

Aerogen Solo/Pro

Instructions for Use

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Preface

To download the latest version of this manual or other documents, free of charge, visit the MyHamilton website. To register, go to <https://www.hamilton-medical.com/MyHamilton>.

Conventions used in this guide

In this manual:

- The graphics shown in this manual may not exactly match what you see in your environment.
- Some figures use callouts in a white circle with a blue border.
 - ① These figures may have an associated legend table, or may provide the legend in the figures title, if a single item. Callouts may be numeric or alphabetic. Callouts are *unrelated* to any nearby procedures and refer only to the figures themselves and their associated legend.
- Some figures use small dark blue callouts.
 - ① These callouts show the sequence of steps. Note that any numbering is *not* directly related to the numbering of any associated procedure.
- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

The Aerogen Pro is *not* available in the USA.

Safety messages are displayed as follows:

WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTICE

Emphasizes information of particular importance.

In tables, safety messages are indicated as follows:

 **WARNING!**

 **CAUTION!**

 **NOTICE!**

1 Safety information

This chapter provides safety information related to setting up and operating the Aerogen Solo^s and Aerogen Pro^s nebulizers.

Be sure to also read the safety information for nebulization with the ventilator, provided in the ventilator *Operator's Manual*.

Review the *Instructions for Use* before using the nebulizer and accessories.

Only trained medical personnel may use these devices.

If you have questions about any of the information in this manual, contact your Hamilton Medical representative or technical service personnel.

See the following sections for safety information that applies to:

- General use, including use with an HMEF
- Aerogen Solo
- Aerogen Pro

Regional approvals

In certain regions it is *not* permitted to use the Aerogen Solo nebulizer as follows:

Between the HMEF and endotracheal tube:

Brazil	China
Japan	Malaysia
Russia	Singapore

With a tracheostomy tube:

Brazil	China
Costa Rica	Japan
Malaysia	Russia
Singapore	USA

During noninvasive ventilation:

Brazil	China
Costa Rica	Japan
Malaysia	Russia
Singapore	

1.1 General safety information

WARNING

- 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 Hamilton Medical technical service personnel.
- Only use physician-prescribed solutions that are approved for use with a general purpose nebulizer. Consult the drug manufacturer's instructions regarding suitability for nebulization.
- Use only with components, connectors, and accessories that are specified by Aerogen in these *Instructions for use* and in the Aerogen documentation (available at www.aerogen.com).
- Do *not* use in the presence of flammable substances or flammable anesthetic mixtures combined with air, oxygen, or nitrous oxide.
- To avoid the risk of fire, do *not* use to aerosolize alcohol-based medications, which can ignite in oxygen-enriched air under high pressure.
- Do *not* modify this equipment without the authorization of the manufacturer.
- Do *not* use or store outside of specified environmental conditions.
- To avoid damage to the nebulizer:
 - Do *not* apply undue pressure to the domed aperture plate in the center of the nebulizer.
 - Do *not* use a syringe with a needle to add medication.
 - Do *not* push out the Aerogen Vibronic^S aerosol generator.

- During use, observe for correct functioning of the nebulizer by regularly verifying aerosol is visible.
- Condensate can collect and occlude the breathing circuit. Always position the breathing circuit so that fluid condensate drains away from the patient.
- To avoid exhaled medication affecting the ventilator, follow the ventilator manufacturer's recommendations for use of a bacterial filter in the expiratory limb of the breathing circuit.

1.1.1 HMEF-related safety information

WARNING

- Do *not* use a filter or HMEF between the nebulizer and the patient airway.
- Only use with HMEF devices for which the manufacturer's instructions allow use with a nebulizer, and always follow the HMEF manufacturer's instructions.
- Always monitor the resistance to flow and excessive rain-out, and change the HMEF device as per manufacturer's instructions.
- Ensure that the total combined volume of the nebulizer, T-piece, and HMEF 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.

Note the volume contributed by the T-piece:

T-piece volume, Adult: 34.3 ml

T-piece volume, Pediatric (OD15/ID15): 19.5 ml

1.1.2 Tracheostomy-related safety information

WARNING

- The combined weight of the tracheostomy tube assembly, nebulizer, and T-piece configuration may cause accidental decannulation.
- Ensure that the total combined volume of the nebulizer, T-piece, and tracheostomy tube assembly is suitable for the tidal volume being delivered, and does not increase the dead air space to the extent that it adversely impacts the respiratory parameters of the patient.

1.2 Aerogen Solo-specific safety information

See also the safety information provided in Chapter 4, Maintenance.

