Drägerwerk AG & Co. KGaA, 23542 Lübeck

SARS-CoV-2 and handling of Dräger Anesthesia Workstations (February 20th, 2020)
Updated March 24th, 2020

Dear Sir or Madam,

The following information and recommendations are targeted for Anesthesia Workstations from Dräger that were used on patients infected or highly suspected to be infected with the novel coronavirus (SARS-CoV-2).

Background:
Coronaviruses (CoV) are a large family of enveloped viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronavirus (SARS-CoV-2) is a new strain that has not been previously identified in humans.
Coronaviruses are transmitted between animals and humans (zoonotic transmission). The possibility of transmission among humans especially of SARS-CoV-2 is confirmed.

The novel coronavirus (SARS-CoV-2) belongs to the category of enveloped viruses that in principle can be removed with disinfectants with limited virucidal effectiveness. However, for a higher safety level it is also possible to use locally registered hospital disinfectant with a label claim for a non-enveloped virus (e.g. norovirus, rotavirus, adenovirus, and poliovirus). Further information you can find on the following websites and further national organization websites:

- https://www.who.int/emergencies/diseases/novel-coronavirus-2019
- https://www.cdc.gov/coronavirus/2019-ncov/index.html
- https://www.ecdc.europa.eu/en/novel-coronavirus-china

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System setup recommendations for confirmed or highly suspected SARS-CoV-2-patients:

A. Essential measures

A1 Anaesthesia device:

- Use of a **mechanical breathing system filter** (BSF) such as MP01790 SafeStar 55 (adults only) at patient side (between tracheal tube and y-piece of the breathing circuit (hoses). **Caution:** The gas sample line of the anesthesia device must be connected on the device side of the BSF in order to avoid contamination of the gas measurement unit and consequently the entire anesthesia device (see figure 1).

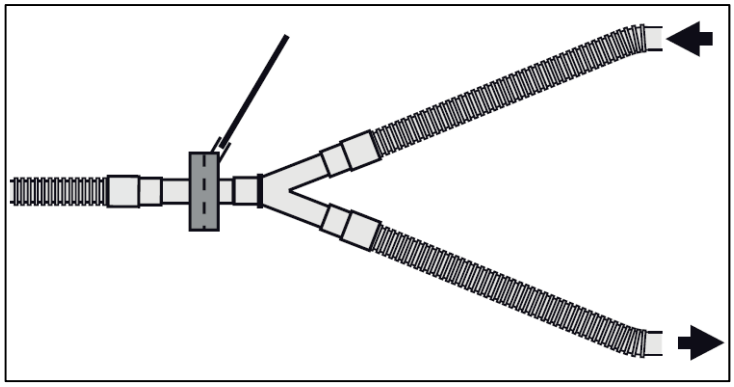

Figure 1

- Deploy **disposable breathing circuit** (hoses) only**.** For types and part numbers please see Dräger Accessory Catalogue.

A2 Endotracheal suctioning device:

- The VarioSafe® disposable filter system (MP00555) has to be used to reliably protect the suctioning device and the patient environment against contamination.
- We recommend to use Dräger Vacusmart Gel inserts for the suction canister.

A3 Monitoring accessories:

Disposable Monitoring accessories should be used and disposed after each patient.

- Disposable ECG leads
- Disposable SpO2 sensors
- Disposable NiBP cuffs
- Disposable temperature probes

For types and part numbers please see the Dräger Accessory Catalogue.

B. Optional measures (recommendation for a higher safety level)

An **additional Breathing System Filter** (BSF) at the expiratory port of the breathing system such as MP01785 SafeStar 80/ MP01795 SafeStar 60A/ MP01790 SafeStar 55 (between breathing hose set and expiratory port of the device) is strongly recommended because of contamination risk of the breathing system during daily disconnection and replacement of the BSF at patient side (see figure 2).

