Aerogen®

Aerosol drug delivery for the treatment of respiratory diseases[1-6]

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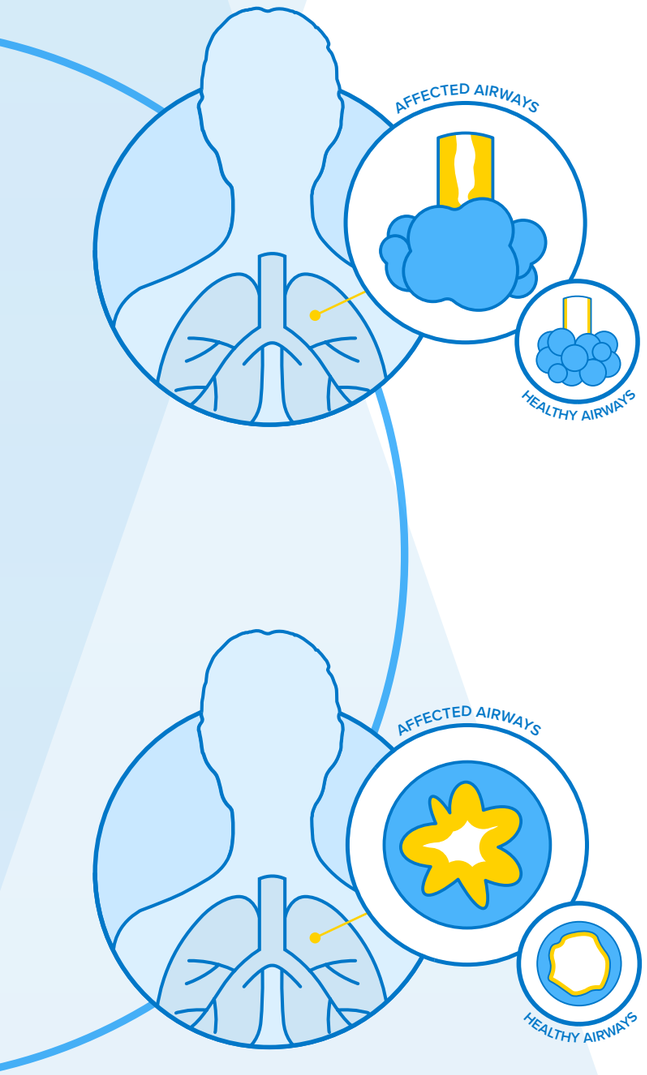
Respiratory diseases affect millions of people worldwide and are associated with considerable morbidity and mortality[7-8]



Chronic Obstructive Pulmonary Disease (COPD)

- **~212 million people** live with COPD (based on 2019 data)[7]
- COPD accounted for **74.4 million disability-adjusted life years (DALYs)** globally in 2019[7]
- In 2019 **3.3 million people** died from COPD[7]

Asthma

- **~262 million people** live with asthma (2019 data)[8]
- Asthma accounted for **21.6 million DALYs** globally in 2019[8]

Aerosol therapy is the cornerstone of treatment for respiratory conditions,[9-10] but challenges exist

GOLD 2023 guidelines (COPD)[10]

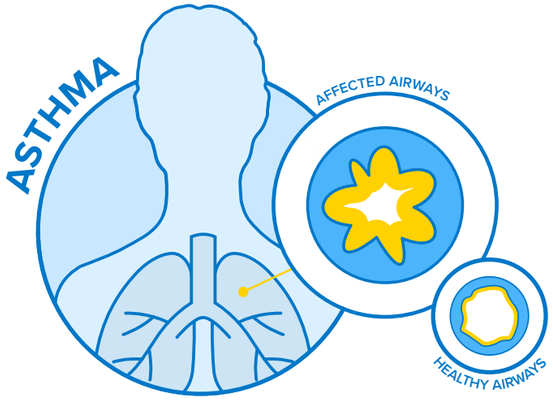
- In acute exacerbations where a nebuliser is used, an air-driven nebuliser is preferable to an oxygen-driven device due to the potential for oxygen-driven devices to increase $PaCO_2$
- GOLD guidelines acknowledge that using a mesh nebuliser in ventilated patients allows medication to be added without interrupting the circuit for aerosol drug delivery
- In critically ill patients with COVID-19 on respiratory support, GOLD guidelines note that it is vital to keep the circuit intact to prevent the transmission of the virus
- Choice of device to be based on a patient's ability to use the device, treatment goals and patient preferences

