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SARS-CoV-2 and handling of Dräger Anesthesia Workstations / System setup and reprocessing recommendations for confirmed or highly suspected SARS-CoV-2- patients

(February 20th, 2020)
Last Updated May 25th

Dear Sir or Madam,

The following information and recommendations are targeted for anesthesia workstations from Dräger that are used on patients infected or highly suspected to be infected with the novel coronavirus (SARS-CoV-2). The recommendations are always based on the currently available scientific information and are not intended to be exhaustive.
Latest version can be obtained on the Draeger COVID19 information webpages.

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 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 viricidal 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

A1. System setup recommendations for confirmed or highly suspected SARS-CoV-2-patients

Information on the setup of the anesthesia machine with its accessories such as breathing hoses, breathing system filters (BSF) or heat and moisture exchangers with integrated filters (HMEF) can be found in the respective Instructions for Use (IfU).

Due to

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

the following enhanced procedure may be considered as an additional precaution:

A1a System setup recommendation for adult patients tidal volumes > 300ml

- Use of a BSF or an HMEF with a mechanical filter medium such as SafeStar 55 (MP01790) or TwinStar HEPA (MP01801) between tracheal tube and the Y-piece of the breathing circuit (hoses) (see position 1/ figure 1).
  Note: The gas sample line of the anesthesia machine must be connected on the device side of the BSF or HMEF (see position 2 / figure 1).

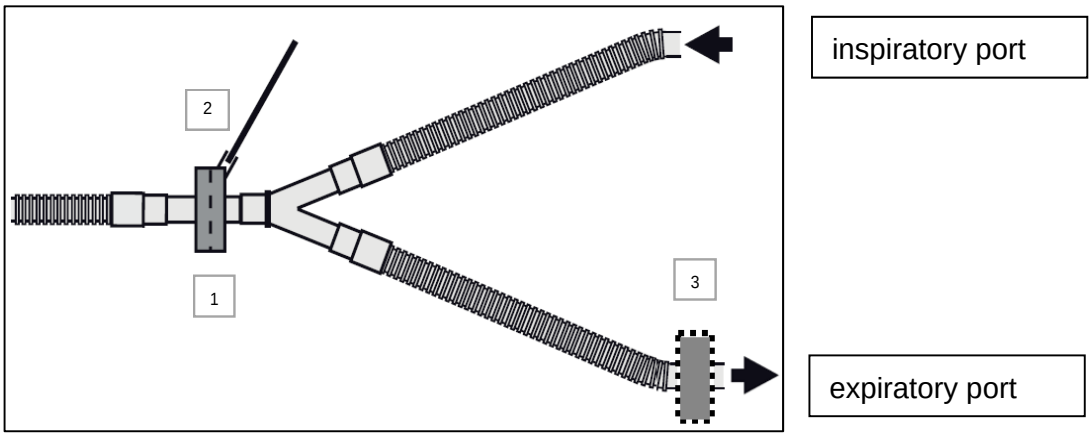

Figure 1: System setup recommendation for adult patients – tidal volumes > 300ml

- Optional measure for enhanced safety: Place an additional BSF such as SafeStar 80 (MP01785) or SafeStar 55 (MP01790) at the expiratory port of the anesthesia machine (see position 3 / figure 1). This measure reduces the risk of contaminating the breathing system during daily disconnection and replacement of the BSF at the patient side**.**
- Check that all connections are securely fitted and tight.

- Perform a system test of the anesthesia machine after the breathing circuit (breathing hoses, BSFs, HMEF, etc.) has been completely installed and prior to connecting a patient.
- Set the alarm limits for *MV low* and *Paw high* to suitable values.
- Regularly check the inside of the BSFs and HMEF for liquids or visible soiling (secretion). The lower the fresh-gas flow and the greater the CO_2 production of the patient, the more humidity may accumulate in the breathing circuit.
- If liquids or visible soiling are found, replace the BSFs and/or HMEF immediately.