WARNING

- (*USA only*) Federal law restricts this device to sale by or on the order of a physician.
- The Aerogen Solo nebulizer is a single patient use device to be used only on one patient to prevent cross infection.
- The Aerogen Solo components and accessories, as packaged, are *not* sterile.
- The Aerogen Solo components and accessories are *not* made with natural rubber latex.
- Do *not* use the Aerogen Solo nebulizer beyond the defined lifetime of the device (see Chapter 5).
- Use of the Aerogen Solo and T-piece during the administration of volatile anesthetics may result in adverse

effects on the constituent plastics. Do not use with volatile anesthetics unless known to be compatible. Aerogen has determined that, using anesthetic ventilators, the following anesthetic agents are compatible at the below listed maximum concentrations and conditions:

- Maximum duration of exposure: 12 hours
- Isoflurane (FORANE[®]): 3.5%
- Sevoflurane (SEVOFLURANE[®]): 8%
- Desflurane (SUPRANE[®]): 10%

NOTICE

Connection of the Aerogen Solo nebulizer on the patient side of a Y-piece is *only* approved for use in the USA.

(*HAMILTON-C6 only*) Aerogen Solo operates continuously during active ventilation when the **Nebulization** function is activated. For nebulization details, see your ventilator *Operator's Manual*.

1.3 Aerogen Pro-specific safety information

See also the safety information provided in Chapter 4, Maintenance.

WARNING

- Clean, sterilize, assemble, and perform a functional test according to the instructions in this guide before first use and between patients.
- Do *not* attach a continuous supply of medication to the nebulizer; the device operates for the set **Duration** during active ventilation when the **Nebulization** function on the ventilator is activated.

- To ensure optimum drug administration, consult the drug manufacturer’s instructions regarding suitability for nebulization.
- To avoid damage to the nebulizer:
 - Do *not* drop the nebulizer.
 - Prior to use, autoclave only according to the directions provided in Chapter 4. Any deviation from directions provided in this guide may cause damage to the nebulizer and render it inoperable.
 - Do *not* use abrasive or sharp tools to clean the nebulizer.
- Always maintain the nebulizer in a vertical orientation, with the filler cap facing up during operation, to ensure proper nebulization and to prevent condensate from blocking the nebulizer.
- Always visually inspect the nebulizer prior to use to assure that no secretions are blocking the Aerogen Vibronic aerosol generator.
- When removing the nebulizer from the breathing circuit, always replace the T-piece plug to maintain circuit pressure.

NOTICE

(HAMILTON-C6 only) Aerogen Pro operates continuously during active ventilation when the **Nebulization** function is activated. For nebulization details, see your ventilator *Operator’s Manual*.

2 Overview

NOTICE

- Not all features or products are available in all markets.
- Product description and order number may differ depending on region.

This guide provides information about the use and set up of Aerogen Solo and Aerogen Pro nebulizers with Hamilton Medical ventilators. It is designed for use together with your ventilator *Operator’s Manual*, and may refer to information provided therein.

Certain Hamilton Medical ventilators support nebulization using the Aerogen Solo or Aerogen Pro nebulizers as an option.

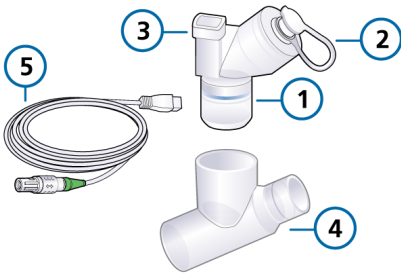
The system comprises the ventilator hardware with **Aerogen** port/module on the ventilator, and an Aerogen nebulizer with T-piece/adapters and connection cable.

2.1 About the Aerogen Solo nebulizer

The Aerogen Solo nebulizer¹ comprises the nebulizer, T-piece, optional breathing circuit adapters, and connection cable.

Figure 1 shows the Aerogen Solo system components. Table 1 provides T-piece and adapter size specifications.

Figure 1. Aerogen Solo nebulizer components



- | | |
|--------------------------|----------------------------------|
| 1 Aerogen Solo nebulizer | 4 T-piece |
| 2 Filler cap | 5 Connection cable to ventilator |
| 3 Cable connection port | |

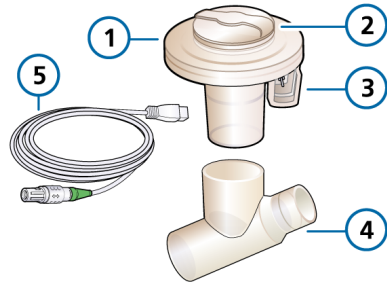
Optional adapters and ventilator hardware not shown.

