Aerogen®

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)

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- The Aerogen supplied filter must be dry and free of secretions. Wet filter material may result in low filtration efficiency (US only)
- Do not attempt to sterilise, autoclave or clean the Aerogen supplied filter
- Do not exceed recommended oxygen flow for system
- Ensure oxygen connection port or tubing is not occluded
- Do not use the Aerogen Ultra without a mouthpiece or face mask
- Visually check the Aerogen Ultra post-rinsing to ensure that valves have not become dislodged
- Do not cover the Aerogen Ultra valves during use
- Do not use the Aerogen Ultra in conjunction with the Aerogen Pro
- Do not autoclave any component of the kit
- Ensure tubing is safely orientated to prevent strangulation hazard
- To be used by trained medical personnel only
- Use only with recommended components
- 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
- 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

30 Minute Mode (intermittent) Warnings

- 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

Aerogen Continuous Nebulisation Tube Set (CNTS) Warnings

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

Electromagnetic Susceptibility Warnings

- 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