Aerogen®

Aerogen® USB Controller

System Instruction Manual

for use with Aerogen® Solo
and Aerogen® Pro



www.aerogen.com

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Introduction

The Aerogen USB Controller System is:

- A portable medical device that is intended to aerosolise physician-prescribed medications for inhalation.
- Approved for use with USB ports on medical electrical equipment for the purposes of power only or the Aerogen USB Controller AC/DC Adapter.
- An alternative to the existing Aerogen® Pro and Aerogen® Pro-X Controllers.

Intended Use

The Aerogen® Pro is a portable medical device for multiple patient uses that is intended to aerosolise physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance in the hospital environment and on vent only in the homecare environment. The Aerogen Pro is suitable for use in adult, paediatric and neonate patients.

The Aerogen® Solo belongs to the Aerogen Pro family, the Aerogen Solo nebuliser is a single patient use device intended for both intermittent and continuous nebulisation. It is intended to nebulise physician-prescribed medications for inhalation which are approved for use with a general purpose nebuliser. The Aerogen Solo is suitable for use with neonate, paediatric and adult patients. It is intended for on and off ventilation or other positive pressure breathing assistance in the hospital environment and on vent only in the homecare environment.

The Aerogen USB Controller can be used with Aerogen nebulisers as follows:

Table 1. Intended Use Summary

Intended Use Summary	Aerogen Solo Nebuliser	Aerogen Pro Nebuliser
Hospital – Ventilated patients	✓	✓
Hospital – Spontaneously Breathing Patients	✓	✓
Homecare – Ventilated patients	✓	✓
Homecare – Spontaneously Breathing Patients	✗	✗
30 Minute Mode Operation	✓	✓
6 Hour Mode Operation	✓	✗

Aerogen USB Controller System

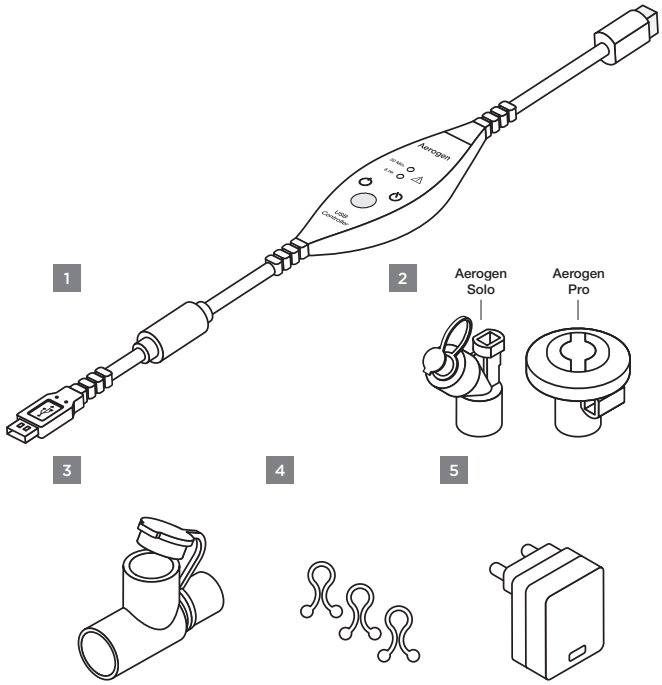


Figure 1. Aerogen USB Controller System (Items Provided)

1. Aerogen USB Controller
2. Aerogen Nebuliser (Aerogen Solo or Aerogen Pro)
3. T-Piece & Silicone Plug
4. Cable Management Clips
5. Aerogen USB Controller AC/DC Adapter

Note: Clips are provided to assist with cable management.

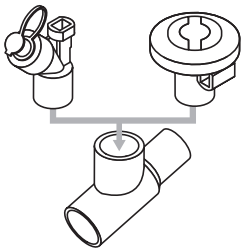
Visit www.aerogen.com for full parts list.

Set Up

Read and study all instructions before using the Aerogen USB Controller.

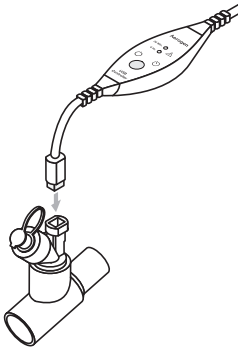
Perform a functional test of the Aerogen nebuliser prior to use as described in the Functional Test section of this manual (see page 27).

1



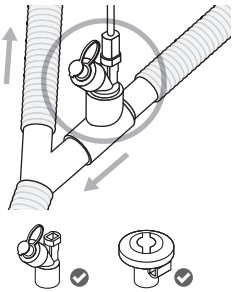
Connect the Aerogen Solo or Aerogen Pro nebuliser by firmly pushing into the T-piece.

2



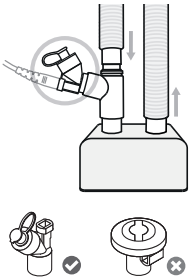
Connect the Aerogen USB Controller to the nebuliser as shown.

