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A decorative horizontal graphic consisting of a solid blue bar on the left, followed by a series of squares and circles of varying sizes and colors (blue and teal) that fade out to the right.

Updating Evidence and Defining Aerosol Generation in
Respiratory Health OLE Therapies and Procedures: Evaluation
of the MetaNeb[®] and Volara[®] Systems

The 2019 global SARS-CoV-2 pandemic had profound impacts on healthcare resources and exposed significant gaps in current literature of what is and is not an aerosol generating procedure (AGP) during respiratory health therapies. Early into the pandemic many professional organizations like the American Thoracic Society (ATS), Society of Critical Care Medicine (SCCM), and American College of Chest Physicians (CHEST) warned that certain therapies such as intubation, bronchoscopy, high frequency chest wall oscillation (HFCWO), Oscillation Lung Expansion (OLE), non-invasive positive pressure ventilation (NIPPV) are or may cause dispersion of aerosolized particles, placing healthcare workers at increased risk of infection.^{1,2,3}

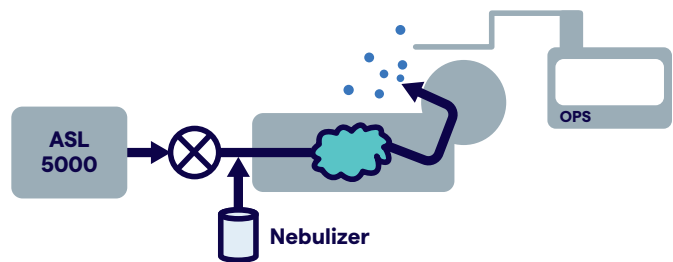
While intubation and bronchoscopy have been well studied and defined as aerosol generating procedures, HFCWO, OLE, and other routine respiratory health therapies have limited evidence. Some position statements early in the 2019 pandemic from health organizations suggested HFCWO and OLE are an AGP citing studies done during a 2003 SARS outbreak. However, it was hard to substantiate if OLE and HFCWO were true AGPs due to small sample size and design limitations. It is important to note that avoiding HFCWO and OLE therapies is considered a ‘weak recommendation’ due to low-level evidence.² Another issue that complicates this matter is rapid advances in medical device technology, HFCWO and OLE systems are no exception.

Several research papers on aerosol generation during respiratory health therapies have recently been published. Gaeckle et al. (2020) found that some non-invasive therapy modalities themselves did not increase aerosols, rather environmental conditions, individual physiology and specific activities (ex/coughing) seemed to play a bigger role in particle dispersion dynamics.⁴ Of course, the mechanism of action within a therapy group can differ from one manufacturer to the next. For this reason, medical device manufacturers can use existing data and laboratory bench tests to measure aerosol dispersion to better inform healthcare workers of their risk when using therapies to treat infectious patients.

Evaluation of the MetaNeb® and Volara™ Systems

An evaluation of OLE systems was conducted at a University Medical Institution. Bench tests were conducted by trained medical staff and mechanical engineers specializing in aerosol research. Four cases applied both the Volara and the MetaNeb systems. For case 4, nebulized aerosol was not introduced via exhalation from the patient simulator, and instead was applied via a nebulizer mimicking nebulization based therapy. (Figure 1)

Figure 1: Schematic diagram of the combined breathing simulator-aerosol source-SimMan 3G®.



The bench model utilized an ASL-5000™ breathing simulator, a custom made aerosolization source and a SimMan 3G® patient simulator. Aerosol was generated within the system and was exhaled into the test room during exhalation. The aerosol dispersion during exhalation simulated that which occurs during spontaneous patient breathing. With the SimMan 3G/ Aerosol system in operation, particles were then measured at two locations 11.8 inches and 19.7 inches from the mouth respectively, (Figure 3) within the room (using a TSI optical particle spectrometer (OPS) 3330) to determine the dispersion of aerosol during simulated patient breathing (Figure 1). After collecting baseline measures, OLE therapy was added to the SimMan 3G/Aerosol system and measurements were repeated with the Volara System and then with the MetaNeb System. Evaluation of aerosol dispersion during therapy was conducted using a number of circuit configurations. Four cases applied both the Volara and the MetaNeb systems. For case 4, nebulized aerosol was not introduced via exhalation from the patient simulator, and instead was applied via a nebulizer mimicking nebulization based therapy. (Figure 1).

Figure 2: A summary of the four cases applied with both OLE Therapies.

