Dear Customer,

We have received multiple inquiries regarding The MetaNeb® System, the patient circuit, device filters, and nebulizer therapy in the context of the COVID-19 disease. We understand the concern for potential exposure to infectious materials, including contaminated air, to patients and caregivers. As such, we would like to address the inquiries related to reducing the potential for infection resulting from aerosolized SARS-CoV-2 (the cause of COVID-19) virus particles.

The CDC recommends health care teams take precaution when performing aerosol-generating procedures or procedures that could induce coughing. When performing these procedures: Wear appropriate PPE, limit caregivers in the room, use AIIRs when possible, follow clean and disinfect procedures promptly in guidance from the CDC and hospital protocol. Refer to the CDC Infection Control website for full recommendations.

The MetaNeb® System Filters:

- The MetaNeb® System has two filters - One inside the control unit and one as part of the Patient Circuit.
  - As per our requirements, the control unit’s filter screen stops particles greater than 0.1mm.
  - Both filters are tested in accordance with ISO 23328-1:2008 with a filtration efficiency of greater than 99% or penetration of less than 1% where the particles used in the testing are sodium chloride particles ranging from 0.1 to 0.3 microns. As a reference point, N95 respirators are designed to block 95% percent of 0.3-micron particles.

- Adding an additional filter between the handset and patient port delivery configuration.
  - While testing of The MetaNeb® System has not been conducted with an additional filter, we do not expect it would have a significant impact on the therapy as it relates to pressure and oscillations. However, make note that if providing aerosol medication through the nebulizer, the amount of aerosol medication received by the patient will be altered.

The MetaNeb® System Nebulizer:

- The MetaNeb System can be delivered without an aerosol medication or, at minimum, saline through the nebulizer.
  - If no medication or saline is used in the nebulizer, a MetaNeb® Therapy is not generating aerosol.
  - Keep the nebulizer component connected to the handset during treatment, even without medication or saline delivery to limit exposure to room air.

While we don’t have COVID-19 specific outcomes data, the intended use of MetaNeb® Therapy is for lung expansion and secretion clearance treatments regardless of etiology. The most common complications of COVID-19 are lower respiratory illness and pneumonia. If in the opinion of a medical professional, the patient can benefit from lung expansion and/or mobilizing of secretions, The MetaNeb® Therapy would be appropriate both in spontaneously breathing patients or for use in-line with ventilators.

Please reach out to your Hillrom representative if you have any additional questions.

Sincerely,

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