

Aerogen[®]



Quick Reference Guide

/ Discover Better

Continuum of care



WARNING: Only trained persons should operate the Aerogen Solo System, Aerogen Solo and associated accessories. Read and study all instructions before using the Aerogen Solo System and accessories. For complete list of warnings, please consult the Warnings section.

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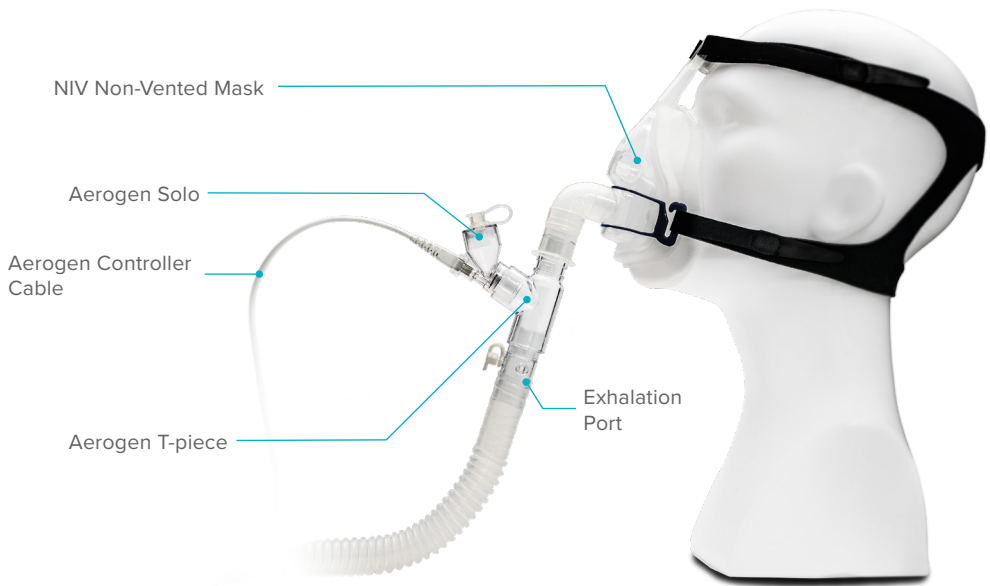
Aerogen[®]

Optimal orientation of the Aerogen® Solo

The Aerogen Solo is a gravity-fed device. Always ensure the proper orientation of the Aerogen Solo within the application.



Non-invasive ventilation (NIV) single limb circuit



1. Place the Aerogen Solo firmly into the Aerogen T-piece. Ensure correct orientation
2. Insert the Aerogen Solo and the Aerogen T-piece between the non-vented mask and the exhalation port*



4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller
5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode



3. Open the plug on the Aerogen Solo, insert medication, then close the plug

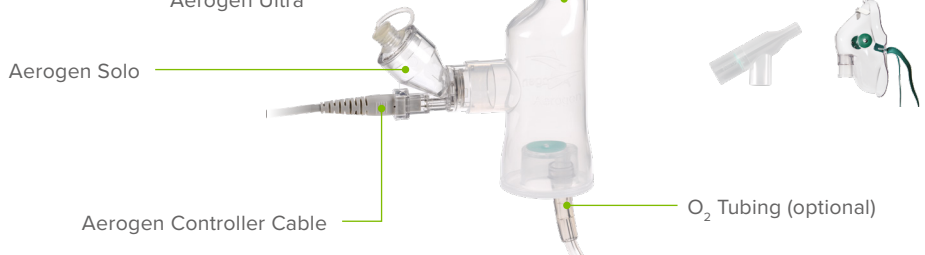


6. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode

*leak port or exhalation valve.

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Aerogen Ultra



1. Place the Aerogen Solo firmly into the Aerogen Ultra. Ensure correct orientation



- 2a. If supplemental oxygen is required, firmly attach oxygen tubing to the Aerogen Ultra. Oxygen flow rate should be set between 1-6 LPM**



- 2b. If a face mask is required, remove the mouthpiece and attach the face mask to the Aerogen Ultra. When using an open face mask, a minimum oxygen flow rate of 1 LPM is required



3. Open the plug on the Aerogen Solo, insert medication, then close the plug



4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller



5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
6. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode
7. Observe and confirm that aerosol is visible once powered on

Warnings:

Performance

- Do not use with a closed face mask or a standard oxygen mask
- **When using with an aerosol face mask, always use supplemental oxygen flow of 1-6 LPM for adult and a maximum of 2 LPM* for paediatric patients less than 18 years of age (US only)
- Performance of the Aerogen Ultra may vary depending upon the type of drug and the Aerogen Ultra configuration used
- Do not exceed recommended oxygen flow for system
- Ensure oxygen connection port or tubing is not occluded
- If using a non-Aerogen supplied filter, change filter as per manufacturer instructions or more frequently if it becomes obstructed (US only)
- Visually check the Aerogen Ultra post-rinsing to ensure that valves have not become dislodged
- Do not cover the Aerogen Ultra valves during use
- The Aerogen supplied filter must be dry and free of secretions. Wet filter material may result in low filtration efficiency (US only)
- Ensure tubing is safely orientated to prevent strangulation hazard
- When connecting a 22mm(M) breathing system filter to the Aerogen Ultra Mouthpiece, ensure that the filter does not occlude the exhalation valve of the mouthpiece

- Change the filter as per manufacturer instruction or more frequently if it becomes obstructed
- Do not attempt to sterilise, autoclave or clean the Aerogen supplied filter. If using the Aerogen Ultra in conjunction with the Aerogen supplied filter, refer to the Warnings section
- The Aerogen Ultra, when used in combination with the Mouthpiece, Aerogen Solo nebuliser and a filter (with a recommended minimum efficiency rating of 99.9% (Bacterial) or 99.8% (Viral)) has the ability to reduce but not eliminate the risk of transmission or acquisition of an infectious agent by healthcare workers or others

General

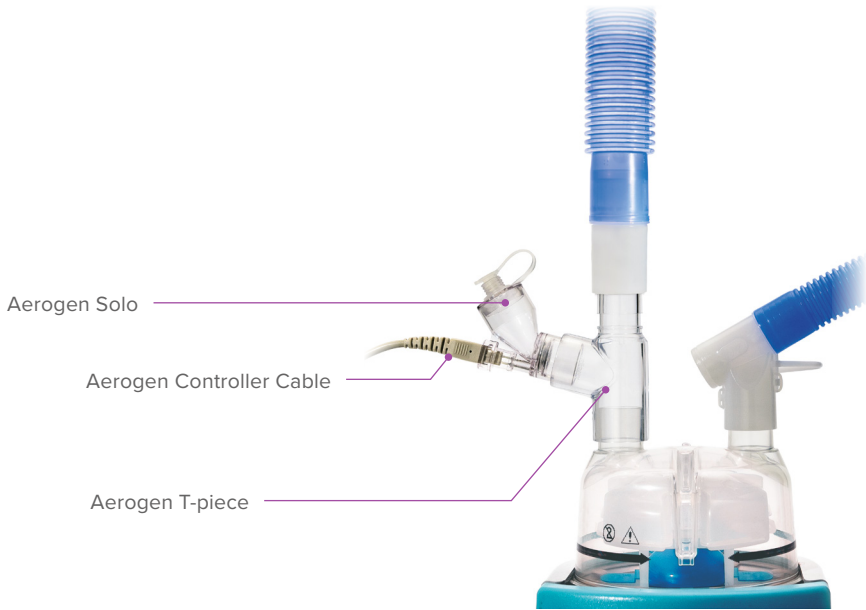
- To be used by trained personnel only
- Use only with recommended components
- Ensure tubing is safely orientated to prevent strangulation hazard
- Ensure oxygen connection port or tubing is not occluded.
- Do not use the Aerogen Ultra without a mouthpiece or face mask
- Do not autoclave any component of the kit
- Do not cover Aerogen Ultra valves during use

*Adult or Paediatric masks not available in all markets.

NOTE: The Aerogen Ultra captures the aerosol in the valved chamber. As a patient inhales you will see the bolus of aerosol being released.

WARNING: Only trained persons should operate the Aerogen Solo System, including Aerogen Solo, Aerogen Ultra and associated accessories. Read and study all instructions before using the Aerogen Solo System and accessories. For complete list of warnings, please consult the Warnings section.

