Drägerwerk AG & Co. KGaA, 23542 Lübeck

SARS-CoV-2 and handling of medical devices for Intensive Care System setup and reprocessing recommendations for confirmed or highly suspected SARS-CoV-2- patients

(January 28th, 2020)
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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 (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 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

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

Information on the setup of the ventilator 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:

A.1 Essential components

A.1a Breathing System Filter (BSF):

Breathing System Filter (BSF) at the patient connecting port (y-piece): Replace daily. For recommendation on different patient categories and use cases please refer to attachment 1.

A.1b Breathing Circuits:

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

A.1c Expiration Valves:

Disposable Expiration Valves should be preferred:
For Evita® 2 dura, Evita® 4, Evita® XL:

- Expiratory valve, disposable, 10 pcs. (8414776)
- Expiratory valve, watertrap, disposable, 10pcs. (MP02600)

For Savina® ,Savina® 300, Evita® V800, Evita® V600:

- Expiration valve, disposable, 10 pcs. (MP01061)

For Evita® V500, Evita® V300

- Expiration valve, Infinity® ID, disposable, 10pcs (MP01060)

A.1d Flow Sensor:

Deploy Flow Sensor listed in the list of accessories of the ventilator such as:

- Flow sensor, Spirolog®, 5 pcs. (8403735)

A.1e 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.

A.1f 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.

A.2. Optional components for ventilator

A.2a Additional Breathing System Filter (BSF) **at the expiratory port (mandatory for active humidification)**

The BSF should be mechanical in HEPA-quality. In order to avoid a potential contamination of the ambient air the following filters are recommended at the exp. device connector.

- for Evita® V300 & V500: Infinity ID Expiratory Filter (MP01780)
  Service life acc. to IfU
- for Savina® 300, Evita® V800 and Evita® V600: Expiratory Filter (MP01781)
  Service life acc. to IfU
- for other Evita and Savina ventilators: preferably Filter SafeStar 80 (MP01785) or SafeStar 55 (MP01790)
  Service life acc. to IfU

A.2b Furthermore, it is possible to use a **Breathing System Filter** (BSF) in HEPA-quality **at the inspiratory port**.

Reprocessing recommendations:
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 2.

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 ventilators 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 which are in contact with the patient's breathing gas:
- the breathing circuit, HME/ breathing system filters, expiration valve, flow sensor, CO_2 cuvette
- the suctioning and monitoring accessories and
- all air inlet filters of the devices 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. 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).

C4. 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.

D5. Wrap the ventilator, 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.

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.
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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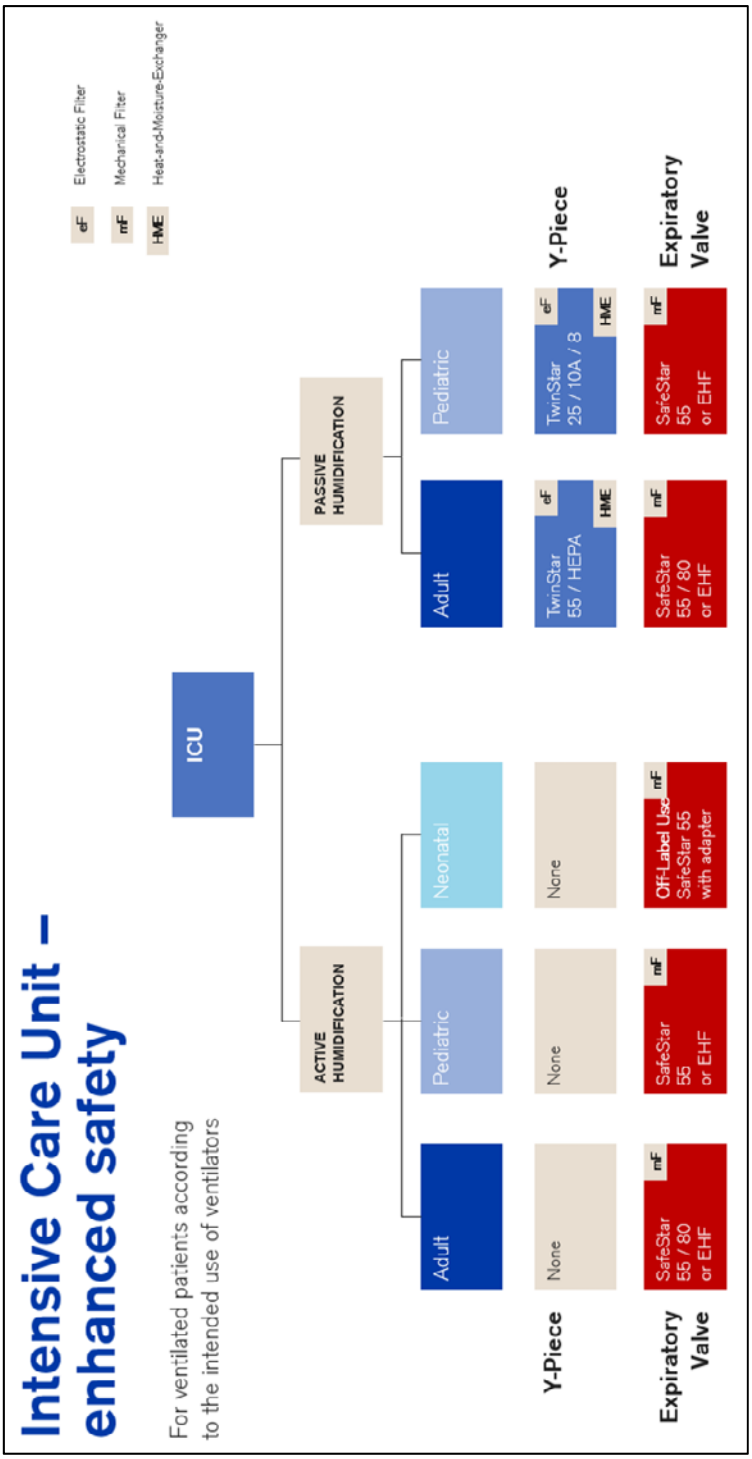
Attachment 1: BSF recommendation for different patient categories and use cases



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