GINA 2022 guidelines (Asthma)[9]

- For children aged 3 or under who require a nebuliser, a nebuliser with a facemask is recommended and for children aged 4–5 years, a nebuliser with a mouthpiece or a facemask
- In young children with asthma, nebulisers are a viable alternative aerosol delivery system for those who are unable to use a pressurised metered-dose inhalers (pMDI) and spacer
- Choice of device to be based on the age and capability of the patient

Challenges associated with aerosol drug delivery	
Support during escalation of care	• Patients admitted to hospital during exacerbations may receive respiratory support (e.g., high-flow therapy [HF]) or ventilatory support (e.g., non-invasive ventilation [NIV], invasive mechanical ventilation [IMV])[9,10]
Difficulties with device use	• Correct technique is required to administer medication via inhaler, which can be affected by age, manual dexterity, cognitive ability and coordination skills[9,10]
Patient distress during respiratory exacerbations	• On presentation, children may be crying or in distress, which may negatively impact the dose delivered during inhaled therapy[11,12] • Jet nebulisers generate noise,[13] which may make it difficult to maintain a calm environment for patients
Concerns about fugitive emissions	• The need to open a pressurised ventilator circuit to administer aerosolised medication is considered a potential risk factor for the release of fugitive aerosol[14-16‡]

‡The study by Joyce et al was performed in an in-vitro model of mechanical ventilation.

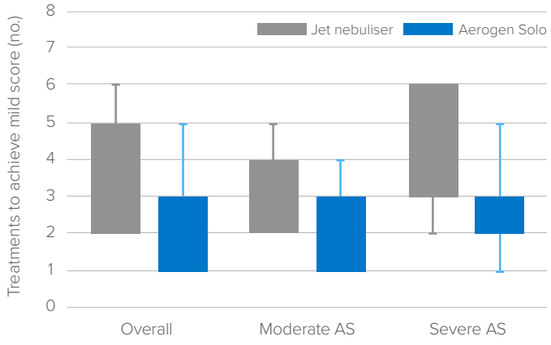


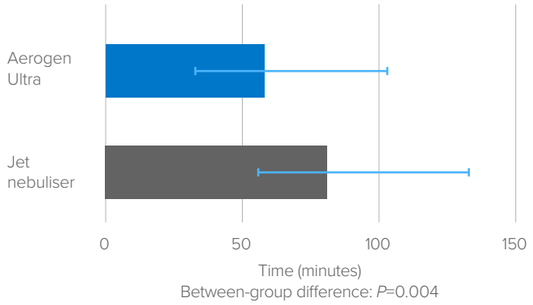
In asthma, Aerogen supports patient care in response to aerosolised medication[2,3]

In a study of self-ventilating (SV) children with a moderate-to-severe asthma exacerbation:

Significantly fewer bronchodilator treatments were required to achieve symptom control[§] with Aerogen Ultra vs a jet nebuliser, irrespective of disease severity[2]

Median (IQR) number of treatments: 2.0 (1–3) vs 3.0 (2–5); *P*<0.001.
[§]Defined as achieving a mild asthma score (AS) following an asthma exacerbation.



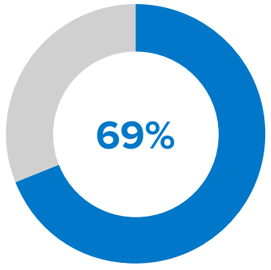


Significantly less time was required to achieve symptom control[§] with Aerogen Ultra vs a jet nebuliser[2]

Median (IQR) time: 58 (33–103) vs 81 (56–133) minutes; *P*=0.004.
[§]Defined as achieving a mild asthma score following an asthma exacerbation.