Adult High-flow



1. Place the Aerogen Solo firmly into the Aerogen T-piece (22mm). Ensure correct orientation
2. Insert the Aerogen Solo and the Aerogen T-piece on the dry side of the humidifier



3. Open the plug on the Aerogen Solo, insert medication, then close the plug

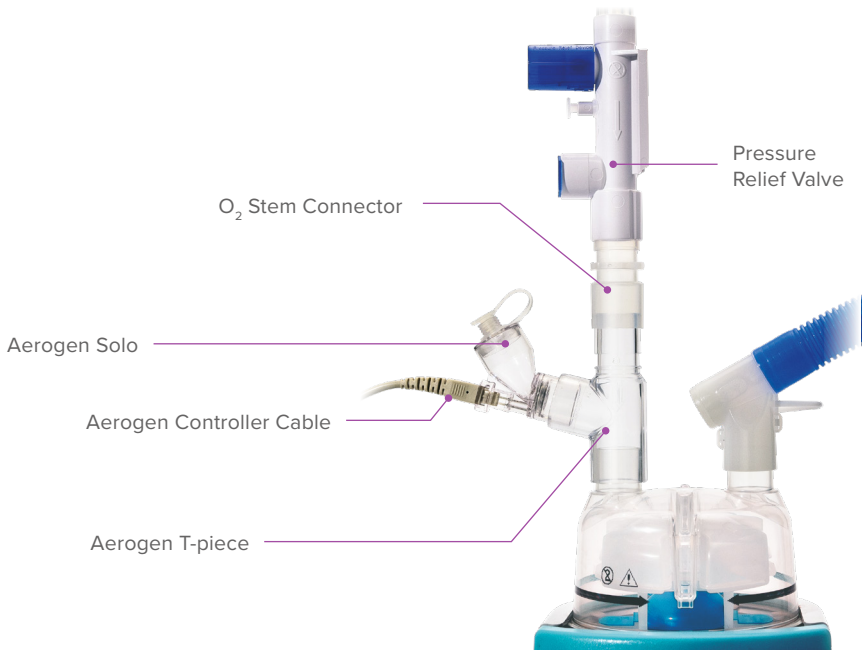


4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller



5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
6. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode

Paediatric High-flow



1. Place the Aerogen Solo firmly into the Aerogen T-piece (22mm). Ensure correct orientation

2. Insert the Aerogen Solo and the Aerogen T-piece on the dry side of the humidifier

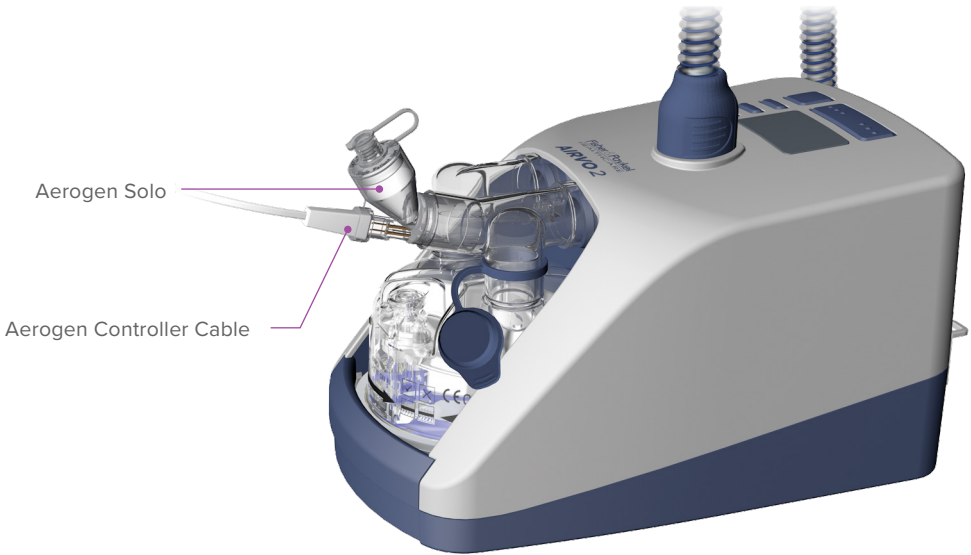


3. Open the plug on the Aerogen Solo, insert medication, then close the plug



4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller
5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
6. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode

Aerogen Solo and the F&P Airvo™ 2



1. Assemble the Airvo Neb tube and chamber kit with nebuliser adapter
2. Remove the nebuliser port plug from the Airvo 2 and connect the Aerogen Solo. Ensure correct orientation
3. Ensure that the Airvo is switched on with humidified gas flowing before the Aerogen Solo is used