2.2 About the Aerogen Pro nebulizer

The Aerogen Pro nebulizer² comprises the nebulizer, T-piece, optional breathing circuit adapters, and connection cable.

Figure 2 shows the Aerogen Pro system components. Table 1 provides T-piece and adapter size specifications.

Figure 2. Aerogen Pro nebulizer components



- | | |
|-------------------------|----------------------------------|
| 1 Aerogen Pro nebulizer | 4 T-piece |
| 2 Filler cap | 5 Connection cable to ventilator |
| 3 Cable connection port | |

Optional adapters and ventilator hardware not shown.

2.3 About the breathing circuits and nebulizer components

To connect the nebulizer to the breathing circuit, a variety of T-pieces and adapters are available.

This section lists parts available for the Aerogen Pro (Table 1) and Aerogen Solo (Table 2) nebulizers.

For more information on breathing circuits, see your ventilator *Operator's Manual*.

¹ (USA only) Aerogen Solo is not approved for use with patients younger than 28 days old.

² (USA only) Aerogen Pro is not approved for use with patients younger than 28 days old.

Table 1. Aerogen Pro T-piece and adapter specifications

Part number	Patient Group	Specification
AGAP1010	Adult	OD22 / ID22 / ID22
AGAP1020	Pediatric	ID15 / ID22 / OD15
AGAP1036	Neonatal	ID10 / ID10 / OD10
Aerogen Pro Adapter Kit		
AGAP1025	Neonatal	OD15 / OD10 to OD7.5 ID15 / OD10 to ID7.5

Table 2. Aerogen Solo T-piece and adapter specifications

Part number	Patient Group	Specification
AGAS3010	Adult	ID22 / ID22 / OD22
AGAS3020	Pediatric	ID15 / ID22 / OD15
AGAS3035	Neonatal	ID12 / ID22 / OD12
AGAS3036	Neonatal	ID10 / ID22 / OD10

For more information on T-pieces and adapters, see the e-catalog on the Hamilton Medical website: <https://www.hamilton-medical.com/Products/Accessories-and-Consumables/E-catalog.html>.

3 Working with the nebulizer

Before proceeding, review the safety information in Section 1.

Setting up the nebulizer comprises the following steps.

Table 3. Nebulizer setup overview

To ...	See ...
Enable Aerogen nebulization on the ventilator	Your ventilator <i>Operator's Manual</i>
Perform the functional test	Section 3.1
Connect the Aerogen Solo nebulizer to the breathing circuit	Section 3.2
Connect the Aerogen Pro nebulizer to the breathing circuit	Section 3.3
Connect the nebulizer cable to the ventilator	Section 3.4
Add medication	Section 3.5

3.1 Performing a functional test

Perform a functional test of the nebulizer:

- Prior to first use
- At any time to verify proper operation
- **Aerogen Pro only:** After each sterilization cycle before use on a patient

To perform the nebulizer functional test

For details on performing tasks on the ventilator, see your ventilator *Operator's Manual*.

1. Visually inspect the nebulizer and each accompanying component for cracks or damage, and replace if any defects are visible.

2. Pour normal saline solution (0.9%) into the nebulizer:
 Aerogen Solo 1 to 6 ml
 Aerogen Pro 1 to 5 ml
3. Connect the nebulizer to the Aerogen port/module on the ventilator using the connection cable.
4. Turn on the ventilator and ensure Aerogen nebulization is enabled.
5. Start nebulization on the ventilator.
6. Perform a visual aerosol check by verifying that aerosol is visible during nebulization.

When aerosol is visible, the test is successful and the nebulizer is ready for use.

If aerosol is not visible, troubleshoot as described in Table 4.

Table 4. Troubleshooting:
Aerosol is not visible

Possible causes	Action needed
There is no medication in the nebulizer.	Refill the medication through the filler cap of the nebulizer.
The cable connection to the ventilator is faulty.	Disconnect and reconnect the cable between the nebulizer and the ventilator.
The incorrect nebulization option is configured on the ventilator.	Verify that Aerogen is selected in Configuration , as described in your ventilator <i>Operator's Manual</i> .
The nebulizer is faulty.	Replace the nebulizer.

3.2 Connecting Aerogen Solo to the breathing circuit

Before proceeding, review the safety information in Section 1.

Use of the Aerogen Solo nebulizer with an HMEF is contraindicated for neonatal patients.

You can connect Aerogen Solo to the breathing circuit using any of the following methods.

