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Use of Getinge oxygenators and cardiopulmonary products in COVID-19 / SARS-CoV-2 patients

Dear valued customers,

Getinge endeavors to support you during the coronavirus (COVID-19/ SARS-CoV-2) pandemic.

Due to the current situation with person-to-person spread of coronavirus (COVID-19/ SARS-CoV-2) we have received frequent inquiries about the usage of our oxygenators and cardiopulmonary products with COVID-19 patients. The following Q&A provides an overview about the current situation.

Getinge points out that it has no test data specific to this topic. The Q&A is mainly based on technical and theoretical considerations of which Getinge is aware.

DISCLAIMER: This is NOT medical advice, the information contained herein is intended for informational purposes ONLY, and should NOT be used as a substitute for the advice of an appropriately qualified and licensed physician or healthcare provider. The responsibility for deciding whether to use an oxygenator rests solely with the attending physician or healthcare provider. Getinge Group urges to strictly follow the instructions for use (IFU) provided with each medical device unit as approved or cleared by the FDA, or country specific regulatory authority. Including, the device specific time utilization limit and adequate unit maintenance. Please, check with a physician or healthcare provider if you have health questions or concerns about medical device interactions, or contact the FDA/other local authorities for a comprehensive list of warnings. Although we attempt to provide accurate and up-to-date information related to our products and COVID-19/SARS-CoV-2, Getinge

makes no representation or warranty of any kind, express or implied, of any information or medical device use not contained or described in the approved medical device instruction for use.

Q&A

Has COVID-19 been identified in blood specimen of patients?

We are currently only aware of a few publications from China^{1,2} in which the COVID-19 virus has been detected in patient blood. Nevertheless, the existing publications show that this scenario is possible.

How likely is coronavirus transmission from Getinge oxygenators with Polymethylpentene (PMP) diffusion membrane fibers?

Oxygenators with PMP fibers are designed to be plasma tight which may prevent leakage, however, specific testing on coronavirus has not been performed. If a fully functional Getinge PMP membrane oxygenator is used in accordance with well-established recommendations, coronavirus might not pass from the blood to the gas side of the membrane due to the plasma tight layer. As of today, Getinge has no evidence that the coronavirus penetrates or diffuses through the PMP membrane used in such oxygenators manufactured by Getinge.

Can the coronavirus, if present in patient's blood, migrate to the water side of the oxygenator?

Liquid and particle-tight thermoplastic polyurethane fiber are used as water-carrying heat exchange fiber. Unless there is a technical defect (e.g. rupture or leakage), it is believed that the coronavirus cannot pass from the blood side to the water side.

Can viruses pass through the hydrophobic membrane of the de-airing port of the oxygenator?

As long as the de-airing port of the oxygenator is closed, no aerosol or liquid may exit from the de-airing membrane, therefore, reducing risk of contamination from a virus. Getinge recommends to keep the de-airing port closed during use and monitor it closely.

If an active de-airing is required during use, viral particles may potentially exit through the micropores of the de-airing membrane. It must be individually decided how to proceed with a given situation (e.g. change out of the tubing set or oxygenator, finalizing the surgery, etc.).

¹ Wang W, Xu Y, Gao R, Lu R, Han K, Wu G, Tan W: Detection of SARS-CoV-2 in Different Types of Clinical Specimens. JAMA 2020.

² Chang L, Yan Y, Wang L: Coronavirus Disease 2019: Coronaviruses and Blood Safety. Transfus Med Rev 2020.

In any case, the Standard Operating Procedures (SOP) for contaminated environment and material respectively of the local institution must be followed.

Which disinfectants can be used against coronaviruses for surface disinfection of medical devices manufactured by Getinge, for example, such as the Cardiohelp-i?

For surface disinfection of cardiopulmonary devices the corresponding sections of the respective instruction for use (IFU) must be followed.

Human coronaviruses such as SARS, MERS, HCoV can be efficiently inactivated by surface disinfection procedures with 62-71% ethanol within 1 min exposure time. A similar effect is expected against the SARS-CoV-2. Also 70% isopropanol efficiently inactivated coronavirus infectivity within 30 seconds exposure time in suspension tests (Kampf et al 2020).

Please note that Ethanol and/or Isopropanol at a concentration of 70% are referenced in all Instructions of Use for surface disinfection of Cardiohelp-i, the Rotaflow Console and Heater Unit HU 35.

The alcohol based disinfectant Bacillol® AF listed in the IFU for surface disinfection of Cardiohelp-i and HU 35 is officially declared as effective against enveloped viruses including 2019-nCoV by the manufacturer BODE Chemie GmbH.

For further information related to device usage, surface cleaning and disinfection refer to the corresponding instruction for use, and where appropriate the user manual.

Will Getinge perform specific tests with the COVID-19 virus in the context of using its oxygenators in coronavirus infected patients?

Our current assessment of the situation is based on scientific publications, expert assessments and technical considerations. Due to the novelty and rapid global spread of coronavirus, empirical laboratory tests evaluating the coronavirus transmission risk from Getinge oxygenators is not available. Should such empirical data become available to Getinge, then Getinge will pass such information on to you.

Getinge has contacted several internal and external experts in order to better understand the current situation with respect to COVID-19 patients who have used our oxygenators. Furthermore, Getinge monitors the development of the coronavirus pandemic situation on a regular basis and will continuously update this Q&A based on any new information obtained by Getinge through the worldwide medical community.

Are there already reported cases of COVID-19 transmission between patients via any Getinge oxygenator?

Getinge currently is not aware of any reported cases of such transmission with our products.