4. Open the plug on the Aerogen Solo, insert medication, then close the plug

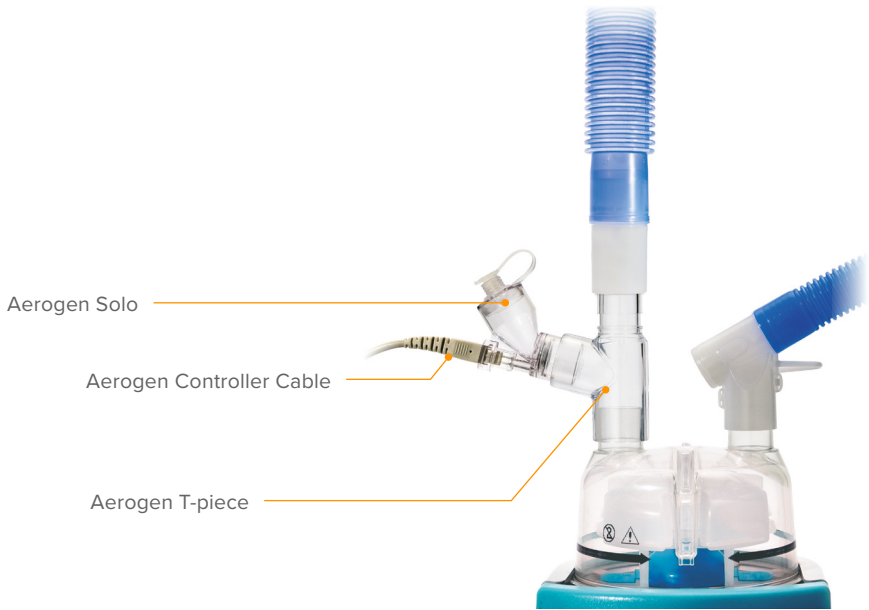


5. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller



6. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
7. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode

Dry Side of the Humidifier



1. Place the Aerogen Solo firmly into the Aerogen T-piece (22mm). Ensure correct orientation
2. Insert the Aerogen Solo and the Aerogen T-piece on the dry side of the humidifier



3. Open the plug on the Aerogen Solo, insert medication, then close the plug

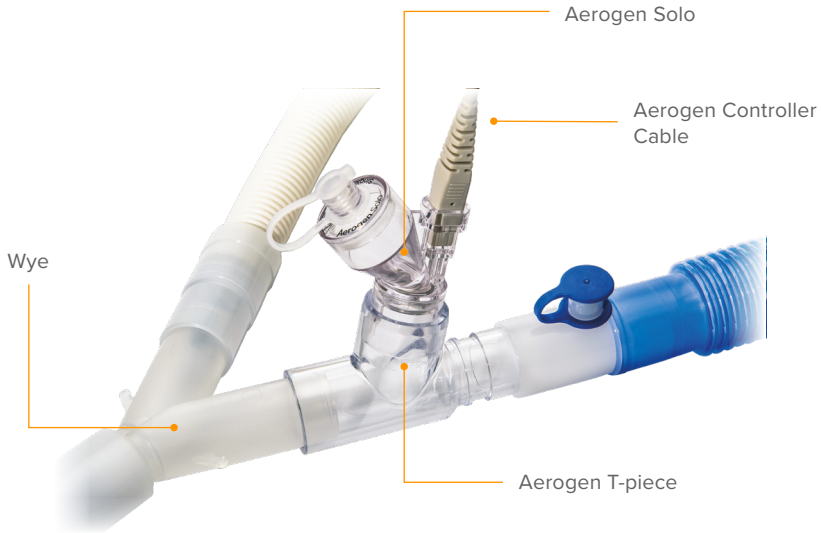


4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller
5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
6. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode

NOTE: Some drugs may change the colour of the water to brown in the heated humidifier.

WARNING: Only trained persons should operate the Aerogen Solo System, Aerogen Solo and associated accessories. Read and study all instructions before using the Aerogen Solo System and accessories. For complete list of warnings, please consult the Warnings section.

