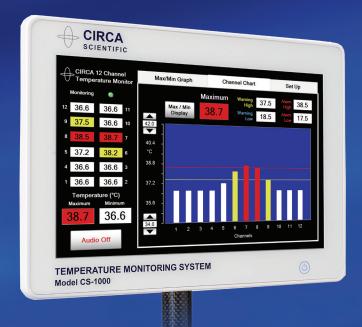


FAST. ACCURATE. SENSITIVE.



## RAPID, RESPONSIVE, CONTINUOUS MONITORING SOFTWARE



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

- 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



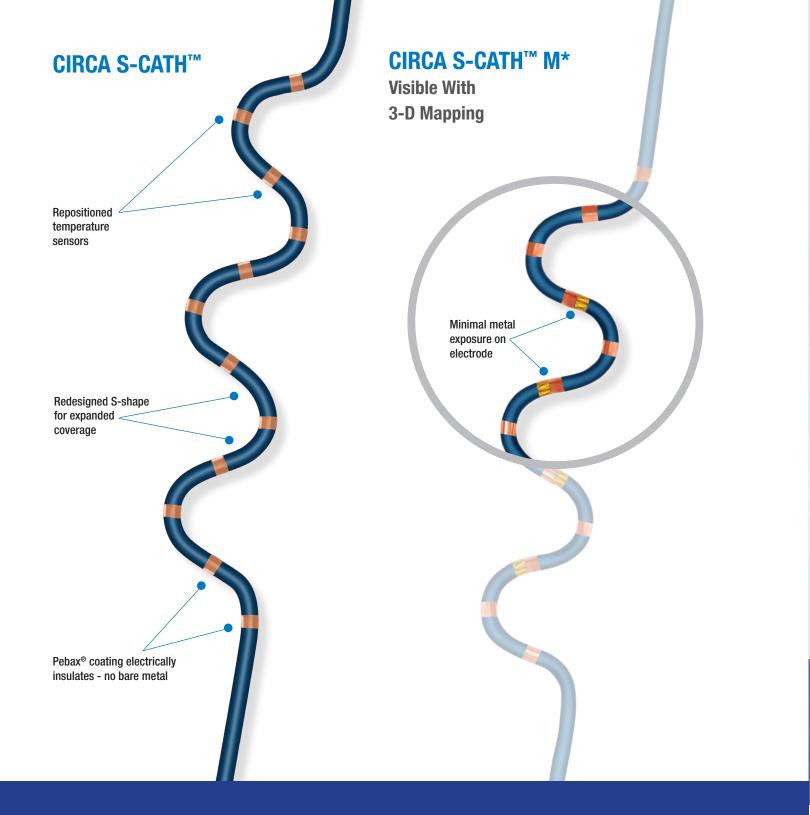


## STATIONARY PLACEMENT

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





## 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

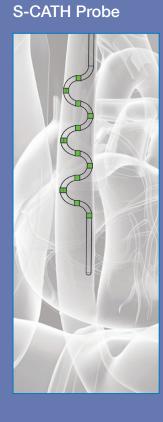
## EDGE-TO-EDGE COVERAGE

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. <sup>2,3,4</sup>

Active Sensor



3-Sensor Probe

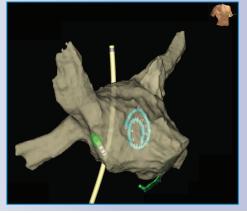


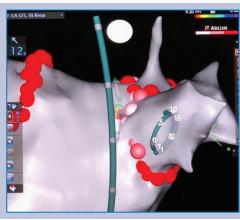
Average Esophageal Width = 18.9mm<sup>5</sup>

## 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)

Seconds Faster

#### **INITIAL TEMPERATURE RISE:**

CIRCA 17 Seconds Faster

S-CATH: Giving you time to respond



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.

# Single Sensor 90% Missed

#### TEMPERATURE RISE >2.0°C RECORDED:

CIRCA S-CATH: 40 Single Sensor Probe: 4

## BENCH DATA7

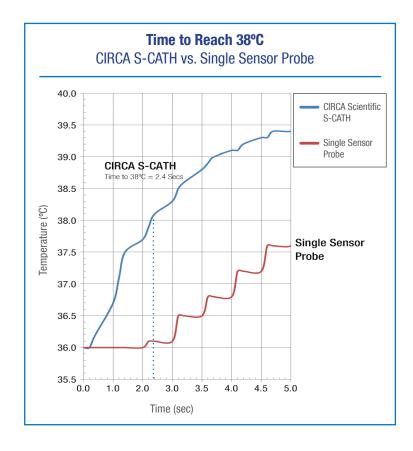
#### Earlier Detection of a 2°C Rise

CIRCA S-CATH vs. single sensor 9F esophageal probe simultaneous submersion in warm water bath, representing optimal sensor positioning. Test conducted by CIRCA Scientific.

## **3X** Faster

#### TIME (SECONDS) TO DETECT A 2°C RISE

CIRCA S-CATH: 2.4 Single Sensor Probe: 8.2



#### **Product Code Description (€** 2797 **CS-1000** CIRCA Temperature Monitoring System™ (Touch Screen Display, Pole Mount Included) **CS-2006** CIRCA S-CATH™ Esophageal Temperature Probe (Single Use, 10Fr O.D., 10 units/Carton) International CE 2797 **CS-46EP\*** CIRCA S-CATH™ M Esophageal Temperature Probe (Single Use, 10Fr. 0.D., 10 units/Carton) International CS-100\* CIRCA S-CATH™ M Mapping Interconnect Cable (Reuseable, 15 Foot Working Length) **CS-101** CIRCA S-CATH<sup>™</sup> Interconnect Cable (Reusable, 15 Foot Working Length) CS-1029 **CIRCA Temperature Standard (Calibration) CS-1083 USB Data-Transfer Drive**

Indications for Use: The CIRCA S-CATH and CIRCA S-CATH M Esophageal Temperature Probes are intended for continuous esophageal temperature monitoring during cardiac ablation procedures. The radiopaque probes are designed for placement in the esophagus. The CIRCA S-CATH M Esophageal Temperature Probe may be used to monitor electrophysiological signals. The CIRCA Temperature Monitor is indicated to display continuous temperature measurement (°C) from 12-sensor temperature probe for esophageal monitoring during cardiac ablation procedures.

- 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 Internal data. Test conducted by CIRCA Scientific



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<sup>\*</sup>Pending 510(K) review. Not available in the United States.