3



Insert the nebuliser and the T-piece* in the breathing circuit.

*Adult T-piece shown here. For full instruction on T-piece location see page 16 (T-Piece Accessories).



Alternative Set Up:
The Aerogen Solo can be placed between the ventilator and the dry side of the humidifier.

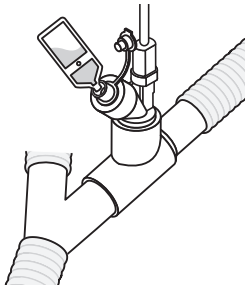
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Connect the Aerogen USB Controller into the USB Port.

Note: The Aerogen USB Controller can only be operated from a USB port on any medical electrical equipment approved to IEC/EN 60601-1 or the Aerogen USB Controller AC/DC Adapter.

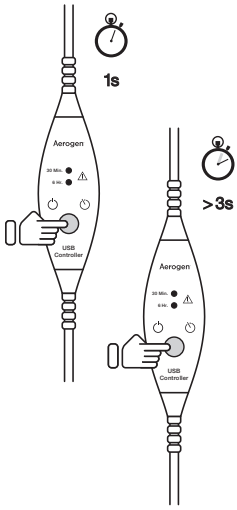
5



Open the plug on the nebuliser and use a pre-filled ampoule or syringe to add medication to the nebuliser. Close the plug.

Note: To avoid damage to the Aerogen Solo, do not use a syringe with a needle.

6

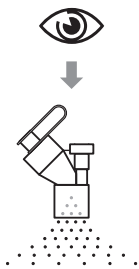


To operate in 30 Minute Mode press the On/Off button once.

To operate in 6 Hour Mode press the On/Off button from the off mode for >3 seconds.

Note: Verify the correct mode of operation is selected.

7



Verify that aerosol is visible.

Note: In the event where crystallisation is observed in the Aerogen Solo, Aerogen recommend to aerosolise a few drops of normal saline solution to clear any residual crystallisation.

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 USB Controller System.

Only trained persons should operate the Aerogen USB Controller System, Aerogen Solo, Aerogen Pro and associated accessories.

If this product is being used to treat a life threatening condition, a backup device is necessary.

During use observe for correct functioning of the nebuliser by regularly verifying aerosol is visible and that no amber indicator lights are illuminated.

Do not use a filter or heat-moisture exchanger (HME) between the nebuliser and patient airway.

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.

The Aerogen nebulisers, T-pieces and accessories are not sterile.

The components and accessories of the Aerogen USB Controller System are not made with natural rubber latex.

Only use physician-prescribed solutions that are approved for use with a general purpose nebuliser. Consult drug manufacturer's instructions regarding suitability for nebulisation.

Only use the Aerogen nebuliser technology with components specified in the instruction manuals. Use of the Aerogen nebuliser technology with components other than those specified in the Instruction Manual may result in increased emissions or decreased immunity of the nebuliser system.

Do not place the Aerogen USB Controller in an incubator during use.

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 modify this equipment without the authorisation of the manufacturer.

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.

Do not immerse or autoclave the Aerogen USB Controller or Aerogen USB Controller AC/DC Adapter.

Do not microwave any parts.

Do not use or store outside of specified environmental conditions.

Follow local laws and recycling plans regarding disposal or recycling of components and packaging.

Do not use in the presence of devices generating high electromagnetic fields such as magnetic resonance imaging (MRI) equipment.

The Aerogen USB Controller must be installed and put into service according to the EMC information provided in the Instruction Manual.

Do not use the Aerogen USB Controller 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.

Portable and mobile radio frequency (“RF”) communication devices can disrupt medical electrical equipment.

The Aerogen Solo is a single patient use device not to be used on more than one patient to prevent cross infection.

Keep all cables tidy to avoid tripping or strangulation hazards and take particular care around children.

Ensure that the Aerogen USB Controller cable is removed from the power supply host using the grip feature provided.

Do not attempt to clean the device while in use.

Do not obstruct the removal of the Aerogen USB Controller AC/DC Adapter from the mains.

Do not store the Aerogen USB Controller System in a location where it is exposed to direct sunlight, extreme heat or cold, dust or moisture. Store out of reach of children.

Do not operate Aerogen USB Controller from USB ports on non-medical equipment.

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.

Adult supervision is required when this product is used by children and individuals who require special assistance.

To avoid damage to the Aerogen Palladium vibrating mesh technology:

- Do not apply undue pressure to the domed aperture plate in the centre of the nebuliser (Figure 2).
- Do not push out the Aerogen Vibronic® aerosol generator.
- Do not use a syringe with a needle to add medication.
- Do not use abrasive or sharp tools to clean the nebuliser.
- Prior to use, autoclave the Aerogen Pro and accessories according to specified directions and temperature given in the Cleaning, Disinfection and Sterilisation section of this Instruction Manual only. Any deviation from directions given in this Instruction Manual may cause damage to the nebuliser and render it inoperable.