At the Wye



1. Place the Aerogen Solo firmly into the Aerogen T-piece. Ensure correct orientation

2. Insert the Aerogen Solo and the Aerogen T-piece into the inspiratory limb of the breathing circuit before the patient Wye



3. Open the plug on the Aerogen Solo, insert medication, then close the plug



4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller

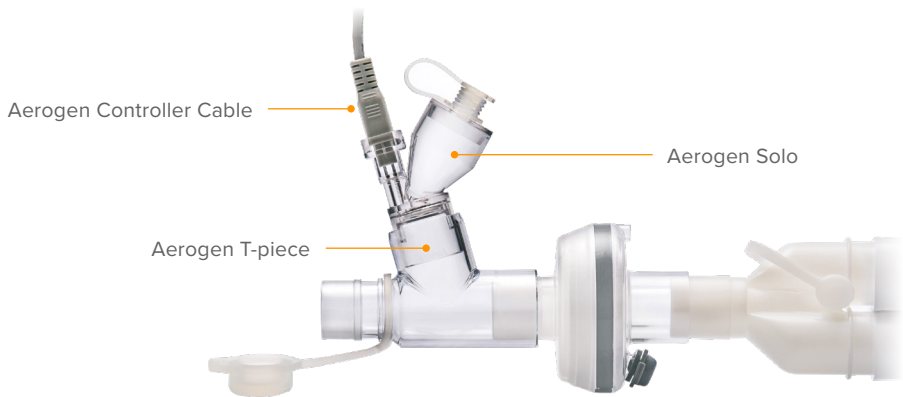
5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode

6. Press and hold the On/Off button for 3 seconds from the off position to operate:

- a. Aerogen Pro-X Controller in continuous mode
- b. Aerogen USB Controller in 6 hours mode



Heat Moisture Exchanger (HME)



1. Place the Aerogen Solo firmly into the Aerogen T-piece. Ensure correct orientation
2. Insert the Aerogen Solo and the Aerogen T-piece between the HME/HMEF and the patient interface



4. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller



3. Open the plug on the Aerogen Solo, insert medication, then close the plug



5. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
6. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode

Contraindications:

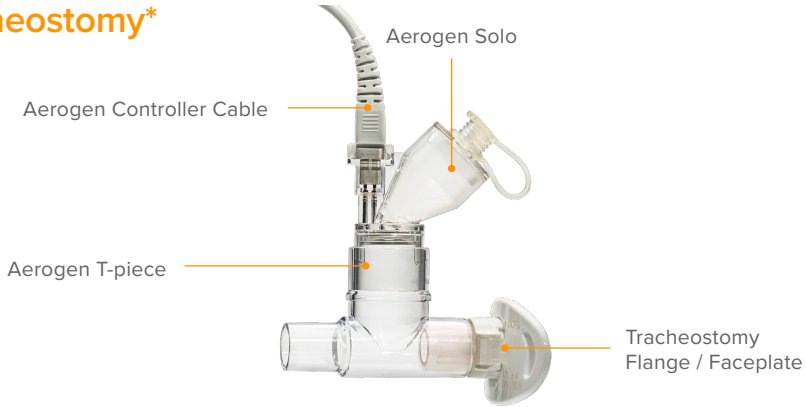
Do not use the Aerogen Solo between the Wye and a neonatal patient*. The total combined volume of the Aerogen Solo nebuliser, Aerogen T-piece and/or HME may increase the dead space to the extent that it adversely impacts the ventilatory parameters of the neonatal patient

Warnings:

- Only use with HME devices whose manufacturer's instructions allow use with a nebuliser, and always follow the HME manufacturer's instructions

- Ensure that the total combined volume of Aerogen Solo, Aerogen T-piece with or without a HME is suitable for the tidal volume being delivered and does not increase dead space to the extent that it adversely impacts the ventilatory parameters of the patient
- Always monitor the resistance to flow and excessive rain-out and change the HME device as per manufacturer's instructions
- Do not use a filter or HME between the Aerogen Solo and patient airway
- Condensate can collect and occlude ventilator circuits. Always position ventilator circuits so that fluid condensate drains away from the patient
- Always connect a bacteria filter to the expiratory inlet of the ventilator, otherwise the function of the expiratory channel may be degraded

Tracheostomy*



1. Place the Aerogen Solo firmly into the Aerogen T-piece (15mm). Ensure correct orientation
2. Attach the Aerogen Solo and the Aerogen T-piece to the tracheostomy tube assembly
3.
 - a. For extra length, insert a connector or extension, as required
 - b. If using a single limb tracheostomy set-up please place the Aerogen Solo and the Aerogen T-piece between the patient and the exhalation port**



