

Instructions for Use

Esophageal Stethoscope with Temperature Sensor

Thermistor: YSI 400 Series Equivalent

Cat. No.: 4009-ES, 40012-ES, 40018-ES, 40024-ES

DESCRIPTION:

Hyperthermia and hypothermia are frequently experienced clinical conditions and their undesirable effects in patients have been well documented in the literature. Body temperature is measured continuously using disposable temperature sensors or probes to detect hyper- or hypothermia. These sensors are inserted in the structure designed to fit a specific anatomy of the human body where temperature is measured. The main component of the temperature sensors is a chip which changes resistance with a change in temperature. The chip used in the Esophageal Stethoscope with temperature sensor is a thermistor equivalent to the YSI 400 series. This thermistor is encapsulated in a plastic cap connected to a lead wire. This lead wire has an insert molded connector on the opposite end to connect with the instrument cable. The accuracy of the sensor is: $\pm 0.1^{\circ}\text{C}$ at 37°C and $\pm 0.2^{\circ}\text{C}$ at 5°C and 45°C .

The Esophageal Stethoscope with temperature sensor is designed for placement inside the esophagus for temperature measurement and the auscultation of heart and lung sounds. This thermistor assembly is placed inside of a PVC tube size 9 Fr, 12 Fr, 18 Fr, or 24 Fr, with sensing tip placed at the tube's proximal end, which is beveled for atraumatic insertion. The tube at its proximal end has several side openings and is covered with a plastic cuff to facilitate heart and lung sound transmission. The tube is made of light weight, medical grade PVC materials. At the distal end a male Luer adaptor is attached to the tube for connection to any standard ear piece for listening to heart and lung sounds.

The probes are disposable and designed to be used with instruments that are compatible with YSI 400 series or equivalent thermistors. The cables to connect the probe to the instrument are Starboard Medical Cable Cat. No. C400-MP-M, C400-MP-MJ, C400-P-M, and C400-P-MJ, or SMITHS Level 1 Cable Cat. No. C400-10. The device is sterile, designed to be disposable, for single use only. The Esophageal Stethoscope with temperature sensor is supplied in 9 Fr, 12 Fr, 18 Fr, and 24 Fr sizes.

INDICATIONS:

The Starboard Medical Esophageal Stethoscope with temperature sensor is intended for use when the esophageal temperature is continuously monitored along with the auscultation of the heart and lung sounds.

CONTRAINDICATIONS:

The Esophageal Stethoscope with temperature sensor usage may be contraindicated in neonates and small infants during laser surgery, internal jugular artery catheterization, or tracheostomy procedures.

ADVERSE REACTIONS:

The following adverse reactions have been reported during clinical application of the Esophageal Stethoscope with temperature sensor:

- Accidental tracheal or bronchial placement accompanied with an airway obstruction.
- Esophageal abrasion and/or perforation
- Tissue burns due to aberrant electro-cautery radio-frequency current pathways.

DIRECTIONS FOR USE:

1. Lubricate probe prior to placement *in situ*.
2. In patients requiring intubation, intubate the patient first and then insert the Esophageal Stethoscope into the esophagus.
3. Verify its location in accordance with clinically acceptable procedures.
4. Connect the instrument's cable connector with the temperature sensor's connector by aligning both and pushing together firmly to assure proper contact. Misalignments and forced connections may cause sensor failure.
5. Connect ear piece extension tubing to the stethoscope Luer connector for listening to heart and lung sounds.

WARNINGS:

If the Esophageal Stethoscope with temperature sensor is utilized during surgical procedures using electro-cautery, the following may occur:

- Artificial fluctuations in temperature readings.
- Localized tissue burns due to the thermistor and lead wire acting as an alternate path for the radio-frequency current to return to ground.

The risk of localized tissue burns can be minimized by having the active and ground probes of the electro-cautery system in a close proximity to each other. All parts of the Esophageal Stethoscope with Temperature sensor and cable shall be away from the electro-cautery probes and connecting cables and, therefore, outside of the radio-frequency current field.

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