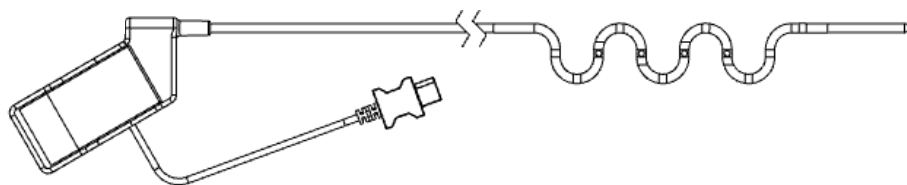


S-CATH™ M Esophageal Temperature Probe

(CS-21EP)

PRODUCT SPECIFICATIONS

FEATURE	SPECIFICATIONS
Product Code	CS-21EP
Manufacturer	CIRCA Scientific, Inc.
Probe Shape	Sinusoidal
Probe Diameter (OD)	10 French (3.3 mm)
Probe Length (Usable)	65 cm
Probe Shaft Material	Tecothane® Urethane (Barium-loaded) with Medical-grade Pebax® Coating Radiopaque: Yes
Temperature Sensors	Type: Thermistor Material: Copper/Gold Quantity: 12 (+1 400-Series Thermistor) Size: 2.5 mm Exposed Metal (per sensor): None Radiopaque: Yes
Temperature Range	0°C - 45°C
Temperature Accuracy	±0.3°C from 25 - 45°C ±0.4°C from 0 - 24.9°C
Mapping Electrodes	Type: Impedance Material: Gold Quantity: 4 Size: 2.5 mm Exposed Metal (per electrode): 6.28 mm ² Radiopaque: Yes
Connector(s)	Unidirectional connector to Temperature Cable Unidirectional connector to Mapping Cable
Electrical Safety	Certification(s): CSA International Meets IEC 60601-1:2005 + A1:2012 when used with CIRCA Cables and Monitor
Packaging	Description: Thermoform tray with Tyvek cover UOM (Shelf): 1 probe per shelf box UOM (Shipping): 10 shelf boxes per case
Natural Rubber Latex Statement	Products and packaging are not made with natural rubber latex.
Sterilization	Sterile (Ethylene Oxide)
Expiration	3 years from date of manufacture
Regulatory Clearances	FDA 510(k): K200943



Indications for Use: The CIRCA Temperature Monitoring System is composed of CIRCA Temperature Monitor and CIRCA S-CATH M Probe and is intended for the continuous detection, measurement and visualization (in °C) of esophageal temperature. The intended environments of use are operating rooms and interventional electrophysiology rooms. The CIRCA Monitor must be used in conjunction with the CIRCA S-CATH M Probe.

The role of esophageal temperature monitoring using this device in reducing the risk of cardiac ablation-related esophageal injury has not been established. The performance of the CIRCA Temperature Monitoring System in detecting esophageal temperature changes as a result of energy delivery during cardiac ablation procedures has not been evaluated.

Other System Components:

- CS-1000 CIRCA Temperature Monitoring System
- CS-100 S-CATH M Mapping Interconnect Cable
- CS-101 S-CATH Interconnect Cable
- CS-1029 CIRCA Temperature Standard (Monitor Calibration)



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