

# VITAL SIGNS® DUAL LIMB & CO-AXIAL ANESTHESIA BREATHING CIRCUITS

SINGLE USE | NON-STERILE | DEHP FREE | LATEX FREE

## DEVICE MANUFACTURING SPECIFICATIONS

Reference Product	Vital Signs Dual Limb and Co-Axial Circuits
Manufacturer (Legal)	AirLife
Manufacturer Address	Vyair Medical Oy (AirLife) Kuortaneenkatu 2 FI-00510 Helsinki, Finland
Made In	China
Classification — US	Class I, Class II
FDA Product Code	OFP - Anesthesia Breathing Circuit Kit (Adult & Pediatric) BYX - Tubing, Pressure, and Accessories CAI - Circuit, Breathing (W Connector, Adapter, Y Piece) BTC - Bag, Reservoir BZA - Airway Connector CAH - Filter, Bacterial, Breathing-Circuit
Classification — Australia	Class IIa
Classification — Brazil	Class II
Classification — Canada	Class II
Classification — Japan	Class II
Classification — EU	Class IIa, Rule 5
CE Mark	0537
EMDN Code	R0302 - Breathing Bag, All SKUs R0302R020102 - Coaxial Breathing Circuits R02010102 - Breathing Circuits, With Water Trap R02010101 - Breathing Circuits, Without Water Trap R020199 - Breathing Circuits, Other
GMDN Code	37704 - Anesthesia Breathing Circuits, Single-Use
UMDNS Code	10139 - Breathing Circuits, Anesthesia
UNSPSC Code	42272505 - Gas Anesthesia Apparatus Tubes, Tubing Assemblies, Tube Fittings, Accessories
Usage	Single Use, 7 Days
Area of Use	Hospital, ICU, Anesthesia, Respiratory Therapy, During Transport, and With Resuscitators
Sterility	Non-Sterile; Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
Patient Population	Pediatric, Adult
Packaging	Individually Packaged, 20/Case
Storage Conditions	-20°C (-4°F) to 40°C (104°F)
Disposal Instructions	Safely dispose in accordance with local, state, or national regulations.

**Description:** Circuits provide a conduit for gases between patient and equipment in general anesthesia, transport, and/or mechanical ventilation. Circuits come in various combinations of tubing, connectors, breathing bags, face masks, passive humidifiers, and filters.

**Intended Purpose:** Intended to deliver anesthetic gas mixtures to, and to remove waste gas from, adult and pediatric patients during general anesthesia, transport, and/or mechanical ventilation.

**Compatibility:** Circuits, breathing tubes, face masks, Y-pieces and connectors, catheter mounts, and breathing bags have commonly used 15 mm/22 mm ISO 5356-1 standard ports. They may be connected to standard breathing systems and components.

**Contraindication:** No contraindications are known at this time.



## DEVICE MATERIAL

Component	Material
Tubing	Low-Density Polyethylene Ethylene Vinyl Acetate
Cuffs	Low-Density Polyethylene
Wye-Piece & T-Connector	Polypropylene
Breathing Bag	Latex-Free Rubber, Polychloroprene
Bag Connector	Styrene Ethylene Butylene Styrene
Bag Arm Connector	High-Impact Polystyrene
Circuit Elbow	Polypropylene
Quick Connector	High Impact Grade Polypropylene
Expandable Extension Hose	Polypropylene
Gas Sampling Line	Thermoplastic Elastomer
Gas Sampling Line - Connector	Acrylonitrile Butadiene Styrene or Polycarbonate
Gas Sampling Line - Coextruded	Polyvinyl Chloride
Water Trap Container	Acrylonitrile Butadiene Styrene
Water Trap Cap (Blue)	Polypropylene
Water Trap Spring	Acrylonitrile Butadiene Styrene, Stainless Steel
Water Trap Gasket	Styrene Ethylene Butylene Styrene
UniFilter Housing	Polypropylene
Filter Media	Technostat 250, Polypropylene 250/Synth.

**Biocompatibility Evaluation:** Per EN ISO 18562-1:2020, ventilator circuits and components are part of the gas pathway. These devices do not contain DEHP, natural rubber latex, or BPA. These devices are REACH compliant and do not contain 3TG conflict minerals.

