Twelve Sensors. Intelligently Positioned.

CIRCA S-CATH™

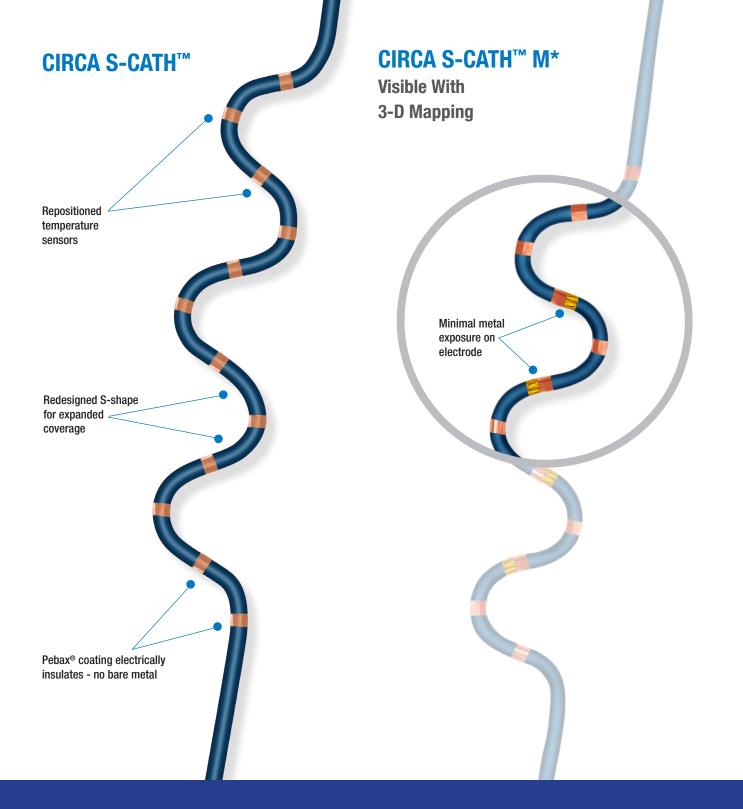
Esophageal Temperature Monitoring System

CIRCA S-CATH[™] M^{*} Visible with 3-D Mapping

*Pending 510(K) review. Not available in the United States.

FAST. ACCURATE. SENSITIVE.





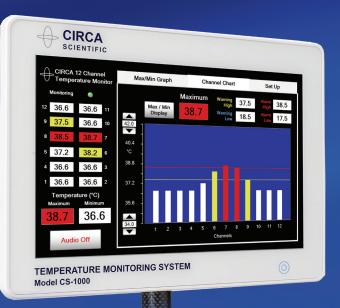
CIRCA S-CATH™ TEMPERATURE PROBES

Edge-to-Edge Coverage

During therapeutic procedures, esophageal temperatures can change quickly. The new and improved S-CATH provides faster, more accurate temperature detection.

- Soft, flexible self-expanding probe conforms to esophageal shape
- Proprietary sensor construction ensures rapid temperature transfer
- Delivers 240 data points per second;12 temperature sensors update 20 times per second

RAPID, RESPONSIVE, CONTINUOUS MONITORING SOFTWARE



Continuous monitoring software is highly accurate in both hot and cold (down to 0°C) temperatures.¹

- Four, user-selectable low and high temperature alarms
- Visual alarms for enhanced recognition
- Graphic and numeric temperature display
- Temperature log retains highest and lowest temperatures
- Conveniently record data for research





STATIONARY PLACEMENT

Sensor placement ensures proximity to the point of treatment; no need to move the probe once placed.

- Radiopaque shaft provides a visual landmark of the esophagus
- · Indicates esophageal width and orientation
- Facilitates reduced use of fluoroscopy



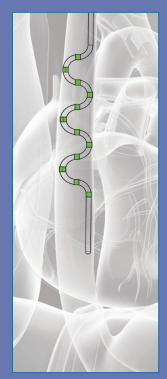
EDGE-TO-EDGE COVERAGE

The S-CATH, with its unique S-shaped design, deploys an array of 12 temperature sensors throughout the length and width of the esophagus, positioning sensors near the source of temperature changes. Independent research has shown that sensor distance has a great effect on temperatures recorded. ^{2,3,4}



3-Sensor Probe

S-CATH Probe



Active Sensor

Average Esophageal Width = 18.9mm⁵

BETTER VISUALIZATION

S-CATH M* is designed for 3-D Mapping Systems

- Four electrodes allow imaging on impedance-based 3-D mapping systems
- Electrodes centrally located to facilitate proper placement using 3-D mapping systems
- Twelve-sensor array provides temperature coverage without need to reposition



IN VIVO DATA⁶

Faster Detection

In an independent study of 198 applications in 10 patients, the S-CATH recognized an initial temperature rise of 0.2°C 17 seconds faster than a single sensor probe. (13.4 ± 7.5 vs. 30.5 ± 15.4 s; P, 0.001)



INITIAL TEMPERATURE RISE:

CIRCA 17 Seconds Faster S-CATH: Giving you time to respond

Multiple Sensors

In the same independent prospective study of 198 applications in 10 patients, a temperature rise of >2.0°C was recorded 40 times by the S-CATH. Single sensor probes missed 90% of those temperature rises.



