Aerogen®

Aerogen® Solo

System Instruction Manual

www.aerogen.com

Contents

Introduction

The Aerogen® Solo System is an iteration of the Aerogen® Pro System. The indications for use of the Aerogen® Pro System are given below. The Aerogen® Solo System consists of the Aerogen® Solo nebuliser and the Aerogen® Pro-X Controller. It is intended for hospital use only to nebulise physician-prescribed medications for inhalation which are approved for use with a general purpose nebuliser. The Aerogen® Solo nebuliser is for single patient use only and the Aerogen® Pro-X Controller is for re-use.

The Aerogen Solo System is suitable for intermittent and continuous nebulisation of neonate, paediatric and adult patients as described in this manual.

Indications for Use

The Aerogen Pro System is a portable medical device for multiple patient use that is intended to aerosolise physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance. The Aerogen Pro System is suitable for use in adult, paediatric and neonate patients as described in the Instruction Manual.

Aerogen Solo System

The Aerogen Solo System includes the following components:

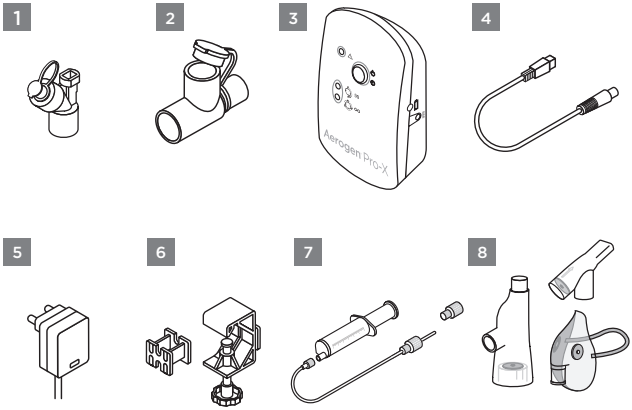


Figure 1. Aerogen Solo System

1. Aerogen Solo With Plug
2. T-Piece (Adult)*
3. Aerogen Pro-X Controller
4. Controller Cable
5. AC/DC Adapter
6. Universal Mounting Bracket & Equipment Mount Adapter
7. Continuous Nebulization Tube Set*
8. Aerogen® Ultra* and I-Guard™ Aerosol Mask

* Neonate and paediatric adapters, Continuous Nebulization Tube Set and the Aerogen Ultra are sold separately. Visit www.aerogen.com for full parts list.

System Contraindications and Warnings

Contraindications

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

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.

System Warnings

Read and study all instructions before using the Aerogen Solo System and accessories. Only trained medical personnel should operate the device.

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 this instruction manual.

Do not use beyond defined life (see page 30).

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.

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

Assembly & Installation

Aerogen Solo System Set-Up

Perform a functional test of the Aerogen Solo before use as described in the Functional Test section of this manual (See page 26).

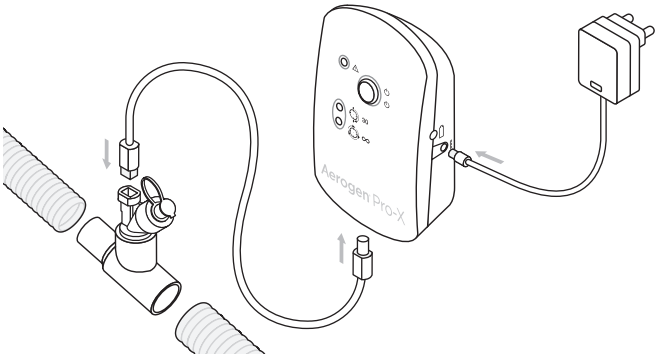


Figure 2. Assembly of the Aerogen Solo System

1. Connect the Aerogen Solo to the T-piece by pushing the nebuliser firmly onto the T-piece.
2. Insert the Aerogen Solo and the T-piece into the breathing circuit.
   Note: For use with other accessories, refer to Figure 13, Figure 14 and Figure 15.
3. Connect the Aerogen Pro-X Controller to the Aerogen Solo using the nebuliser cable.
4. To operate on AC power (the primary mode of operation), connect the Aerogen Pro-X AC/DC adapter to the Aerogen Pro-X Controller.
5. Plug the adapter into an AC power source.
6. The Aerogen Pro-X Controller can be battery-operated for portable applications. The rechargeable battery can power the System for up to 45 minutes when fully charged. In the case of AC power failure the controller will automatically switch to battery operation.

7. Use the universal mounting bracket to attach the controller to an IV pole or bed rail in either a vertical or horizontal orientation (Figure 3).
8. Where a standard equipment mount is available, use the equipment mount adapter to support the controller (Figure 3).

