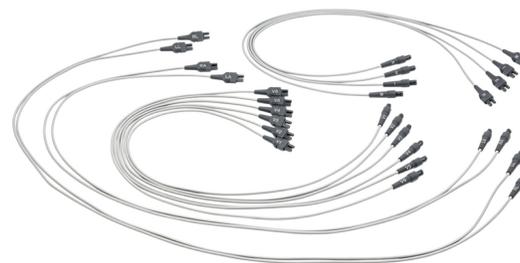


VITAL SIGNS® DCAR ECG (UNIVERSAL END) AND CABLE SET

NON-STERILE | REUSABLE | LATEX FREE | DEHP FREE | PVC FREE | BPA FREE

DEVICE MANUFACTURING SPECIFICATIONS

Product Family	Vital Signs Diagnostic Cardiology Leadwires and Cable Set
Manufacturer	AirLife Finland Oy
Manufacturer Address	Kuortaneenkatu 2, FI-00510 Helsinki, Finland
Country of Origin/Made In	China
Classification - US/510k #	Class II
FDA Product Code	DSA - Patient Transducer and Electrode Cable
Classification - Australia	Class I
AUS Authorized Representative	AirLife Australia Holdings Pty Ltd
Classification - Canada	Class II
Classification - UK	Class I
UK Authorized Representative	MT Promed Consulting Ltd
Classification - EU	Class I, Rule 1, According to the European Medical Device Regulation 2017/745, Annex VIII
CE Mark/Notification Body	CE
EMDN Code	Z12050380 - Electrocardiographs - Hardware Accessories
GMDN Code	35562 - Electrocardiographic Leadset, Reusable
UMDNS Code	15754 - Electrocardiographic Lead Set, Reusable
UNSPSC Code	42181702 - Cables/Leads, ECG
Usage	Up to 80 Reprocessing Cycles
Patient Population	Adult and Pediatric
Area of Use	Medical Professional Environment
Sterility	Non-Sterile
Magnetic Resonance	MR Unsafe
Packaging	Single Unit Packaged in Polyethylene (PE) Pouch
Storage Conditions	Store in a dry and well-ventilated area. Vertically hang cables and leadwires. Do not coil leadwires or cables tightly around any medical device. Avoid kinking. Storage temperature -30°C/-22°F to +60°C/+140°F.
Disposal Instruction	Reprocess products prior to disposal. Dispose electrical and electronic devices in compliance with WEEE or dispose per local and state environmental regulations.



DEVICE MATERIAL

COMPONENT	MATERIAL	DIRECT CONTACT
Mold Universal (Overmold)	Thermoplastic Polyurethane (TPU)	Yes
Plug Overmold	Polyurethane (PU), Dark Gray	Yes
ML Wire	Polyurethane (PU)	Yes
Connector Contacts	Phosphor Bronze; Finish: Gold Over Nickel	No
Mold Universal (Premold)	Acrylonitrile Butadiene Styrene (ABS)	No
Insert, AM4 Leadwire	Acrylonitrile Butadiene Styrene (ABS)	No
LDWR Plugface Single	Acrylonitrile Butadiene Styrene (ABS)	No
MLTLNK LW (Premold)	Acrylonitrile Butadiene Styrene (ABS)	No

Biocompatibility: 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.

Description: Diagnostic cardiology products are used to form electrical connections between the patient electrodes and instrumentation that displays and/or records patient data in diagnostic cardiology. These products are intended for use in adult and pediatric patients requiring an electrocardiography. The leadwires are compatible with GE HealthCare® equipment.

Intended Purpose: ECG leadwire and cable assemblies provide connection between ECG surface electrodes and various electrocardiograph recorders/monitors to transmit electrical signal for diagnostic and monitoring purposes. The products are available in various configurations depending on the length, number and color coding of the leadwires and type of the electrode connection. These products are reusable devices.

Contraindications: None Known.

TECHNICAL SPECIFICATIONS

DESCRIPTION	SPECIFICATION
Lead Sets	Mixed 10, Mixed 14, V3R, V4R, V7
Length	66 cm (26")
ECG Color Code	AHA or IEC
IEC 60601-1	Defibrillation-Proof Type CF Applied Part

The product meets the requirements of the standard, ECG trunk cables and patient leadwires (ANSI/AAMI EC53). AHA cable and leadwire set conform to American Heart Association labeling while IEC conforms to the International Electrotechnical Commission

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PART	DESCRIPTION	LEADS	COLOR CODE	LENGTH	CONNECTOR	EACH UDI/GTIN
2089797-001	DCAR Leadwire Set	Mixed 14/Set	AHA	66 cm (26")	Universal-Ended	10889483577516
2089797-002	DCAR Leadwire Set	Mixed 10/Set	AHA	66 cm (26")	Universal-Ended	10889483577523
2089797-003	DCAR Leadwire Set	Mixed 14/Set	IEC	66 cm (26")	Universal-Ended	10889483577530
2089797-004	DCAR Leadwire Set	Mixed 10/Set	IEC	66 cm (26")	Universal-Ended	10889483577547
2089799-001	DCAR Leadwire	V3R	AHA	66 cm (26")	Universal-Ended	10889483577554
2089799-002	DCAR Leadwire	V4R	AHA	66 cm (26")	Universal-Ended	10889483620045
2089799-003	DCAR Leadwire	V7	AHA	66 cm (26")	Universal-Ended	10889483577561