



Understanding the Role of Oscillation and Lung Expansion Therapy (OLE) During the COVID-19 Outbreak

Background on COVID-19

COVID-19, a disease caused by Coronavirus, SARS-CoV-2 started in late 2019 as a cluster of cases in Wuhan, China. Clinicians there described the pathology as a respiratory disease that often progressed into pneumonia with bilateral ground-glass opacities.¹

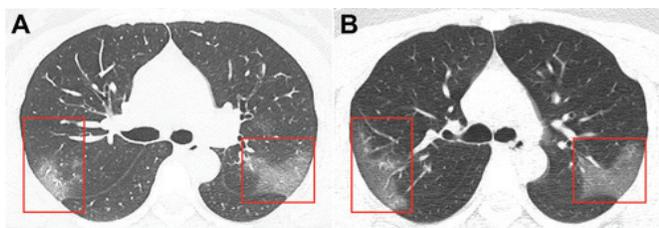


Image from Lei et al. CT Imaging of the 2019 Novel Coronavirus (2019-nCoV). Pneumonia

The Center for Disease Control (CDC)² states that elderly patients and those with underlying conditions like hypertension, cardiovascular disease or diabetes, are more likely to develop serious complications like pneumonia secondary to COVID-19 including septicemia due to cytokine activity and fluid build-up in the lower lobe.³ Hospitalized COVID-19 patients often need respiratory support. Prominent features based on recent publications³ include cough, increased amounts of thick mucus in lower airways and respiratory distress.

Below is a list of respiratory related symptoms reported on patients with COVID-19:³

- 75% experienced cough³
- 55% of patients experienced dyspnea³
- 20-30% required ICU admission and of those, 47-71% required mechanical ventilation²
- 20-30% of patients had significant respiratory mucus production²
- 17-29% of hospitalized patients developed Acute Respiratory Distress Syndrome (ARDS)²
- 5% had hemoptysis³

Clinical considerations for treating pulmonary complications with Oscillation and Lung Expansion (OLE) Therapy

- OLE therapy delivered by the MetaNeb® System helps expand the lungs using Continuous Positive Expiratory Pressure (CPEP) and Continuous High Frequency Oscillation (CHFO) for mobilization of secretions and for prevention and treatment of pulmonary atelectasis. Therapy can be delivered with or without medicated aerosol both in spontaneously breathing patients or for use in-line with ventilators
- MetaNeb System therapy can be utilized to deliver treatment across various inpatient departments, including ED and ICU. The MetaNeb System has been shown to treat pneumonia, trauma, post-op, chronic respiratory conditions, and other conditions to improve respiratory status and reduce pulmonary complications. In studies of other patient populations, use of OLE therapy has been associated with:
 - Reduced ICU length of stay⁴
 - Reduced hospital length of stay⁴
 - Reduced time on the mechanical ventilation⁴
 - Reduction in dyspnea⁵
 - Improvement in chest x-ray⁵

Rationale for Use of the MetaNeb System in COVID-19 Patients with Pulmonary Complications

Early publications and reports on the clinical manifestations of COVID-19 suggest that up to 30% of patients with severe disease have significant pulmonary mucus production. Additionally, lung disease in many of these patients progresses to Acute Respiratory Distress Syndrome (ARDS). While there are currently no COVID-19 specific outcomes data with the MetaNeb System, the intended use of MetaNeb System therapy is for lung expansion and secretion clearance treatments regardless of etiology. The therapy may therefore be helpful in preventing and/or treating such complications. Therapy with the MetaNeb

System may be appropriate either in spontaneously breathing patients or for use in-line with patients on mechanical ventilators. As with all therapies, the appropriateness of the therapy in individual patients is determined by the treating physician and the health care team.

Universal Infection Prevention & Control Recommendations with COVID-19 and Aerosolizing Therapies

Like many other respiratory illnesses, it is believed COVID-19 may be transmitted by airborne particles. As such, patients are generally placed in isolation rooms with specific infection control and prevention guidelines that must be followed.

