

## Instructions for Use

### Tympanic Temperature Sensor

Thermistor: YSI 400 Series Equivalent  
Cat. No.: 400-TY, 400-TYP

#### 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 Tympanic Temperature sensor is a thermistor equivalent to the YSI 400 series. This thermistor is encapsulated in a plastic cap connected to a lead wire. The 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  $37^{\circ}\text{C}$  and  $\pm 0.2^{\circ}\text{C}$  at  $5^{\circ}\text{C}$  and  $45^{\circ}\text{C}$ .

The Starboard Medical Tympanic Temperature sensor is intended for use in routine continuous monitoring of the tympanic temperature as an indicator of core body temperature when this type of measurement is clinically indicated. The Tympanic Temperature sensor is designed for atraumatic placement within the ear canal in the proximity of the tympanic membrane. The Thermistor Temperature sensor is placed at the end of the PVC tubing with the sensor's tip outside of the tubing. A small compressible foam on the sensor tip guards against traumatic effect on the tympanic membrane. A large compressible foam distal to the tip secures the sensor in place, and prevents the communication of air between the ear canal and the outside. This design provides for accurate measurement under the condition when the sensor is not touching the tympanic membrane.

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. C400MP-M, C400MP-MJ, C400P-M, and C400P-MJ, or SMITHS Level 1 Cable Cat. No. C400-10. The device is sterile, designed to be disposable, for single use only. The Tympanic Temperature sensor is supplied in Adult and Pediatric sizes.

#### INDICATIONS:

The Starboard Medical Tympanic Temperature sensor is intended for use in routine continuous monitoring of tympanic temperature as an indicator of core body temperature when this type of measurement is clinically indicated.

#### CONTRAINDICATIONS:

Use of the tympanic temperature sensor is contraindicated in neonates and patients having ear pathology, such as: infections, tumors, perforated ear drums, and polyps.

#### ADVERSE REACTIONS:

Reported adverse reactions associated with the usage of tympanic sensors are: ear-ache, otitis externa, decreased hearing, bleeding from tympanic membrane or ear canal, and perforation of the tympanic membrane.

#### DIRECTIONS FOR USE:

1. Prior to insertion, verify that the ear canal designated for insertion of the sensor does not have any pathology or obstruction.
2. Insert the sensor as follows:
  - a. Squeeze and roll both small and large foam cylinders between your fingers.
  - b. Pull the pinna (upper portion of the earlobe) in a superior and posterior direction.
  - c. Verify that both foams are in a squeezed position, if they are not, repeat step (a).
  - d. Hold the tube portion of the sensor and insert it inside the ear with a gentle twisting motion. If resistance is felt, stop and slightly withdraw the sensor.
  - e. In awake patients who experience discomfort, the sensor should be withdrawn until the discomfort disappears.
  - f. Tape the lead wire to the patient's head to secure sensor in situ. Caution should be used not to apply additional pressure on the sensor by touching or by moving the patient's head over the sensor or by any other means.
  - g. Align the temperature sensor's connector with the instrument's cable connector and push firmly to ensure proper contact.
  - h. Allow several minutes of equilibration prior to the start of monitoring.
  - i. When monitoring is completed, remove the sensor as follows: disconnect the sensor from the instrument cable, hold the tube portion and carefully remove the sensor from the ear canal, remove the tape.
  - j. Perform otoscopic examination.

#### WARNINGS:

During insertion, if resistance is felt, stop and pull the sensor slightly. Following in situ sensor placement no extra pressure by any external means should be applied to the sensor. Extra pressure may traumatize the tympanic membrane. In neonates and pediatric patients because of short ear canal, extra care should be applied while using this approach to monitor temperature. If the Tympanic 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 Tympanic 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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