A1b System setup recommendation for pediatric patients tidal volume approx. 30 - 300 ml

- Use HME or an HMEF such as TwinStar 25 (MP01815), TwinStar 10A (MP01825) or TwinStar 8 (MP01820) between the tracheal tube and the Y-piece of the breathing circuit (hoses) (see position 1/ figure 2).
  Caution*: The sample line should be connected on the device side of the HME / HMEF (see position 3/ figure 2). If a filter is used between the tracheal tube and the Y-piece of the breathing circuit (hoses) and the sample line is connected on the patient side of the HME / HMEF air can be drawn from the patient's lungs if the filter material gets clogged.*
- Use mechanical BSFs (adult) e.g. Dräger SafeStar 55 (MP01790) at each the expiratory and the inspiratory port of the anesthesia machine (see position 2/ figure 2).

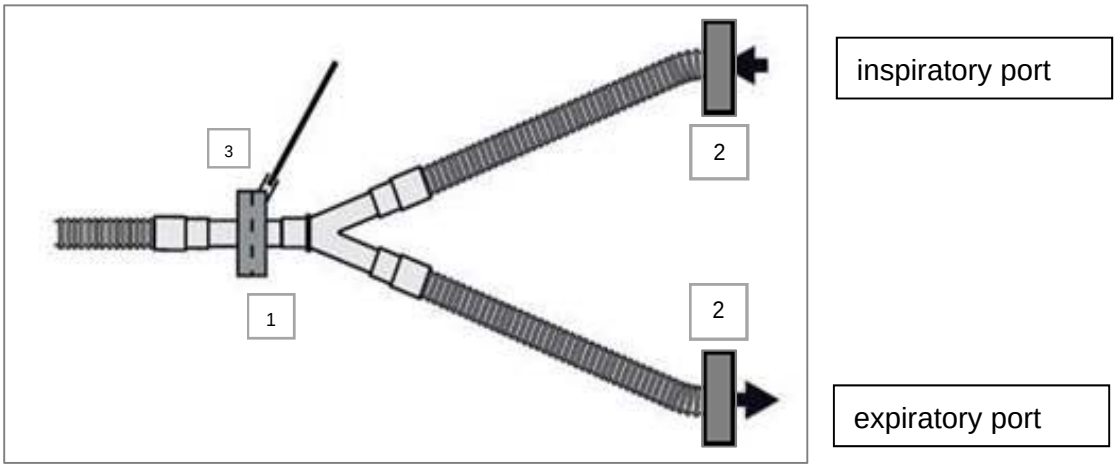

Figure 2: System setup recommendation for pediatric patients (tidal volume approx. 30 - 300 ml)

- Check that all connections are securely fitted and tight.

- Perform a system test of the anesthesia machine after the breathing circuit (breathing hoses, BSFs, HME/ HMEF, etc.) has been completely installed and prior to connecting a patient.
- Set the alarm limits for *MV low* and *Paw high* to suitable values.
- Regularly check the inside of the BSFs and HME/ HMEF for liquids or visible soiling (secretion). The lower the fresh-gas flow and the greater the CO_2 production of the patient, the more humidity may accumulate in the breathing circuit.
- If liquids or visible soiling are found, replace the BSF and/or HME / HMEF immediately.

A1c System setup recommendation for neonatal patients tidal volume approx. < 30 ml

- For neonatal patients, it is frequently necessary to sample breathing gas for the monitoring of CO2, O2, N2O and anesthetic agents from the patient side of an HME (see position 1/ figure 3). Otherwise the quality of the measured gas parameters might not be sufficient.
- Use HME at the Y-piece for sufficient humidification of the airways.
  e.g. Dräger HumidStar 2 (MP01745) for tidal volumes above 10ml
  (see position 2/ figure 3).
  Caution*: Do not use BSF or HMEF for neonatal patients at the Y-piece of the breathing circuit (hoses). Filters can get clogged and air would be drawn from the patient's lung if the sample line is connected on the patient side of the BSF or HMEF.*
- Use mechanical BSFs such as SafeStar 55 (MP01790) at each the expiratory and the inspiratory port of the anesthesia machine (see position 3/ figure 3).