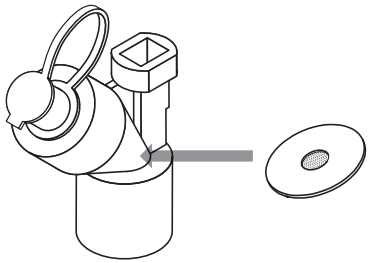


Figure 2. Aerogen Palladium Vibrating Mesh Technology

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

Controls & Indicators

Caution: For use with the Aerogen Pro, the Aerogen USB Controller is intended to be used in 30 Minute mode only.

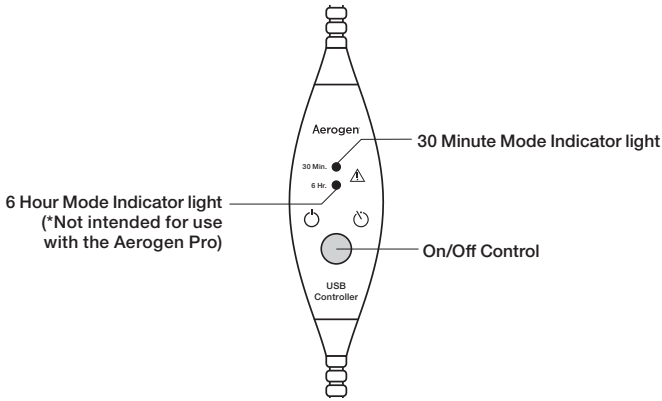


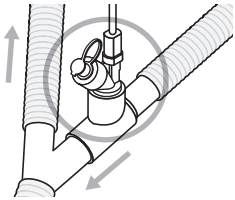
Figure 3. Aerogen USB Controller Controls & Indicators

Table 2. Aerogen USB Controller Controls & Indicators

Control / Indicator	Function
30 Min. Indicator	• Green = 30 Minute nebulisation cycle on. • Amber = Nebuliser disconnect. • Aerogen USB Controller automatically powers off after 30 minutes have elapsed.
6 Hr. Indicator	• Green = 6 Hour nebulisation cycle on. • Amber = Nebuliser disconnect. • Aerogen USB Controller automatically powers off after 6 hours have elapsed.
Error Indicator	• 30 Minute and 6 Hour Indicators flash amber alternatively twice = Internal error condition. Aerogen USB Controller automatically powers off.

On/Off Power Button	• To operate in 30 Minute Mode press the On/Off button once. • To operate in 6 Hour mode press and hold the On/Off button for greater than 3 seconds. • Pressing during nebulisation turns off power to the nebuliser.

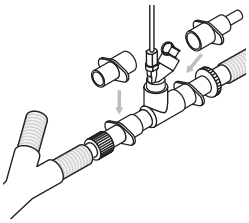
Accessories



T-Pieces – Connection To A Breathing Circuit

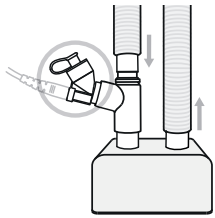
Adult & Paediatric Circuit

For adult and paediatric patients, connect the nebuliser with T-piece into the inspiratory limb of the breathing circuit before the patient Y.



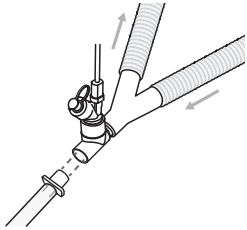
Neonate Circuit

Connect the nebuliser with the paediatric T-piece and the neonate adapters approximately 30 cm (12 in.) back from the patient Y. Alternatively connect the nebuliser with the Neonate T-piece 30 cm (12 in.) back from the patient Y.



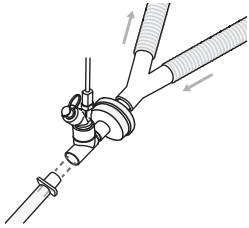
Dry Side of the Humidifier

The Aerogen Solo can be placed between the ventilator and the dry side of the humidifier. A set up for the Aerogen Solo at the dry side of the humidifier is shown. The Aerogen Solo can be used with a nasal interface in this configuration. The Aerogen Pro is not recommended for use in this position.



Between the Wye and Endotracheal Tube

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



Between the HME and Endotracheal Tube

Only a HME approved for use with a nebuliser should be used in this configuration (as shown). 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 10.

See Table 5 for T-piece volumes.

Note: Always perform a leak test of the breathing circuit after inserting or removing the nebuliser.
Follow ventilator manufacturer instructions for performing a leak test.
For additional T-piece Adapters visit www.aerogen.com for full parts list.

