STARBOARD MEDICAL

Instructions for Use
Skin Temperature Sensor

Thermistor: YSI 400 Series Equivalent

REF 400-SK

	Read Instructions for use
	Single patient use
	Do not use if package is damaged
	Product does not contain natural rubber latex
STERILE EO	Sterilized with Ethylene Oxide
Rx only	Federal (U.S.A.) Law restricts this device to be sold by or on the order of a physician.

DESCRIPTION:

The Starboard Medical Skin temperature sensor is designed for placement on the skin surface for routine monitoring of skin temperature. 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 a cut out on the center of the foam to reduce the risk of sensor tip pressure on the skin surface. The adhesive backed Mylar reflective foam disk holds the thermistor sensor in place on the skin surface. The accuracy of the sensor is: ±0.1˚C at 37˚C and ±0.2˚C at 5˚C and 45˚C. The Starboard Medical Skin temperature sensor is designed for use with patient temperature monitoring equipment compatible with YSI 400 Series or equivalent thermistors. The skin temperature sensor interfaces with Starboard Medical cables (C400MP-M, C400P-M, and C400MR) for connection to the temperature monitoring equipment. The skin temperature sensor is a disposable, single patient use item.

INDICATIONS:

The Starboard Medical Skin temperature sensor is indicated for continuous patient temperature monitoring when the skin placement site is clinically recommended. The sensor is designed for placement on the surface of the skin.

CONTRAINDICATIONS:

The Starboard Medical Skin temperature sensor is contraindicated for use 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.

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.

- The Starboard Medical Skin temperature sensor has not been evaluated for safety and compatibility in the MR environment
- DO NOT use sensor without sensor cover. Use without sensor cover can cause inaccurate readings and potentially lead to patient injury

DIRECTIONS FOR USE:

1. Verify the compatibility of the temperature sensor, connecting cable, and temperature monitoring equipment.
2. Remove the skin sensor from its sterile package.
3. Prepare skin by cleansing and drying the area the temperature sensor will be placed.
4. Remove the paper backing and place the sensor in the dry skin area of axila, forehead or any other skin surface as clinically indicated.
5. Connect the sensor to the appropriate reusable temperature cable. Align the connectors and push firmly together. Misalignments and forced connections may cause sensor failure.
6. Connect the cable to the temperature cable receptacle on the temperature monitoring equipment. Secure the cable to avoid pulling the temperature sensor.
7. Follow clinical best practices to reduce the risk of device related pressure injury. Do not place the sensor or cable directly under the patient.
8. Check the location of the device regularly.
9. Upon completion of temperature monitoring, carefully remove the sensor from the skin surface according to currently accepted clinical practice.
10. Disconnect the sensor from the cable by grasping both the cable connector and sensor connector firmly and pulling apart.
11. Dispose of the sensor according to facility protocol.

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