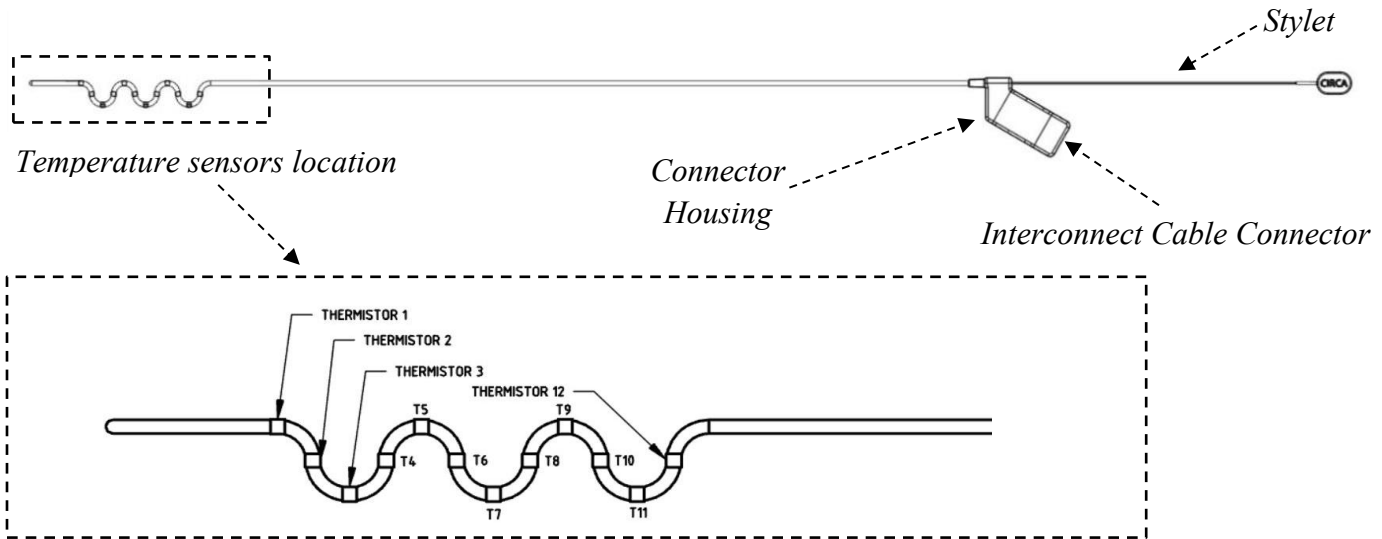


Instructions for Use: CIRCA S-CATH™ Esophageal Temperature Probe

1 DESCRIPTION

The CIRCA S-CATH™ Esophageal Temperature Probe provides continuous temperature measurement (°C) and operates in direct mode.



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.

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. In addition, ‘reduced risk of esophageal thermal injury’ can be considered as the indirect clinical benefit of the device.

2B Contraindications: do not use this device in patients with anomalies or disease of the nose, throat, or esophagus.

2C Limitations: device(s) should only be connected to the CIRCA Esophageal Temperature Monitoring System for temperature reading, but not other temperature monitoring systems.

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 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. Failure to use fluoroscopic x-ray during placement could result in accidental tracheal or bronchial intubation, airway obstruction.



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- 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.
- The CIRCA S-CATH™ Esophageal Temperature Probe is designed for use with CIRCA Scientific Interconnect Cable and CIRCA Scientific Temperature Monitor only. Incompatible components can result in degraded performance and could lead to damage.
- 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
- Epistaxis

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 probe, interconnect cable, and monitor before use. Ensure only CIRCA Scientific components and equipment is connected.

- 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 Probe

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



O2) Insert S-CATH Probe into Esophagus

- a. Apply water-soluble lubricant to outside of probe.

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- b. Insert probe into esophagus under fluoroscopic x-ray. Advance distal tip to approximately 1 cm (0.4”) superior to the gastroesophageal junction.

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.

Remove stylet completely and discard



- d. Verify position of probe under fluoroscopic x-ray. If probe end does not appear as an S-shape, 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 Probe to Temperature Monitor

- a. Connect S-CATH 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 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) Disposition After Use

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

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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); 13mm (approximate temperature sensor spacing)
Electrical Safety	Meets IEC 60601-1:2005 + A1:2012 + A2:2020 when used with CIRCA Scientific interconnect cable and monitor
Transient Response	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.)
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.

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™ temperature 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”

Patent www.circascientific.com/en-us/patents