

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	
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		
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
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.		

GLOBAL HEADQUARTERS

Vyaire Medical, Inc.
26125 North Riverwoods Blvd
Mettawa, IL 60045
USA

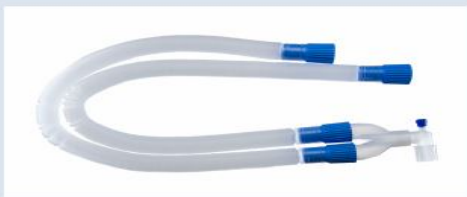
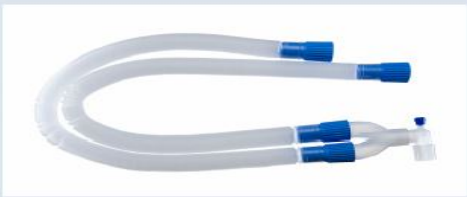
 Vyaire Medical
Kuortaneenkatu 2
FI-00510 Helsinki
Finland

Vyaire Medical Pty Ltd
Level 5, 7 Eden Park Drive
Macquarie Park, NSW, 2113
Australia

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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>
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	<p>5108EX: DEHP Free, BPA Free, Latex Free, PVC Free</p> <p>5163EL: DEHP Free, BPA Free, Latex Free, PVC Free</p> <p>A4UXXXXX: DEHP Free, BPA Free, Latex Free, PVC Free</p> <p>A4VXXXXX: DEHP Free, BPA Free, Latex Free, PVC Free</p> <p>AZXXXXXX6: DEHP Free, BPA Free, Latex Free, PVC Free</p>
Legal Manufacturer	Vyaire Medical Inc., 26125 N. Riverwoods Blvd., Mettawa, IL 60045 USA

A4UXXXXX		Expanderbar narkosgasslang fast Y-stycke knä med port	0.9 – 2.74m
A4VXXXXX		Expanderbar narkosgasslang löst Y-stycke knä med port	0.9 – 2.74m

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