Connection To A Face Mask – Mouthpiece

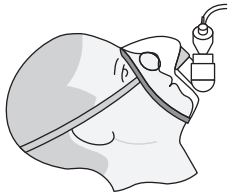
(Hospital Use Only)



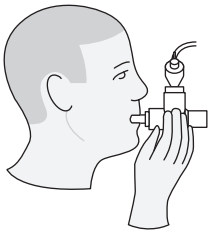
Face Mask

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

Note: When using a mask, connect the vented elbow, mask elbow and mask to the nebuliser by firmly pushing the parts together.



Rotate the vented elbow to suit the position of the patient.



Mouthpiece

When using a standard ISO 22 mm mouthpiece, connect the nebuliser to the T-piece as shown, and connect the T-piece to the mouthpiece by pushing the parts firmly together.

Note: To ensure correct nebulisation, maintain the nebuliser in a vertical orientation.

Use With A Nasal Interface

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

Connection to a Tracheostomy Tube

The Aerogen Solo is compatible with standard tracheostomy tubes.

The Aerogen Solo is suitable for use with mechanically ventilated tracheostomy patients (see 'Adult & Paediatric Circuit', and 'Dry side of the Humidifier', 'Between the Wye and Endotracheal Tube' and 'Between the HME and Endotracheal Tube' on page 16 & 17).

The Aerogen Solo is suitable for use with spontaneously breathing tracheostomy patients (Figure 4). 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 10.

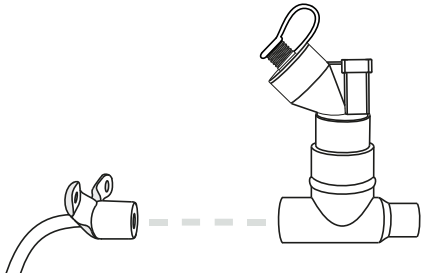


Figure 4. Connecting to a tracheostomy tube

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.

Connection to Non-Invasive Ventilation

The Aerogen Solo is suitable for use with non-invasive ventilation in a dual limb circuit as shown above (see 'Adult & Paediatric Circuit', 'Dry side of the Humidifier', 'Between the Wye and Endotracheal Tube' and 'Between the HME and Endotracheal Tube' on page 16 & 17).

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 5.

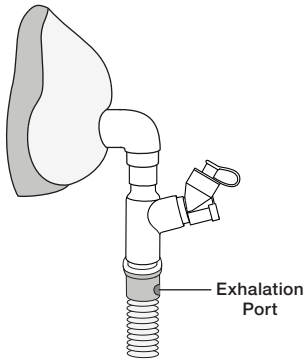


Figure 5. Connecting the Aerogen Solo to a non-invasive single limb circuit

Aerogen® Ultra
(Hospital Use Only)

The Aerogen Ultra is an accessory specific to the Aerogen Solo nebuliser. It facilitates intermittent and continuous nebulisation and optional supply of supplemental oxygen to paediatric and adult patients via mouthpiece. The device can alternatively be used with the I-Guard™ Aerosol 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 valved mouthpiece or valved aerosol face mask with low/no oxygen flow.

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

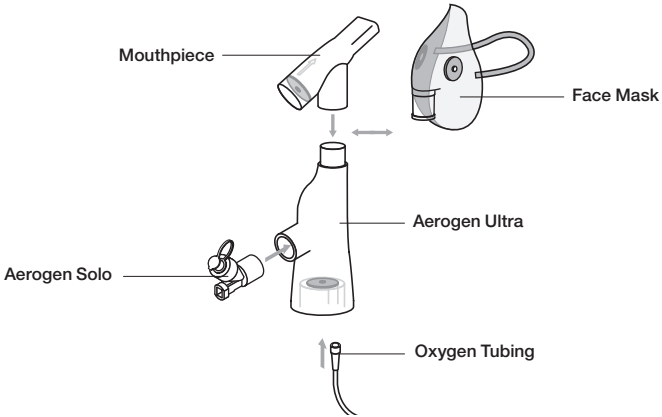


Figure 6. Assembly of Aerogen Ultra

1. Insert the Aerogen Solo nebuliser firmly into the Aerogen Ultra in orientation shown in Figure 6.
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 the Aerogen Solo.
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.

Continuous Nebulization Tube Set
(Hospital Use Only)

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.

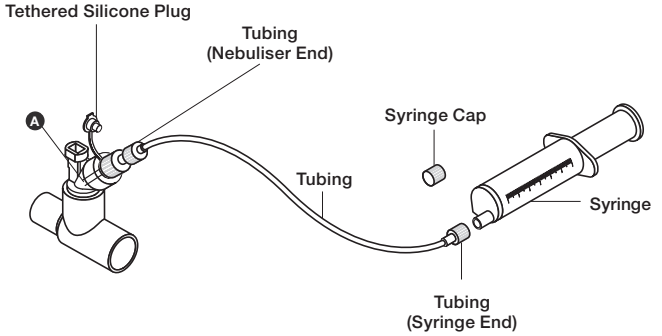


Figure 7. Continuous Nebulization Tube Set

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 7).
8. Turn on the 6 Hour Mode option on the Aerogen USB Controller and turn on the infusion pump (refer to pump manual or manufacturer for guidance).
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.