Like all other Aerosol Generating Procedures (AGP), MetaNeb® System therapy can generate aerosols when using the medicated nebulizing component. Additionally, any therapy or procedure that may result in patient coughing or clearing secretions is considered an AGP. The CDC recommends health care providers take airborne precautions when performing any AGP in known or suspected COVID-19 patients.² When performing these procedures:

- Wear appropriate personal protective equipment (PPE) including, but not limited to an N95 fit tested respirator, gown, gloves, and face shield/eye protection
- Limit number of caregivers in the room
- Use negative airflow rooms
- Follow cleaning and disinfection procedures promptly in guidance with hospital's protocols
- Refer to facility specific Infection Control guidelines for full recommendations

Considerations with the MetaNeb System and Device Filters:

- MetaNeb System therapy can be delivered with aerosol medication or with normal saline through the nebulizer. MetaNeb System therapy can also be delivered without aerosol medication or saline. If no medication or saline is used in the nebulizer, MetaNeb System, therapy will not generate aerosol.
- The MetaNeb System has two filters - The device has a filter screen inside the control unit and a biofilter on the Patient Circuit at the connection to the Control Unit.

- The Control Unit's filter screen stops particles greater than 0.1mm.
- The biofilter has 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. The filter has been tested in accordance with ISO 23328-1:2008. As a reference point, N95 respirators are designed to block 95% percent of 0.3 micron particles.

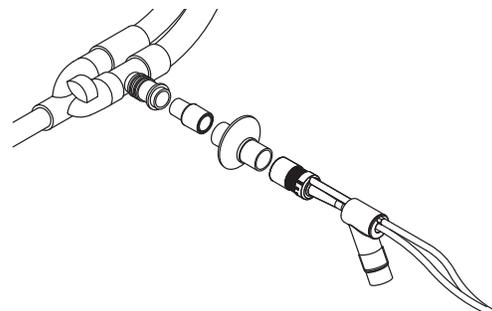
Adapting the MetaNeb System for Additional Precautions During the COVID-19 Outbreak

For additional protection when used with patients under airborne precautions, additional filters can be added between the handset and patient interface connection as well the nebulizer can be placed between the filter and the patient interface. This system, when used in mechanically ventilated patients provides a barrier that contains the aerosol generated by the therapy within the ventilator circuit.

The options for the use of the MetaNeb System with a filter in-line are as follows:

- 1) The filter is inserted distal to the MetaNeb System handset to contain potentially contaminated aerosol particles (from patient breathing or coughing) within the ventilator breathing circuit. With this configuration, the nebulizer is not used (Alternatively, the nebulizer can be attached with no medication or saline added for therapy Figure 1).

FIGURE 1: Handset/Filter Configuration (Designed to incorporate a filter to minimize aerosolization)

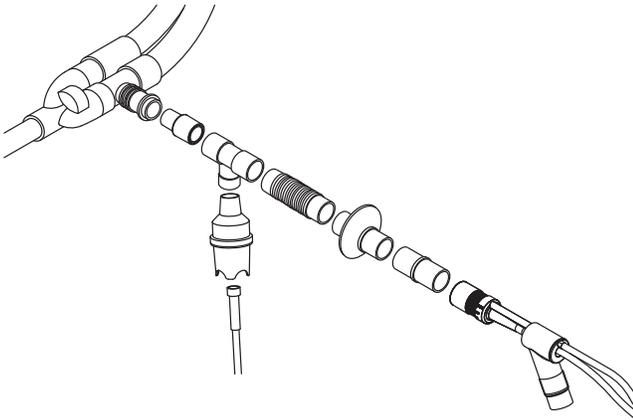


2) The filter is inserted distal to the MetaNeb® System handset and the nebulizer is inserted distal to the filter to contain potentially contaminated aerosol particles and prevent aerosolization outside of the ventilator breathing circuit. With this configuration, medication or saline may be added to the MetaNeb nebulizer for therapy (Figure 2).