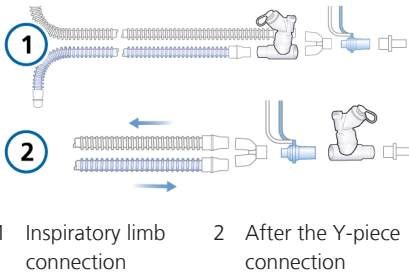
Table 5. Aerogen Solo connection options

To connect ...	See ...
To the inspiratory limb	Section 3.2.1
To the dry side of the humidifier	<i>Nebulizer Positioning Guidelines</i> and Aerogen documentation
After the Y-piece ³ (without humidification)	Section 3.2.2
To a tracheostomy tube	Section 3.2.3

For additional connection details, also see the *Nebulizer Positioning Guidelines* (PN ELO2020-124-TW) available at MyHamilton.

³ Only approved for use in the USA.

Figure 3. Aerogen Solo connection options



Adapters and dry-side of the humidifier connection not shown.

3.2.1 Connecting Aerogen Solo to the inspiratory limb

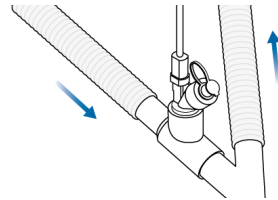
You can connect Aerogen Solo to the inspiratory limb of the breathing circuit, with or without humidification. The connection is the same in both cases.

Before proceeding, perform the functional test on the nebulizer (Section 3.1).

To connect to an adult breathing circuit

1. Connect the nebulizer to the adult T-piece (Table 1).
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit in front of the Y-piece (Figure 4).
3. Connect the nebulizer cable to the **Aerogen** port/module on the ventilator (Section 3.4).

Figure 4. Connecting Aerogen Solo to the inspiratory limb of the breathing circuit (adult circuit shown)



To connect to a pediatric breathing circuit

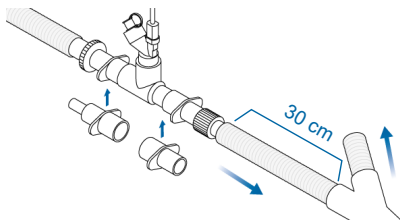
1. Connect the nebulizer to the pediatric T-piece, and if required, neonatal adapters (Table 1).
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit (Figure 4 or 5).
3. Connect the nebulizer cable to the **Aerogen** port/module on the ventilator (Section 3.4).

To connect to a neonatal breathing circuit⁴

1. Connect the nebulizer using either of the following:
 - Neonatal T-piece
 - Pediatric T-piece and neonatal adapters
 For specifications, see Table 1.
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit, approximately 30 cm away from the patient Y-piece (Figure 5). The 30 cm distance allows for placement of the nebulizer outside of an incubator.
3. Connect the nebulizer cable to the **Aerogen** port/module on the ventilator (Section 3.4).

⁴ (USA only) Aerogen Solo is not approved for use with patients younger than 28 days old.

Figure 5. Connecting Aerogen Solo with adapters to the inspiratory limb of the breathing circuit



3.2.2 Connecting Aerogen Solo after the Y-piece

Before proceeding, review the safety information in Section 1.

You can connect Aerogen Solo to the breathing circuit after the Y-piece, with or without an HMEF.⁵

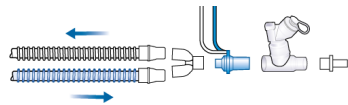
If using an HMEF, be sure to read the safety information in Section 1.1.1.

Before proceeding, perform the functional test on the nebulizer (Section 3.1).

To connect Aerogen Solo after the Y-piece

1. If using an HMEF, connect it to the patient end of the breathing circuit.
2. Connect the flow sensor to the HMEF, if used; if not, connect the flow sensor to the patient end of the breathing circuit.
3. Connect the nebulizer to the appropriate T-piece and any required adapters.
4. Connect the T-piece and nebulizer to the flow sensor (Figure 6).
5. Connect the nebulizer cable to the Aerogen port/module on the ventilator (Section 3.4).

Figure 6. Connecting Aerogen Solo after the Y-piece



3.2.3 Connecting Aerogen Solo to a tracheostomy tube

Before proceeding, review the safety information in Section 1.

Use of the Aerogen Solo nebulizer with a tracheostomy tube is contraindicated for neonatal patients.

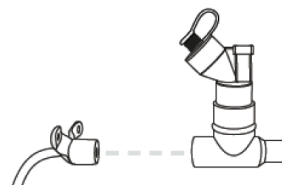
The Aerogen Solo nebulizer is compatible with standard tracheostomy tubes.