Note: 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 28.

Note: In the event where crystallisation is observed in the Aerogen Solo, Aerogen recommend to aerosolise a few drops of normal saline solution to clear any residual crystallisation.

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.

Functional Test

Perform a functional test prior to first use, or after each sterilisation (Aerogen Pro only) to verify correct 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 solution (0.9%) into the nebuliser.
3. Connect the nebuliser to the Aerogen USB Controller. Connect the Aerogen USB Controller to the USB port provided on the medical electrical equipment (or Aerogen USB Controller AC/DC Adapter).
4. Press and release the On/Off power button and verify that the 30 Minute Mode indicator light is green 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. If using the Aerogen Solo press the On/Off power button again to turn the system off. Press and hold the button for at least 3 seconds. Verify that the 6 Hour Mode indicator light is green and that aerosol is visible.
7. As with step 5 above, disconnect the nebuliser from the controller. Verify that the amber Error Indicator lights. Reconnect the nebuliser to the controller.
8. Turn the system off and verify that the 30 Minute Mode and 6 Hour Mode indicator lights are off.
9. Discard any remaining liquid before patient use.

Aerogen Solo Aerosol Flow Rate Calculation
(Optional)

Note: This calculation only applies to 6 Hour operating mode for the Aerogen Solo.

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:

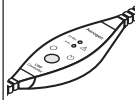
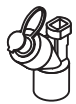
1. Transfer 0.5 mL of normal saline solution (0.9%) or intended drug into the Aerogen Solo medication cup.
2. Turn on the nebuliser.
3. Using a stop-watch, measure the length of time it takes from the start of nebulisation until all the saline/drug has been nebulised.
4. Calculate the flow rate using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

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

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

Cleaning of the Aerogen USB Controller System

Table 3. Cleaning Summary

Product	Wipe Clean	Disinfect	Boil	Sterilise (Autoclave)	
 Aerogen USB Controller	✔	✖	✖	✖	See instructions below.
 Aerogen Solo	✖	✖	✖	✖	The Aerogen Solo and accessories are single patient use only and are <u>not</u> intended to be cleaned, disinfected or sterilised.
 Aerogen Pro	✖	✔	✔	✔	See instructions below.

Aerogen USB Controller, controller cables and Aerogen USB Controller Adapter.

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 if any are visible.
3. Visually inspect for damage and replace the Aerogen USB Controller if any damage is observed.

Note: Do not spray liquid directly onto the Aerogen USB Controller. Do not immerse Aerogen USB Controller in liquid.

Cleaning, Disinfection & Sterilisation of the Aerogen Pro Nebuliser

The Aerogen Pro components are:

- Nebuliser (including filler cap)
- T-piece (including T-piece plug) for adult and paediatric
- Neonate Adapters

Manual Cleaning of Aerogen Pro & Accessories

1. Ensure there is no medication remaining in the device.
2. Remove nebuliser from T-piece. Remove filler cap from nebuliser.
3. Clean all parts with warm water and mild liquid detergent.
4. Rinse parts with sterile water.
5. Shake excess water from parts and allow parts to fully air dry.

Warning: Do not use abrasive or sharp tools to clean the nebuliser unit.

Disinfection of the Aerogen Pro & Accessories

Automated Washing Cycle

The Aerogen Pro Nebuliser has been qualified for the following automated washing cycles.

Automated Cycle One

Detergent: Liquid alkaline cleaner (diluted as per manufacturers instruction).
Water Quality: Mains water.

Method:

1. Load the components in the automated washer.
2. Pre-rinse the components for 3 minutes.
3. Clean the components with liquid alkaline cleaner at 55°C (131°F) for 10 minutes.
4. Rinse for 1 minute.
5. Rinse using thermal disinfection cycle at 93°C (199.4°F) for 10 minutes.

Automated Cycle Two:

Detergent: The following cycle was validated without the use of a detergent.
Water Quality: Mains water.

Method:

1. Load the components in the automated washer.
2. Wash components for 10 minutes at 91°C (195.8°F).
3. Drain the machine for 40 seconds.
4. Rinse at 90°C (194°F) for 1 minute.
5. Drain the machine for 40 seconds.
6. Rinse at 90°C (194°F) for 1 minute.
7. Drain the machine for 40 seconds.
8. Dry at 90°C (194°F) for 15 minutes.