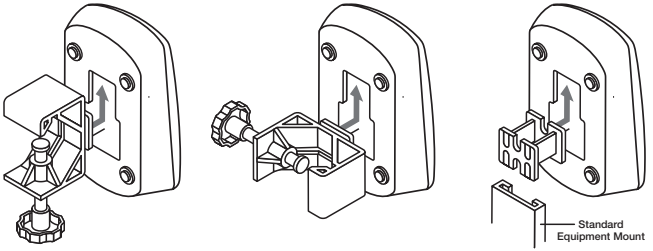


Figure 3. Aerogen Pro-X Controller and universal mounting bracket configurations

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

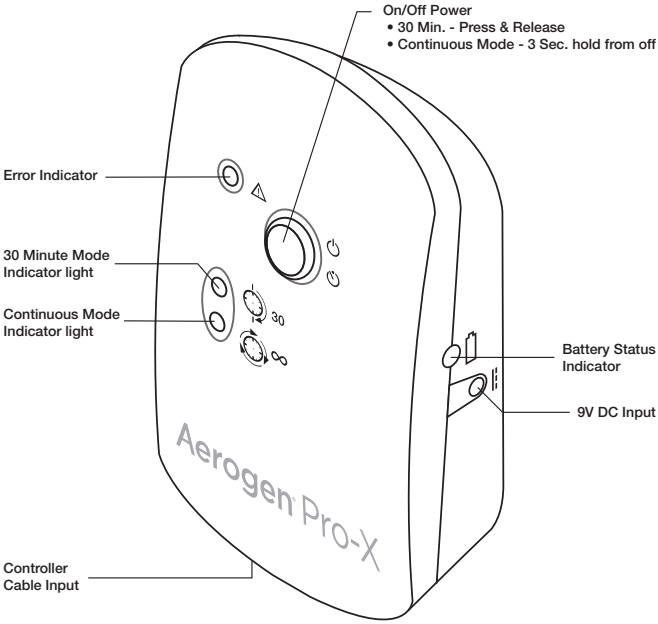


Figure 4. Aerogen Pro-X Controls & Indicators

Table 1. Aerogen Pro-X Controls & Indicators

Control / Indicator	Function
30 Min. Indicator	• Green (steadily lit) = 30 Minute nebulisation cycle on • Green (flashing) = Low battery power • Nebuliser automatically powers off after 30 minutes have elapsed
Continuous Indicator	• Green (steadily lit) = Continuous nebulisation cycle on • Nebuliser does not power off automatically
Error Indicator	• Amber (steadily lit) = Aerogen Solo nebuliser disconnected from Aerogen Pro-X Controller • Amber (flashing) = Aerogen Pro-X drive voltage error
On/Off Power Button	• To operate in 30 Minute Mode, press the On/Off button once • To operate in Continuous Mode, press and hold the On/Off button for greater than 3 seconds from off • Pressing during nebulisation turns off power to the nebuliser
Battery Status Indicator	• Green = Battery fully charged • Amber = Battery charging • No light = Battery in operation

Recharging the Battery

To recharge the battery, connect the AC/DC adapter to the controller and connect to AC power source. The battery status indicator is amber while charging and green when fully charged.

If the controller is placed in long-term storage, it is recommended that the battery be recharged every 3 months.

Allow a minimum of four hours for the internal battery to fully recharge.

Cleaning the Aerogen Pro-X Controller

Cleaning of controller and controller cable, AC/DC adapter and mounting brackets:

1. Wipe clean with an alcohol based disinfectant wipe or a quaternary ammonium compound based disinfectant wipe.
2. Check for exposed wiring, damaged connectors, or other defects and replace controller if any are visible.
3. Visually inspect for damage and replace the controller if any damage is observed.

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.

Installation for use with a Ventilator

T-Pieces - Connection to a Breathing Circuit

1. For 22mm **adult breathing circuits** connect the nebuliser with adult T-piece into the inspiratory limb of the breathing circuit before the patient Y (Figure 5).

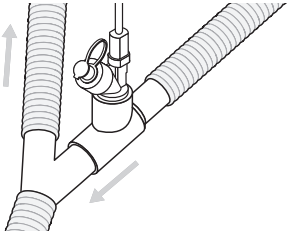


Figure 5. Connecting the Aerogen Solo to an adult breathing circuit

For 15mm **paediatric breathing circuits** connect the nebuliser with the paediatric T-piece into the inspiratory limb of the breathing circuit before the patient Y, as shown for the adult T-piece in Figure 5.

The Aerogen Solo can connect to 10mm **neonate breathing circuits** with the 15mm paediatric T-piece and the neonate adapters. This can be positioned approximately 30cm (12 in.) back from the patient Y (Figure 6).