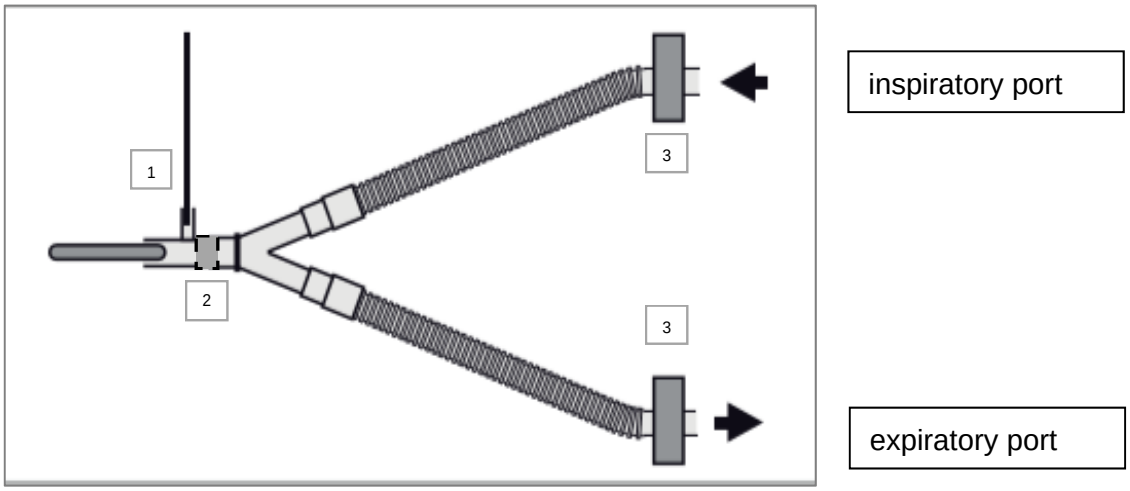

Figure 3: System setup recommendation for neonatal patients (tidal volume approx. < 30 ml)

- Check that all connections are securely fitted and tight.
- Perform a system test of the anesthesia machine after the breathing circuit (breathing hoses, BSFs, HME, etc.) has been completely installed and prior to connecting a patient.
- Set the alarm limits for *MV low* and *Paw high* to suitable values.
- Regularly check the inside of the BSFs and HME for liquids or visible soiling (secretion). If liquids or visible soiling are found, replace the BSFs and/or HME immediately.

Caution: If this is not done, there is a risk of pressure build-up and insufficient patient ventilation and/ or of drawing air from the patient's lung.

A2 Breathing circuits

- Deploy breathing circuits (hose systems) that are listed in the list of accessories of the anesthesia machine. Disposable breathing circuits (hoses) should be preferred.

A3 Endotracheal suctioning device

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

A4 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.

Reprocessing recommendation

Follow the national infection prevention policies and reprocessing regulations. Follow the infection prevention policies and reprocessing regulations of the healthcare facility (e.g. concerning the reprocessing cycles). An overview chart of the standard reprocessing procedures and additional measures for an enhanced safety level can be found as attachment 1.

B. Standard Reprocessing Measures

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 optional measures for anesthesia machines contaminated with SARS-CoV-2 are based on general guidelines and practice for infectious diseases.

Due to

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

the following enhanced procedure may be considered as an additional precaution:

C. Measures for an enhanced safety level

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

C2. Remove all disposable device components:

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

C3. Reprocess all components listed in the reprocessing list as described in the Instructions for Use (e.g. in case the system setup recommendation in section A1 was not followed).

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

C5. Clean and disinfect thoroughly all accessible surfaces of the anaesthesia machine, 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 B (according to the instructions for use) and using suitable disinfectants.

For a further enhanced safety level, the following optional measures are possible (e.g when recommended by national infection prevention policies and reprocessing regulations or infection prevention policies and reprocessing regulations of the healthcare facility).

Prerequisite: All steps described in section C (measures for an enhanced safety level) were performed.

D7. Wrap the anaesthesia machine, the other devices and reusable components completely with a plastic cover and store them safely for an appropriate time (e.g. 14 up to 21 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.

D10. Allow to air dry.

D11. 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. 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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Overview Chart: SARS-CoV-2 and handling of Dräger Anesthesia Workstations / System setup and reprocessing recommendations for confirmed or highly suspected SARS-CoV-2- patients.