5. Connect the Aerogen Controller Cable to the Aerogen Solo and either the Aerogen Pro-X Controller or Aerogen USB Controller
6. Press the On/Off button on either Aerogen Controller for 1 second to select the 30 minutes mode
7. Press and hold the On/Off button for 3 seconds from the off position to operate:
 - a. Aerogen Pro-X Controller in continuous mode
 - b. Aerogen USB Controller in 6 hours mode



4. Open the plug on the Aerogen Solo, insert medication, then close the plug

Contraindications:

- Do not use the Aerogen Solo nebuliser with neonatal tracheostomised patients. The total combined volume of the Aerogen Solo nebuliser, T-piece and tracheostomy tube assembly may increase the dead-space to the extent that it adversely impacts the respiratory parameters of the neonatal patient

Warnings:

- The combined weight of the tracheostomy tube assembly, nebuliser and T-piece configurations may cause de-cannulation
- Ensure that the total combined volume of nebuliser, T-piece and tracheostomy tube assembly is suitable for the tidal volume being delivered and does not increase dead space to the extent that it adversely impacts the respiratory parameters of the patient

*Aerogen is not approved for use in tracheostomy patients in the US. **Leak port or exhalation valve.

Suitable for mechanically ventilated and spontaneously breathing tracheostomy patients.

WARNING: Only trained persons should operate the Aerogen Solo System, Aerogen Solo and associated accessories. Read and study all instructions before using the Aerogen Solo System and accessories. For complete list of warnings, please consult the Warnings section.

Warnings

System Warnings

- Read and study all instructions before using the Aerogen Solo System and accessories
- Only trained persons should operate the Aerogen Solo System, Aerogen Solo and associated accessories
- This is a single patient use device not to be used on more than one patient to prevent cross infection
- The components and accessories of the Aerogen Solo System, as packaged, are not sterile
- The components and accessories of the Aerogen Solo System are not made with natural rubber latex
- Inspect all parts before use, and do not use if any parts are missing, cracked or damaged. In case of missing parts, malfunction or damage, contact your sales representative
- Only use physician-prescribed solutions that are approved for use with a general purpose nebuliser. Consult drug manufacturer's instructions regarding suitability for nebulisation
- Use only with Aerogen Solo components, connectors and any accessories, which are specified by Aerogen in the instruction manual
- Do not use beyond defined life
- To avoid exhaled medication affecting the ventilator, follow ventilator manufacturer's recommendations for use of a bacterial filter in the expiratory limb of a breathing circuit
- Do not use in the presence of flammable substances or flammable anaesthetic mixtures combined with air, oxygen or nitrous oxide
- To avoid the risk of fire, do not use to aerosolise alcohol-based medications, which can ignite in oxygen-enriched air and under high pressure
- Do not autoclave any component or accessory of the Aerogen Solo System
- Keep all cables tidy to avoid tripping or strangulation hazards and take particular care around children
- Do not store the Aerogen Solo System in a location where it is exposed to direct sunlight, extreme heat or cold, pests, dust or moisture. Store out of reach of children and pets
- Adult supervision is required when this product is used by children and individuals who require special assistance to avoid small parts being inhaled or swallowed
- Do not modify this equipment without the authorisation of the manufacturer
- Do not use or store outside of specified environmental conditions
- To avoid damage to the nebuliser:
 - Do not apply undue pressure to the domed aperture plate in the centre of the nebuliser
 - Do not push out the Aerogen Vibronic® aerosol generator
 - Do not use a syringe with a needle to add medication
 - Do not attempt to clean the nebuliser
- Condensate can collect and occlude ventilator and/or patient circuits. Always position ventilator and/or patient circuits so that fluid condensate drains away from the patient
- Use of the Aerogen Solo and T-piece during the administration of volatile anaesthetics may result in adverse effects on the constituent plastics. Do not use with volatile anaesthetics unless known to be compatible. Aerogen have determined that, using anaesthetic ventilators, the following volatile anaesthetic agents are compatible under the stated conditions below:

Anaesthetic Agent	Proprietary Name	Maximum Percentage of Anaesthetic	Maximum Duration of Exposure
Isoflurane	FORANE®	3.5%	12 hours
Sevoflurane	SEVOFLURANE®	8%	12 hours
Desflurane	SUPRANE®	10%	12 hours