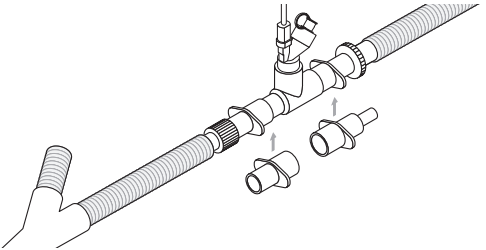


Figure 6. Connecting to a neonate breathing circuit

2. The Aerogen Solo can be placed between the ventilator and the dry side of the humidifier. Figure 7 illustrates a set up for the Aerogen Solo at the dry side of the humidifier. The Aerogen Solo can be used with a nasal interface in this configuration.

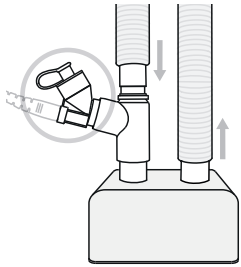


Figure 7. Aerogen Solo on dry side of humidifier

3. The Aerogen Solo can be placed between the wye and endotracheal tube as shown in Figure 8. The Aerogen Solo can be used with a Heat and Moisture Exchange Device (HME) which may contain a filter.

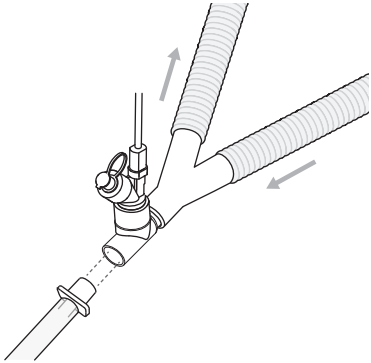


Figure 8. The Aerogen Solo placed between the wye and endotracheal tube.

4. Only a HME approved for use with a nebuliser should be used in this configuration (Figure 9). Follow the HME manufacturer instructions regarding use with a nebuliser. Ensure the total combined volume of nebuliser, T-Piece with or without a HME is suitable for the tidal volume being delivered. Do not use a nebuliser between the wye and neonate patient. Please refer to contraindication on page 4.

   See Table 3 for T-piece volumes.

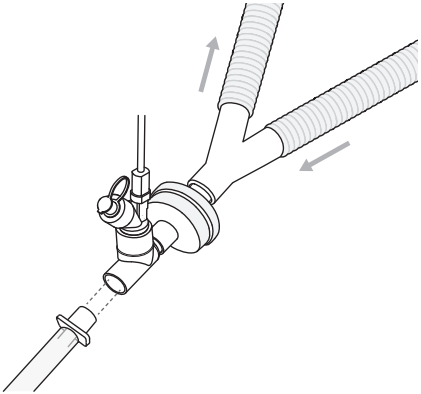


Figure 9. The Aerogen Solo placed between the HME and endotracheal tube.

5. Follow ventilator manufacturer instructions for performing a leak test after inserting or removing the nebuliser.

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 instructions.

- 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.

Installation for use with Tracheostomy

The Aerogen Solo is compatible with standard tracheostomy tubes.

The Aerogen Solo is suitable for use with mechanically ventilated tracheostomy patients (Figures 5, 7, 8 and 9).

The Aerogen Solo is suitable for use with spontaneously breathing tracheostomy patients (Figure 10). When using with a tracheostomy tube, connect the Aerogen Solo to the tracheostomy tube assembly with a T-piece.

For extra length, insert a connector or extension (which are not provided), as required, to support the additional weight of the nebuliser on an adjacent surface to reduce the risk of de-cannulation and/or to increase patient comfort.

Please refer to contraindication on page 4.

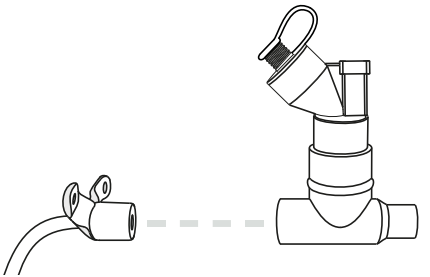


Figure 10. Connecting to a tracheostomy tube

Warning

- 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.

Installation for use with Non-Invasive Ventilation

The Aerogen Solo is suitable for use with non-invasive ventilation in a dual limb circuit as shown in Figures 5, 7, 8 & 9.

The Aerogen Solo can be used with single limb NIV circuits using non vented masks where the nebuliser can be placed between the exhalation port and the patient as shown in Figure 11.

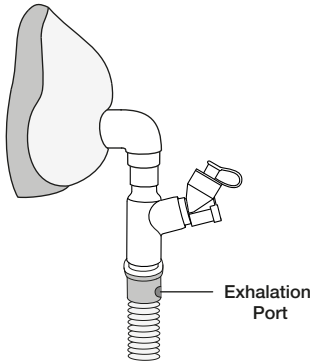


Figure 11. Connecting the Aerogen Solo to a non-invasive single limb circuit

Optimum Use

For optimum use of the Aerogen Solo, ensure it is correctly orientated as shown in Figure 12. This applies to both 30 Minute and Continuous modes.

