

March 24th, 2020

SARS-CoV-2 and handling of medical thermoregulation devices for Neonatal Intensive Care

Dear Sir or Madam,

The following information and recommendations are targeted for Dräger warming therapy devices that were used with 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 a 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 disinfectants 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 components

A1 Warming Therapy devices:

Disposable accessories should be used and disposed after each patient:

Babyleo TN500

MX11000	Central Skin Temperature Probe
MX11001	Peripheral Skin Temperature Probe
MX17018	Water Transfer Hose
MU06943	Cover for skin temperature probe CARE-FOR-ME, large
MU06944	Cover for skin temperature probe CARE-FOR-ME small

Isolette 8000

MU12551	Skin temperature probe Premi-Probe 5, disposable
MU06943	Cover for skin temperature probe CARE-FOR-ME, large
MU06944	Cover for skin temperature probe CARE-FOR-ME small
MU21120	Condensate management hoses for Isolette® 8000 and 8000 plus
MU10918	Suction bottle with filter and tube for Isolette® 8000, disposable, 800 mL

Isolette 8000 Plus

MU26041	Skin temperature probe Premi-Probe for Isolette® 8000 plus, disposable, yellow, central
MU26042	Skin temperature probe Premi-Probe for Isolette® 8000 plus, disposable, white, peripheral
MU06943	Cover for skin temperature probe CARE-FOR-ME, large
MU06944	Cover for skin temperature probe CARE-FOR-ME, small
MU21120	Condensate management hoses for Isolette® 8000 and 8000 plus
MU10918	Suction bottle with filter and tube for Isolette® 8000, disposable, 800 mL

Isolette C2000

MU06943	COVER,PROBE,CFM,LGE,Box/100
MU06944	Temp. probe,cover,CFM,STD,Box/100
MU12551	PROBE 5, LG, SKIN TMP, BOX/10
MU03876	IRIS PORT SLEEVE,BOX/100
MU06570	ACS PORT CUFFS,0V,REPL,BOX/100

Resuscitaire

MP00310	Breathing circuit for Resuscitaire VentStar®, disposable
MP00311	Breathing circuit for Resuscitaire VentStar®, disposable, with pressure measurement line
MU10841	Breathing hose for Resuscitaire® with AutoBreath, disposable
MU10900	Breathing hose for breathing bag, disposable
MP01502	Neonatal Breathing Mask
MU10915	Hydrophobic Replacement Filters
MU11228	Skin temperature probe Premi-Probe 3, disposable
MU06943	Cover for skin temperature probe CARE-FOR-ME, large
MU06944	Cover for skin temperature probe CARE-FOR-ME, small
MU10916	Suction bottle with holder for Resuscitaire, disposable, 40 mL
MU10917	Suction bottle, disposable, 40 mL

Babytherm 8004/8010

MX11000	Central Skin Temperature Probe
MX11001	Peripheral Skin Temperature Probe
MU06943	Cover for skin temperature probe CARE-FOR-ME, large
MU06944	Cover for skin temperature probe CARE-FOR-ME, small

Transport Incubator TI-500

MU06933	Skin temperature probe Premi-Probe 1, disposable
MU06943	Cover for skin temperature probe CARE-FOR-ME, large
MU06944	cover for skin temperature probe CARE-FOR-ME, small
MU06011	Restraining strap, disposable

Globe-Trotter GT-500

MU04771	Breathing hose for TI 500 Globe-Trotter, disposable
MU04772	Disposable Exhalation Valve
MU06011	Restraining strap, disposable
MU06933	Skin temperature probe Premi-Probe 1, disposable

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.

Reprocessing recommendations:

Reprocessing of products, components and surfaces potentially contaminated by SARS-CoV-2 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 virucidal effectiveness. The following recommendations for warming therapy 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 warming therapy device and/or contact your local sales organization.

Due to

- the to date 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 the following enhanced procedure as an additional precaution for the time being:

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 (please refer to the list of accessories under section A1).
- C3. Clean and disinfect thoroughly all accessible surfaces of the warming therapy device, the other devices and reusable components with a suitable disinfectant (concentration and exposure time according to manufacturer's instructions). Please refer especially for the Softbed & Gel Mattress to the instruction for use.
- C4. Allow to air dry.

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 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. Please also visit our Dräger website for further information on Covid-19 and related product information.

With best regards,



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