
S-CATH™ M

Esophageal Temperature Probe

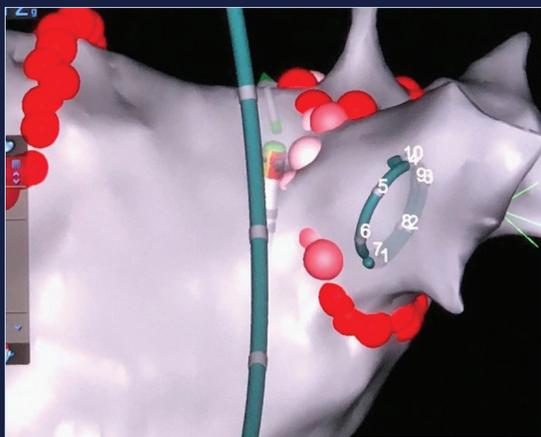
Accuracy you can trust.
Now visible on 3D cardiac mapping systems.



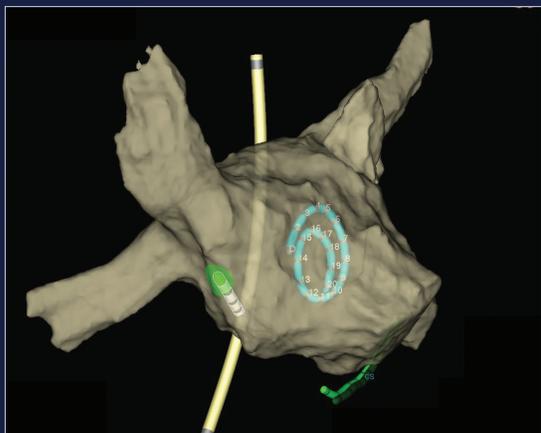
Visibility in Context

S-CATH M's visibility on impedance-based 3D cardiac mapping systems allows physicians to view the location of the esophageal probe in the context of nearby anatomical structures without depending solely on fluoroscopy.^A

- Four new electrodes mark the centerline of probe
- Place, position, and visualize the probe on 3D mapping
- May assist with planning and delivering therapies near the esophagus^B



S-CATH M on CARTO3



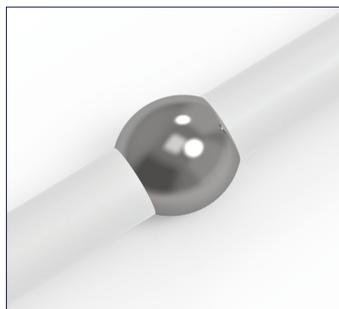
S-CATH M on Ensite NavX

Minimal Metal Exposure

Impedance-based mapping systems require direct contact between an electrode and the nearby tissue to detect and display the device. As a result, mapping electrodes (unlike temperature sensors) cannot be fully insulated.

S-CATH M's proprietary electrode design utilizes Pebax insulation to cover 75% of the electrode's surface area, limiting the amount of exposed metal to only what is absolutely necessary to be detected on 3D cardiac mapping systems and limiting the opportunity for RF interaction.

In contrast, other multi-sensor probes on the market have fully-exposed metal electrodes, which may be inadvertently heated when used in close proximity to the RF field.¹⁻³ **S-CATH M only has 11% the amount of exposed metal vs. competitive multi-sensor probes.**



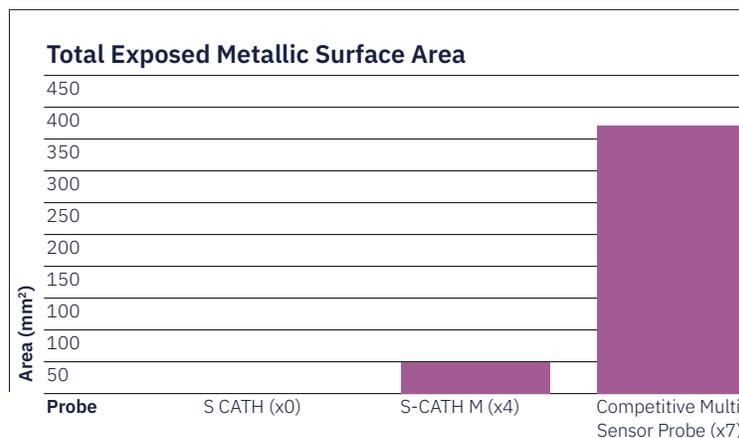
Competitive Probe

Fully exposed metallic elements



S-CATH M

Minimally-exposed metallic elements (Pebax insulation)



Steep temperature gradients may be observed in the esophagus during therapeutic procedures, with maximum luminal esophageal temperatures differing as much as 10°C over distances as small as 3mm.¹ These temperature changes may be underestimated or missed if using a probe with inadequate surface area coverage.