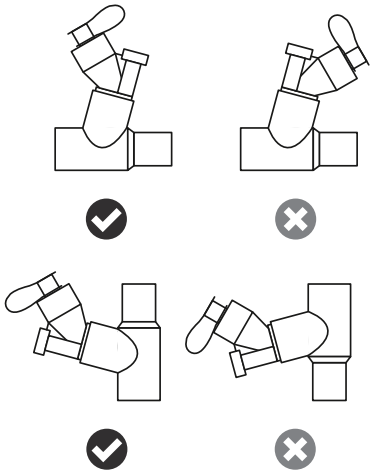


Figure 12. Optimum Use of the Aerogen Solo

Installation for use Off-Ventilator

Use with a Face Mask

Mask kits, which include a vented elbow and mask elbow, are available separately (visit www.aerogen.com for full parts list).

1. When using a mask, connect the vented elbow, mask elbow and mask to the nebuliser by firmly pushing the parts together.
2. Rotate the vented elbow to suit the position of the patient (Figure 13).

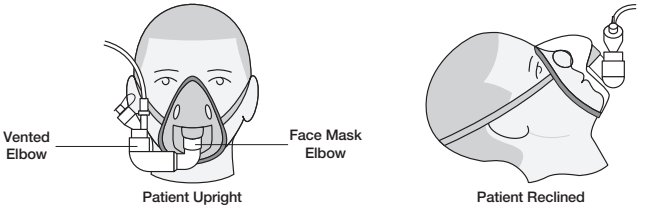


Figure 13. Connecting to a mask

Use with a Mouthpiece

The Aerogen Solo is compatible with any standard ISO 22mm nebuliser mouthpiece inserted into the adult T-piece.

When using a mouthpiece, connect the nebuliser to the T-piece and then connect the T-piece to the mouthpiece by pushing the parts firmly together as shown in Figure 14.

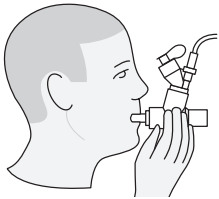


Figure 14. Connecting to a mouthpiece

Warning: To ensure correct nebulisation, maintain the nebuliser in a vertical orientation (Figure 13 & Figure 14).

Use with a Nasal Interface

The Aerogen Solo can be used on/off ventilator with a nasal interface when configured with a humidifier (Figure 7).

Aerogen Ultra

The Aerogen Ultra is an accessory specific to the Aerogen Solo nebuliser. It facilitates intermittent and continuous nebulisation, with optional supply of supplemental oxygen to paediatric and adult patients via mouthpiece. The device can alternatively be used with a face mask, as supplied.

It is a single patient use device which is qualified for 20 intermittent use treatments (at a rate of four 3 mL doses per day over 5 days) or 3 hours of continuous use.

Optimal aerosol delivery is achieved with a valved mouthpiece or valved aerosol face mask with low/no oxygen flow.

Inspect for device integrity and correct valve placement prior to use.

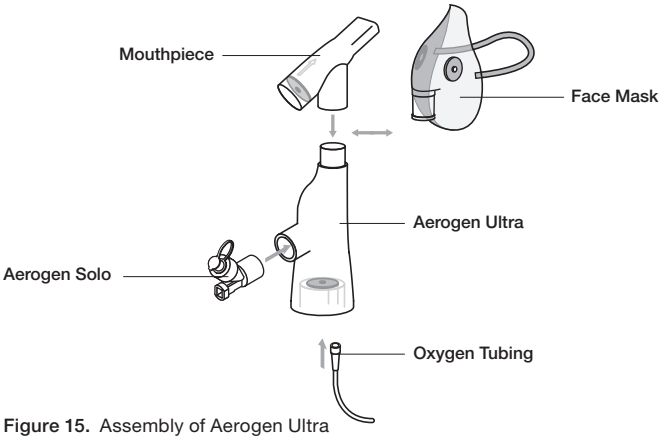


Figure 15. Assembly of Aerogen Ultra

1. Insert the Aerogen Solo nebuliser firmly into the Aerogen Ultra in orientation shown in Figure 15.
2. If supplemental oxygen is required, firmly attach oxygen tubing to the Aerogen Ultra.
   Note: Oxygen flow rate should be set between 1-6 LPM.
3. If a face mask is required, remove mouthpiece and attach face mask to the Aerogen Ultra.
   Note: When using an open face mask, a minimum oxygen flow of 1 LPM is required.
4. Add medication to nebuliser.
5. Connect cable to the Aerogen Solo and power on controller.
6. Introduce the Aerogen Ultra to patient and observe aerosol flow to ensure correct operation.
7. Remove excess rainout from the Aerogen Ultra periodically (hourly with continuous nebulisation).
8. To ensure optimum performance of the Aerogen Ultra, remove any residue by rinsing through with sterile water, shake off excess and allow to air dry.

