Drägerwerk AG & Co. KGaA, 23542 Lübeck

SARS-CoV-2 and handling of medical devices for Patient Monitoring System reprocessing recommendations for confirmed or highly suspected SARS-CoV-2-patients.

July 22, 2020

Dear Sir or Madam,

The following information and recommendations are targeted for Patient Monitoring 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

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A. System setup recommendation for confirmed or highly suspected SARS-CoV-2-patients.
Information on the setup of the patient monitor with its accessories such as ECG cables, NIBP cuffs, SpO2 sensors, etc., 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:

A1 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

A2 Monitoring Pods:

- ☐ Mcable Analog/sync pod
- ☐ etCO2 Mainstream Module
- ☐ etCO2 Microstream Smart pod
- ☐ Mcable Mainstream etCO2
- ☐ EEG Pod
- ☐ BISx Smart pod
- ☐ MultiMed 12 pod
- ☐ MultiMed/NeoMed Cables
- ☐ CNAP Smart pod
- ☐ Trident NMT Smart pod
- ☐ HemoMed pod
- ☐ MPod QuadHemo
- ☐ Mcable DualHemo pod
- ☐ Masimo SET SpO2 Smart pod
- ☐ Mcable Masimo Rainbow SET pod
- ☐ Mcable Nellcor OxiMax pod
- ☐ Nellcor OxiMax SpO2 Smart pod

Reusable Monitoring pods and accessories should follow the manufacturer recommended reprocessing instructions.
For types and part numbers please see the Dräger Accessory Catalogue.

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 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.

B1. Follow the occupational safety and reprocessing guidelines of the hospital and the local/ national health authorities.

B2. Remove all disposable device components:

- ☐ Disposable ECG cables and patient electrodes
- ☐ Disposable SpO2 sensors
- ☐ Disposable NIBP cuffs
- ☐ etCO2 Filter lines

B3. Reprocess all components listed in the reprocessing list as described in the Instructions for Use.

B3. Clean and disinfect thoroughly all accessible surfaces of the patient monitor, the other devices and reusable components with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions).

B4. Allow to air dry

C. Optional measures

The reprocessing of potentially contaminated products/components is achieved by performing the standard procedures described in section B (according to the IfU) 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 B (standard reprocessing measures) were performed.

C5. Wrap the patient monitor, 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.

C6. Remove plastic cover and dispose of safely.

C7. Clean and wipe disinfect thoroughly with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions) all accessible surfaces of the monitor and other devices and reusable components.

C7 Allow to air dry.

C8. 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 recommended for patient monitors when used in a manner consistent with their intended use. 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 Patient Monitoring / System setup and reprocessing recommendations for confirmed or highly suspected SARS-CoV-2- patients.