

Instructions for Use

Skin Temperature Sensor

Thermistor: YSI 400 Series Equivalent

Cat. No.: 400-SK

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 hypo- thermia. 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 Skin Temperature Sensor is a thermistor equivalent to a 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 Starboard Medical skin temperature sensor is designed for placement on the surface of the skin. In order to minimize the interference of the ambient temperatures with the skin temperature measurement, the sensor is covered with closed cell foam and a Mylar metallic film. The thermistor temperature sensor is placed in the center of the foam cut out to prevent pressure on the skin below the sensor. The adhesive on the foam surface holds the skin sensor in situ. 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.

INDICATIONS:

The Starboard Medical Skin Temperature sensor is intended for continuous monitoring of skin temperature.

CONTRAINDICATIONS:

The Starboard Medical Skin Temperature sensor is contraindicated for usage over traumatized and hypo-perfused areas.

ADVERSE REACTIONS:

The following adverse reactions have been reported during clinical application of the skin temperature sensors:

- Skin irritations.
- Skin burns due to aberrant electro-cautery radio-frequency current pathways.

DIRECTIONS FOR USE:

1. Dry skin in the area where the sensor is to be placed.
2. Remove the paper backing, and place the sensor in the dry skin area of axilla, forehead or any other skin surface as clinically indicated.
3. Align the temperature sensor's connector with the instrument's cable connector and push firmly to assure proper contact. Forced misalignment may cause sensor to fail.

WARNINGS:

If the Skin 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 Skin 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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