Warnings

- Do not use with a closed face mask.
- When using with an open face mask, always use supplemental oxygen flow of 1-6 LPM.
- 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.
- 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.

Nebulisation Modes

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.

For intermittent doses less than or equal to 6 mL:

1. Open the plug on the nebuliser.
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the nebuliser (Figure 16).
3. Close the plug.

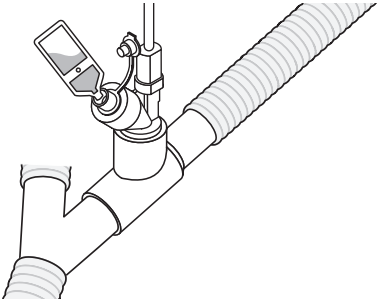


Figure 16. Filling the nebuliser with a pre-filled ampoule

4. To start a 30 Minute nebulisation cycle, press and release the blue On/Off power button (Figure 4). The green 30 Minute indicator light illuminates to indicate that the 30 Minute nebulisation cycle is in progress.
5. To stop the nebuliser at any time, press the On/Off power button. The indicator turns off to indicate that nebulisation has stopped.

Note: Medication can be added to the Aerogen Solo during nebulisation. This does not interrupt nebulisation or ventilation.

Continuous Nebulization Tube Set

The Aerogen Continuous Nebulization Tube Set is an accessory specific to the Aerogen Solo nebuliser which enables safe continuous infusion of liquid medication for aerosolisation.

Note: Place the syringe cap on the syringe after it is filled with medication.

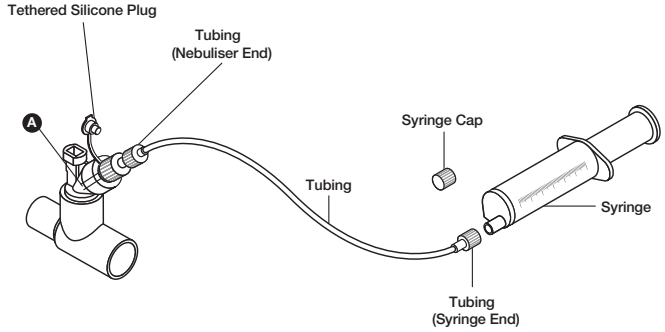


Figure 17. Continuous Nebulization Tube Set

1. Ensure the Aerogen Solo nebuliser is firmly fitted into the Aerogen Solo T-piece in the breathing circuit.
2. Remove the syringe cap from the medication-filled syringe.
3. Attach the syringe end of the tubing onto the syringe.
4. Prime the tubing until the medication reaches end of tubing (Point A). **Note:** The tubing priming volume is maximum 3.65 mL.
5. Unplug the tethered silicone plug from the Aerogen Solo nebuliser, but do not remove it from the nebuliser.
6. Screw the nebuliser end of the tubing onto the top of the nebuliser.
7. Insert the syringe filled with medication into the syringe infusion pump (pump not shown in Figure 17) and set the appropriate flow rate (refer to pump manual or manufacturer for guidance).

8. To start a continuous nebulisation cycle, press and hold the blue On/Off power button from the off state for at least three seconds. Verify the green, 'Continuous Nebulization' indicator light is on (Figure 4).
9. Observe nebuliser for correct operation. During continuous nebulisation, the nebuliser is on continuously and the medication is nebulised on a drop by drop basis. Nebulisation should be visible with regular intermittent pauses. Medication level in the nebuliser reservoir should not rise during use.
10. To stop the nebuliser at any time, press the On/Off power button. The indicator turns off to indicate that nebulisation has stopped.

Aerogen's recommended input rate of medication into the Aerogen Solo nebuliser during continuous nebulisation is up to a maximum of 12 mL per hour. The upper limit of 12 mL per hour is based on Aerogen's specification for the minimum nebuliser flow rate. For directions on determining flow rates, refer to the Optional Flow Rate Calculation method in the Functional Test section, page 27.

Warnings Specific to the Continuous Nebulization Tube Set

- 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.

Note: If the mains power is disconnected during a continuous nebulisation cycle and reconnected within 10 seconds, the controller shall return to Continuous Nebulization mode automatically.

Functional Test

Perform a functional test of the Aerogen Solo System prior to first use or at any time to verify proper operation. This test is to be carried out prior to inserting the nebuliser into a circuit or accessory.