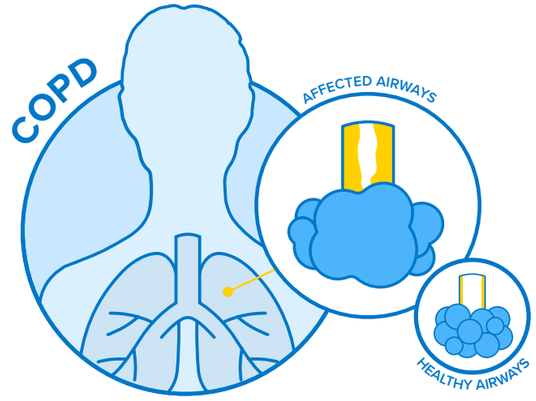
In a study of patients with COPD or asthma, in-line aerosol drug delivery with Aerogen during HF was associated with:

Comparable bronchodilator response[¶] to a pMDI + valved holding chamber, with 69% of patients achieving response with 1.5 mg of nebulised salbutamol[3]



Percentage of patients achieving response with 1.5 mg nebulised salbutamol via Aerogen

[¶]As defined by ATS/ERS criteria for bronchodilator responses in patients with mild-to-moderate asthma and COPD.

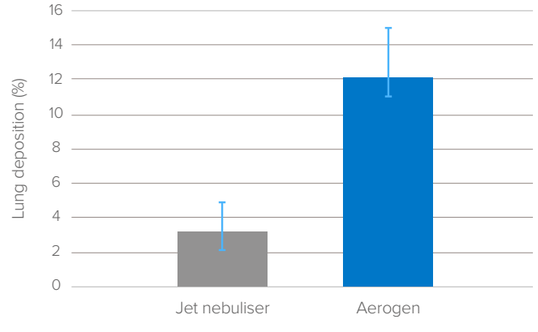


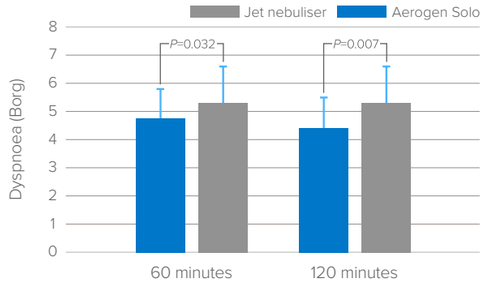
In COPD, Aerogen supports effective aerosol drug delivery[4-6]

In a study of patients with stable moderate-to-severe COPD receiving NIV:

~4x more medication was delivered to the lungs using Aerogen during NIV vs a jet nebuliser[4]

Mean (±SD) lung deposition: 12.05 ± 2.96% vs 3.14 ± 1.71%; *P*<0.001.





Borg dyspnoea score in patients experiencing acute exacerbations of COPD at 60 mins and 120 mins post-treatment with bronchodilator delivered via Aerogen Solo or a jet nebuliser. *P*-value indicates difference in change from baseline between two groups.

In a study of patients with an acute exacerbation of COPD receiving NIV:

Significant improvements in lung function (FEV_1, FVC, breathlessness score [Borg], respiratory rate [RR] and $PaCO_2$) was observed with bronchodilator therapy delivered via Aerogen Solo vs jet nebuliser[5]

Between-group difference in change from baseline to 120 minutes: FEV_1, *P*=0.001; FVC, *P*<0.001; dyspnoea (Borg) score: *P*=0.007; $PaCO_2$:*P*=0.004.

In a study of patients admitted to the intensive care unit for severe exacerbation of COPD and receiving HF:

In-line β-agonist administration via Aerogen during HF was associated with improvements in lung function (FEV_1, FVC) vs HF alone[6]

	HF alone	In-line salbutamol via Aerogen during HF	Mean percentage difference	*P*-value
FEV_1, mL	931 (383)	1,019 (432)	**9.4% (2.6–16.1)**	0.01
FVC, mL	1,601 (633)	1,775 (661)	**13.7% (5.4–22.0)**	0.003

Variables are expressed as mean (standard deviation [SD]), mean differences, and mean percentage differences (95% CI).

