

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 ventilators in combination with CPAP helmets in the context of the COVID-19/SARS-CoV-2 pandemic

Dear Sir or Madam,

Due to the current pandemic situation, we are receiving an increased number of inquiries regarding the use of WEINMANN ventilators in combination with CPAP helmets. We wish to comment on this in this letter.

Please note that, due to a lack of clinical data, we cannot currently explicitly demonstrate the compatibility of WEINMANN ventilators and CPAP helmets.

The use of WEINMANN ventilators in combination with a CPAP helmet is therefore deemed "off-label use".

<u>Warning:</u> 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.

However, in the current situation, it can be useful to comprehensively weigh the benefits against the risk to protect against infection. We would therefore like to provide you with the following instructions for carrying out a risk-benefit assessment that is as well-founded as possible. This risk-benefit assessment and the resulting decision must be carried out on a case-by-case basis by the responsible medical staff.

To do so, please observe the following instructions:

The instructions for use for CPAP helmets (e.g. Castar type) require a purge flow of at least 40 l/min for adults. This cannot be guaranteed by WEINMANN ventilators in pure CPAP therapy without pressure support. At most, it is as high as the respiratory minute volume of the patient and is therefore between 10 l/min and 20 l/min for an adult.

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- For this reason, only use CPAP helmets in combination with MEDUMAT Transport and MEDUMAT Standard² when using a pressure support (ASB) in CPAP mode or with pressure-controlled ventilation (e.g. BiLevel+ASB). This lead to an improved CO2 washout in comparison to CPAP mode. Nevertheless, we have not determined a precise value, although the expiratory respiratory minute volume measured by the device can be adopted as a reference point.
- Continuously monitor the expiratory minute volume and the end-tidal CO2 using capnography (either on an external monitor or with MEDUMAT Transport/ MEDUMAT Standard²). If necessary, it can be useful to additionally monitor the CO₂ concentration within the helmet using an external hand-held sensor.
- If the CPAP helmet has an inlet and outlet for the inspiration and expiration, seal the outlet with a suitable plug as MEDUMAT Transport and MEDUMAT Standard² can only be operated with a single-tube system. Make sure that the expiration valve installed in the breathing circuit is connected between the flexible breathing tube and the helmet.

We hope that we have given you an improved basis for decision-making regarding the use of MEDUMAT Transport and MEDUMAT Standard² with CPAP helmets.

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

Kind regards,

WEINMANN Emergency Medical Technology GmbH + Co. KG

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