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 *prion 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

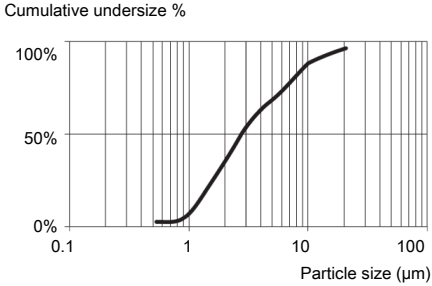
5.3 Performance specifications

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	**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 **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**[9] **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 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

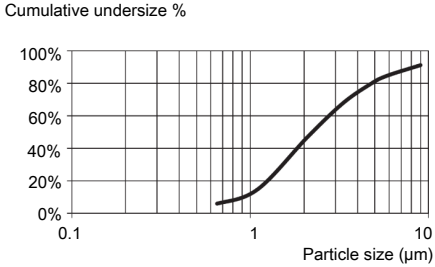
Dimension	Specification
Nebulizer dimensions	45 mm H x 50 mm W x 50 mm D 1.8 in H x 2.0 in W x 2.0 in D
Nebulizer weight	25 g (0.9 oz) nebulizer and filler cap
Nebulizer capacity	Maximum 10 ml

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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For more information:
www.hamilton-medical.com

HAMILTON MEDICAL

Intelligent Ventilation since 1983

Hamilton Medical AG
Via Crusch 8, 7402 Bonaduz, Switzerland
☎ +41 (0)58 610 10 20
info@hamilton-medical.com
www.hamilton-medical.com

EC REP medin Innovations GmbH
Adam-Geisler-Strasse 1
DE – 82140 Olching