Boiling the Aerogen Pro & Accessories

1. Rinse the Aerogen Pro nebuliser components under running hot tap water after every use.
2. Shake off excess water, and allow parts to fully air dry on a clean, dry towel, out of the reach of children.
3. Bring a saucepan of DISTILLED water to the boil and allow it to continue to boil.
   Note: Using regular tap water to boil the nebuliser will greatly reduce the life of the nebuliser.
4. Carefully immerse the Aerogen Pro nebuliser in the boiling water. Leave the nebuliser immersed in the boiling water for a maximum of 20 minutes.
5. Carefully remove the Aerogen Pro from the boiling water and shake off the excess water. Allow parts to fully air dry on a clean, dry towel, out of the reach of children.
6. Make certain that all parts are completely dry before you store or use them.

Similarly, the Aerogen Pro may be steam disinfected in a standard baby bottle steam steriliser for 15 minutes. Refer to manufacturer's instructions.

For Hospital Use

Disinfection of Aerogen Pro, T-pieces and Neonate Adapters with disinfection agents.

Completely immerse parts in appropriate disinfecting agent in accordance with current hospital protocols and disinfectant agent manufacturer guidelines.

Note: Aerogen approves the following disinfection solutions for use with its Aerogen Pro nebuliser only regarding material compatibility. With respect to microbiological effectiveness, please ask the manufacturer. Refer to the product labelling for specific instructions regarding activation, safe use and disposal of these solutions.

- Isopropyl (70%)
- CIDEX®
- NU-CIDEX®
- CIDEX® OPA
- Hexanios G+R

Warning: The use of any other means of cleaning, disinfection or sterilisation has not been qualified and is likely to reduce the life of your nebuliser and will invalidate your warranty.

Sterilisation of the Aerogen Pro

Sterilisation of Aerogen Pro Nebuliser, T-Pieces & Neonate Adapters

1. Disconnect the nebuliser from the Aerogen USB Controller, and then remove the nebuliser and Adapters from the ventilator circuit, mask or mouthpiece.
2. Disassemble the nebuliser and Adapters into individual components.
3. Remove the filler cap from the nebuliser.
4. Clean all parts with warm water and mild liquid detergent in accordance with current hospital protocols. Rinse thoroughly and air dry.
5. Check for cracks or damage and replace if any defects are visible.
6. Place the disassembled components into appropriate sterilisation wrapping.

Warning: Do not reassemble parts prior to autoclaving.

Sterilise Components

Steam sterilisation can be performed using the following three methods:

1. Autoclave wrapped parts using steam sterilisation pre-vacuum cycle, a minimum of 134°C (270°F – 275°F) for 3.5 minutes with drying cycle (134°C wrapped cycle).
2. Autoclave wrapped parts using steam sterilisation pre-vacuum cycle, a minimum of 121°C (250°F) for 20 minutes with drying cycle (121°C wrapped cycle).
3. Autoclave wrapped parts using steam sterilisation pre-vacuum cycle, a minimum of 134°C (270°F – 275°F) for 20 minutes with drying cycle (sometimes referred to as a "Prion cycle").

Note: Sterilisation using the long autoclave cycle (No. 3 above) may cause some areas of the nebuliser to become discolored. This is not indicative of the performance of the nebuliser.

To sterilise with hydrogen peroxide gas plasma, place wrapped parts in a STERRAD® System and use the long cycle.

Warning: Users should refer to the product labelling for the STERRAD® 100S Sterilisation System for specific instructions regarding its correct operation.

Prior to next use:

1. Check for cracks or damage and replace if any defects are visible.
2. Perform a functional test as described in this manual.

Troubleshooting

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

Table 4. Aerogen USB Controller System Troubleshooting

If this happens:	It could mean:	Try this:
The 30 Minute or 6 Hour indicator light is green, but aerosol is not visible.	No medication in nebuliser.	Refill medication.
	The Aerogen Pro has not been properly cleaned.	Clean the Aerogen Pro.
	Nebuliser used beyond life of product.	See Warranty and Life of Product.
The 30 Minute or 6 Hour indicator does not light when On/Off power button is pressed.	There is no power to the system.	Verify Aerogen USB Controller is securely attached to a functioning power source.
		Verify green power indicator light on AC/DC is on (if using Aerogen USB Controller AC/DC Adapter).
The 30 Minute or 6 Hour indicator lights amber.	The Aerogen USB Controller cable is incorrectly connected.	Verify the Aerogen USB Controller cable is correctly connected to the nebuliser.
	Nebuliser used beyond life of product.	See Warranty and Life of Product.
Longer than expected treatment time e.g. 6 mL of Normal Saline (0.9%) should take no longer than 30 minutes to nebulise.	The Aerogen Pro has not been properly cleaned.	Clean the Aerogen Pro.
	The nebuliser used beyond life of product.	See Warranty and Life of Product.
Medication is left in the nebuliser after nebulisation cycle.	Nebuliser was not turned on or connected to power.	Ensure that the nebuliser is connected to power and turned on.
	Aerogen Pro has not been properly cleaned.	Clean the Aerogen Pro.
	Aerosol was not generated.	Verify aerosol is visible.
	It may be time to replace the nebuliser.	See Warranty and Life of Product.

