# Technical Data Sheet Single and Dual Limb Heated Circuit (Adult)

Product Codes and Product Description	AH102 AirLife™ Adult Heated Wire Circuit, single-limb, single-heated circuit AH180 AirLife™ Adult Heated Wire Circuit, dual-limb, dual-heated circuit AH202 AirLife™ Adult Heated Wire Circuit Kit, single-limb, single-heated circuit; Contains AH102 Circuit, AH290 Chamber AH280 AirLife™ Adult Heated Wire Circuit Kit, dual-limb, dual-heated circuit; Contains AH180 Circuit, AH290 Chamber
General Product Description	Single-limb Heated Wire Circuit: The AirLife™ Single-limb Heated Wire Circuit is intended to deliver and warm breathing gases before they enter he patient's airway. The wire heated circuit and accessories are a combination of tubes and connectors that act as an airway conduit between a breathing machine and the patient. The breathing circuit contains a heating wire and temperature flow brobe ports to locate the sensing probes of the humidifier. The humidifier controls the heating wires based upon the sensed temperature in the breathing circuit in order to control gas temperature and help prevent condensation from forming inside the breathing circuit. Dual-limb Heated Wire Circuit: The AirLife™ Adult Dual-limb Heated Wire Circuit contains heating wires on one or both limbs and temperature flow probe ports to locate the sensing probes of the humidifier. The humidifier controls the heated wires based upon
	he sensed temperature in the breathing circuits in order to control gas temperature and help prevent condensation from forming inside the breathing circuit.
Intended Use	The AirLife <sup>™</sup> Adult Heated Wire Circuit is intended to warm breathing gases before they enter a patient's airway. The AirLife <sup>™</sup> Adult Heated Wire Circuit is used with the adult patient population hat requires mechanical ventilation, positive pressure breathing or general medical gases. The product is a single use device, non-sterile and used in professional healthcare environments and intrahospital transport environments under a doctor's supervision and by skilled clinicians. The AirLife <sup>™</sup> Adult Heated Wire Circuit is compatible to the Fisher & Paykel MR850 humidifier.
Pack Factor	AH102 – 10 AH180 – 10 AH202 – 10 AH280 – 10
EAN/UPC	AH102 CS 50885403416666 AH202 CS 50885403276208 AH102 EA 10885403416668 AH202 EA 10885403276200 AH180 CS 50885403416680 AH280 CS 50885403276222
Instructions for Use	AH180 EA 10885403416682 AH280 EA 10885403276224  Please refer to the Instructions for Use (IFU)

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Characteristics	These devices are intended for short term use for 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	AH290 Heated Circuits are designed to be used with ventilators, endotracheal tubes, MR850 heater base, nasal cannulas, and NIV masks
Shelf Life	The Respiratory Heated Breathing Circuits have a two-year shelf life, and this is incorporated in the traceability matrix and the expiration dates can be found on the labels. There are no safety related performance or safety-related characteristics which are likely to deteriorate over time
Regulation	Single-limb and Dual-limb Circuits are class IIa, Rule 2, short term, non-invasive, and active devices
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents: CF-1318-B, CF-1172-B
Materials	AH180: Wire - Alloy 294 (55% Cu, 45% Ni). Insulation - Wacker Silicone SLM 60077318, No Post Cure, Thermoplastic Polyolefin, Adflex Q200F (CF52-121), Processing Aide: Dow Masterbatch MB50-001 (CF52-120), Clarifier: Polyone Masterbatch CC10139775WX (CF52-119) BASF IRGACLEAR XT386, Colorant: Polyone Colors CC10118742WX, Purple Pantone Q270-2-1 (CF52-122), Mixture: Mix 1.5 LBS CF52-120 and 2.5 LBS CF52-119 to 100 LBS CF52-121, 70% Isopropyl Alcohol in distilled water, CAS No. 67-63-0, High Density Polyethylene, DOW DMDA 8904 NT7, P/N 52-1445, Polypropylene, Huntsman P5M4R-034 Radiation Grade, P/N 52-1199, LyondellBasell Polypropylene, Copolymer, Pro-Fax SR549M, CareFusion P/N 52-1277, Gold Plated Brass, Adhesive-Ethyl Cyanoacrylate with photo initiator, Montel USA Inc., Polypropylene Homopolymer, Pro-Fax 6323, P/N 52-902., Cyanoacrylate (CA) suitable for use in the assembly of disposable medical devices per Henkel ISO 10993 protocol., Medical device adhesive primer adhesion promoter for Loctite instant adhesives on hard-to-bond elastomers. ISO-10993 Biological tested for medical device use  AH102: Wire - Alloy 294 (55% Cu, 45% Ni). Insulation - Wacker Silicone SLM 60077318, No Post Cure, Thermoplastic Polyolefin, Adflex Q200F (CF52-121), Processing Aide: Dow Masterbatch MB50-001 (CF52-120), Clarifier: Polyone Masterbatch CC10139775WX (CF52-119) BASF IRGACLEAR XT386, Colorant: Polyone Masterbatch CC10139775WX (CF52-119) BASF IRGACLEAR XT386, Colorant: Polyone Masterbatch CC101139775WX (CF52-119), Montel USA Inc, Polypropylene Homopolymer, Pro-Fax 6323, P/N 52-902. Alcohol, 70%, Medical device adhesive primer adhesion promoter for Loctite instant adhesives on hard-to-bond elastomers. ISO-10993 Biological tested for medical device use, LyondellBasell Polypropylene, Copolymer, Pro-Fax SR549M, CareFusion P/N 52-1199, Adhesive, UV, Cyanoacrylate (CA) suitable for use in the assembly of disposable medical devices per Henkel ISO 10993 protocol. High Density Polyethylene, DOW DMDA 8904 NTT, P/N 52-1445  AH290: Acrylic base



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Storage	There are no special storage conditions required. Packaging for non-sterile devices is intended to protect the product from dust and does not provide a sterile barrier
GMDN Code	37706; Breathing Circuit, Ventilator, Single Use
Disposal	Dispose of in accordance with national and local authority regulations
Does it contain PVC, DEHP and/or Latex	DEHP Free, Latex Free, BPA Free
Country of Origin	AH290 China AH102, AH180 Mexico
Legal Manufacturer	Vyaire Medical Inc. 26125 N. Riverwoods Blvd. Mettawa, IL 60045 USA

## GLOBAL HEADQUARTERS

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





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## **AUSTRALIAN SPONSOR**

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