To connect Aerogen Solo to a tracheostomy tube

1. Connect the nebulizer to the T-piece.
2. Connect the T-piece to the tracheostomy tube assembly (see Figure 7).
3. If needed, attach an extension piece so that the nebulizer can be placed on an adjacent surface.

The additional weight of the Aerogen Solo nebulizer may cause accidental decannulation.

Figure 7. Connecting Aerogen Solo to a tracheostomy tube



⁵ Use of the Aerogen Solo nebulizer with an HMEF is contraindicated for neonatal patients.

3.3 Connecting Aerogen Pro to the breathing circuit

Before proceeding, review the safety information in Section 1.

Connection of the Aerogen Pro nebulizer is only supported in the inspiratory limb of the breathing circuit.

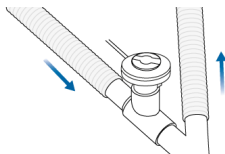
Always maintain the nebulizer in a vertical orientation (with the filler cap uppermost) while positioned in the patient circuit (Figures 8 and 9). This orientation prevents condensation from blocking the nebulizer and ensures proper nebulization.

Before proceeding, perform the functional test on the nebulizer (Section 3.1).

To connect Aerogen Pro to an adult breathing circuit

1. Connect the nebulizer to the adult T-piece (Table 1).
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit (Figure 8).
3. Connect the nebulizer cable to the **Aerogen** port/module on the ventilator (Section 3.4).

Figure 8. Connecting Aerogen Pro to the inspiratory limb of the breathing circuit (adult circuit shown)



To connect Aerogen Pro to a pediatric breathing circuit

1. Connect the nebulizer to the pediatric T-piece, and if required, neonatal adapters (Table 1).
2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit (Figure 8 or 9).
3. Connect the nebulizer cable to the **Aerogen** port/module on the ventilator (Section 3.4).

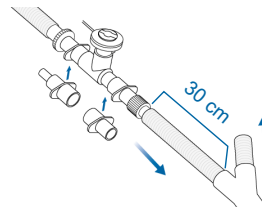
To connect Aerogen Pro to a neonatal breathing circuit⁶

1. Connect the nebulizer using either of the following:
 - Neonatal T-piece
 - Pediatric T-piece and neonatal adapters

For specifications, see Table 1.

2. Connect the T-piece and nebulizer to the inspiratory limb of the breathing circuit, approximately 30 cm away from the patient Y-piece (Figure 9). The 30 cm distance allows for placement of the nebulizer outside of an incubator.
3. Connect the nebulizer cable to the **Aerogen** port/module on the ventilator (Section 3.4).

Figure 9. Connecting Aerogen Pro with adapters to the inspiratory limb of the breathing circuit



⁶ (USA only) Aerogen Pro is not approved for use with patients younger than 28 days old.

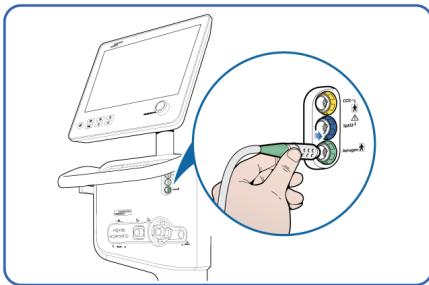
3.4 Connecting the nebulizer to the ventilator

After connecting the nebulizer to the breathing circuit, you must connect it to the ventilator. During nebulization, the ventilator powers and controls the nebulizer.

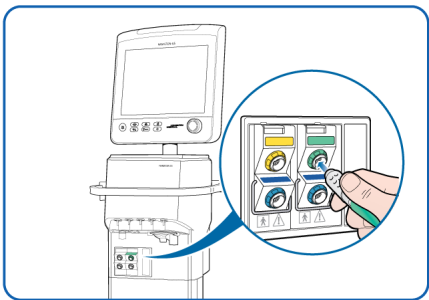
To connect the nebulizer to the ventilator

1. Insert the connection cable into the port on the nebulizer (Figures 1 and 2).
2. Connect the other end of the cable to the Aerogen port/module on the ventilator (Figure 10).

Figure 10. Connecting the nebulizer to the ventilator



HAMILTON-C6



HAMILTON-G5/S1

3.5 Adding medication to the nebulizer

You can add medication during nebulization without interrupting operation or ventilation.

To add medication to the nebulizer

1. Open the filler cap on the nebulizer.
2. Use a pre-filled ampoule or syringe to add medication into the filler port of the nebulizer (Figures 11 and 12).
3. Close the filler cap.

Do *not* fill the nebulizer beyond the maximum capacity. Table 6 shows the maximum capacity for the nebulizers.