Table 4. Aerogen USB Controller System Troubleshooting (Continued)

If this happens:	It could mean:	Try this:
The 30 Minute and 6 Hour indicators flash amber alternatively twice.	Internal error condition.	See Warranty and Life of Product.

Warranty

The Aerogen warranty covers defects in manufacturing as follows:

- Aerogen USB Controller and Aerogen USB Controller AC/DC Adapter: 1 year
- Aerogen Pro: 1 year
- Aerogen Solo: Intermittent use for a maximum of 28 days and continuous use for a maximum of 7 days.

All warranties are based on typical usage specified. There is no service life associated with the Aerogen USB Controller System.

Life Of Products

Aerogen USB Controller has been qualified for use for:

- 1460 doses (4 treatments per day, over a 1 year period.)

The Aerogen Pro nebuliser and components have been qualified for:

- 730 doses (4 doses per day.)
- 26 autoclave cycles (1 autoclave cycle per week, where the device is assumed to be in service for 50% of the time over a 1 year period.)
- 104 disinfecting treatments, boiling or baby bottle steam steriliser (2 disinfecting treatments per week, over a 1 year period.)

The Aerogen Solo nebuliser has been qualified for:

- Intermittent use for a maximum of 28 days (4 treatments per day.)
- For continuous use, the life of the Aerogen Solo nebuliser and the Continuous Nebulization Tube Set have been validated for use for a maximum of 7 days.

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

Specifications

Table 5. Physical Specification of the Aerogen Solo Nebuliser

Dimensions		67 mm H x 48 mm W x 25 mm D (2.6 in. H x 1.88 in. W x 1 in. D)
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
Nebuliser Capacity		Maximum 6 mL
T-piece Volume	Adult	34.3 mL
	Paediatric (15 mm)	19.5 mL

Table 6. Physical Specification of the Aerogen Pro Nebuliser

Dimensions	45 mm H x 50 mm W x 50 mm D (1.8 in. H x 2.0 in. W x 2.0 in. D)
Nebuliser Weight	25 g (0.9 oz.) nebuliser and filler cap
Aerogen Pro Adult T-Piece Weight	30 g (1.1 oz.) T-Piece and plug
Aerogen Pro Paediatric T-Piece Weight	17.1 g (0.6 oz) T-Piece and plug
Aerogen Pro Neonate T-Piece Weight	14 g (0.5 oz) T-Piece and plug
Nebuliser Capacity	Maximum 10 mL

Table 7. Physical Specification of the Aerogen USB Controller

Dimensions	2865 mm L X 28 mm W X 25.2 mm H (112.8 in. L X 1.1 in. W X 1 in. H)
Aerogen USB Controller Weight	91g (3.2 oz)

Table 8. Environmental Specifications of the Aerogen USB Controller System

Operating	Maintains specified performance at circuit pressures up to 90 cm H_2O and temperatures from 5°C (41°F) up to 40°C (104°F).	
	Atmospheric Pressure	700 to 1060 mbar
	Humidity	15 to 93% relative humidity
	Noise Level	< 35 dB measured at 1m distance
Transport & Storage	**Transient Temperature Range**	-25 to +70°C (-13 to +158°F)
	Atmospheric Pressure	450 to 1060 mbars
	Humidity	Up to 93% relative humidity.

Performance

Table 9. 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 for the Aerogen Solo.

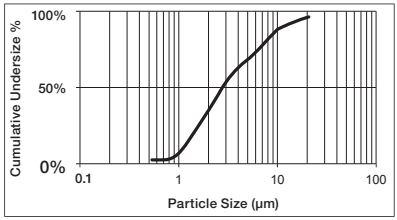
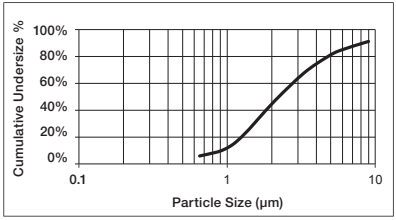


Table 10. Performance Specifications of the Aerogen Pro

Flow Rate	>0.2 mL/min (Average: ≈ 0.4 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, with a starting dose of 2 mL:** • Aerosol Output rate: 0.24 mL/min • Aerosol Output: 1.08 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 for the Aerogen Pro.



Power

Power Source: The Aerogen USB Controller can operate from an AC/DC Adapter (input 100 to 240 VAC 50 – 60 Hz, output 5 V).

Note: The Aerogen USB Controller is approved for use with Aerogen USB Controller AC/DC Adapter AG-UC1040-XX* (Manufacturer Reference: FRIWO FW8002MUSB/05 / FW7721M)

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

Power Consumption: ≤ 2.0 Watts (nebulising).

