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.

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.

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.

Tony Spaccarotella, Director, QA/RA
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Robert Pasquale, QA/RA Specialist
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