Table 6. Maximum capacity of Aerogen nebulizers

Nebulizer	Max. capacity (ml)
Aerogen Solo	6
Aerogen Pro	10

Figure 11. Adding medication to the Aerogen Solo nebulizer using a pre-filled ampoule

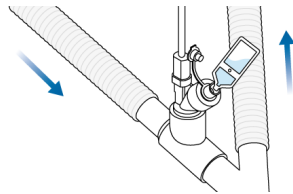
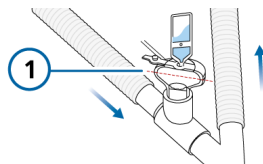


Figure 12. Adding medication to the Aerogen Pro nebulizer using a pre-filled ampoule



1 Do not fill beyond this point

4 Aerogen Pro maintenance

Note that the Aerogen Solo is a single patient use device, and therefore maintenance and cleaning are not permitted.

WARNING

- Always clean, sterilize, and disinfect components as approved by your institution's protocols.
- Disassemble all parts before autoclaving.
- The use of any other means of cleaning, disinfection, or sterilization has *not* been qualified and is likely to reduce the lifetime of your nebulizer. It will also invalidate your warranty.
- Do *not* autoclave any Aerogen Solo components or accessories.

NOTICE

Aerogen Solo and its accessories are approved for single patient use only, and are *not* intended to be cleaned, disinfected, or sterilized.

This section describes how to clean, disinfect, sterilize, and inspect Aerogen Pro components.

Be sure to clean and sterilize Aerogen Pro components prior to first patient use.

The Aerogen Pro components comprise:

- Aerogen Pro (including filler cap)
- T-piece (including T-piece plug) for adults and pediatrics
- Neonatal adapters

4.1 Manually cleaning the Aerogen Pro nebulizer

Before proceeding, review the safety information in Section 1.

To clean the Aerogen Pro nebulizer, T-piece and plug, and adapters

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

4.2 Disinfecting the Aerogen Pro nebulizer

Before proceeding, review the safety information in Section 1.

To disinfect the Aerogen Pro nebulizer, T-piece and plug, and adapters

1. Ensure there is no medication remaining in the device.
2. Disassemble the components:
 - Remove the nebulizer from the T-piece.
 - Remove the filler cap from the nebulizer.
3. Clean all parts with warm water and mild liquid detergent.

4. Completely immerse all parts in an appropriate disinfecting agent (Section 4.2.1) in accordance with your institution's protocols and the disinfectant agent manufacturer's recommendations.
5. Dry the components, and rinse if required, according to the disinfectant agent manufacturer's recommendations.

4.2.1 Approved disinfection agents

The following disinfection solutions are approved for use with the Aerogen Pro nebulizer:

- Isopropyl (70 %)
- Hexanios G+R
- CIDEX[§]
- CIDEX[§] OPA
- NU-CIDEX[§]

Follow the cleaning/disinfection agent manufacturer's recommendations and refer to the product labeling for specific instructions regarding microbiological effectiveness, activation, safe use, and disposal.

4.3 Automated washing for the Aerogen Pro nebulizer

Before proceeding, review the safety information in Section 1.

The Aerogen Pro nebulizer has been qualified for the automated washing cycles described in Table 7.

Table 7. Automated washing cycles

Step	Description	Temperature	Duration
Automated washing cycle 1			
Detergent: Liquid alkaline cleaner (diluted per the manufacturer's instructions)			
Water quality: Tap water			
1	Load the components into the automated washer.	--	--
2	Pre-rinse the components.	--	3 minutes
3	Clean the components with liquid alkaline cleaner.	55°C (131°F)	10 minutes
4	Rinse the components.	--	1 minute
5	Rinse using a thermal disinfection cycle.	93°C (199.4°F)	10 minutes
Automated washing cycle 2			
Detergent: This cycle was validated without the use of detergent			
Water quality: Tap water			
1	Load the components into the automated washer.	--	--
2	Wash the components.	91°C (195.8°F)	10 minutes
3	Drain the machine.	--	40 seconds
4	Rinse the components.	90°C (194°F)	1 minute
5	Drain the machine.	--	40 seconds
6	Rinse the components.	90°C (194°F)	1 minute
7	Drain the machine.	--	40 seconds
8	Dry the components.	90°C (194°F)	15 minutes

4.4 Sterilizing the Aerogen Pro nebulizer

WARNING

- Do *not* reassemble parts prior to autoclaving.
- If using the hydrogen peroxide gas plasma sterilization method, refer to the STERRAD[®] 100S Sterilization System Directions for use for proper operation.