Aerogen helps to address some of the challenges of aerosol drug delivery in the treatment of respiratory disease

Support during escalation of care

- One system used throughout a patient's respiratory journey (IMV, NIV, HF, SV),[1] supporting continuity of care

Difficulties with inhaler use

- Aerogen is quick and easy to set up[1]
- No added flow required[1]

Patient distress during exacerbations

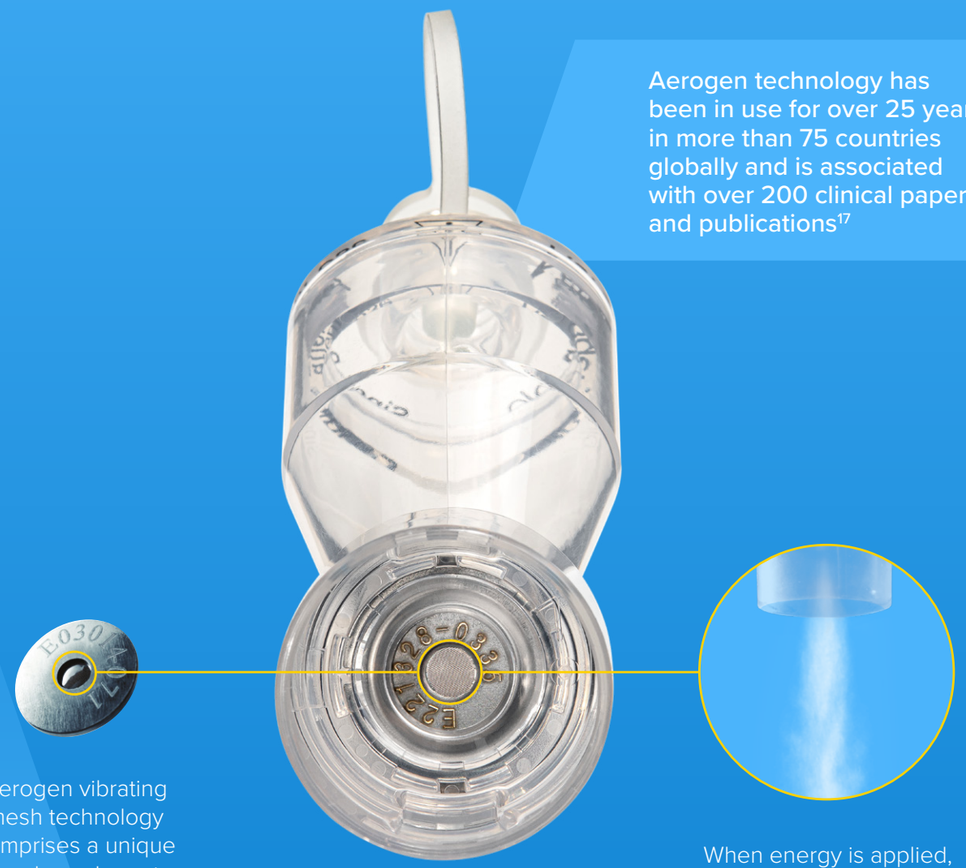
- Aerogen is virtually silent,[1,17] keeping a calm environment for your patients

Concerns about fugitive emissions

- Aerogen Solo is a closed-circuit aerosol drug delivery system,[1] which eliminates the need to open the circuit when administering medication during IMV or NIV

At the heart of every Aerogen device is our unique palladium vibrating mesh technology

Aerogen technology has been in use for over 25 years, in more than 75 countries globally and is associated with over 200 clinical papers and publications[17]



Aerogen vibrating mesh technology comprises a unique dome-shaped aperture plate perforated with over 1,000 precision formed tapered holes[17]

When energy is applied, the aperture plate vibrates at 128,000 times a second producing a low-velocity, fine particle, nebulised mist of consistently sized droplets (1-5 µm)[17], an ideal particle size for deep lung penetration[18]

Aerogen Solo

Single-patient-use device that facilitates aerosol drug delivery at every stage of a patient's respiratory journey (IMV, NIV, HF and SV).[1]

