

VENTLAB® HYPERINFLATION SYSTEM

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

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Ventlab Hyperinflation System
Company	AirLife
Manufacturer and Manufacturer Address	Ventlab LLC 2710 Northridge Dr. NW 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 Instructions	Safely dispose of device in accordance with local, state, or national biohazard regulations.

Description: The Hyperinflation System is intended to deliver a high concentration of oxygen, or a controlled mixture of oxygen and anesthetic gases, to the patient prior to suctioning, during transport, or in situations requiring manual respiratory support. The system is designed with an integrated bleed-off mechanism (flow-control valve) to prevent the buildup of unintended positive end-expiratory pressure (PEEP), ensuring safe operation across a range of clinical scenarios. The hyperinflation system is available in various configurations with the options of manometer, pop-off valve, mask, and/or oxygen tubing. The device is suitable for use in adult, pediatric, infant, and neonatal patient populations, consistent with its intended purpose.

Intended Purpose: A pulmonary-assist device intended to provide controlled or assisted ventilation to patients. It is designed for patients suffering from respiratory insufficiency. The system's mode of operation is to hyper-ventilate a patient by forcing a volume of fresh gas into the patient via compression of the reservoir bag. Typical treatment consists of hyper-inflating the patient's lung(s) over several respiration cycles. The operating clinician controls peak pressure and monitors pressure in the lungs by means of a user-supplied manometer.

Area of Use: Hospitals, medical clinics, homes, pre-hospital settings, surgical centers, and skilled nursing facilities.

Contraindications: None known.

TECHNICAL SPECIFICATIONS

Description	Specification
Inflation Bag	0.5 L, 1 L, 2 L, or 3 L
Pop-Off (Optional)	25 ± 5 cmH ₂ O or 40 ± 5 cmH ₂ O
Manometer (Optional)	0–60 cmH ₂ O ± 5
O ₂ Tubing (Optional)	7' or 14'
Masks Size (Optional)	0, 1, 2, 3, 4, or 5 (Neonatal–Adult)
Patient Port	15 mm ID/22 mm OD Coaxial Port



DEVICE MATERIAL

Component	Material
Masks - Cone & Cushion	Polyvinyl Chloride (PVC) (DEHP-Free)
Oxygen Tubing, Tubing Connectors, O ₂ Tubing Adapter, Connecting Tube, Pressure Tubing	Polyvinyl Chloride (PVC) (DEHP-Free)
Tethered Override Cap, Pressure Port Cap, Red Crescent (Thumbwheel)	Polyvinyl Chloride (PVC) (DEHP-Free)
White Bushing, Bag Neck	Polyvinyl Chloride (PVC) (DEHP-Free)
Breathing Bag (Green, Dipped)	Polychloroprene (CR) (Not Made With Latex)
Swivel Port & Cap, Hyperinflation	Polypropylene (PP)
Swivel O-Ring, Manometer Diaphragm	Silicone
Hyperinflation Elbow & Elbow With Manometer & With Pop-Off	Styrene-Acrylonitrile Copolymer (SAN)
Temperature Port Plug, Patient Port Plug	Low Density Polyethylene (LDPE)
Hose Cuff	Homopolymer, Low Density Polyethylene (LDPE) Film
Pivot Cap, Pointer Helix	Acetal (POM)
Plug, Temperature Port, Patient Port Ring, Hose Cuff	Polyethylene, Low Density Polyethylene (LDPE)
HS Locking C-Ring	Nylon
Gasket	Ethylene-Vinyl Acetate (EVA), Black
Pressure Gauge Spring, Pop-Off Spring	Stainless Steel
Tape, White	Vinyl (DEHP-Free)
Tape, Hyperinflation Green	Non-Latex

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 1 L, 2 L, and 3 L Hyperinflation Systems do not contain DEHP. The 0.5 L hyperinflation bags have DEHP in the tape- no patient contact. The devices do not contain blood derivatives, or materials derived from animals or human tissue.