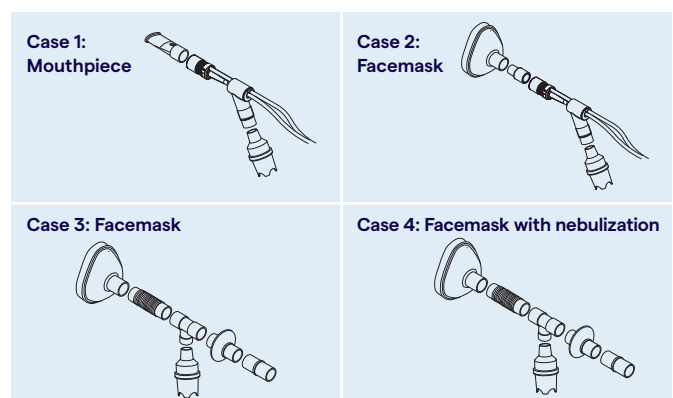
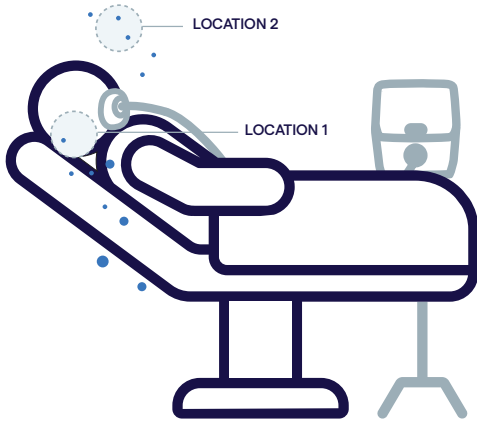
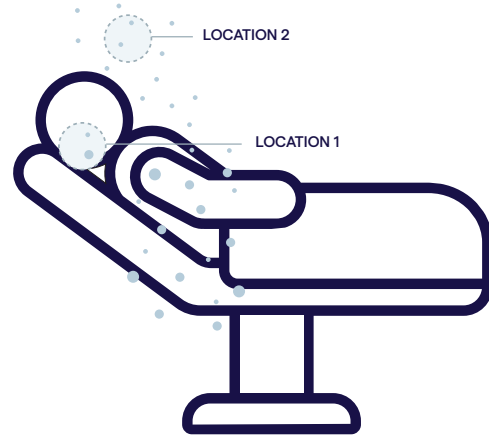


Figure 3: Visual Representation of Exhaled Aerosol Concentration Ratios (OLE Therapy with Volara vs. Normal Unassisted Breathing)

Patient using the Volara™ System



Patient Breathing Normally



NOTE: Data drawn from Case 3 of bench test study. Mask was not removed during cough.

Results

Aerosol concentrations were evaluated at selected locations at the patient simulator mouth and at a bedside location. Particle dispersion during therapy with OLE therapy, with either the Volara System or the MetaNeb® System, was generally found to be near or lower than baseline (measurements with simulated patient breathing alone) (Figure 4 & Figure 5). An increase in particles was noted during a simulated cough in both the OLE therapy tests and was also observed during simulated breathing alone. This increase was, in most instances, near the patient cheek. Our study results suggest that application of OLE therapy does not increase aerosol dispersion.

Figure 4: MetaNeb system results from Case 3: face mask with HEPA filter placed in-line.

Measuring Aerosol Particles > 0.7 µm: MetaNeb OLE w/HEPA Filter vs. Normal Breathing Patient

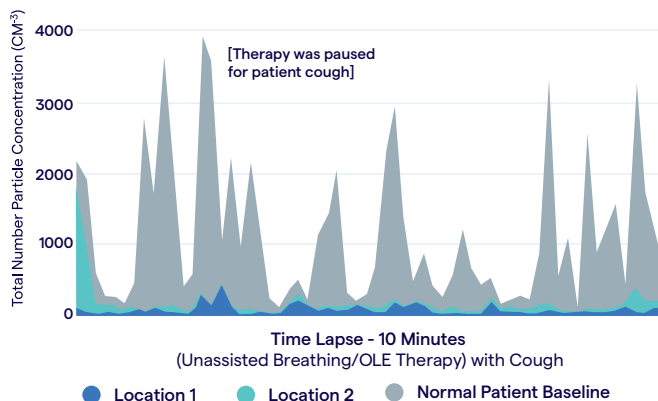
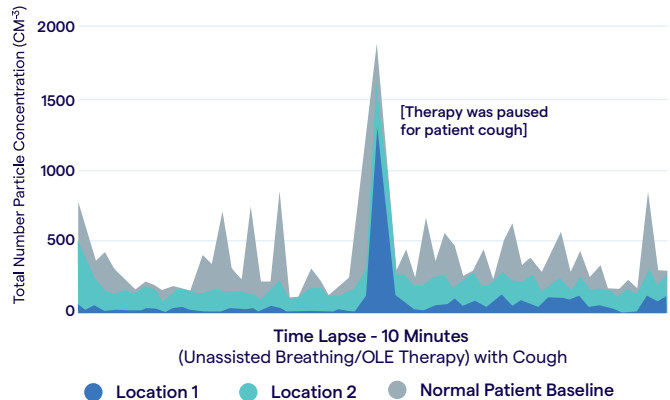


Figure 5: Volara system results from Case 3: face mask with HEPA filter placed in-line.

Measuring Aerosol Particles > 0.7 µm: Volara OLE w/HEPA Filter vs. Normal Breathing Patient





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References

- ¹ Pasnick, S. et al. (2020). SARS-CoV-2 Transmission and the Risk of Aerosol-Generating Procedures. *Am J Respir Crit Care Med* Vol. 202, P13-P14, 2020. <https://doi.org/10.1164/rccm.2024P13>
- ² Alhazzani, W. et al. (2020) Surviving Sepsis Campaign: Guidelines on the Management of Critically Ill Adults with Coronavirus Disease 2019 (COVID-19), *Critical Care Medicine*: June 2020 - Volume 48 - Issue 6 - p e440-e469 doi: 10.1097/CCM.0000000000004363.
- ³ <https://www.chestnet.org/Guidelines-and-Resources/COVID-19/Guidelines-and-Statements>
- ⁴ Gaeckle, N. T., Lee, J., Park, Y., Kreykes, G., Evans, M. D. & Hogan, C. J. (2020). Aerosol Generation from the Respiratory Tract with Various Modes of Oxygen Delivery. *American Journal of Respiratory and Critical Care Medicine* 202:1115-1124.

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