WEINMANN Emergency Medical Technology GmbH + Co. KG
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To operators of WEINMANN ventilators

Hamburg, April 6, 2020

Reuse of WEINMANN disposable accessories for MEDUMAT/MEDUVENT emergency and transport ventilators in the context of the COVID-19/SARS-CoV-2 pandemic

Dear Sir or Madam,

Due to the current pandemic situation and associated bottlenecks in the availability of disposable accessories such as flexible breathing tubes, ventilation masks and hygiene filters, we would like to provide you with some information on the reuse and hygienic reprocessing of disposable accessories.

According to the Medical Device Regulation (MDR), a “disposable product” refers to a product that is intended to be used on a single person for a single measure.

The reuse of disposable consumables 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**.

Furthermore, according to the MDR, the party reprocessing a disposable product is regarded as the manufacturer of the reprocessed product and is therefore subject to all obligations that are incumbent upon manufacturers as per this regulation.

However, in the context of the current pandemic situation and the associated limited availability of disposable breathing circuits, for example, the benefit of reprocessing may outweigh the resulting risk. Consequently, this letter is to provide you with some information, including the limitations of WEINMANN disposable accessories in terms of their reuse, so that you are able to carry out a risk-benefit analysis that is as comprehensive 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:

- **WEINMANN hygiene filters CANNOT be reprocessed.** In case of limited availability, continue to use the hygiene filter after (suspected) contamination and only replace it if requested to do so in the function check.

- Do **not use thermal processes** (e.g. steam sterilization) for the hygienic reprocessing of WEINMANN disposable accessories such as breathing circuits and ventilation masks, as the materials are not designed for such temperatures.

- Should it be necessary to hygienically reprocess disposable breathing circuits or ventilation masks, preferably carry out manual reprocessing by means of immersion disinfection (similar to the method described in the chapter on reusable breathing circuits in the instructions for use). Please note that neither the material compatibility nor the effectiveness of these reprocessing methods has been validated for disposable breathing circuits.

- Please note that the disposable breathing circuits of the MEDUMAT Transport and MEDUMAT Standard², in particular, cannot be completely dismantled, as some components are glued together. Please do not attempt to detach these components "by force", but rather reprocess the breathing circuit as a whole. It is possible, however, that the adhesive bond may be dissolved by the immersion disinfectant. We do not have any information about this. Should this happen, please make sure that the components are assembled correctly.

- After reprocessing, always make sure that the components are assembled correctly (according to the instructions for use) and **carry out a function check after all reprocessing**.

- **Warning:** During immersion disinfection of the FlowCheck sensors for MEDUMAT Standard², it is possible for liquid to enter between the sensor chip and the printed circuit board. This may result in sensor measurement errors.

  For this reason, always leave the flow measurement cable plugged in during immersion disinfection of the FlowCheck sensor and ensure a sufficient drying period (at least 12 hours). Remove the flow measurement cable from the sensor during the drying period.

  In addition, carry out a plausibility check with the FlowCheck sensor after reprocessing as follows:

  - Assemble all components of the breathing circuit correctly
  - Connect testing bag WM 1454 to the breathing circuit
  - Perform a function check
  - Start **IPPV** ventilation with the following settings:
    Vt = 150 ml, Freq = 18/min, PEEP = 3 mbar, pMax = 30 mbar
  - Check whether the measured Vte is within a range of 100-200 ml
  - If the measured expiratory tidal volume is within a range of 100-200 ml, you can continue to use the FlowCheck sensor.

- Should this not be the case, you can reorder individual disposable sensors under article no. WM 29154.
- Alternatively, it is possible to combine disposable breathing circuits with a reusable FlowCheck sensor (WM 28835), which has been qualified for up to 50 reprocessing cycles.

- We cannot guarantee that both the disposable FlowCheck sensor and the disposable BiCheck sensor will maintain the measured value tolerances specified in the instructions for use over a longer period of use. For this reason, regularly examine the measured volume and frequency values displayed by the device and check their plausibility.

- For devices with CO2 measurement technology: Remove the water filter on the silicone measuring block before all reprocessing and insert a new filter after reprocessing.

- Also observe the “Infection prevention during anaesthesia ventilation by the use of breathing system filters” [i] recommendation on the use of disposable breathing circuits for up to 7 days, including with patient changes.

  According to this recommendation, disposable breathing circuits can be used for up to 7 consecutive days in a clinical environment if the breathing system filter is replaced for each patient, its functionality is still guaranteed and the manufacturer allows this in the instructions for use.

- **From a technical perspective**, in our view, there is no reason not to use our disposable breathing circuits (incl. flow sensors) for up to seven consecutive days.

  Nevertheless, please observe the following instructions:

  - Always use a suitable breathing system filter and replace it for each patient after a maximum of 24 hours.
  - Disinfect your hands before you carry out a function check on the device or come into contact with the breathing circuit.
  - Carry out a function test on the device before each use.
  - Seal the breathing circuit with a suitable cap (e.g. protective cap WM 28624) during storage.

We hope that we have given you an improved basis for decision-making regarding the reuse of our disposable components.

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

Kind regards,

WEINMANN Emergency Medical Technology GmbH + Co. KG

on behalf of KG Dennis Horstmann
Head of Quality Management
and Safety Officer

on behalf of Vanessa Kühn
Senior Product Manager
Emergency and Transport Ventilation

[i] Source: Kramer et al. **Infection prevention during anaesthesia ventilation by the use of breathing system filters (BSF): Joint recommendation by German Society of Hospital Hygiene (DGKH) and German Society for Anesthesiology and Intensive Care (DGAI)**. GMS Krankenhaushyg Interdiszip 2010;5(2).