

# 8900 SMALL VOLUME NEBULIZER

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

## DEVICE MANUFACTURING SPECIFICATIONS

Reference Number	8900, 8900TG
Manufacturer	SunMed LLC/Salter Labs
Classification – US	Class II
FDA Product Code	CAF
Classification – EU	Class IIa
CE Mark/Notified Body	CE 2797/BSI Group
EU Authorized Representative	Mt Promedt Consulting GmbH
Classification – Canada	Class 2
EMDN Code	R060101 Cold Nebulizing System
GMDN Code	35457, Nebulizing System, Non-Heated
UMDNS Code	12712, Nebulizers
Usage	Disposable, Single Patient Multiple Use
Sterile	Non-Sterile
Patient Population	Infant, Pediatric and Adults
Packaging	Individually Packaged, 25 or 50/Case
Shelf Life	5 Years

**Description:** Hand-held, small-volume pneumatic nebulizer which connects to a t-piece with a mouthpiece and reservoir tube.

**Intended Purpose:** The pneumatic powered nebulizer is intended to use where liquid medications are to be delivered to a patient in an aerosol form.

**Area of Use:** Hospitals, sub-acute, medical clinics, pre-hospital, home, and other medical facilities.

**Duration of Use:** Replace the nebulizer every 7 days, or sooner if it becomes damaged, contaminated or is not functioning properly.

**Contraindications:** None known.

## DEVICE SPECIFICATIONS

Description	Specification
Supply Tubing Length	3-Channel, 7' (2.1 m), 14' (4.2 m)
Tubing End Connector TG	Female Thread Grip
Tubing End Connector	Trumpet
Nebulizer Gas Source	Air or Oxygen
Gas Flow Rate Minimum	5 LPM ( $\geq$ 10 psi)
Gas Flow Rate Maximum	8 LPM ( $\leq$ 50 psi)
Minimum Fill Volume	2 mL
Maximum Fill Volume	6 mL
Mouthpiece Outlet	22 mm O.D.
Nebulization Angle	45° Angle to Vertical Position
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C



## DEVICE MATERIAL

Component	Material
Medication Cup	Polystyrene
Nebulizer Cap	Polypropylene
Cone (Insert)	Polystyrene, Transparent Green
One-Way Valve	High Density Polyethylene
Flutter Valve	Silicone
Mouthpiece	High Density Polyethylene, White
Supply Tubing	Polyvinyl Chloride, 3-Channel
Connector, End Piece	Polyvinyl Chloride

**Latex:** AirLife® does not utilize latex or latex-containing material to manufacture products. To the best of our knowledge latex does not contact components or finished goods during the manufacturing process.

**Phthalates:** The selected materials are Non-DEHP; DEHP was not intentionally added as part of the manufacturing process.

**Mercury-Lead:** The selected materials do not contain lead or mercury.

**Biocompatible** per device classification in ISO 10993. SunMed manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMPs) as listed in 21 C.F.R. (U.S. Code of Federal Regulations).

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## PERFORMANCE DATA FOR 8900 SMALL VOLUME NEBULIZER

Parameter	4 LPM	6 LPM	8 LPM
Aerosol Output Rate	0.18 mL/min	0.27 mL/min	0.31 mL/min
Aerosol Output Rate	181 µg/min	270 µg/min	311 µg/min
Aerosol Output	0.81 mL	0.92 mL	0.97 mL
Aerosol Output	807 µg	916 µg	967 µg
Percentage of Fill Volume Emitted	20.2%	22.9%	24.2%
Percentage of Fill Volume Emitted Per Minute	4.5%	6.7%	7.8%
Nebulization Time	14.0 min	7.83 min	6.25 min
Residual Volume	1.67 mL	1.68 mL	1.51 mL
Aerosol Output Fraction	0.81	0.92	0.97

Aerosol characteristic will vary depending on flow rate, source pressure and solution used. Particle size characterization was performed using 3 mL of 0.083% albuterol solution and flow rate of 8 L/min (50 psi). Cascade impactor sampled nebulizer aerosol through the t-piece and mouthpiece

## PARTICLE SIZE DATA

Parameter	Data
Mass Median Aerodynamic Diameter (MMAD)	3.73 µm
Geometric Standard Deviation (GSD)	2.87

Part Number	UOM	GTIN/UDI
8900-7	Each	00607411890031
8900-7-50	Case	10607411890038
8900-8	Each	00607411005695
8900-8-50	Case	10607411005692
8900-14	Each	00607411000737
8900-14-25	Case	10607411000734
8900TG-7	Each	00607411890055
8900TG-7-50	Case	10607411890052