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Part Number	Description	UOM	GTIN
HM10	1 Liter Disposable Breathing Bag	Each	10889483084861
		Case	30889483084865
HM20	2 Liter Disposable Breathing Bag	Each	10889483087886
		Case	30889483087880
HM30	3 Liter Disposable Breathing Bag	Each	10889483093795
		Case	30889483093799
HS1001	Hyperinflation System Elbow & O ₂ Tubing	Each	10889483087893
		Case	30889483087897
HS1010	1 Liter Hyperinflation Bag System	Each	10889483085554
		Case	30889483085558
HS1020	2 Liter Hyperinflation Bag System	Each	10889483083444
		Case	30889483083448
HS1030	3 Liter Hyperinflation Bag System	Each	10889483106105
		Case	30889483106109
HS1050	½ Liter Hyperinflation System	Each	10889483096529
		Case	30889483096523
HS1150	½ Liter Hyperinflation System & Mask	Each	10889483096369
		Case	30889483096363
HS1250	½ Liter Hyperinflation System & Mask	Each	10889483099537
		Case	30889483099531
HS1310	1 Liter Hyperinflation System & Mask	Each	10889483106129
		Case	30889483106123
HS4000	Hyperinflation System Elbow & Manometer	Each	10889483084823
		Case	30889483084827
HS4001	Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & O ₂ Tubing	Each	10889483084564
		Case	30889483084568
HS4011	1 L Hyperinflation System, Manometer, & 40 cmH ₂ O Pop-Off	Each	10889483110850
		Case	30889483110854
HS4011-T	1 L Hyperinflation System & Manometer	Each	10889483105429
		Case	30889483105423
HS4020	2 L Hyperinflation System & Manometer	Each	10889483106563
		Case	30889483106567
HS4021	2 L Hyperinflation System, Manometer, & 40 cmH ₂ O Pop-Off	Each	10889483086940
		Case	30889483086944
HS4021-O	2 L Hyperinflation System, Manometer, & 40 cmH ₂ O Pop-Off	Each	10889483106570
		Case	30889483106574
HS4030-W	3 L Hyperinflation System, Manometer, & Large Thumbwheel	Each	10889483481240
		Case	30889483481244
HS4031	3 L Hyperinflation System, Manometer, & 40 cmH ₂ O Pop-Off	Each	10889483085332
		Case	30889483085336
HS4050	½ L Hyperinflation System & Manometer	Each	10889483110867
		Case	30889483110861
HS4051	½ L Hyperinflation System, Manometer, & 40 cmH ₂ O Pop-Off	Each	10889483105214
		Case	30889483105218

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Part Number	Description	UOM	GTIN
HS4051-M0	½ L Hyperinflation System, Manometer, 40cmH ₂ O Pop-Off, & Size 0 Mask	Each	10889483080986
		Case	30889483080980
HS4051-M0-00T	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, 14' O ₂ Tubing, & 2 Masks	Each	10889483075661
		Case	30889483075665
HS4051-M012	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Size 0, 1, & 2 Masks	Each	10889483110874
		Case	30889483110878
HS4051-W	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Large Thumbwheel	Each	10889483481226
		Case	30889483481220
HS4054	½ L Hyperinflation System, Manometer, & 25 cmH ₂ O Pop-Off	Each	10889483095188
		Case	30889483095182
HS4111	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Size 1 Mask	Each	10889483076941
HS4151	½ L Hyperinflation System, Manometer, 40cmH ₂ O Pop-Off, & Mask	Each	10889483096642
		Case	30889483096646
HS4151-D2	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & 2 Masks, Size 1 & 2	Each	10889483113240
		Case	30889483113244
HS4151-D2Z	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & 2 Masks	Each	10889483100721
		Case	30889483100725
HS4151-M	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Size 1 Mask	Each	10889483086971
		Case	30889483086975
HS4151-M0	½ Liter Hyperinflation System & 2 Masks, Size 0 & 1	Each	10889483103074
		Case	30889483103078
HS4154	½ L Hyperinflation System, Manometer, 25 cmH ₂ O Pop-Off, & Size 1 Mask	Each	10889483157480
		Case	30889483157484
HS4211	1 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Mask	Each	10889483101339
		Case	30889483101333
HS4250	½ L Hyperinflation System, Manometer, Size 2 Mask, & No Pop-Off	Each	10889483096536
		Case	30889483096530
HS4251	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Mask	Each	10889483098059
		Case	30889483098053
HS4251-M	½ L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Mask	Each	10889483107171
		Case	30889483107175
HS4254	½ L Hyperinflation System, Manometer, 25 cmH ₂ O Pop-Off, & Size 2 Mask	Each	10889483157497
		Case	30889483157491
HS4311	1 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Mask	Each	10889483098066
		Case	30889483098060
HS4321	2 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Mask	Each	10889483098073
		Case	30889483098077
HS4411	1 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & D4 Mask	Each	10889483109489
		Case	30889483109483
HS4421	2 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Size 4 Mask	Each	10889483085738
		Case	30889483085732
HS4521	2 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Size 5 Mask	Each	10889483105931
		Case	30889483105935
HS4531	3 L Hyperinflation System, Manometer, 40 cmH ₂ O Pop-Off, & Size 5 Mask	Each	10889483081020
		Case	30889483081024
7-N7910	Hyperinflation Elbow, 7' O ₂ , & Pressure Lines	Each	00709078060304
		Case	20709078060308

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