7900 High Flow Bubble Humidifier

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

7900 High Flow Bubble Humidifier	
Reference Number	7900-0-10, E7900-0-10
Manufacturer	SunMed LLC/Salter Labs
Classification-USA	FDA Class II Medical Device, K113542
Classifications-EU	Class IIa EC Directive 93/42/EEC Annex IX
Classification-Canada	Class II Canadian Medical Device Regulations
CE Mark/ 93/42 Notified Body Number	CE 2797 / Mt Promedt Consulting GmbH
Product Code	BTT- Bubble humidifier
GMDN Code	35113, Unheated Inspiratory Line Humidifiers
UMDNS Code	12051, Humidifiers, Unheated35113
Sterile	No
Usage	Disposable, Single Patient Multiple Use
Patient population	Adult
Packaging	Individually Packaged, 50 Case

Intended use: A bubble-type humidifier intended to add humidity to oxygen delivered via a nasal cannula or oxygen mask for spontaneously breathing patient. For flow rates 6 LPM to 15 LPM.

Usage: The bubble humidifier is indicated for use with oxygen concentrators or gas sources in home care, hospital, extended care facilities and hospice environments. Do not use on more than one person. Note: This device is not heated and does not create an aerosol. The purpose is to increase the relative humidity of oxygen delivered to the patient.

Area of use: Hospitals, medical clinics, home, surgical centers, skilled nursing facilities.

Duration of use:

- Home: Replace bubble humidifier every 90 days (3 months), or sooner if it malfunctions or unable to remove mineral deposits by cleaning.
- Hospital: Replace bubble humidifier every 14 days.

Contraindications: None known.

Warning:

- Using flow rates outside the recommend range may affect the function of the safety pressure relief valve.
- A potential for bacteria contamination if humidifiers are not properly cleaned or replaced as indicated in the instruction for use.
- Leaks may partially or fully reduce oxygen being delivered to the patient.
- Patient may become hypoxic if oxygen flow is interrupted.

Device Specifications	
Description	Specification
Pressure Relief Valve	6 PSI (410 mbar)
Oxygen Flow Rate	6 LPM to 15 LPM
Jar Capacity	350 cc
Wing Nut Adapter	DISS Oxygen Inlet Connector
Outlet Port	Tapered Outlet Accepts Universal Supply Tubing End Connector
Humidity Output	<10 mg H_2O/L
Operating Temperature	5°C to 40°C
Storage Temperature	-20°C to 50°C
ISO Standard	10993:2012

Product Material	
Part Description	Material
Lid	ABS-Acrylonitrile Butadiene Styrene, Tan Color
Inlet Nut	ABS-Acrylonitrile Butadiene Styrene, Tan Color
Slug	Brass
Pop-off Cap	ABS-Acrylonitrile Butadiene Styrene, Tan Color
Diffusor	Polyvinylchloride
Diffusor Tubing	Polyvinylchloride
Humidifier bottle	Polypropylene, Semi-Clear

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.

BPA: SunMed does not intentionally add or use material with bisphenol A (BPA) to manufacture bubble humidifiers.

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

Biocompatible per device classification in ISO 10993. Salter Labs manufactures product from medical grade materials in compliance with Good Manufacturing Practices (GMP's) as listed in 21 C.F.R. (U.S. code of Federal Regulations).

Part Number	UOM	GTIN
7900-0	Each	607411700057
7900-0-10	Case	10607411700054
E7900-0	Each	607411000898
E7900-0-10	Case	10607411000895

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