Unfortunately, all linear probes are prone to far lateral positioning, and clinical research has shown that linear probes may be malpositioned over 50% of the time.⁴ If the distance between a temperature sensor and heated tissue is too great, peak temperatures may be underestimated or missed.⁴

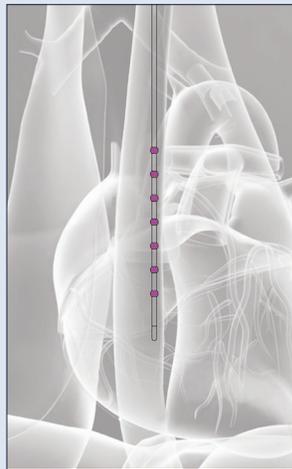
The new S-CATH M, with its familiar sinusoidal shape, continues to provide the high-density, edge-to-edge coverage you expect from CIRCA Scientific. S-CATH M intelligently positions 12 sensors throughout the length and width of the esophagus, ensuring critical temperature changes are not missed.

The Top 5 EP Programs in the US trust the accuracy of CIRCA Scientific's Esophageal Temperature Monitoring Products.⁶

(by procedure volume, 2019)



General Purpose Probe (Single-sensor)



Linear Multi-Sensor Probe (7 sensors)



S-CATH M (12-sensor array)

■
Active Temperature Sensor

Average Esophageal Width = 18.9mm⁵

Ordering Information

Product Code	Description
CS-21EP	S-CATH™ M Esophageal Temperature Probe Single Use, Sterile, 10Fr. O.D., 10 units/carton
CS-1000	CIRCA Temperature Monitoring System™ Touch Screen Display, Pole Mount Included
CS-100	S-CATH™ M Mapping Interconnect Cable Connects S-CATH M to 3D Mapping System, Reusable, 15-foot working length
CS-101	S-CATH™ Interconnect Cable Connects S-CATH M to CIRCA Temperature Monitoring System, Reusable, 15-foot working length
CS-1029	CIRCA Temperature Standard Reusable, Calibration

Notes

- A Always make sure to have a primary and secondary imaging source available, and retain the ability to verify probe location with fluoroscopy as needed.
- B Location data obtained using the CIRCA S-CATH M Esophageal Temperature Probe does not delineate the full width of the esophagus, the actual location of the esophageal wall, the location of individual temperature sensors, or the actual (sinusoidal) shape of the probe. Location data solely delineates the centerline of the CIRCA S-CATH M Probe.
- C Accuracy of the temperature sensors is $\pm 0.3^{\circ}\text{C}$ within the rated output range of 25°C to 45°C and $\pm 0.4^{\circ}\text{C}$ within the rated extended output range of 0° to 24.9°C .

References

- 1 Pérez, J. J., et al. "Electrical and Thermal Effects of Esophageal Temperature Probes on Radiofrequency Catheter Ablation of Atrial Fibrillation Results from a Computational Modeling Study." *Journal of Cardiovascular Electrophysiology* (2015): 556-564.
- 2 Müller, P., et al. "Higher incidence of esophageal lesions after ablation of atrial fibrillation related to the use of esophageal temperature probes." *Heart Rhythm* (2015): 1464-1469.
- 3 Halbfass, P., et al. "Incidence of asymptomatic oesophageal lesions after atrial fibrillation ablation using an oesophageal temperature probe with insulated thermocouples: a comparative controlled study." *Europace* (2017): 385-391.
- 4 Knecht, S., et al. "Reliability of Luminal Oesophageal Temperature Monitoring During Radio frequency Ablation of Atrial Fibrillation: Insights From Probe Visualization and Oesophageal Reconstruction Using Magnetic Resonance Imaging." *EP Europace* (2017): 1123-1131.
- 5 Cury, R.C., et al. "Relationship of the esophagus and aorta to the left atrium and pulmonary veins: implications for catheter ablation of atrial fibrillation." *Heart Rhythm* 2.12 (2005): 1317-1323.
- 6 Decision Resources Group. "ProcedureFinder: U.S. Atrial Fibrillation Ablation Procedure Volumes (Q1 2016-Q2 2019)." 2020. Top Programs defined by highest 2019 procedure volumes.

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 $^{\circ}\text{C}$) 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.

Rx Only: Federal (USA) law restricts this device to sale by or on the order of a physician.

U.S. Patents 9,155,476 B2 and 9,668,655. Other U.S. and foreign patents pending.

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CS-ART2103 Rev. 00

For Use with the CIRCA Temperature Monitoring System

S-CATH M is the latest addition to CIRCA Scientific's portfolio of Advanced Esophageal Temperature Monitoring products. It may be used with the existing CIRCA Temperature Monitoring System and S-CATH Interconnect Cable. Additional required equipment includes the new S-CATH M Mapping Interconnect Cable for connection to impedance-based 3D cardiac mapping systems.

Key Features:

- Continuous monitoring software samples data 20X per second for real-time recognition of temperature changes
- Highly accurate in both hot and cold temperatures (down to 0°C)^c
- Intuitive user interface with graphic and numeric data visualization options
- User-selectable visual and audible alarms



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