




Hillrom™



Updating Evidence and Defining Aerosol Generation in
Respiratory Health NIPPV Therapies and Procedures:
An Evaluation of the Life2000® System

Background and Rationale

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, NIPPV and other routine respiratory health therapies have limited evidence. Some position statements early in the pandemic from health organizations called NIPPV an AGP citing data from a 2003 SARS outbreak in which several healthcare workers may have contracted the virus during NIPPV use on patients. However, this was hard to substantiate due to PPE being used incorrectly. It is important to note that avoiding NIPPV therapies was considered a 'weak recommendation' due to low-level evidence.² Another issue that complicates this matter is rapid advances in medical device technology, NIPPV systems are no exception.

Several research papers on aerosol generation during respiratory health therapies have recently been published. Gaeckle et al. (2020) suggested that oxygen modalities: high flow nasal cannula (HFNC) and NIPPV themselves do 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 Life2000 Device

An evaluation of NIPPV using the Life2000 proportional open ventilation (POV) system was conducted at a University Medical Institution. Bench tests were conducted by trained medical staff and mechanical engineers specializing in aerosol research.

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 patient breathing (Figure 1). With the SimMan 3G/Aerosol system in operation, particles were then measured at three locations within the room to determine the dispersion of aerosol during simulated patient breathing, 11.8 inches, 11.8 inches, and 19.7 inches from the mouth, respectively. (Figure 2). After collecting baseline measures, the Life2000 System was added to provide NIPPV support to the SimMan 3G/Aerosol system and measurements were repeated. Evaluation of aerosol dispersion during NIPPV therapy was conducted at a number of different therapeutic settings (Table 1).

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

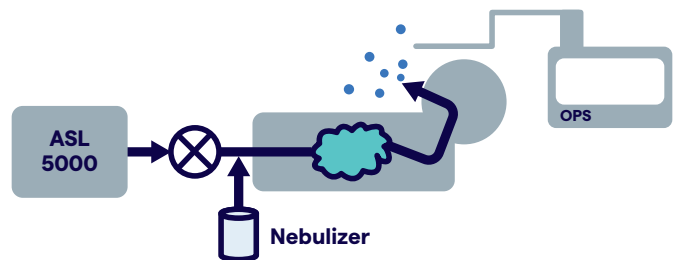
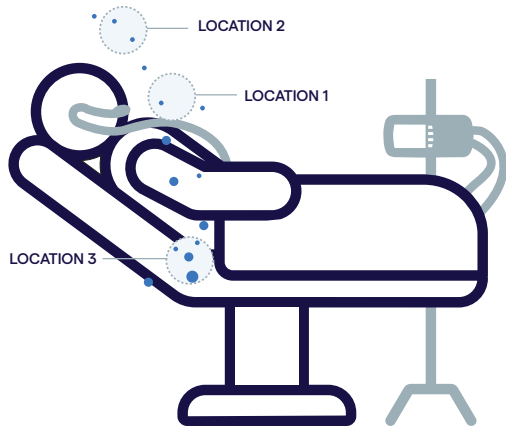
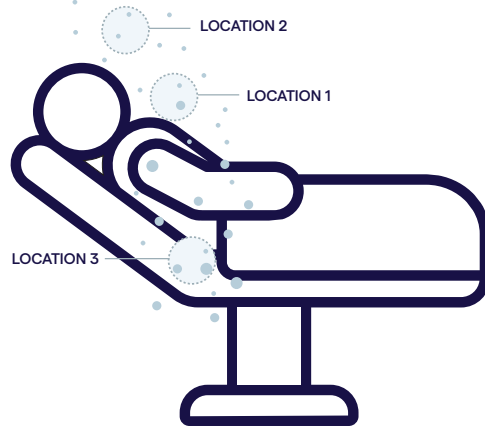


Figure 2: Visual Representation of Exhaled Aerosol Concentration Ratios (Life2000 POV vs. Normal Unassisted Breathing)

Patient with the Life2000® System



Patient Breathing Normally



NOTE: Surgical mask was placed in-line with nasal pillows.

Table 1: A summary of Life2000 system settings applied for the 12 cases, with color used to denote the ASL-5000™ settings applied.

TEST CASE SCENARIOS	CASE 1	CASE 2	CASE 3	CASE 4	CASE 5	CASE 6	CASE 7	CASE 8	CASE 9	CASE 10	CASE 11	CASE 12
Volume (mL)	180	180	180	180	230	230	230	230	250	250	250	250
Time (s)	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
BR (BPM)	12	25	25	30	12	25	25	30	12	25	25	30
PEEP (cm H ₂ O)	0	3	5	10	0	3	5	10	0	3	5	10

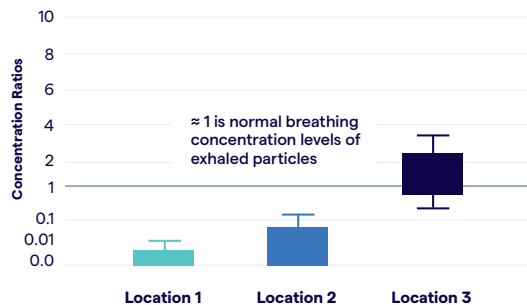
● Mild ARDS 12 bpm ● Mild ARDS 25 bpm ● Moderate ARDS 30 bpm

Results

When evaluating aerosol concentrations at selected locations within 1 m from the patient simulator mouth and at nasal passages, similar particle dispersion patterns were found during simulation patient breathing alone and with simulation patient breathing with the addition of NIPPV using the Life2000 System. Results suggest that application of Life2000 does not increase aerosol dispersion (Figure 3).

Figure 3: Summary of Life2000 system aerosol bench tests 1-12

Life2000 System Bench Tests Cases 1-12





Hillrom™

For more information or to place an order, please contact your local Hillrom sales representative or call Hillrom Customer Service at 1-800-426-4224.

hillrom.com

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.

Life2000® is a registered trademark of Breathe Technologies, Inc., a Hill-Rom company. SimMan 3G® is a registered trademark of Laerdal Medical. ASL-5000™ is a trademark of IngMar Medical. Hill-Rom reserves the right to make changes without notice in design, specifications and models. The only warranty Hill-Rom makes is the express written warranty extended on the sale or rental of its products.