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Description	Specification
Tubing Length	36" (0.9 m), 72" (1.8 m), 96" (2.4 m), 120" (3.0 m)
Tubing Internal Diameter	22 mm (Adult)
Connectors/Adapters	15 mm/22 mm ISO 5356-1 Standard Ports
Breathing Bag	2.0 L, 3.0 L
Gas Sampling Line	10' (3.0 m)
Ventilator Corrugated Tubing Connector	22 mm M – 22 mm M
Adult Circuit Compliance	2.4 mL/hPa (mL/cm H <sub>2</sub> O) @ 60 hPa
Adult Circuit Resistance Flow	0.02 hPa/LPM (cm H <sub>2</sub> O/min) @ 30 LPM

Part Number	Description	Size	Length	Bag Size	Wye	Elbow	Gas Sampling Line	Accessories	UOM	GTIN/UDI
2066478-004	Co-Axial Circuit, ABS Ext, Bag, Gas Sampling Line	Adult	72" (1.8 m)	2 L	—	—	—	15" Expandable Extension Tube, T-Connector	Each	10190752135925
									Case	70190752135927
M1019521	Manual Vent Kit for ABS, Bag	Adult	72" (1.8 m)	2 L	—	—	—	—	Each	10190752136151
									Case	70190752136153
M1019523	Manual Vent Tube, Bag	Adult	72" (1.8 m)	3 L	—	—	—	—	Each	10190752136168
									Case	50190752136166
M1128262	Manual Ventilation Tube, ABS Arm & Connector	Adult	36" (0.9 m)	—	—	—	—	ABS Connector	Each	10190752136786
									Case	50190752136784
M1152225	Co-Axial Circuit, Ext Tube, Bag	Adult	96" (2.4 m)	2 L	Co-Axial Wye	Gas Sampling Elbow	—	Circuit Tee, Blue Manual Ventilation Tube (Corrugated)	Each	10190752136892
									Case	20190752136899
M1152226	Co-Axial Circuit, Ext Tube, Bag	Adult	96" (2.4 m)	2 L	Co-Axial Wye	Gas Sampling Elbow	—	96" Corrugated Blue Tubing (22 mm M – 22 mm M)	Each	10190752136908
									Case	20190752136905
M1170051	Co-Axial Circuit for ABS, Ext Tube, Bag	Adult	72" (1.8 m)	2 L	T-Connector	Gas Sampling Elbow	10' (3.0 m)	15" Manual Ventilation Tube	Each	10190752136977
									Case	50190752136975
M1170052	Co-Axial Circuit, Ext Tube, GSL	Adult	96" (2.4 m)	—	Co-Axial Wye	Gas Sampling Elbow	10' (3.0 m)	15" Expandable Tubing	Each	10190752136984
									Case	20190752136981
M1209145	Co-Axial Circuit, GSL	Adult	60" (1.5 m)	—	—	Gas Sampling Elbow	—	—	Each	10190752137080
									Case	20190752137087
M1209146	Co-Axial Circuit, GSL	Adult	96" (2.4 m)	—	Co-Axial Wye	Gas Sampling Elbow	—	—	Each	10190752137097
									Case	20190752137094
M1019517	Manual Vent Kit for ABS Arm, Bag	Adult	36" (0.9 m)	2 L	—	—	—	ABS Connector	Each	10190752136137
									Case	70190752136139
M1100487	Co-Axial Circuit	Adult	120" (3.0 m)	—	Co-Axial Wye	Gas Sampling Elbow	—	15" Expandable Tubing	Each	10190752136717
									Case	50190752136715
M1100486	Co-Axial Circuit	Adult	72" (1.8 m)	—	Co-Axial Wye	Gas Sampling Elbow	—	15" Expandable Tubing	Each	10190752136700
									Case	50190752136708
M1135144	Co-Axial Circuit, ABS Ext Tube, Bag, GSL	Adult	72" (1.8 m)	2 L	Co-Axial Wye	Gas Sampling Port	10' (3.0 m)	40" Ventilation Tube, ABS Bag Arm Connector	Each	10190752136823
									Case	20885403262996
M1152224	Co-Axial Circuit, Ext Tube, Bag	Adult	60" (1.5 m)	2 L	Co-Axial Wye	Gas Sampling Port	—	Blue Ventilation Tube (22 mm M – 22 mm M)	Each	10190752136885
									Case	20190752136882

TDS-20534-C1 Rev. 1