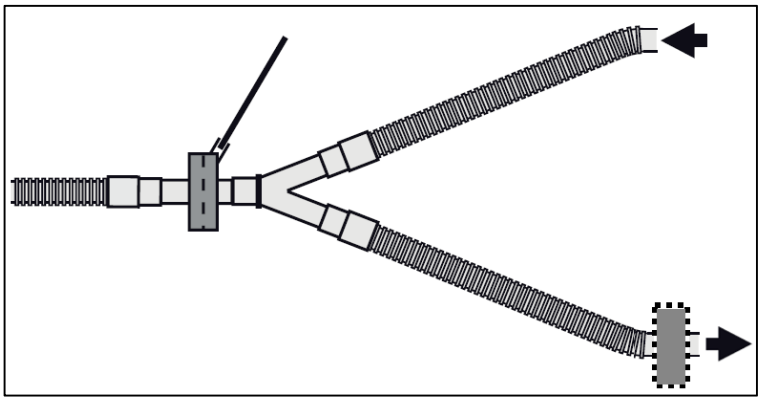

Figure 2

Important:

- During ventilation using the above-mentioned setup, the resistance can potentially exceed values demanded by the standard (ISO 80601-2-13:2011). Close monitoring of the respective ventilation and vital parameters is compulsory.
- All Filters used as mentioned above must be mechanical in HEPA Quality (e.g. Dräger SafeStar 80 HEPA (MP01785) and need to be exchanged daily and after each patient.
- For types and part numbers of recommended disposable products, please see the Dräger Accessories Catalogue.

Reprocessing recommendations:

Reprocessing of products, components and surfaces potentially contaminated can be achieved by following the standard procedures described in the Instruction for Use (IfU) and the usage of suitable disinfectants with at least limited viricidal effectiveness. The following recommendations for anesthesia devices contaminated with SARS-CoV-2 are based on general guidelines and practice for infectious diseases. For further details please refer to the newest ‘list of surface disinfectants’ in the Instructions for Use of your device and/or contact your local sales organization.

Due to

- the so far uncertain severity of COVID19/ SARS-CoV-2 (percentage of cases of severe disease progression) and
- missing definitive data on its susceptibility to reprocessing measures,

we recommend for the time being the following enhanced procedure as an additional precaution:

C. Essential measures

C1. Follow the occupational safety and reprocessing guidelines of the hospital and the local/ national health authorities.

C2. Remove all disposable device components which are in contact with the patient’s breathing gas:

- the breathing circuit (hoses),
- HME/ breathing system filters,
- sample line and the water trap,
- endotracheal suction accessories, tubes and filters and
- dispose of all of these components safely.

C3 Regarding breathing system reprocessing (including valves & flow sensors), please proceed as described in the Instructions for Use.

C4 Regarding suction system, please refer to the Instruction for use.

C5 Clean and disinfect thoroughly all accessible surfaces of the anaesthesia device, other devices and reusable components with a suitable disinfectant (concentration and exposure time according to manufacturer’s instructions).

C6 Allow to air dry.

D. Optional measures The reprocessing of potentially contaminated products/components is achieved by performing the standard procedures described in section C (according to the instructions for use) and using suitable disinfectants. Furthermore, the following optional measures are possible. This part should be in line with the general hospital guideline for all medical devices in the patient vicinity. Prerequisite: All steps described in section C (essential measures) were performed.

D7. Wrap the anaesthesia device, the other devices and reusable components completely with a plastic cover and store them safely for a specified time (e.g. 21 or 28 days [safety margin incl.]/to be adapted on current information regarding persistence of SARS-CoV-2) at room temperature or higher. Make sure all devices are switched off using the main switch to avoid deep discharge of batteries.

D8. Remove plastic cover and dispose of safely.

D9. Clean and wipe disinfect thoroughly with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions) all accessible surfaces of the anesthesia device, other devices and reusable components.

D9 Allow to air dry.

D10. Device can be released for reuse.

General Remark: Based on the individual situation, the hospital management responsible for infection control and epidemiology has the task to decide on the required measures. The measures described above are intended for devices used in the recommended manner. Devices used without a Breathing System Filter (BSF) have to be managed in each individual case in consultation with the competent authority. In justified cases of doubt we recommend the safe disposal of contaminated devices and reusable accessories.

If you have further questions, please do not hesitate to ask your local Dräger office for assistance.

Due to the currently high demand for personal protective equipment with regard to the SARS-CoV-2 virus, the capacity level of all suppliers is very strained. The primary concern should therefore be to have protection equipment, irrespective of the manufacturer.

With best regards,

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