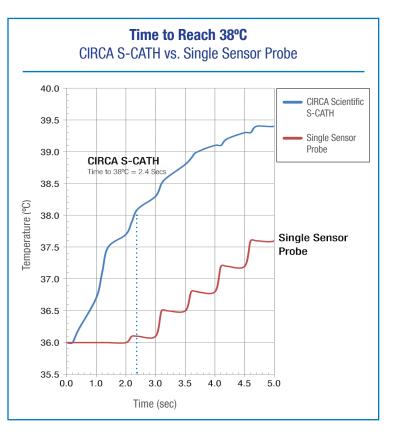
TEMPERATURE RISE >2.0°C RECORDED:

CIRCA S-CATH: 40 Single Sensor Probe: 4

BENCH DATA⁷

Earlier Detection of a 2°C Rise CIRCA S-CATH vs. single sensor 9F esophageal probe simultaneous submersion in warm water bath, representing optimal sensor positioning. Test conducted by CIRCA Scientific.





Product Code	Description
CS-1000	CIRCA Temperature Monitoring System [™] Software Package (Touch Screen Display, Pole Mount Included)
CS-2006	CIRCA S-CATH [™] Esophageal Temperature Probe (Single Use, 10Fr 0.D.,10 units/Carton) International
CS-46EP*	CIRCA S-CATH [™] M Esophageal Temperature Probe (Single Use, 10Fr. 0.D., 10 units/Carton) International
CS-100 *	CIRCA S-CATH [™] EP Interconnect Cable (Reuseable, 15 Foot Working Length)
CS-101	CIRCA S-CATH [™] Interconnect Cable (Reusable, 15 Foot Working Length)
CS-1029	CIRCA Temperature Standard (Calibration)
CS-1083	CIRCA USB Data-Transfer Drive

All products which carry the CE mark comply with Medical Device Directive 93/42/EEC and are manufactured to Quality Systems IS013485.

This product is listed by CSA International as certified.

*Pending 510(K) review. Not available in the United States.

Indications for Use: The CIRCA S-CATH Esophageal Temperature Probe is intended for continuous temperature monitoring. The radiopaque probe is designed for placement in the esophagus. The CIRCA Temperature Monitor is indicated to display continuous temperature measurement (°C) from 12-sensor temperature probe.

 $\label{eq:caution:Federal} \mbox{ (U.S.A.) law restricts this device to sale by or on the order of a physician. }$

- 1 Accuracy of the temperature sensors is \pm 0.3°C within the rated output range of 25°C to 45°C and \pm 0.4°C within the rated extended output range of 0° to 24.9°C.
- 2 Jose L. Merino, Martin Arceluz, Reina Delgado, Estela Falconi, Federico Cruz, Carlos C. Vasquez, Marta Ortega. Sensitivity and accuracy of Sensitherm/Esotherm oesophageal temperature probe: reply Europace 2016;18:468-469.
- 3 Nakagawa H, Yamanashi WS, Pitha JV, Arruda M, Wang X, Ohtomo K, et al. Comparison of in vivo tissue temperature profile and lesion geometry for radiofrequency ablation with a saline-irrigated electrode versus temperature control in a canine thigh muscle preparation. Circulation 1995;91:2264–73.
- 4 Moreno J, Quintanilla JG, Molina-Morúa R, García-Torrent MJ, Angulo-Hernández MJ, Curiel Llamazares C, et al. Morphological and thermodynamic comparison of the lesions created by 4 open irrigated catheters in 2 experimental models. J Cardiovasc Electrophysiol 2014;25:1391–9. Medline.
- 5 Cury RC, Abbara S, Schmidt S, Malchano ZJ, Neuzil P, Weichet J, Ferencik M, et al. Relationship of the esophagus and aorta to the left atrium and pulmonary veins: Implications for catheter ablation of atrial fibrillation. Heart Rhythm 2005; 2:1317-1323.
- 6 Tschabrunn, CM, Silverstein J, Berzin T, Ellis E, Buxton AE, Josephson ME, Anter E. Comparison between single- and multi-sensor oesophageal temperature probes during atrial fibrillation ablation: thermodynamic characteristics, Europace 2015 doi:10.1093/europace/euu356.

7 In-house data. Test conducted by CIRCA Scientific.



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



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