1. Visually inspect each part of the system for cracks or damage and replace if any defects are visible.
2. Pour 1-6 mL of normal saline (0.9%) into the nebuliser.
3. Connect the nebuliser to the controller using the controller cable. Connect the AC/DC adapter to the controller and plug the AC/DC adapter into an AC power source.
4. Press and release the blue On/Off power button and verify that the green 30 Min. indicator light illuminates and that aerosol is visible.
5. Disconnect the nebuliser from the controller. Verify that the amber Error Indicator lights. Reconnect the nebuliser to the controller.
6. Disconnect the AC/DC adapter from the controller and verify that nebulisation continues and that the battery status indicator turns off.
7. Power off the controller. Reconnect the AC/DC adapter to the controller. Press and hold the button for at least 3 seconds. Verify that the green Continuous indicator light illuminates and that aerosol is visible.
8. Turn the system off and verify that the 30 Min. and Continuous indicators are off.

Aerogen Solo Aerosol Flow Rate Calculation (Optional)

Flow rates may vary between individual Aerogen Solo nebulisers. The minimum flow rate for all Aerogen Solo nebulisers is 0.2 mL per minute. In order to calculate the flow rate of an individual Aerogen Solo nebuliser, follow these steps:

1. Transfer 0.5 mL of normal saline (0.9%) or intended drug into the Aerogen Solo medication cup.
2. Turn on the nebuliser.
3. Using a stop-watch, measure the length of time it takes from the start of nebulisation until all the saline/drug has been nebulised.
4. Calculate the flow rate using the following equations:

$$\text{Flow rate in mL/min} = \left(\frac{\text{Volume of normal saline or drug}}{\text{Nebulisation time in seconds}} \right) \times 60$$

$$\text{Flow rate in mL/hr} = \left(\left(\frac{\text{Volume of normal saline or drug}}{\text{Nebulisation time in seconds}} \right) \times 60 \right) \times 60$$

Troubleshooting

If these suggestions do not correct the problem, discontinue use of any device and contact your local Aerogen sales representative.

Table 2. Aerogen Pro-X Controller Troubleshooting

If this happens:	It could mean:	Try this:
The 30 Min. indicator flashes during nebulisation.	Battery power is low.	Recharge battery (see Recharging the Battery).
Battery will not recharge. Controller is connected to the AC/DC adapter and the battery charging light is illuminated green and the 30 Min. indicator light is flashing.	It may be time to replace the battery.	Contact your local Aerogen sales representative.
Battery will not retain initial charge.	Rechargeable battery may need to be replaced.	Contact your local Aerogen sales representative.
The 30 Min. or Continuous light illuminates, but aerosol is not visible.	No medication in nebuliser.	Refill medication through filler cap in the nebuliser (see page 22).
	It may be time to replace the nebuliser.	See Warranty and Life of Product. Refer to the Aerogen Solo parts list by visiting www.aerogen.com.
30 Min. or Continuous indicator does not light when On/Off power button is pressed.	There is no power to the system.	Verify that AC/DC adapter is securely attached to controller.
	Rechargeable battery is depleted.	Recharge battery (see Recharging the Battery).
The error indicator light illuminates.	The controller cable is incorrectly connected to the nebuliser, or electronics are malfunctioning.	Verify that controller cable is correctly connected to both the nebuliser and the controller.

Table 2. Aerogen Pro-X Controller Troubleshooting (Continued)

If this happens:	It could mean:	Try this:
Medication is left in the nebuliser after nebulisation cycle.	Nebuliser was not turned on or connected to power.	Ensure that nebuliser is connected to power and turned on.
	Rechargeable battery is depleted.	Recharge battery (see Recharging the Battery).
	A 30 Minute cycle was selected when connected to the continuous feed system.	Run a continuous cycle.
	It may be time to replace the nebuliser.	See Warranty and Life of Product. Refer to the Aerogen Solo parts list by visiting www.aerogen.com.
Flashing amber light.	It may mean that it is time to replace controller.	Contact your local Aerogen sales representative.

Note: The rechargeable battery in the Aerogen Pro-X Controller should only be replaced by Aerogen authorised personnel: contact your Aerogen sales representative.

Warranty

Aerogen warrants that the Aerogen Solo nebuliser shall be free from defects of workmanship and materials for a period of the defined life of the nebuliser when used in accordance with this instruction manual.

The Aerogen Pro-X Controller and AC/DC adapter are warranted against defects in manufacturing for a period of two years from the date of purchase. All warranties are based on typical usage, detailed below.

Life of Product

As with all active electronic components, the Aerogen Solo nebuliser has a defined life. In the case of the Aerogen Solo, the life of the nebuliser has been validated for intermittent use for a maximum of 28 days based upon a typical usage profile of 4 treatments per day.

For continuous use, the life of the Aerogen Solo nebuliser and the Continuous Nebulization Tube Set have been qualified for use for a maximum of 7 days.

The user should note that use in excess of these periods is not qualified by Aerogen.