Usage, Assembly and Installation Warnings

Aerogen Solo Warnings

- To ensure uninterrupted operation of the Aerogen Solo, secure both the AC/DC adapter cable and the controller cable so they cannot become disconnected during treatment. If clips are available on patient circuits, run the cables through the eyes of the clips. If clips are not available, ensure that all cables are routed safely
- The AC/DC adapter is the means of isolating the Aerogen Solo System from the mains power supply
- The continuous mode can only be operated from AC power supply
- Do not over-tighten knob on the universal mounting bracket

Aerogen Pro-X Controller Warnings

- Do not immerse or autoclave the Aerogen Pro-X Controller, cable or AC/DC adapter
- Do not place the Aerogen Pro-X Controller in an incubator during use
- Do not use abrasive or sharp tools
- Do not spray liquid directly onto the controller
- Do not wrap the nebuliser cable tightly around any of the system components
- Do not use in the presence of devices generating high electromagnetic fields such as magnetic resonance imaging (MRI) equipment
- The Aerogen Pro-X Controller contains a nickel metal hydride (NiMH) rechargeable battery, which should be disposed of in accordance with local governing regulations at the end of its useful life
- Follow local laws and recycling plans regarding disposal or recycling of components, batteries and packaging

Aerogen HME Warnings

- Only use with HME devices whose manufacturer's instructions allow use with a nebuliser, and always follow the HME manufacturer's instructions
- Ensure that the total combined volume of nebuliser, T-piece with or without a HME is suitable for the tidal volume being delivered and does not increase dead space to the extent that it adversely impacts the ventilatory parameters of the patient
- Always monitor the resistance to flow and excessive rain-out and change the HME device as per manufacturer's instruction
- Do not use a filter or heat-moisture exchanger (HME) between the nebuliser and patient airway
- Condensate can collect and occlude ventilator circuits. Always position ventilator circuits so that fluid condensate drains away from the patient
- Always connect a bacteria filter to the expiratory inlet of the ventilator. Otherwise the function of the expiratory channel may be degraded

Aerogen Tracheostomy Warnings

- The combined weight of the tracheostomy tube assembly, nebuliser and T-piece configurations may cause de-cannulation
- Ensure that the total combined volume of nebuliser, T-piece and tracheostomy tube assembly is suitable for the tidal volume being delivered and does not increase dead space to the extent that it adversely impacts the respiratory parameters of the patient

Aerogen Face Mask and Mouthpiece Use Warnings

- To ensure correct nebulisation, maintain the nebuliser in a vertical orientation

Aerogen Ultra Warnings

- Do not use with a closed face mask or a standard oxygen mask
- When using with an open face mask, always use supplemental oxygen flow of 1-6 LPM
- **When using with an aerosol face mask, always use supplemental oxygen flow of 1-6 LPM for adult and a maximum of 2 LPM† for paediatric patients less than 18 years of age (*US only)
- Performance of the Aerogen Ultra may vary depending upon the type of drug and the Aerogen Ultra configuration used
- If using a non-Aerogen supplied filter, change filter as per manufacturer instructions or more frequently if it becomes obstructed (US only)

- Do not clean or sterilise
- Do not connect to any nebuliser other than the Aerogen Solo

- Only use the Aerogen Solo nebuliser with components specified in the Instruction Manual. Use of the Aerogen Solo nebuliser with components other than those specified in the Instruction Manual may result in increased emissions or decreased immunity of the Aerogen Solo nebuliser system
- Do not use the Aerogen Solo adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify normal operation in this configuration
- The Aerogen Solo needs special precautions regarding electromagnetic compatibility ("EMC") and must be installed and put into service according to the EMC information provided in the Instruction Manual
- Portable and mobile radio frequency ("RF") communication devices can disrupt medical electrical equipment

- To avoid damage to the Aerogen Solo, do not use a syringe with a needle
- During use observe for correct functioning of the nebuliser
- The maximum capacity of the nebuliser is 6 mL

