

HIGH CONCENTRATION, NON-REBREATHER OXYGEN MASK WITH SAFETY VENT

NON-STERILE | DISPOSABLE | SINGLE PATIENT MULTIPLE USE | LATEX FREE | DEHP FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Non-Rebreather Oxygen Masks
Manufacturer	AirLife
Manufacturer Address	Salter Labs, 60 Spur Road, El Paso, TX 79906
Country of Origin/Made In	Mexico
Classification – US/510k #	Class I
FDA Product Code	BYG-Oxygen Mask
Classification – Canada	Class II
Classification – EU	Class IIa
CE Mark/Notification Body	CE 2797/BSI Group
EU Authorized Representative	Mt Promedt Consulting GmbH
EMDN Code	R03010201 – Air/Oxygen Masks
GMDN Code	35172 – Aerosol Face Mask, Non-Rebreathing
UMDNS Code	12449 – Masks, Air-Oxygen, Aerosol Administration
UNSPSC Code	42271708 – Medical oxygen masks or parts
Usage	Disposable, Single Patient Use
Patient Population	Pediatric, Adult
Area of Use	Hospitals, Pre-Hospital, Home, Surgical Centers, Skilled Nursing Facilities, Medical Clinics
Sterility	Non-Sterile
Packaging	Individually Packaged, 50/Case
Shelf Life	5 Years
Disposal Instruction	Used or damaged products must be disposed according to applicable national and international legal directives.

Description: A clear mask connected to 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 one of the mask's exhalation ports.

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

Contraindications: No known contraindications.

PART	SIZE	UOM	GTIN
1130-7	Pediatric	Each	00607411800764
1130-7-50	Pediatric	Case	10607411800761
1130TG-7	Pediatric	Each	00607411301407
1130TG-7-50	Pediatric	Case	10607411301404
8130-7	Adult	Each	00607411800412
8130-7-50	Adult	Case	10607411800419
8130TG-7	Adult	Each	00607411800436
8130TG-7-50	Adult	Case	10607411800433



TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Flow Rate	≥ 10 LPM, Adjust Flow to Keep Bag 1/3 Full During Inspiration up to 15 LPM
% FDO ₂	Variable 60% to 90%
Operating Temperature	+5°C (41°F) to +40°C (104°F)
Storage Temperature	-20°C (-4°F) to +50°C (122°F)
Tubing	3-Channel Safety
Tubing Length	7' (2.1 m), 9' (2.7 m), 10' (1.0 m), 14' (4.2 m)
End Connector (1130, 8130)	Ribbed, Push-On
End Connector (1130TG, 8130TG)	Female, Thread Grip
Reservoir Bag	1000 mL

DEVICE MATERIAL

COMPONENT	MATERIAL
Tubing	Polyvinyl Chloride
End Connector	Polyvinyl Chloride
Mask	Polyvinyl Chloride
Grommet	Polyvinyl Chloride
Nose Bar	Aluminum
Strap	Green, Braided Polyester Elastic/Polyisoprene
Valve	Silicone, Clear
Reservoir Bag	Polyvinyl Chloride

Biocompatibility: The masks are biocompatible, meeting cytotoxicity requirements, skin irritation and sensitization requirements per ISO 10993.

The masks do not contain natural rubber latex, DEHP or BPA.

The masks are REACH compliant and do not contain 3TG conflict minerals.

The masks do not contain blood derivatives or materials derived from animal or human tissue.