Specifications

Table 3. Physical Specifications of the Aerogen Solo System

Nebuliser Dimensions		67 mm H x 48 mm W x 25 mm D 2.6" H x 1.88" W x 1.1" D
Aerogen Pro-X Controller Dimensions		33mm H x 75mm W x 131mm D 1.3" H x 2.9" W x 5.2"D
Controller Cable Length		1.8 m (5.9 ft.)
AC/DC Adapter Cable Length		2.1 m (6.7 ft.)
Nebuliser Weight		13.5 g (0.5 oz) nebuliser and plug
Adult T-Piece Weight		28.7 g (1.0 oz) T-Piece and plug
Paediatric T-Piece Weight		16.8 g (0.6 oz) T-Piece and plug
Neonate T-Piece Weight		14 g (0.5 oz) T-Piece and plug
Aerogen Pro-X Controller Weight		230 g (8.1 oz.), including battery and cable
Nebuliser Capacity		Maximum 6 mL
T-piece Volume	Adult	34.3 mL
	Paediatric (15mm)	19.5 mL

Table 4. Environmental Specifications of the Aerogen Solo System

Operating	Maintains specified performance at circuit pressures up to 90cm H_2O and temperatures from 5 °C (41°F) up to 45 °C (113°F).	
	Atmospheric Pressure	450 to 1100 mbars
	Humidity	15% to 95% relative humidity
	Noise Level	< 35 dB measured at 0.3 m distance
Storage & Transport	**Transient Temperature Range**	-20 to +60°C (-4 to +140°F)
	Atmospheric Pressure	450 to 1100 mbars
	Humidity	15 to 95% relative humidity

Table 5. Power Specifications of the Aerogen Solo System

Power Source	FRIWO (AG-AP1040-XX*) AC/DC adapter (input 100 to 240 VAC 50 – 60 Hz, output 9 V) or internal rechargeable battery (4.8 V nominal output). **Note:** The Aerogen Pro-X Controller is approved for use with the Aerogen AC/DC adapter AG-AP1040-XX* (Manufacturer Reference: FRIWO FW8000M/09 / FW7660M/09)
Power Consumption	≤ 8.0 Watts (charging), ≤ 2.0 Watts (nebulising).
Patient Isolation	Controller circuitry provides 4 kilovolt (kV) patient isolation and complies with IEC/EN 60601-1.

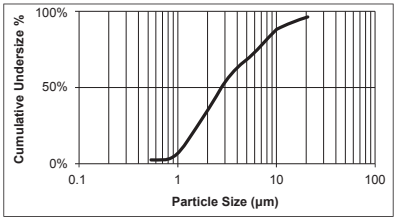
***** Consult your local representative for the order number extension specific to your country and for pricing information.

Performance

Table 6. Performance Specifications of the Aerogen Solo

Flow Rate	> 0.2 mL/min (Average ~ 0.38 mL/min)
Particle Size	**As measured with the Andersen Cascade Impactor:** Specification Range: 1-5 µm Average Tested: 3.1 µm **As measured with the Marple 298 Cascade Impactor:** Specification Range: 1.5-6.2 µm Average Tested: 3.9 µm **As per EN 13544-1:** Aerosol Output rate: 0.30 mL/min Aerosol Output: 1.02 mL emitted of 2.0 mL dose Residual Volume: <0.1 mL for 3 mL dose
Performance may vary depending upon the type of drug and nebuliser used. For additional information contact Aerogen or drug supplier.	
The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.	

Representative particle size distribution for Albuterol as per EN 13544-1 is shown below.



Symbols

Table 7. Aerogen Solo System Symbols

Symbol	Meaning	Symbol	Meaning
YYXXXXX	Serial number designation, where YY is the year of manufacture and XXXXX is the serial number		Transient storage temperature limitations -20 °C to +60 °C
	Caution Attention: Consult accompanying documents	QTY	Quantity (Number of units contained in package)
	Degree of protection against dripping water		Certified by TUV with respect to electric shock, fire and mechanical hazards
	Class II equipment per IEC/EN 60601-1		Controller Input - DC voltage
	Type BF equipment per IEC/EN 60601-1		Controller Output – AC voltage
	On/Off power button		Output
	30 Minute operating mode		Battery status indicator
	Continuous operating mode (International)		Refer to instruction manual/booklet
Rx Only	Federal (US) Law restricts this device to sale by or on the order of a physician		Not made with natural rubber latex

Appendix 1

Electromagnetic Susceptibility

This device meets the requirements of the Electromagnetic Compatibility (EMC), pursuant to the Collateral Standard, IEC/EN 60601-1-2, which addresses EMC in North America, Europe and other global communities. This includes immunity to radio frequency electric fields and electrostatic discharge, in addition to the other applicable requirements of the standard. Compliance with EMC standards does not mean a device has total immunity; certain devices (cellular phones, pagers, etc.) can interrupt operation if they are used near medical equipment. Follow institutional protocol regarding the use and location of devices that could interfere with medical equipment operation.

