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Your request regarding the surface disinfection of Dräger medical devices

Dear Sir or Madam,

The following information and recommendations are targeted for ventilation devices from Dräger that were used on patients infected with Ebola.

Background:

Ebola is a rare, often fatal virus originating in tropical Africa and associated with symptoms of hemorrhagic fever. This means both internal and external bleeding (hemorrhages) of the body. The mortality rate is around 90 percent. However, the risk of infection for people without any direct contact to those infected is very low.

The virus is transmitted by direct contact with blood and bodily fluids of an infected person or animal. The virus can also be transmitted via contaminated objects, such as needles. Unprotected contact with infected corpses can also result in the spread of the virus.

Until now there are no indications of transmission of the virus from inhalation. However, infection may be spread by the mouth, nose and eyes from fluid splashes or drops such as the aerosols released when coughing, sneezing or as a consequence of medical treatment methods. The risk of Ebola entering the respiratory system can be reduced by using suitable respiratory protection.

The Ebola virus belongs to the category of enveloped viruses that in principle can be removed with disinfectants with limited virucidal effectiveness. Due to high infection risk it is recommended by the CDC and other organizations to use EPA registered hospital disinfectant with a label claim for a non-enveloped virus (e.g., norovirus, rotavirus, adenovirus, poliovirus).

Further information and links to guidelines from WHO, CDC and national organizations you can find in the document: 141017_information_letter_ebola.pdf.



Reprocessing recommendations:

Dräger has tested the following EPA listed full virucidal surface disinfectants to be compatible with all the materials of the Dräger Medical product portfolio.

- OxyCide from Ecolab (reg. no. 1677-237, FF-ATH)
- BruTab 6S from Brulin (reg. no. 71847-6-106, Klorsept from Medentech)
- Rely on Virkon from Dupon (reg.no.71654-7, Virkon from DuPont)

In general we can say that Oxygen and Chlorine releasing disinfectants show better material compatibility. Nevertheless we must as well advise against the use of O2 releasing agents that contain AHP (accelerated hydrogen peroxide licensed by Virox). Chlorine releasing disinfectants may cause color changes in soft or bright materials over time. This well-known effect and does not justify warranty claims.

The following recommendations for the handling of ventilation devices contaminated with Ebola are based on general guidelines and practice for highly infectious diseases. Ebola viruses should be removed with standard procedures described in the IFU including the use of virucidal disinfectants, but due to the high infection risk and missing definitive data on its susceptibility to reprocessing measures and its viability on inanimate surfaces we recommend for the time being the following enhanced procedure as an additional precaution.

A. essential component

- 1. In general please follow the occupational safety and reprocessing guidelines of the hospital and the local/national health authorities.
- 2. Remove the breathing circuit, expiration valve, flow sensor and air inlet filters and dispose safely as highly infectious waste (e.g. incinerate).
- 3. Wipe disinfect thoroughly with a full virucidal disinfectant (concentration and exposure time according to manufacturer's instructions) all outer surfaces of the ventilator.
- 4. Allow to air dry.

B. optional component (recommendation for a higher safety level, if required. This part depends on the assessment of the transmission characteristics and should be in line with the general hospital guideline for all medical devices in the patient vicinity)

- 5. Wrap the ventilator completely with a plastic cover and store safely for a specified time (e.g. 30 or 60 days).
- 6. Remove plastic cover and dispose safely as highly infectious waste (e.g. incinerate).
- 7. Clean and disinfect device as described in point 3.
- 8. Device can be released for reuse.

Based on the individual situation, hospital management responsible for infection control and hygiene hygienic needs to decide on the required measures.



If there are 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 provided by the Dräger Safety division.

With best regards,

Ernst W. Schubert

Global Marketing Manager Corporate Structural Platforms

Segment Hospital