- It is important to ensure that the maximum flow rate through the tube set into the nebuliser must not exceed the output rate of the nebuliser
- Check for leaks from the system prior to and during use
- The graduations on the syringe are for indication use only
- Store at room temperature and use product within labelled shelf life
- To ensure correct and safe connection between the nebuliser and the medication reservoir, trace the medication tube from the nebuliser back to the medication reservoir to make sure the medication tube is connected to the correct source
- The recommended syringe pump software setting with the Aerogen syringe is typically the "60mL BD Plastipak" setting. This must be established locally before use. Refer to pump manual or manufacturer for guidance. These pumps may also be used in accordance with local hospital or ward policies
- Ensure that the tethered silicone plug is attached to the Aerogen Solo when connecting tube set
- Ensure that the tubing is safely orientated to prevent a trip hazard
- Rising level of medication in the reservoir may occur if the Aerogen Solo nebuliser is turned off while the feed system is still on or the nebuliser is not in its recommended orientation
- The level of the medication in the reservoir of the Aerogen Solo nebuliser should be periodically monitored to ensure that the fill rate of medication does not exceed the output rate of the nebuliser. A rising level of medication in the reservoir indicates that the fill rate is exceeding the output rate of the nebuliser
- Replace both the tube set and syringe when changing the type of medication
- If the syringe needs to be replaced during use (even when empty), turn off the syringe pump and disconnect the nebuliser end of the tube set first. Failure to do this may result in primed medication in the tube flowing into the nebuliser reservoir
- To avoid spillage of medication when changing the syringe tubing, keep both ends of the tubing at the same height
- Do not connect the tube set and syringe to non-respiratory equipment

Clinical and scientific societies around the world recommended closed circuit or vibrating mesh technology systems during COVID-19

- ✓ GOLD[†]: Science Committee Report 2020¹
- ✓ AARC[†]: Guidance 2020²
- ✓ ISAM[†]: Interim Guidance 2020³
- ✓ Spanish Scientific Societies: Expert Clinical Consensus 2020⁴
- ✓ Chinese Thoracic Society: Respiratory Care Committee 2020⁵
- ✓ Indian Society of Critical Care Medicine: Position Statement 2020⁶
- ✓ Indian Chest Society: Guidance 2020⁷



200+ peer reviewed studies and reviews related to Aerogen technology⁸

[†]GOLD (Global Initiative for Chronic Obstructive Lung Disease), AARC (American Association for Respiratory Care), ISAM (The International Society for Aerosols in Medicine)

1. Halpin DMG, Criner GJ, Papi A, Singh D, Anzueto A, Martinez FJ et al. Global Initiative for the Diagnosis, Management, and Prevention of Chronic Obstructive Lung Disease: The 2020 GOLD Science Committee Report on COVID-19 & COPD. *Am J Respir Crit Care Med* 2020. doi:10.1164/rccm.202009-3533SO. 2. American Association for Respiratory Care SARS CoV-2 Guidance Document. <https://www.aarc.org/wp-content/uploads/2020/03/guidance-document-SARS-COVID19.pdf> (accessed 13 Jul 2020). 3. Fink JB, Ehrmann S, Li J, Dailey P, McKiernan P, Darquenne C et al. Reducing Aerosol-Related Risk of Transmission in the Era of COVID-19: An Interim Guidance Endorsed by the International Society of Aerosols in Medicine. *J Aerosol Med Pulm Drug Deliv* 2020; : jamp.2020.1615. 4. Cinesi Gómez C, Peñuelas Rodríguez O, Luján Torné M, Egea Santaolalla C, Masa Jiménez JF, García Fernández J et al. Clinical consensus recommendations regarding non-invasive respiratory support in the adult patient with acute respiratory failure secondary to SARS-CoV-2 infection. *Med Intensiva* 2020. doi:10.1016/j.medin.2020.03.005. 5. Chinese Respiratory Therapy Group, Chinese Medical Association Respiratory Branch. Expert Consensus on Respiratory Therapy Related to New Coronavirus Infection in Severe and Critical Patients. *Chinese J Tuberc Respir Med* 2020; 17: 1-12. 6. Kumar GP, Kulkarni AP, Govil D, Dixit SB, Chaudhry D, Samavedam S et al. Airway Management and Related Procedures in Critically Ill COVID-19 Patients: Position Statement of the Indian Society of Critical Care Medicine. *Indian J Crit Care Med* 2020; 24: 630-642. 7. Swamakar R, Gupta NM, Halder I, Khilnani GC. Guidance for nebulization during the COVID-19 pandemic. *Lung India*. 2021 Mar;38(Supplement):S86-S91. 8. Data on file in Aerogen, 2022. PubMed search conducted January 2022 looking at publications related to Aerogen technology (Jan 1998-Jan 2022).

Distributed By



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