


General Purpose Temperature Probes

Technical Data Sheet



Product Codes and Product Description	M1024229VY - General Purpose, 9FR M1024231VY - General Purpose, 12FR	
General Product Description	<p>The Vyairé General Purpose Temperature Probe is a sterile, individually packaged sensor used for routine monitoring of core body temperature. The probe can be inserted into the nasal, nasopharynx, esophageal and rectal cavities. The temperature sensor, beneath the cuff at the distal tip, is highly accurate and designed to be compatible with the temperature monitor using the appropriate Vyairé reusable interface cable.</p>	
Pack factor	50/CA	
EAN/GTIN	M1024229VY EA: 00749756984072 CA: 50749756984077 M1024229VY-D EA: 00749756984089 CA: 50749756984084 M1024231VY EA: 00749756992084 CA: 50749756992089 M1024231VY-D EA: 00749756992091 CA: 50749756992096	
Intended Use	Used for the routine monitoring of core body temperature	
Instructions for Use	Please refer to the Instructions for Use (IFU)	
Characteristics	<ul style="list-style-type: none">- Versatile design allows for oral, nasal or rectal introduction- Low-friction surface for ease of insertion- Positive-locking connector for secure cable connection- Completely enclosed sensor wires for improved stability and hygiene- Thin, flexible design ensures optimal patient safety- Non-toxic, non-porous material for patient safety- Fully compatible with most monitors- Available in regular and soft flexibility for enhanced patient comfort- Not manufactured with natural rubber latex	
Compatibility	Compatible with monitors, given the appropriate interface cable, that use a 400 series or 700 series probes (where applicable)	
Shelf Life	The shelf life is 60 months after date of manufacture	
Regulation	Classifications: FDA – Class II EU – Class IIb Canada – Class II Products are compliant with REACH and RoHs directives. Presafe Denmark/AS 0543	
Biocompatibility	All materials are biocompatible, meeting skin irritation and sensitization requirements documents	
Storage	<ul style="list-style-type: none">- Keep away from sunlight.- Do not use if package is damaged.- Relative humidity: 85% non-condensing- Storage temperature: -25°C to +55°C- Operating temperature: 25°C to 45°C	

For International distribution.

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GMDN Code	35254
Does it contain PVC, DEHP and/or Latex	Contains PVC with alternative plasticizer
Country of Origin	Costa Rica
Legal Manufacturer	DeRoyal® Industries, Inc.
Probe Accuracy	Accurate to $\pm 0.1^{\circ}\text{C}$
MR Compatibility	The General Purpose Probe has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the General Purpose Probe in the MR environment is unknown. Scanning a patient who has this medical device may result in patient injury.
Operating Specifications	<ul style="list-style-type: none">- 25°C to 45°C- The reference body site is core body temperature- The measuring site is the esophagus, nasopharynx, or rectum
Time response	<ul style="list-style-type: none">- The temperature probe has a direct mode of operation- The maximum heating transient time is 1 minute- The maximum cooling transient time is 45 seconds

GLOBAL HEADQUARTERS

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