NOTICE

The Aerogen Pro nebulizer contains active electronic components. Aerogen has validated the methods of cleaning, disinfection, and sterilization provided in this section.

The use of any other means of cleaning, disinfection, or sterilization has not been validated and is likely to reduce the life of your nebulizer, and will invalidate your warranty.

To sterilize the Aerogen Pro nebulizer, T-piece, and adapters

1. Remove the nebulizer and adapters from the breathing circuit.
2. Disassemble the nebulizer and adapters into individual components, including removing the filler cap.
3. Clean all parts with warm water and a mild liquid detergent in accordance with your institution's protocols.
4. Rinse thoroughly and air dry.
5. Check for cracks or damage, and replace if any defects are visible.

6. Package the disassembled components into appropriate sterilization wrapping.
7. Perform steam sterilization using one of the following methods:
 - Prevacuum at a minimum of 134°C (270°F to 275°F) for 3.5 minutes with drying cycle (134°C wrapped cycle).
 - Prevacuum at a minimum of 121°C (250°F) for 20 minutes with drying cycle (121°C wrapped cycle).
 - **Long autoclave cycle:** Prevacuum at a minimum of 134°C (270°F to 275°F) for 20 minutes with drying cycle^{7,8}.

Using this method of sterilization may cause some areas of the nebulizer to become discolored. This is not indicative of the performance of the nebulizer.

– **Hydrogen peroxide gas plasma:** Place wrapped parts in a STERRAD 100S Sterilization System and use the **long cycle** according to the manufacturer's recommendations.

Prior to the next use of the sterilized nebulizer

1. Check the nebulizer for cracks or damage, and replace if any defects are visible.
2. Perform the functional test as described in Section 3.1.

⁷ Not approved for use in the USA.

⁸ This option is referred to as a *prior cycle*.

5 Specifications: Aerogen Solo

This section describes the Aerogen Solo intended use, performance specifications, lifetime, and warranty.

Additional information and specifications are available at the Aerogen website, www.aerogen.com.

5.1 Intended use

Rest of the world (ROW)

The Aerogen Solo is part of the Aerogen Pro product family. The Aerogen Pro is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aerogen Pro is suitable for use in adult, pediatric, and neonate patients as described in the Instruction Manual.

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

USA

The Aerogen Solo nebulizer is a portable medical device for single patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aerogen Solo is suitable for intermittent and continuous nebulization of pediatric (29 days or older) and adult patients as described in this guide.

5.2 Physical characteristics

Table 8. Aerogen Solo physical characteristics

Dimension		Specification
Nebulizer dimensions		67 mm H x 48 mm W x 25 mm D 2.6 in H x 1.88 in W x 1.1 in D
Nebulizer weight		13.5 g (0.5 oz) nebulizer and plug
T-piece weight	Adult	28.7 g (1.0 oz) T-piece and plug
	Pediatric	16.8 g (0.6 oz) T-piece and plug
	Neonatal	14 g (0.5 oz) T-piece and plug
Nebulizer capacity		Maximum 6 ml
T-piece volume	Adult	34.3 ml
	Pediatric (15 mm)	19.5 ml

5.3 Performance specifications

Table 9 shows the results of aerosol performance testing for the Aerogen Solo using an 8 stage cascade impactor running at a continuous flow rate of 28.3 LPM. Indicated ranges correspond to confidence intervals with a confidence level of 95%.

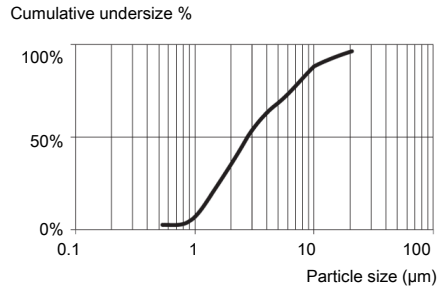
Table 9. Aerogen Solo performance specifications

Parameter	Specification
Flow rate	> 0.2 ml/min (average ~ 0.38 ml/min)
Particle size	<p>As per EN 13544-1</p> <p>Aerosol output rate: 0.30 ml/min</p> <p>Aerosol output: 1.02 ml emitted of 2.0 ml dose</p> <p>Residual volume: < 0.1 ml for 3 ml dose</p> <p>As measured with the Andersen Cascade Impactor</p> <p>Specification range: 1 to 5 µm</p> <p>Average tested: 3.1 µm</p> <p>As measured with the Marple 298 Cascade Impactor⁹</p> <p>Specification range: 1.5 to 6.2 µm</p> <p>Average tested: 3.9 µm</p>

Performance may vary depending on the type of drug and nebulizer used. For additional information, contact Aerogen or the drug supplier.

