8900TG Small Volume Nebulizer

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

8900TG Small Volume Nebulizer	
Reference Number	8900TG-7-50
Manufacturer	SunMed | Salter Labs
Classification – USA	FDA Class II Medical Device, K884947
Classifications – EU	Class IIa, Rule 20-Noninvasive Devices, MDR 2017/745
Classification – Canada	Class II, Rule 5 Canadian Medical Device Regulations
CE Mark/Notified Body	CE 2797/BSI Group
Product Code	CAF
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, 50 Case
Made In	Mexico
Shelf Life	5 Years

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

Indication for use: To administer prescribed aerosolized medication to spontaneously breathing patients. Patient population includes infant, pediatric and adult patients.

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 after 21 cleaning cycles, whichever is first.

Contraindications: None known.

Warning:

- This product is disposable and is not intended for prolonged or extended use.
- Position tubing to avoid strangulation.
- Device contains components that may present choking hazard.
- To avoid risk of infection and contamination follow instruction for use for cleaning and maintenance of the nebulizer.
- If using oxygen, do not use near flame or heat source.
- The tubing presents a strangulation hazard. Always use close supervision when administrating a treatment to a child. Do not leave a child unattended during treatment.
- All parts should be seated firmly in place. Improperly assembled nebulizer could prevent adequate delivery of medication.

8900TG Small Volume Nebulizer

Performance Data for 8900TG Small Volume Nebulizer

Parameter	4 LPM	6 LPM	8 LPM
Aerosol Output Rate (mL/min)	0.18	0.27	0.31
Aerosol Output Rate (µg/min)	181	270	311
Aerosol Output (mL)	0.81	0.92	0.97
Aerosol Output (µg)	807	916	967
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	7.83	6.25
Residual Volume	1.67	1.68	1.51
Aerosol Output Fraction	0.81	0.92	0.97

Test Solution: 4 mL of albuterol 0.1% (M/V) concentration in 0.9% sodium chloride solution.
Performance Characteristic Source Pressure: 50 psi

Particle Size Data

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

Test Solution: 4 mL of albuterol 0.1% (M/V) concentration in 0.9% sodium chloride solution.
Performance Characteristic Source Pressure: 50 psi at 8 LPM

Product Material

Part Description	Material
Medication Cup	Polystyrene
Nebulizer Cap	Polypropylene
Cone (insert)	Polystyrene, Transparent Green
Top T	Styrene/Butadiene Copolymer
Mouthpiece	High Density Polyethylene, White
Supply Tubing	Polyvinyl Chloride, 3-Channel
Connector, End Piece	Polyvinyl Chloride

Device Specifications

Description	Specification
Supply Tubing Length	3-Channel, 7′ (2.1 m) or 8′ (2.4 m)
Tubing End Connector	Female Thread Grip
Nebulizer Gas Source	Air or Oxygen
Gas Flow Rate Minimum	4 LPM (≥ 25 psi)
Gas Flow Rate Maximum	8 LPM (≤ 52 psi)
Minimum Fill Volume	2 mL
Maximum Fill Volume	5 mL
Mouthpiece Outlet	22 mm O.D.
Nebulization Angle	45° Angle to Vertical Position
Operating Temperature	5°C to 40°C
Storage Temperature	-40°C to 60°C

Latex: SunMed® 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).

Part Number	UOM	GTIN/UDI
8900-7	Each	607411890031
8900-7-50	Case	10607411890038
8900-8	Each	607411005695
8900-8-50	Case	10607411005692

TDS-10269 Rev 1