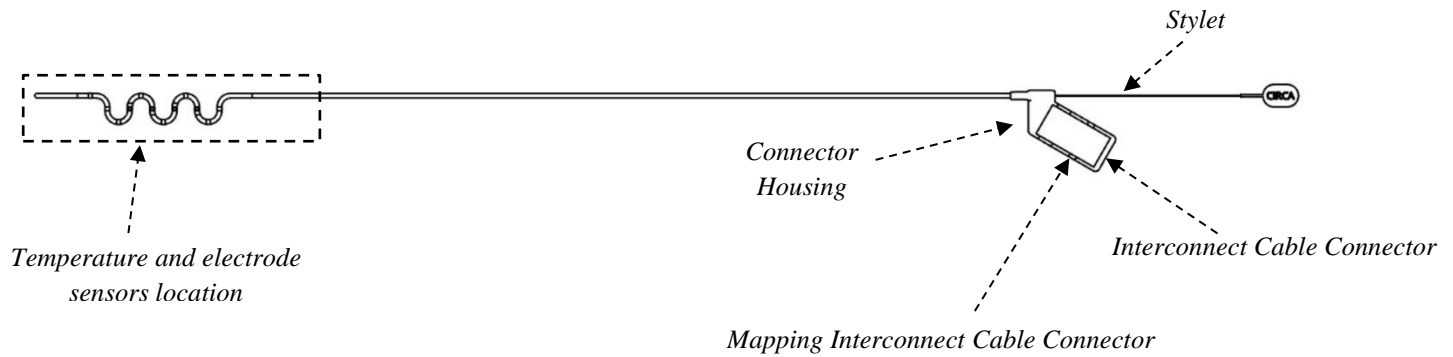


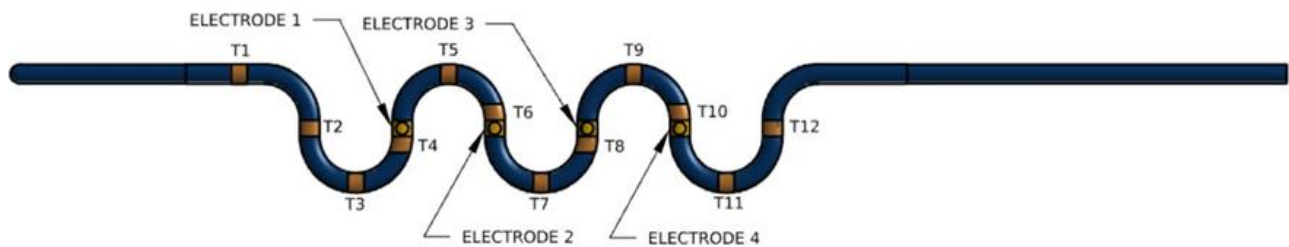
Instructions for Use: CIRCA S-CATH™ M Esophageal Temperature Probe

1 DESCRIPTION

The CIRCA S-CATH™ M Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode. It is equipped with 4 electrodes that may be used to assist in obtaining generalized location of the probe if connected to a 3D cardiac mapping system.



ELECTRODE WIDTH	2.5mm
DISTANCE (CENTER)	
1 – 2	22mm
2 – 3	22mm
3 – 4	22mm



2 INTENDED PURPOSE

The Esophageal Temperature Probe is intended for continuous esophageal temperature monitoring during cardiac ablation procedures. The radiopaque probe is designed for placement in the esophagus and is equipped with electrodes that assist in visualizing the general location of the probe if connected to a 3D cardiac mapping system.

2A Clinical benefits: as this is a temperature-monitoring device, there can be no direct clinical benefits attributed to the device. The clinical benefits associated with the overall procedure is applicable to the device and can be used as the parameter to measure the performance of the device.

2B Contraindications: there are no known contraindications associated with the equipment or its accessories.

2C Limitations: patients with dysphagia and other esophageal diseases/abnormalities.

2D Intended Users: the target user group is trained medical professionals. The probe is placed and used by a trained medical professional, e.g. surgical nurse, anesthesiologist, cardiologist, electrophysiologist, or ENT physician.

