

Technical Data Sheet

Anesthesia Breathing Circuits

Product Codes and Product Description	5108EX	Extension Set For Vital Signs® Adult Anesthesia Breathing Circuit	
	5163EL	Vital Signs® Pediatric Anesthesia Breathing Circuit	
	A4UXXXXX	Vital Signs® Adult Anesthesia Breathing Circuit	
	A4VXXXXX	Vital Signs® Adult Anesthesia Breathing Circuit	
	AZXXXXXX6	Vital Signs® Adult Anesthesia Breathing Circuit	
	A4AXXXXX	Vital Signs® Adult Anesthesia Breathing Circuit	
	B15XXXXX	Vital Signs® Pediatric Anesthesia Breathing Circuit	
	M1154610	Vital Signs™ Manual Ventilation Tube for ABS Bag Arm, Expandable, Disposable, 1.8 m/72 in With ABS Bag Arm Connector	
	M1209146	Vital Signs™ Co-axial Breathing Circuit, Adult, Disposable, 2.4m/96in With Gas Sampling Elbow	
	M1170051	Vital Signs™ Co-axial Circuit for ABS, Adult, Disposable, 1.8 m/72 in With Manual Ventilation Tube, 1.8 m, ABS Bag Arm Connector, Manual Bag, 2 L and Gas Sampling Line, 3.0 m	
General Product Description	An anesthetic machine is the pathway by which the volatile anesthetic agent and oxygen are conveyed to the patient and carbon dioxide is removed. The two methods for removal of carbon dioxide are that of venting all expired gases to the exterior, and the method of absorbing the carbon dioxide chemically and rebreathing the expired gas. They can be rebreathing (also known as circle system) or non-rebreathing. Circuits are provided for adult, pediatric and neonatal patients. The basic circuits consists of an inspiratory limb, an expiratory limb, a wye to connect the two limbs, an elbow with gas sampling port to connect the wye to the patient, and a breathing bag.		
Pack factor	5108EX – 20 5163EL – 20 A4UXXXXX - 20 A4VXXXXX - 20 AZXXXXXX6 - 20 A4AXXXXX - 20 B15XXXXX – 20 M1154610 - 20 M1209146 - 20 M1170051 - 20		
EAN/GTIN	5108EX	CS	50885403272170
	5108EX	EA	10885403272172
	5163EL	CS	50885403242531
	5163EL	EA	10885403242533
	A4UXXXXX	CS	50885403249486
	A4UXXXXX	EA	10885403249488
	A4VXXXXX	CS	50885403297753
	A4VXXXXX	EA	10885403297755
	AZXXXXXX6	CS	50885403300040
	AZXXXXXX6	EA	10885403300042

GLOBAL HEADQUARTERS

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	<p>A4AXXXX CS 50885403297197</p> <p>A4AXXXX EA 10885403297199</p> <p>B15XXXXX CS 50885403300330</p> <p>B15XXXXX EA 10885403300332</p>
Intended Use	Intended to administer medical gases to a patient during anesthesia.
Instructions for Use	Please refer to the Instructions for Use (IFU)
Characteristics	These devices are intended for short term at more than sixty minutes and less than thirty days as defined by section 1.1 of Annex IX of the Medical Device Directive 93/42/EEC.
Compatibility	Anesthesia Circuits are designed to be used in combination with anesthesia machines.
Shelf Life	The Anesthesia Circuit and its components do not require a “use-by” date because they are sold non-sterile and single use, disposable. There are no safety related performance or safety-related characteristics which are likely to deteriorate over time.
Regulation	Anesthesia Circuits, Face Masks, Breathing Bags and Gas Sampling Lines are class IIa by rule 2, short term, non-invasive, and non-active.
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents: DOC1300853: Cytotoxicity, DOC1300853, DOC1300882, DOC1300887, DOC1300890, DOC1300890: Sensitization, DOC1304936: Cytotoxicity
Materials	<p>5163EL: Polypropylene, Polypropylene, HDPE, LDPE, blue colorant, 9% EVA,</p> <p>5108EX: Polypropylene, 9% EVA, Polypropylene, blue colorant, Polypropylene</p> <p>A4UXXXXX: Polypropylene, Polypropylene, HDPE, Polypropylene, 9% EVA, Polypropylene, blue colorant</p> <p>A4VXXXXX: Polypropylene, Polypropylene, HDPE, Polypropylene, 9% EVA, Polypropylene, blue colorant</p> <p>AZXXXXXX6: PP, elastomer, blue colorant, TPE, Polypropylene, blue colorant, Polypropylene</p> <p>A4AXXXX: 9% EVA Polypropylene Polypropylene, HDPE Polypropylene, blue colorant</p> <p>B15XXXXX: LDPE, blue colorant Polypropylene, HDPE Polypropylene Polypropylene, 9% EVA</p> <p>M1154610: Tubing: Polypropylene+ethylene vinyl acetate (PP+EVA); Cuffs: low-density polypropylene (LDPE), High-impact polystyrene (HIPS)</p> <p>M1209146: Tubing: Polypropylene+ethylene vinyl acetate (PP+EVA), low-density polyethylene+ethylene vinyl acetate (LDPE+EVA); Cuffs: low-density polyethylene (LDPE), Polypropylene (PP)</p> <p>M1170051: Tubing: Polypropylene+ethylene vinyl acetate (PP+EVA), low-density polyethylene+ethylene vinyl acetate (LDPE+EVA); Cuffs: low-density polyethylene (LDPE), Line: Thermoplastic elastomer (TPE); Connector: Acrylic, Acrylonitrile butadiene styrene (ABS) or Polycarbonate , High-impact polystyrene</p>

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	(HIPS), Bag: Latex free rubber, polychloroprene; Connector: Styrene ethylene butylene styrene (SEBS) Shore 80A, Styrene ethylene butylene styrene (SEBS) Shore 80A, Polypropylene (PP)
Storage	There are no special storage conditions or handling requirements. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier.
GMDN Code	37704 Anesthesia Breathing Circuits, single use
Disposal	Dispose of in accordance with national and local authority regulations.
Does it contain PVC, DEHP and/or Latex	5108EX: DEHP Free, BPA Free, Latex Free, PVC Free 5163EL: DEHP Free, BPA Free, Latex Free, PVC Free A4UXXXXX: DEHP Free, BPA Free, Latex Free, PVC Free A4VXXXXX: DEHP Free, BPA Free, Latex Free, PVC Free AZXXXXXX6: DEHP Free, BPA Free, Latex Free, PVC Free A4AXXXXX: DEHP Free, BPA Free, Latex Free, PVC Free B15XXXXX: DEHP Free, BPA Free, Latex Free, PVC Free M1154610: DEHP Free, BPA Free, Latex Free, PVC Free M1209146: DEHP Free, BPA Free, Latex Free, PVC Free M1170051: DEHP Free, BPA Free, Latex Free, PVC Free
Legal Manufacturer	Vyaire Medical Inc., 26125 N. Riverwoods Blvd., Mettawa, IL 60045 USA

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