The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.

Figure 13. Representative particle size distribution for Albuterol as per EN 13544-1



⁹ Not applicable in the USA.

Table 10. Aerogen Solo aerosol performance testing

Element	Albuterol sulphate (1mg/ml)	Ipratropium (0.25 mg/ml)	Budesonide (0.5 mg/ml)
Results obtained using an 8-stage cascade impactor running at a continuous flow rate of 28.3 l/min. Indicated ranges correspond to confidence intervals with a confidence level of 95%.			
Particle size (μm)	2.90 to 3.23	3.07 to 3.42	3.45 to 3.79
Geometric standard deviation (GSD)	2.09 to 2.35	1.80 to 1.93	1.92 to 2.14
Emitted dose (% of fill)	97.23 to 99.30	97.61 to 98.64	94.12 to 97.84
Respirable dose (0.5 to 5.0 μm) (% of fill)	67.66 to 73.50	71.78 to 76.69	62.32 to 66.90
Coarse particle dose (> 4.7 μm) (% of fill)	27.00 to 31.11	23.62 to 28.21	32.31 to 36.12
Fine particle dose (< 4.7 μm) (% of fill)	66.33 to 72.07	68.58 to 73.84	59.36 to 64.17
Ultra-fine particle dose (< 1.0 μm) (% of fill)	5.91 to 9.93	1.85 to 4.19	2.36 to 4.51

5.4 Lifetime

As with all active electronic components, the Aerogen Solo nebulizer has a defined lifetime.

The lifetime of the Aerogen Solo nebulizer has been validated for intermittent use for a maximum of 28 days based on a typical usage profile of four (4) treatments per day.

For continuous use, the life of the Aerogen Solo nebulizer and the continuous nebulization tube set have been qualified for use for a maximum of 7 days.

Use in excess of this period is not qualified by Aerogen.

5.5 Warranty

Aerogen warrants that the Aerogen Solo nebulizer shall be free from defects of workmanship and materials for a period of the defined life of the nebulizer when used in accordance with these *Instructions for use*.

6 Specifications: Aerogen Pro

This section describes the Aerogen Pro intended use, performance specifications, lifetime, and warranty.

Additional information and specifications are available at the Aerogen website, www.aerogen.com.

6.1 Intended use

Rest of the world (ROW)

The Aerogen Pro is a portable medical device for multiple patient use that is intended to aerosolize physician-prescribed solutions for inhalation to patients on and off ventilation or other positive pressure breathing assistance.

The Aerogen Pro is suitable for use in adult, pediatric, and neonate patients.

The Aerogen Pro is *not* available in the USA.

6.2 Physical characteristics

Table 11. Aerogen Pro physical characteristics

Dimension	Specification
Nebulizer 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
Nebulizer weight	25 g (0.9 oz) nebulizer and filler cap
Nebulizer capacity	Maximum 10 ml

6.3 Performance specifications

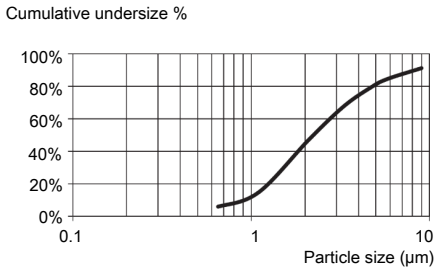
Table 12. Aerogen Pro performance specifications

Parameter	Specification
Flow rate	> 0.2 ml/min (average ~0.4 ml/min)
Particle size	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 As measured with the Andersen Cascade Impactor Specification range: 1 to 5 µm Average tested: 3.1 µm As measured with the Marple 298 Cascade Impactor Specification range: 1.5 to 6.2 µm Average tested: 3.9 µm

Performance may vary depending on the type of drug and nebulizer used. For additional information, contact Aerogen or the drug supplier.

The temperature of the medication will not rise more than 10°C (18°F) above ambient during normal use.

Figure 14. Representative particle size distribution for Albuterol as per EN 13544-1



6.4 Lifetime

As with all active electronic components, the Aerogen Pro nebulizer has a defined life.

The lifetime of the Aerogen Pro nebulizer and components has been validated for use for 730 doses and 26 sterilization cycles based on a typical one year usage profile of four (4) patient treatments per day and one (1) sterilization cycle per week, where the device is assumed to be in service for 50% of the time.

Use in excess of these limits may result in reduced life of the product.

6.5 Warranty

The Aerogen Pro nebulizer is warranted for one year from date of purchase against defects in manufacturing. All warranties are based on typical usage.

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