- Quick and easy to set up[1]
- Virtually silent[1,17]
- Single patient use[1]
- 28 days intermittent or 7 days continuous use[1]
- No added flow[1]
- Refill medication cup without opening the circuit[1]

Aerogen Ultra

The Aerogen Ultra is a handheld device that is used in conjunction with the Aerogen Solo to deliver inhalation treatment either during exacerbations or post-ventilation.[19]

- Oxygen port enables optional delivery of oxygen[19]
- An ergonomic, valved mouthpiece controls the flow of air through the chamber to facilitate aerosol drug delivery[19]
- Innovative chamber design provides an aerosol reservoir intended for optimal drug delivery[19]
- Extended mouthpiece[§§] to easily add bacterial or viral filter[19]

[§§]The Aerogen Ultra with an extended mouthpiece is only available in selected regions, refer to the relevant instruction manual for your region to determine availability.

Aerogen Continuous Nebulisation Tube Set

- Drop-by-drop precise medication control for continuous nebulisation[20]
- Works with most standard syringe pumps

Aerogen Controllers

- Aerogen Solo powered by Aerogen Pro-X Controller[1] or Aerogen USB Controller[21]

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ATS, American Thoracic Society; COPD, chronic obstructive pulmonary disease; DALYs, disability-adjusted life years; ERS, European Respiratory Society; FEV_1 forced expiratory volume in 1 second; FVC, forced vital capacity; HF, high-flow therapy; ICU, intensive care unit; IMV, invasive mechanical ventilation; IQR, interquartile range; NIV, non-invasive ventilation; $PaCO_2$, partial pressure of carbon dioxide; pMDI, pressurised metered dose inhaler; RR, respiratory rate; SD, standard deviation; SV, self-ventilating

1. 30-354 Rev U Aerogen Solo System Instruction Manual. **2.** Moody GB, Luckett PM, Shockley CM, et al. Respir Care 2020;65(10):1451–1463. **3.** Li J, Zhao M, Hadeer M, Luo J, Fink JB. Respiration. 2019;98(5):401-409. **4.** Galindo-Filho VC, Alcoforado L, Rattes C, et al. Respir Med. 2019;153:60-67. **5.** Avdeev SN, Nuralieva GS, Soe AK, et al. J Aerosol Med Pulm Drug Deliv. 2021;34(6):358-365. **6.** Beuvon C, Coudroy R, Bardin J, et al. Respir Care. 2021; respcare.09242. **7.** Safiri S, Carson-Chahhoud K, Noori M, et al. BMJ. 2022;378:e069679. **8.** Global burden of diseases, injuries, and risk factors study, 2019. eClinicalMedicine. 2023:101920. **9.** 2022 GINA Report, Global Strategy for Asthma Management and Prevention. Available at: www.ginasthma.org/gina-reports/ Accessed: May 2023. **10.** Global Initiative for Chronic Obstructive Lung Disease: Global strategy for prevention, diagnosis and management of COPD, 2023. Available at: www.goldcopd.org/2023-gold-report-2/. Accessed: May 2023. **11.** Ari A. Ann Transl Med. 2021;9(7):593. **12.** Corcoran TE. Ann Transl Med. 2021;9(7):595. **13.** Li J, Fink JB. Ann Transl Med. 2021;9(7):588. **14.** Joyce M, McGrath JA, Mac Giolla Eain M, et al. Pharmaceutics. 2021;13(2):199. **15.** O'Toole C, Joyce M, McGrath JA, et al. Ann Transl Med. 2021;9(7):592. **16.** Fink JB, Ehrmann S, Li J, et al. J Aerosol Med Pulm Drug Deliv. 2020;33(6):300-304. **17.** Aerogen Data on File. **18.** Labiris NR, Dolovich MB. Br J Clin Pharmacol. 2003;56(6):588-599. **19.** 30-1487 Rev A Aerogen Ultra Instruction Manual. **20.** 30-593 Rev D Aerogen CNTS flyer. **21.** 30-763 Rev H Aerogen USB Controller Instruction Manual.

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