or, if available, in the MEDUMAT).
- Only MEDUMAT Transport and MEDUMAT Standard² have expiratory volume and frequency monitoring technology. An additional external expiratory volume monitoring device may be necessary for the other MEDUMAT/MEDUVENT ventilators.
- Always keep an alternative ventilation option ready (e.g. a bag-valve mask).
- Carry out a regular function check (every 24 hours if possible) on the device and accessories according to the instructions for use.
- Regularly check the functionality of the device.
- The drying-out of the airways can be an undesired side effect of long-term ventilation. For this reason, please always use an HME filter to ensure the passive humidification of the respiratory air. For MEDUMAT Transport and MEDUMAT Standard², the **Hygrovent Gold** humidifier manufactured by Medisize can be used as an alternative to a “standard HME”.
- Only MEDUMAT Transport and MEDUMAT Standard² have the option of a pressure support (ASB/PS) during CPAP therapy and pressure-controlled ventilation modes to treat acute respiratory insufficiency or ARDS.
- Only MEDUMAT Transport, MEDUMAT Standard² and MEDUVENT Standard have a hygiene filter at the dust filter to protect against viruses and bacteria. Please note that this filter must be replaced after 24 hours of operation of the device in AirMix mode.
- Furthermore, please observe the instructions in our letter of 3/23/2020 on dealing with highly infectious germs.
- The biocompatibility of our devices (except MEDUMAT Transport) and breathing circuits was verified for use up to 24 hours. As a result, we do not know how the devices behave in terms of biocompatibility during use > 24 hours. However, we currently have no reason

to assume that the biocompatibility of the devices and breathing circuits could not also be guaranteed for use > 24 hours.

- MEDUMAT Transport, MEDUMAT Standard² and MEDUVENT Standard have an internal rechargeable battery with a limited operating time. For this reason, these devices must (and can) be continuously operated with a 230 V power supply unit and charger (WM 28937) if they are used for long-term ventilation.
- MEDUMAT Standard/Standard a have an internal non-rechargeable battery with an operating time of **at least** 100 hours. The internal battery in the MEDUMAT Easy CPR has a maximum operating time of 100 hours. For this reason, monitor the devices very closely.
- Flammable gases and anesthetics can cause spontaneous explosions, resulting in injuries to the patient, the user and bystanders. For this reason, do not use the device in conjunction with flammable gases or gaseous anesthetics.

We hope that we have given you an improved basis for decision-making regarding the use of our MEDUMAT and MEDUVENT emergency and transportation ventilators for long-term ventilation.

If you have any questions, we would be pleased to assist.

Kind regards,

WEINMANN Emergency Medical Technology GmbH + Co. KG



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