Patient Isolation: Aerogen USB Controller circuitry provides 4 kilovolt (kV) patient isolation and complies with IEC/EN 60601-1.

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. It is the responsibility of the user/equipment manufacturer to ensure their equipment meets IEC/EN 60601-1 and IEC/EN 60601-1-2, and that any additional assessment as deemed necessary is completed prior to use of the Aerogen USB Controller.

Note: This device is classified as Class II Type BF, transit operable, portable medical electrical equipment and the device complies with specified safety levels for electrical isolation and leakage current. The USB Controller AC/DC Adapter has no connection to earth ground because the necessary level of protection is achieved through the use of double insulation.

Refer to Appendix 1 for EMC tables as per IEC/EN 60601-1-2.

Symbols

Table 11. Aerogen USB Controller System Symbols

Symbol	Title / Description (if applicable)	Symbol	Title / Description (if applicable)
YYXXXXX	Aerogen Serial number designation, where YY is the year of manufacture and XXXXX is the serial number.		**Transient Temperature Limit:** -25°C to +70°C. Indicates the temperature limits to which the medical device can be safely exposed.
	**Caution:** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	QTY	Quantity (Number of units contained in package)
 IP22	Protection against foreign objects equal to or greater than 12.5mm in diameter and against drops of water falling at up to 15° from vertical.		Controller Input – DC voltage
	Class II equipment per IEC/EN 60601-1.		Controller Output – AC voltage
	Type BF equipment per IEC/EN 60601-1.		On/Off power button
	Timer selection (to select the 30 minute or 6 hour nebulisation cycle).		Refer to instruction manual/booklet.
	Not made with natural rubber latex.	**Rx Only**	Federal (US) Law restricts this device to sale by or on the order of a physician.

Table 11. Aerogen USB Controller System Symbols (Continued)

Symbol	Title / Description (if applicable)	Symbol	Title / Description (if applicable)
	Classified by TUV with respect to electric shock, fire and mechanical hazards.		**Manufacturer:** Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.
	**Serial Number:** Indicates the manufacturer's serial number so that a specific medical device can be identified.		**Fragile, handle with care:** Indicates a medical device that can be broken or damaged if not handled carefully.
	**Keep Dry:** Indicates a medical device that needs to be protected from moisture.		**Catalogue Number:** Indicates the manufacturer's catalogue number so that the medical device can be identified.
	**Consult instructions for use:** Indicates the need for the user to consult the instructions for use.		The **CE mark** indicates conformity to the Medical Device Directive 93/42/EEC as amended by 2007/47/EC. The 0050 number under the CE mark denotes the Notified Body identification number (0050 -NSAI).
 *	This product is supplied non-sterile.*	 *	This product is supplied non-sterile.*

* The use of the non-sterile symbol (represented within △) is being phased out by Aerogen. Applicable Aerogen labelling is transitioning to the new non-sterile symbol (represented within □). To reflect all current Aerogen labelling, both versions are included within this table. Once labelling transition is complete the non-sterile symbol (represented within △) will be removed.

Appendix 1: EMC Tables

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

Table 12. Guidance and manufacturer's declaration – electromagnetic emissions

The Aerogen USB Controller system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen USB Controller 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 USB Controller 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 USB Controller 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	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3 EN 61000-3-3: 2013	Not Applicable	

Table 13. Recommended separation distances between portable and mobile RF communication equipment and the Aerogen USB Controller system that is not life supporting

The Aerogen USB Controller system is intended for use in an electromagnetic environment specified in Table 12. The customer or the user of the Aerogen USB Controller system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Aerogen USB Controller 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 14. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen USB Controller system that is not life supporting

This Aerogen USB Controller system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen USB Controller 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 USB Controller system requires continued operation during power mains operation, it is recommended that the Aerogen USB Controller system be powered from an uninterruptible power supply.

Table 14. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen USB Controller system that is not life supporting (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
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 15. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen USB Controller system that is not life supporting

This Aerogen USB Controller system is intended for use in the electromagnetic environment specified below. The customer or the user of the Aerogen USB Controller 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 USB Controller 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 15. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen USB Controller 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 28 V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28 V/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 9 V/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 28 V/m, 18 Hz PM 810 MHz 28 V/m, 18 Hz PM 870 MHz 28 V/m, 18 Hz PM 930 MHz 28 V/m, 217 Hz PM 1720 MHz 28 V/m, 217 Hz PM 1845 MHz	d = [1.17] √P... 80 MHz to 800 MHz d = [2.33] √P... 800 MHz to 2.5 GHz 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 15. Guidance and manufacturer's declaration – electromagnetic immunity for the Aerogen USB Controller system that is not life supporting (Continued)

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
	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 9 V/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 USB Controller system is used exceeds the applicable RF compliance level above, the Aerogen USB Controller 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 USB Controller system.

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

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