STARBOARD MEDICAL, LLC

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Instructions for Use

Esophageal / Rectal Temperature Probe

Thermistor: YSI 400 Series Equivalent

Cat. No.: 4009-ER, 40012-ER

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 Esophageal / Rectal Temperature Probe 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: ±0.1˚C at 37˚C and ±0.2˚C at 5˚C and 45˚C.

The Esophageal / Rectal Temperature Probe is designed to be inserted into the esophagus, nasopharynx, or rectum. The thermistor assembly is placed inside of a PVC tube size 9 Fr or 12 Fr, with sensing tip placed at the tube's proximal end. The tube has a bullet tip which allows for atraumatic insertion and is made of medical grade PVC. 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 / Rectal temperature probes are supplied in both 9Fr and 12Fr sizes.

INDICATIONS:

The Starboard Medical Esophageal / Rectal Temperature Probe is to be used in routine continuous monitoring of esophageal or rectal temperature as an indicator of the patient's core body temperature.

CONTRAINDICATIONS:

The Esophageal / Rectal Temperature probe may be contraindicated in neonates or small infants, during: laser surgery, internal jugular artery catheterization, or tracheotomy procedures.

ADVERSE REACTIONS:

The following adverse reactions have been reported during clinical application of the Esophageal / Rectal Temperature probe:

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

DIRECTIONS FOR USE:

1. Lubricate probe prior to insertion, and place the probe *in situ* in accordance with currently accepted clinical procedures.
2. In patients requiring intubation, intubate the patient first and then insert the Esophageal / Rectal Temperature probe 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.

WARNINGS:

If the Esophageal / Rectal Temperature probe 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 / Rectal Temperature sensor and cable shall be away from the electro-cautery probes and connecting cables and, therefore, outside of the radio-frequency current field.

Note: This product has been tested for biocompatibility-Category B Prolonged Mucosal Tissue Contact (24h-30d), per ISO 10933.

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