

High Concentration, Non-Rebreather Oxygen Mask – Adult

LATEX FREE | SINGLE PATIENT USE | DISPOSABLE

High Concentration, Non-Rebreather Oxygen Mask without Safety Vent, Adult

Reference Number	8140-7-50
Manufacturer	SunMed LLC/Salter Labs
FDA Classification	Class I Exempt, Medical Device
FDA Product Code	BYG-Oxygen Mask
Canadian Medical Device	Class II Conformity Assessment Route: MDL
Classifications – EU	Class IIa, Rule 2, EU MDR 2017/745, Annex VIII
CE Mark/ Notified Body	CE 2797, BSI
EMDN Code	R03010201, Air/Oxygen Masks
GMDN Code	35172, Aerosol Face Mask, Non-Rebreathing
UMDNS Code	12449, Masks, Air-Oxygen, Aerosol Administration
Made In	Mexico
Usage	Disposable, Single Patient Use
Sterile	Non-Sterile
Patient Population	Adult
Packaging	Individually Packaged, 50/Case

Description: A clear mask connected a reservoir bag and oxygen supply tubing. The mask is placed over a patient's nose and mouth and held in place with an elastic fixation device. The non-rebreather mask with a safety vent has a one-way valve above the reservoir bag to prevent the patient from rebreathing previously exhaled gases and a one-way valve over both exhalation ports on the mask.

Intended use: To provide supplemental oxygen to a spontaneously breathing patient.

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

Contraindications: No known contraindications.

Benefits. Provide supplemental oxygen to help treat hypoxia, relieve shortness of breath, and pre-oxygenate a patient.

Device Specifications

Description	Specification
Flow Rate	≥ 10 LPM, Adjust flow to keep bag 1/3 full during inspiration
% FDO ₂	Variable 60% to 90%
Operating Temperature	6° C to 40° C
Storage Temperature	-40° C to 60° C
Tubing	3-Channel Safety
Tubing Length	7' (2.1 m)
End Connector	Ribbed Universal Push-On

Product Material

Part Description	Material
Tubing	Polyvinyl Chloride
End Connector	Polyvinyl Chloride
Mask	Polyvinyl Chloride
Grommet	Polyvinyl Chloride Rigid
Nose Bar	Aluminum
Strap	Elastic Cloth
Valve	Silicone, clear
Reservoir bag	Polyvinyl Chloride

Part Number	UOM	GTIN/UDI
8140-7	Each	607411800450
8140-7-50	Case	10607411800457



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).

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