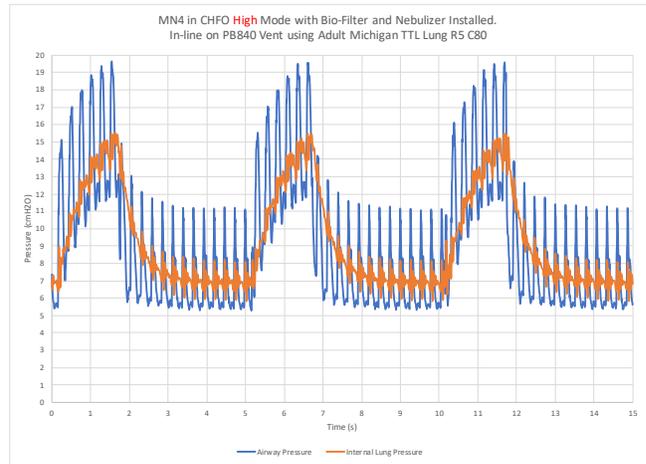
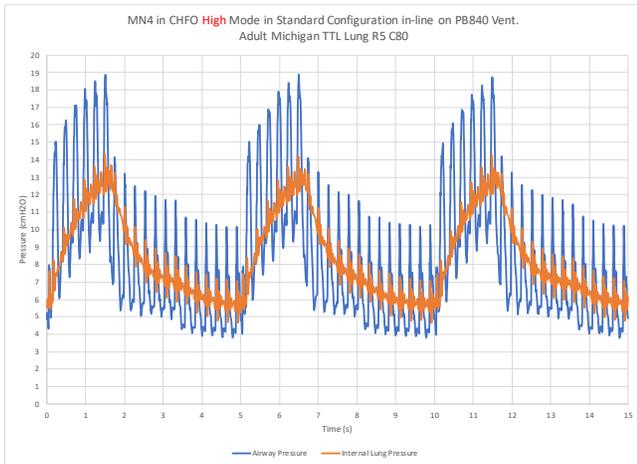
Testing of the MetaNeb System with this additional filter configuration shows a that placing the additional filter inline has minimal impact on oscillation wave and pressure delivered by the MetaNeb System.

- Important: Limiting aerosol generation using the MetaNeb filter setup assumes that the expiratory outlet from the ventilator is also protected by a biofilter.

FIGURE 2: Handset/Filter/Nebulizer Configuration (Designed to incorporate a filter and place a nebulizer distal to the filter to minimize aerosolization)



Side by side pressure results for standard setup versus biofilter setup with the MetaNeb System in CHFO High mode



Disclaimer: This additional configuration was submitted to the FDA under the recently Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency



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References

- ¹ Lei, J. (2020) CT Imaging of the 2019 Novel Coronavirus (2019-nCoV) Pneumonia. From the 2019-nCoV Investigating and Research Team, The First Hospital of Lanzhou University, 1 Donggang West Rd, Lanzhou 730000, China. Received and accepted January 29, 2020. <https://doi.org/10.1148/radiol.2020200236>
- ² <https://www.cdc.gov/coronavirus/2019-ncov/hcp/underlying-conditions.html>
- ³ Huang et al. (2020). Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. [https://doi.org/10.1016/S0140-6736\(20\)30183-5](https://doi.org/10.1016/S0140-6736(20)30183-5)
- ⁴ Huynh TT, Liesching TN, Cereda M, Lei Y, Frazer MJ, Nahouraii MR, Diette GB, Efficacy of Oscillation and Lung Expansion in Reducing Postoperative Pulmonary Complication, Journal of the American College of Surgeons (2019)
- ⁵ https://www.atsjournals.org/doi/pdf/10.1164/ajrccm-conference.2018.1971_MeetingAbstracts.A1744

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