Drägerwerk AG & Co. KGaA, 23542 Lübeck

2019-nCoV and handling of medical devices for Intensive Care January 28, 2020

Dear Sir or Madam,

The following information and recommendations are targeted for Intensive Care devices from Dräger that were used on patients infected or highly suspected to be infected with the novel coronavirus (2019-nCoV).

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 (2019-nCoV) 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 2019-vCoV is now confirmed, but the extent of human-to-human transmission is still not clear (status Jan. 24th, 2020/ WHO).

The novel coronavirus (2019-nCoV) 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
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- https://www.who.int/csr/don/en/
- https://www.cdc.gov/outbreaks/index.html
- https://www.ecdc.europa.eu/en/novel-coronavirus-china
- https://www.rki.de/DE/Content/Infekt/Ausbrueche/respiratorisch/Pneumonien-China.html

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System setup recommendations for confirmed or highly suspected 2019-nCoV-patients:

A. Essential components

A1 Ventilators:

Breathing System Filter (BSF) at the **y-piece**. The BSF must be mechanical in HEPA-quality. **Replace daily.**

- with Heat and Moisture Exchanger (HME): Filter/HME TwinStar HEPA (MP01801)
- without HME: Filter SafeStar 55 (MP01790) – for adults only! Use on the device side, if the patient is a neonate or child and use the hoses single patient only.

* If this product is not available, an electrostatic HMEF at the Y-piece and an additional BSF at the expiration valve could be used**.**

Disposable Breathing Circuits: For types and part numbers please see Dräger Accessory Catalogue.

Disposable Expiration Valves:

- Disposable expiratory valve for Evita (8414776)
- Single Use ExpV Evita Watertrap (MP02600)
- Disposable RFID expiratory valve (MP01060)
- Expiratory valve (single use) (MP01061)

A2 Suctioning devices:

The VarioSafe® disposable filter system (MP00555) must be used to reliably protect the VarioVac® series, the VarioAir® series and the patient environment against contamination.

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 components (strongly recommended for a higher safety level) for ventilators
Additional Breathing System Filter (BSF) **at the expiratory device connector**. The BSF should be mechanical in HEPA-quality. This is strongly recommended due to the contamination risk of the breathing system during daily disconnection and replacement of the BSF at the y-piece. Replace daily (before the replacement of the BSF at the y-piece).

- for Evita V300 & V500: Infinity ID Expiratory Filter (MP01780)
- for Savina 300: Expiratory Filter (MP01781)
- for other Evita and Savina ventilators: preferably Filter SafeStar 80 (MP01785)

Furthermore, it is possible to use a **Breathing System Filter** (BSF) in HEPA-quality **at the inspiratory device connector**.

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 ventilators contaminated with 2019-nCoV 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 ventilator and/or contact your local sales organization.

Due to

- the so far uncertain infection risk, 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, HME/ breathing system filters, expiration valve, flow sensor
- the suctioning and monitoring accessories and
- all air inlet filters of the devices and
- dispose of all of these safely

C3. Clean and disinfect thoroughly all accessible surfaces of the ventilator, the other devices and reusable components with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions) all accessible surfaces of devices and reusable components.

C4. Allow to air dry.

D. Optional measures following C, if devices were used without a Breathing System Filter (BSF). This part should be in line with the general hospital guideline for all medical devices in the patient vicinity.

D5. Wrap the ventilator, 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) at room temperature or higher.

D6. Clean and wipe disinfect thoroughly with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions) all accessible surfaces of the ventilator and other devices and reusable components

D7 Allow to air dry

D8. Device can be released for reuse.

General Remark: Based on the individual situation, the hospital management responsible for infection control and epidemiology has he 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.

Dräger can also provide personal protective equipment (PPE) for healthcare professionals.

With best regards,

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