2E Intended Patient Population: adult patients of both men and women indicated as clinically suitable and in need to undergo cardiac ablation prescribed by a suitability qualified clinician.

3 GENERAL WARNINGS AND PRECAUTIONS [S-CATH M Esophageal Temperature Probe]

- Single use only. Do not re-use. If re-used, cross-infection to patient may occur.
- Do not rinse, soak, wash, or sterilize. Material degradation and temperature inaccuracy may occur.
- Insert probe into esophagus under fluoroscopic x-ray or by visualization on a non-fluoroscopic mapping system. Failure to verify placement could result in accidental tracheal or bronchial intubation, airway obstruction.
- Do not use this device in patients with anomalies or disease of the nose, throat or esophagus.
- During device introduction, care must be taken to avoid device migration into the trachea. Damage to the lung could occur should the device be introduced into the tracheo/bronchial tree.
- If any resistance is felt during device introduction, determine the cause of the resistance and proceed only as appropriate. Do not use excessive force to advance or withdraw the probe when resistance is encountered. Such resistance may lead to damage or perforation of the trachea or esophagus.
- Do not re-insert stylet, probe damage may occur.



Manufactured for:
CIRCA Scientific, Inc.
14 Inverness Drive East, H-136
Englewood, CO 80112 USA
(303) 951-8767



MedNet EC-REP IIb GmbH
Borkstrasse 10,
48163 Muenster, Germany

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- The CIRCA S-CATH™ M Esophageal Temperature Probe is designed for use with CIRCA Scientific Interconnect Cables, CIRCA Scientific Temperature Monitor, and compatible 3D cardiac mapping systems only. Incompatible components can result in degraded performance and could lead to damage.
- Only equipment complying with the requirement of IEC 60601-1 for medical equipment patient protection should be used within the patient environment. Other equipment not complying with patient protection should be used outside the patient environment.
- Additional equipment connected to the probe must be certified to respective IEC or ISO safety standards. When connecting external equipment to probe, make sure that the whole combination complies with safety standard for Medical Electrical Systems according to IEC 60601-1 3rd edition (clause 16) and with the requirements of local laws and governing agencies. Hospital personnel who connect additional equipment configure a medical system, and are therefore responsible for the system complying with the requirements for Medical Electrical Systems.
- Location data obtained using the CIRCA S-CATH™ M Esophageal Temperature Probe may not delineate the full width of the esophagus, the actual location of the esophageal wall, and may not delineate the actual shape of the probe.
- Part of defibrillation proof protection is provided by the CIRCA S-CATH™ M Esophageal Temperature Probe with the CIRCA Scientific Temperature Monitor (Defibrillation-Proof Type CF Applied Part). When S-CATH M Mapping Interconnect Cable is connected to 3D cardiac mapping system, consult equipment manufacturer's accompanying documents for the system's defibrillation-proof classification.
- Do not use the device if any of the 12 temperatures displayed are meaningfully lower than 37°C (<35°C), in absence of particular justifying situations, or a difference $\geq 2^\circ\text{C}$ is among the twelve displayed values.

4 POTENTIAL ADVERSE EVENTS

Potential risks for serious incidents associated with the use of the probe include:

- Infection
- Airway obstruction
- Lung damage or perforation
- Trachea damage or perforation
- Esophagus damage or perforation
- Esophagus thermal injury

Notice: any serious incident that occurs in relation to this device should be reported to CIRCA Scientific and the Competent Authority of the Member State in which the user is established.

5 SETUP INSTRUCTIONS

The operator is responsible for checking the compatibility of the S-CATH M Probe, interconnect cables, and monitor before use. Ensure only CIRCA Scientific Interconnect Cables are connected to S-CATH M Probe Connector Housing.

S1) Remove device from package.

S2) Visually inspect for damage, kinks, visible debris, and missing components. Do not use if any defects are observed.

S3) Proceed with operating instructions below.

CAUTION: Do not use this device in patients with anomalies or disease of the nose, throat or esophagus.

