AKTINA MEDICAL

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Active Breathing Coordinator Viral and Bacterial Efficiency

As we continue to monitor the latest updates and information about the global COVID-19 outbreak, Aktina would like to take this opportunity to address questions that you, your clinic or your patients may have regarding risks of transmission of COVID-19 or other respiratory bacteria or viruses when using the Active Breathing Coordinator (ABC) for treatment.

The mouthpiece and filter kits are designed for single patient use only. The ViroMax® viral/ bacterial filter is constructed of a Styrene-Acrylonitrile Copolymer which supports the filter media constructed from a mod acrylic blend of fibers. This filter been tested and certified to >99.99% viral and >99.999% bacterial efficiency.

The filter was manufactured to FDA GMP and ISO 13485:2016. The FDA 510(k) clearance number is K063526. The filter's technical data sheet is attached.

Regarding filter efficiency for the COVID-19 virus, specifically:
The ABC filter is effective against viral particles as small as 0.1 micron in size. As a comparison, the CDC recommends use of N95 face masks for health care providers caring for COVID-19 patients. The FDA states that N95 masks have been rated for particles as small as 0.3 micron in size. Excerpts of both statements are below:

*Most HCP caring for confirmed or suspected COVID-19 patients should not need to use surgical N95 respirators and can use **standard N95 respirators**.*
Source: https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirator-use-faq.html

The 'N95' designation means that when subjected to careful testing, the respirator blocks at least 95 percent of very small (0.3 micron) test particles.
Source: https://www.fda.gov/medical-devices/personal-protective-equipment-infection-control/n95-respirators-and-surgical-masks-face-masks

Since the CDC recommends 0.3 microns or smaller, the Viromax filtration efficiency of 0.1 microns clearly meets or exceeds the CDC guidelines.

Other cleaning precautions:
Elekta recommends you use Control III or Wavicide-01 to clean and sterilize the turbine cartridge contained in the patient respiratory system. Please note that Control III can only be used as a disinfectant. Wavicide-01 or other similar glutaraldehyde-based sterilant solutions may be used as either a disinfectant or a sterilant. For disinfection, use 10 minute immersion. For a sterilant, use 10 hour immersion for Wavicide-01, or as recommended by the manufacturer of the similar sterilant solution. The full instructions can be found in section 7.3.3, "Cleaning the turbine" of the ABC R3.0 Installation and Service Manual [Doc. 1504311_02].

General cleaning guidelines for surface areas of the device can been found in the Active Breathing Coordinator™ User Manual – Instructions for Use. [Doc. 1501433 02].

Please contact your Elekta representative for the two manuals referenced above.

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