

BABY SAFE™ HYPERINFLATION SYSTEM

NON-STERILE | DISPOSABLE | SINGLE USE | LATEX FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Baby Safe Hyperinflation System
Company	AirLife
Manufacturer	AirLife
Manufacturer Address	2710 Northridge Dr NW, Suite A Grand Rapids, MI 49544 USA
Country of Origin/Made In	China
Classification - US	Class II
FDA Product Code	BTM, Ventilator, Emergency, Manual Resuscitator
Classification- GHFT	Class B, Rule 2 (i) According to the Principles of Medical Device Classification, GHFT/SG1/N15
Classification - Canada	Class II
GMDN Code	36086 - Pulmonary Resuscitator, Manual, Single Use
UMDNS Code	13367 - Resuscitators, Pulmonary, Manual
UNSPSC Code	42272211 - Hyperinflation Products
Usage	Short Term Use Up to 30 Days
Patient Population	Neonatal, Infant, Pediatric, Adult
Sterility	Non-Sterile
Packaging	Individually Packaged in Polybag, 20/Case
Shelf Life	5 years
Storage Conditions	There are no special storage conditions.
Disposal Instruction	Dispose of all materials in accordance with local, state, and federal regulations. Decontaminate and dispose of all potentially biohazardous material.

Description: The Baby Safe Hyperinflation System is a flow-inflating resuscitator that features a unique adjustable pressure-limiting (APL) valve which helps maintain peak inspiratory pressure and reduces the risk of barotrauma and an optional bleed vent to help control positive and expiratory pressure (PEEP). Baby Safe comes preassembled with the optional pressure manometer attached.

Intended Purpose: To deliver a high concentration of oxygen to the patient before suctioning or during transport.

Contraindications: None Known.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Inflation Bag	0.5 Liter, 1 Liter
Pop-Off (Optional)	35 cm H ₂ O, or 60 cm H ₂ O
Gas Elbow	15 mm ID / 22 mm OD Coaxial Port
Oxygen Tubing	7'
Pressure Tubing	6'
O ₂ Tubing Connector	U/Connect-It
Manometer (Accuracy)	(±) 1 cm H ₂ O from 0-10 cm H ₂ O (hPa) (±) 2 cm H ₂ O from 10-40 cm H ₂ O (hPa) (±) 3 cm H ₂ O from 40 cm H ₂ O (hPa)
35 cm H ₂ O APL Valve without Bleed Vent	35 ± 5 cm H ₂ O at 10 LPM
35 cm H ₂ O APL Valve with Bleed Vent	6 ± 3 cm H ₂ O at 5 LPM 35 ± 5cm H ₂ O at 25 LPM
60 cm H ₂ O APL Valve without Bleed Vent	60 ± 10 cm H ₂ O at 10 LPM
60 cm H ₂ O APL Valve with Bleed Vent	6 ± 3 cm H ₂ O at 5 LPM 60 ± 10 cm H ₂ O at 25 LPM



DEVICE MATERIAL

COMPONENT	MATERIAL
Masks - Cone and Cushion	Polyvinyl Chloride (PVC) DEHP-Free
Oxygen and Pressure Tubing, Tubing Connectors, O ₂ Tubing Adapter, Connecting Tube	Polyvinyl Chloride (PVC) DEHP-Free
Elbow with Port, Elbow with Male Luer	Polypropylene (PP)
Vital Gauge	Polyvinyl Chloride (PVC), Polycarbonate, Barrel, Stainless Steel Spring, Nitrile Ring
Breathing Bag (Green, Dipped)	Neoprene, Not Made with Latex
APL Valve	Polypropylene Body, High Density Polyethylene Cap and Disc, Stainless Steel Spring

Material Statement: Utilized the EN ISO 10993-1:2020 and EN ISO 18562-1:2020 guidelines within a risk management process and in compliance with the U.S. Food and Drug Administration (FDA). The subject devices are not made of natural rubber latex. The selected materials are not formulated with BPA. The hyperinflation bags contain DEHP. The devices do not contain blood derivatives, or materials derived from animals or human tissue.

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PART	DESCRIPTION	SIZE	BLEED VALVE PRESSURE	PRESSURE TUBING	O ₂ TUBING	ACCESSORIES	UOM	GTIN
5401L1	Hyperinflation with Elbow	1 L	35 cm H ₂ O Valve	N/A	7'	N/A	Case Each	30889483585812 10889483585818
5404BD	Hyperinflation with NRPR Vent	0.5 L	35 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483585836 10889483585832
5424BDG1	Hyperinflation with NRPR Vent	0.5 L	35 cm H ₂ O Valve	6'	7'	Manometer, Infant Mask	Case Each	30889483585881 10889483585887
5404BDL1	Hyperinflation with NRPR Vent	0.5 L	35 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483585843 10889483585849
5424D	Hyperinflation	0.5 L	35 cm H ₂ O Valve	6'	7'	Infant Mask	Case Each	30889483585898 10889483585894
5424BD	Hyperinflation with NRPR vent	0.5 L	35 cm H ₂ O Valve	6'	7'	Infant Mask	Case Each	30889483585874 10889483585870
54039VS	Flow-Inflating Transport, Fresh Gas Elbow	N/A	35 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483585829 10889483585825
5524BDH	Hyperinflation with NRPR vent	0.5 L	60 cm H ₂ O Valve	6'	7'	10" Hose, Infant Mask	Case Each	30889483586512 10889483586518
5404L1	Hyperinflation	0.5 L	35 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483585867 10889483585863
5504BD	Hyperinflation with NRPR valve	0.5 L	60 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483586406 10889483586402
5504BDL1	Hyperinflation with NRPR Vent	0.5 L	60 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483586413 10889483586419
5504BGL1	Hyperinflation with NRPR Vent	0.5 L	60 cm H ₂ O Valve	N/A	7'	Manometer	Case Each	30889483586437 10889483586433
5504DHL1	Hyperinflation	0.5 L	60 cm H ₂ O Pop-Off	6'	7'	10" Extension Hose	Case Each	30889483586444 10889483586440
5504DL1	Hyperinflation	0.5 L	60 cm H ₂ O Pop-Off	6'	7'	N/A	Case Each	30889483586451 10889483586457
5401L1	Hyperinflation	0.5 L	35 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483585812 10889483585818
5501BD	Hyperinflation with NRPR Vent	1 L	60 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483586239 10889483586235
5501DL1	Hyperinflation	1 L	60 cm H ₂ O Valve	6'	7'	N/A	Case Each	30889483586246 10889483586242
5501HL1	Hyperinflation	1 L	60 cm H ₂ O Valve	N/A	7'	10" Extension Hose	Case Each	30889483586260 10889483586266
5501L1	Hyperinflation	1 L	60 cm H ₂ O Valve	N/A	7'	N/A	Case Each	30889483586277 10889483586273
5503H	Flow-Inflating Transport, 10" Tubing, Fresh Gas Elbow, Valve	N/A	N/A	N/A	7'	N/A	Case Each	30889483586376 10889483586372
5503EU	Flow-Inflating Transport, Fresh Gas Elbow, APL Valve	N/A	N/A	N/A	7'	N/A	Case Each	30889483586369 10889483586365