

# 3M™ SpotOn™ Temperature Monitoring System



## Frequently Asked Questions

### How does the sensor measure core body temperature?

The 3M™ SpotOn™ system uses a technique known as zero heat flux thermometry to measure the temperature of the tissue beneath the sensor. The sensor creates a layer of “perfect insulation” which prevents heat from escaping the body, thus preventing heat loss from the tissue beneath the sensor. This condition enables an isothermal tunnel to form, allowing the temperature on the skin surface to be equivalent to the core temperature where it is measured.

### How closely does the 3M SpotOn system agree with other core temperature monitoring devices?

The SpotOn system provides a direct measurement of core temperature, which, when measured at the lateral forehead, produces a clinically-acceptable agreement with gold-standard estimates of core temperature (which are typically invasive type monitors). See the results of our clinical trials showing the average difference between the PA catheter and the SpotOn system is 0.2°C.

### What clinical evidence is there to show the SpotOn sensor works?

3M has conducted two clinical trials of the SpotOn system in cardiac and general hospital patients. This data was submitted to the FDA as part of a premarket submission. The cardiac study showed that the 3M temperature monitoring system was in agreement with the PA catheter by 0.2°C.

### Can the sensor be removed and reapplied to the patient after initial placement?

The sensor is designed to be used once on a single patient and then discarded. Reattachment of the sensor may result in unreliable performance.

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## How should the skin be prepped for the sensor?

The skin at the target site should be clean and free of lesions or sunburn. An alcohol wipe should be used to clean surface oils from the skin, but the skin should be completely dry prior to placing the sensor.

## What should I do if my patient has adhesive allergies or sensitivities?

The medical-grade adhesive has undergone extensive biocompatibility testing that confirms its safety on humans. Moreover, none of the subjects in the clinical trials exhibited signs of a skin reaction to the adhesive. For patients with known atopy, the clinician should weigh the potential benefits of continuous core temperature monitoring with the SpotOn system against the potential for producing an allergic skin reaction.

## Is the sensor affected by moisture on the skin or the effects of moisture from a fever?

To date, there have been no indications that diaphoresis affects the reliability of the temperature reported by the SpotOn system.

## How does the sensor capture data?

Each sensor is embedded with a flex circuit that contains a memory chip. The average temperature at the end of every five minute increment is written to the sensor's memory for two hours – always displaying on the control unit the last two hours of data. If the sensor is disconnected, regardless of the length of time, this will be indicated on the display as a missing bar on the trend line.

## What happens to the trend data display if the procedure goes past two hours?

The trend data will always show the last two hours of patient temperature data.

## Is the SpotOn sensor latex free?

The SpotOn sensor is not constructed with natural latex rubber components.

## How does the environment affect the sensor's ability to accurately read core temperature?

The reliability of the system is not affected by changes in ambient temperature or airflow when used in typical clinical settings.

## Are there any types of patients on whom the use of the SpotOn system should be restricted?

Patients with head trauma or who are undergoing neurosurgical procedures may not be suitable candidates for the SpotOn system.



## What should be done if the sensor comes off the patient?

The best option is to place a new sensor on the patient to make sure the adhesive is sufficient and that the electronics have not been damaged in the sensor.

## Is the SpotOn sensor reusable?

No. The SpotOn sensor is disposable and designed for single patient use only.

## Does the unit or system alarm for any reason?

Any software and hardware errors that may occur are indicated on the control monitor screen. The SpotOn system does not contain an audible alarm.

## How do we clean the sensor cable?

The sensor cable should be cleaned with an approved cleaner. See the operator's manual for more information on cleaning.

## Is the SpotOn system compatible with diagnostic equipment like x-ray or MRI equipment?

The SpotOn sensor is not x-ray transparent, so it should be removed if radiographs or CT scans of the head are needed. The SpotOn sensor must be removed before an MRI procedure, as it is not MRI-safe.

## Is the SpotOn system compatible with existing patient monitors in the OR, PACU or pre-op?

Yes. The SpotOn system emulates the resistance response of a standard YSI-400 temperature sensor. The emulation cables can connect to either a standard ¼ or ⅛ -inch phone jack.

## Does the system read temperature in Celsius and Fahrenheit?

The SpotOn system can display temperatures in either Celsius or Fahrenheit. There is a toggle on the back of the unit that allows the unit to switch back and forth between Celsius and Fahrenheit, however, the trend data display is always in Celsius.

## How is the trend data shown on the screen populated with information from the patient?

The average temperature of the preceding five minute interval is written to memory on the sensor. The capacity of the memory display is two hours.





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