6 OPERATING INSTRUCTIONS

O1) Straighten S-Curve Portion of S-CATH M Probe

- Grasp connector housing of probe with one hand and push stainless steel stylet until end of stylet reaches housing.



O2) Insert S-CATH M Probe into Esophagus

- Apply water-soluble lubricant to outside of probe.
- Insert probe into esophagus. Advance distal tip to approximately 1 cm (0.4") superior to the gastroesophageal junction.

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CAUTION: During device introduction, care must be taken to avoid device migration into the trachea. Damage to the lung could occur should the device be introduced into the tracheo/bronchial tree.

CAUTION: If any resistance is felt during device introduction, determine the cause of the resistance and proceed only as appropriate. Do not use excessive force to advance or withdraw the probe when resistance is encountered. Such resistance may lead to damage or perforation of the trachea or esophagus.

- c. Once probe is placed, grasp connector housing of probe with one hand and with the other hand, grasp finger grip end of stylet and remove completely. Discard stylet.

Caution: do not re-insert stylet, probe damage may occur.



- d. Verify position of probe under fluoroscopic x-ray or mapping system if used. If probe end does not appear as an S-shape under fluoroscopic x-ray, grasp connector housing and rotate probe until S-shape is visible. Grasp connector housing to reposition probe as required for desired placement.

NOTE: The temperature sensors (located along S-shape) must be appropriately aligned to the area where cardiac ablation is planned.

O3) Connect S-CATH M Probe to Temperature Monitor

- a. Connect S-CATH M Probe to CIRCA Scientific Temperature Monitor via CIRCA Scientific Interconnect Cable by aligning connectors and pushing firmly.
- b. Verify temperatures are displayed on monitor. If no temperature displays, verify connections are fully seated and resolve any error messages displayed on temperature monitor.

CAUTION: Do not use the device if any of the 12 temperatures displayed are meaningfully lower than 37°C (<35°C), in absence of particular justifying situations, or a difference $\geq 2^\circ\text{C}$ is among the twelve displayed values.

O4) Connect S-CATH M Probe to 3D Cardiac Mapping System (If using to assist in visualizing general location of the probe.)

- a. If used, connect S-CATH M Probe to 3D cardiac mapping system via CIRCA Scientific Mapping Interconnect Cable by aligning connectors and pushing firmly.

O5) Disposition After Use














- a. Disconnect S-CATH M Probe from Interconnect Cables by grasping connectors and pulling apart.
- b. Remove probe from patient.
- c. Discard probe according to hospital's disposal procedures.

7 TECHNICAL INFORMATION

Temperature Sensors (12)	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°C to 24.9°C
Outside Diameter	10 Fr
Length	65 cm (tip to connector housing)
Electrical Safety	Meets IEC 60601-1:2005 + A1:2012 when used with CIRCA Scientific interconnect cable and monitor
Transient Response (Sensors 1 – 12)	Heating transient response time is approximately six seconds and cooling transient response time is approximately eight and a half seconds. (Note: time is for probe plunged from reference water bath to a water bath with a 2°C differential.)
Electrodes	Width = 2.5mm. Distance: 1 – 2 = 22mm; 2 – 3 = 22mm; 3 – 4 = 22mm.
Storage & Transport	Temperature: -20°C to 60°C (-4°F ~ 140°F); Humidity: 10% to 85%RH, non-condensing
Natural Rubber Latex Statement	Products and packaging are not made with natural rubber latex.

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8 SYMBOLS KEY

	Catalogue Number		Medical device
	Lot Number		Single use only. Do not re-use.
QTY	Quantity		Consult instructions for use.
	Use By Date		Caution: part of defibrillation-proof protection is provided by the S-CATH™ M Esophageal Probe. Do not use with any other applied part.
	Manufacturer		Defibrillation-Proof Type CF Applied Part
	Humidity limitation		Temperature limits
	Authorized Representative in the European Union		“Conformité Européenne” “European Conformity”

U.S. Patent 9,155,476 and 9,668,655.