

AIRLIFE® VOLUMETRIC INCENTIVE SPIROMETER

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

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Incentive Spirometer
Manufacturer (Legal)	AirLife
Manufacturer Address	SunMed, LLC 2710 Northridge Dr. NW, Suite A Grand Rapids, MI 49544 USA
Made In	China
Classification – US	Class II
FDA Product Code	BWF, Spirometer Therapeutic (Incentive)
Classification – Canada	Class II
Classification – Brazil	Class I
CE Mark	CE Only: 001902A-CE & 001904A-CE
EMDN Code	Y030327 – Spirometers, Incentive
GMDN Code	31266 – Incentive Spirometer
UMDNS Code	13679 – Spirometers, Monitoring
UNSPSC Code	42271602 – Spirometers or Accessories
Usage	Single Patient, Multiple Use Incentive spirometers are used intermittently for brief periods as lung exercisers
Sterility	Non-Sterile
Patient Population	Pediatric, Adult
Packaging	Individually Packaged, Polybag; 12/Case
Storage Conditions	No special storage requirements
Disposal Instructions	Dispose in a container that is clearly labeled, leak-proof, and color-coded per local standards and state environmental regulations.

Description: The AirLife® Volumetric Incentive Spirometer prompts patients to correctly perform and monitor their own breathing exercises. A volume target can be adjusted and allows patients to monitor their own progress. Dual-sided calibrations clearly identify achieved volumes of up to 2,500 mL (pediatric) and 4,000 mL (adult). The flexible tubing allows the patient to adjust the mouthpiece for use in various positions, and a mouthpiece holder provides storage when not in use.

Intended Purpose: The Incentive Spirometer's intended use is to promote deep breathing in patients.

Area of Use: Hospitals, surgical centers, skilled nursing facilities, and home environments.

Contraindications: No known contraindications at this time.

Part Number	Description	UOM	GTIN/UDI
001901A	4,000 mL with One-Way Valve	Each	10889483570807
		Case	308894835790801
001902A	4,000 mL without One-Way Valve	Each	10889483570814
		Case	30889483570818
001903A	2,500 mL with One-Way Valve	Each	10889483570821
		Case	3088948357082
001904A	2,500 mL without One-Way Valve	Each	150889483570838
		Case	30889483570832
001905A	2,500 mL with One-Way Valve & Colorful Targets	Each	10889483570845
		Case	30889483570849
001902A-CE	4,000 mL without One-Way Valve	Each	10889483642313
		Case	30889483642317
001904A-CE	2,500 mL without One-Way Valve	Each	10889483642320
		Case	30889483642324



DEVICE MATERIAL

Component	Material
Volume Target	High Density Polyethylene Plastic (HDPE) with Blue Colorant
Corrugated Tubing	Polypropylene Copolymer
Mouthpiece	High Density Polyethylene Plastic (HDPE), Silicone Lubricant
Volume Indicator	Polypropylene with Blue Colorant
Calibration Chip	Polypropylene Copolymer
Housing	General Purpose Polystyrene (GPPS)
Piston Ring	High Density Polyethylene Plastic (HDPE)
One-Way Valve	High Density Polyethylene Plastic (HDPE)
Flow Rate Guide	Rigid Polyvinyl Chloride (PVC)

Biocompatible Evaluation: The devices do not contain DEHP, natural rubber latex, or BPA. These devices are REACH compliant and do not contain 3TG conflict minerals. These devices do not contain blood derivatives or materials derived from animal or human tissue.

DEVICE SPECIFICATIONS

Description	Specification
Capacity	2,500 mL or 4,000 mL
Calibration Markings	250 mL increments for 4,000 mL capacity 125 mL increments for 2,500 mL capacity