Note: This device is classified as Class II Type BF medical electrical equipment and the device complies with specified safety levels for electrical isolation and leakage current. The Aerogen Solo AC/DC adapter (AG-AP1040-XX*) has no connection to earth ground because the necessary level of protection is achieved through the use of double insulation.

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.

***** Consult your local representative for the order number extension specific to your country and for pricing information.

Appendix 1: EMC Tables

The following tables are provided in accordance with IEC/EN 60601-1-2:

Table 8. Guidance and manufacturer's declaration – electromagnetic emissions

The Aerogen Solo nebuliser system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen Solo nebuliser system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions Conducted and Radiated CISPR 11 EN 55011: 2009 + A1: 2010	Group 1	The Aerogen Solo nebuliser system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions Conducted and Radiated CISPR 11 EN 55011: 2009 + A1: 2010	Class B	The Aerogen Solo nebuliser system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2 EN 61000-3-2: 2014	Compliant	
Voltage fluctuations / flicker emissions IEC 61000-3-3 EN 61000-3-3: 2013	Compliant	

Table 9. Recommended separation distances between portable and mobile RF communication equipment and the Aerogen Solo nebuliser system that is not life supporting

This Aerogen Solo nebuliser system is intended for use in an electromagnetic environment specified in Table 8. The customer or the user of the Aerogen Solo nebuliser system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aerogen Solo nebuliser system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = [1.17] √P	80 MHz to 800 MHz d = [1.17] √P	800 MHz to 2.5 GHz d = [2.33] √P
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.75
1	1.17	1.17	2.33
10	3.70	3.70	7.36
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (w) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Table 10. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen Solo nebuliser system that is not life supporting

This Aerogen Solo nebuliser system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen Solo nebuliser system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2 EN 61000-4-2: 2009	±8 kV contact ±15 kV air	±2, 4, 6 & 8 kV contact ±2, 4, 6, 8 & 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast Transient/burst IEC 61000-4-4 EN 61000-4-4: 2012	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5 EN 61000-4-5: 2006	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 EN 61000-4-11: 2004	<5 % Ut (>95 % dip in Ut) for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	<5 % Ut (>95 % dip in Ut) for 0.5 cycle @ 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 70 % Ut (30 % dip in Ut) for 25 cycles <5 % Ut (>95 % dip in Ut) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Aerogen Solo nebuliser system requires continued operation during power mains operation, it is recommended that the Aerogen Solo nebuliser system be powered from an uninterruptible power supply or battery.

Table 10. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen Solo nebuliser system that is not life supporting (Continued)

Power frequency (50/60 Hz) Magnetic field **IEC 61000-4-8 EN 61000-4-8: 2010**	**30 A/m**	**30 A/m**	**Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.**
Note: Ut is the A.C. mains voltage prior to application of the test level.			

Table 11. Guidance and manufacturer's declaration - electromagnetic immunity for the Aerogen Solo nebuliser system that is not life supporting

This Aerogen Solo nebuliser system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen Solo nebuliser system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Aerogen Solo nebuliser system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6 EN 61000-4-6: 2014	**3 Vrms outside industrial, scientific and medical (ISM) and amateur radio bands. 6 Vrms in ISM and amateur radio bands 150 kHz to 80 MHz**	**10 Vrms 150 kHz to 80 MHz**	**Recommended Separation Distance** $d = [1.17] \sqrt{P}$

Table 11. Guidance and manufacturer's declaration - electromagnetic immunity for the Aerogen Solo nebuliser system that is not life supporting (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3 EN 61000-4-3: 2010	10 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz 28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz	10 V/m 80 MHz to 2.7 GHz 27 V/m, 18 Hz PM 385 MHz 28 V/m, 50 %18 Hz PM 450 MHz 9 V/m, 217 Hz PM 710 MHz 9 V/m, 217 Hz PM 745 MHz 9 V/m, 217 Hz PM 780 MHz 28V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz	d = [1.17] √P... 80MHz to 800MHz d = [2.33] √P... 800MHz to 2.5GHz where P is the maximum output power rating of the transmitter in Watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 11. Guidance and manufacturer's declaration - electromagnetic immunity for the Aerogen Solo nebuliser system that is not life supporting (Continued)

	9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	28 V/m, 217 Hz PM 1970 MHz 27 V/m, 217 Hz PM 2450 MHz 9V/m, 217 Hz PM 5240 MHz 9 V/m, 217 Hz PM 5500 MHz 9 V/m, 217 Hz PM 5785 MHz	

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Aerogen Solo nebuliser system is used exceeds the applicable RF compliance level above, the Aerogen Solo nebuliser system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the Aerogen Solo nebuliser system.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1]V/m.

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Source No. 30-983 Rev D
P/N 30-354 Rev T

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