

# Bair Hugger for measuring core temperature during perioperative care

Medtech innovation briefing

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## Summary

- The **technology** described in this briefing is the Bair Hugger temperature monitoring system (formerly known as SpotOn). It is used for measuring core temperature in people having surgery.
- The **innovative aspects** are that it can non-invasively monitor core temperature in both awake and anaesthetised patients during the perioperative phase. Temperature is monitored by an insulated zero-heat flux sensor on the patient's forehead.
- The intended **place in therapy** would be before, during and after surgical procedures as an alternative to minimally invasive and invasive temperature monitoring.
- The **main points from the evidence** summarised in this briefing are from 7 prospective cohort studies including a total of over 513 adults who had general anaesthesia. They show that the Bair Hugger temperature monitoring system is as accurate as invasive and minimally invasive methods to monitor temperature during anaesthesia.

- **Key uncertainties** are that the evidence base is developing, both in availability and scope. There is currently no evidence linking temperature measurement using this device and changes in clinical outcomes.
- The **cost** of the Bair Hugger temperature monitoring system is £250 per unit (provided at no extra cost if enough consumables are bought) and the single-use sensors are £7.46 (exclusive of VAT). The resource impact is likely to be similar to standard care. Invasive measures that directly estimate core temperature cost between £2 and £7 for single-patient use and between £103 and £160 for re-useable devices.

## The technology

The Bair Hugger temperature monitoring system (3M UK) is a non-invasive device that can accurately and continuously measure the patient's core body temperature before, during and after surgery (known collectively as the perioperative phase). The system consists of a single-use zero-heat flux sensor and a reusable sensor cable, control unit and power supply. An optional monitor cable is also available for connection to other patient monitoring systems. The sensor is placed on the patient's forehead and is held in place by an adhesive backing. It is connected to the control unit through the sensor cable. If needed, it can be disconnected and reconnected to a different sensor cable and control unit each time the patient is moved to a different location. The system was marketed as SpotOn until 2016.

The control unit shows the patient's current temperature and a graphical display of up to 2 hours of previous temperature data. The current temperature can also be displayed on a patient vital signs monitor if connected by the optional cable.

The single-use sensor consists of a thermal insulator next to the skin that is covered by a flex circuit containing a heating element. The temperature of the sensor is regulated by the Bair Hugger temperature monitoring system in the control unit. The thermal insulator is designed to prevent heat loss to the environment. This establishes an isothermal pathway under the sensor, bringing the core temperature to the skin surface and enabling the temperature to be recorded and monitored. The sensor takes several minutes to reach this temperature balance.

The control unit, sensor and mains cables are cleaned after each use. The control unit needs verification every 12 months, or in accordance with the NHS trust's own maintenance protocol. A calibration verification stick is needed for this.

## Innovations

Because it is not invasive, the Bair Hugger temperature monitoring system can directly monitor core temperature in both awake and anaesthetised patients throughout the perioperative phase. Typically, invasive core temperature monitoring systems can only be used with heavily sedated or anaesthetised patients, with minimally invasive technologies used on conscious patients pre- and post-operatively.

Minimally invasive methods only provide indirect estimates of core temperature and are monitored and recorded at set intervals, for example every 15 or 30 minutes. The continuous temperature display and 2-hour temperature recording by the Bair Hugger temperature monitoring system allow changes in temperature to be detected immediately so that any appropriate management can be considered. The company claims that by using a single sensor that stays on the patient, any variability in measurement between different healthcare professionals or monitoring devices is avoided.

## Current NHS pathway

People having surgery under regional or general anaesthesia are at risk of developing hypothermia. Hypothermia can occur before, during and after surgery. Inadvertent perioperative hypothermia occurs frequently but is preventable and can be treated.

As an aid to prevention and detection of hypothermia, the patient's temperature is monitored during the perioperative phase. According to NICE's guideline on [hypothermia](#), the temperature should be monitored and recorded in the hour before surgery, before the anaesthesia is induced and then every 30 minutes until the end of surgery. The temperature should then be monitored and documented on admission to the recovery room and then every 15 minutes. Once on the ward, the temperature should be recorded every 4 hours.

During surgery a direct estimate of core temperature can be monitored accurately through invasive methods such as oesophageal, nasopharyngeal, rectal or pulmonary artery catheters. Other direct estimates of core temperature include zero-heat flux sensors (such as Bair Hugger), and oral or axilla measures which can be used in the perioperative phase. In the pre- and post-surgery periods temperature is usually measured at intervals with minimally invasive methods such as oral thermometers, although tympanic thermometers (indirect measures) may also be used. NICE's guideline on [hypothermia](#) recommends that adjustments may need to be made to indirect minimally invasive recorded temperature to

obtain the core temperature, and that indirect estimates of core temperature should not be used during surgery. In 2010, the national patient safety agency (now NHS Improvement) released [guidance](#) stating that the method used for taking the temperature should be clearly identified and recorded.

NICE is not aware of any CE-marked devices that appear to fulfil a similar function as the Bair Hugger temperature monitoring system.

## Population, setting and intended user

The Bair Hugger temperature monitoring system is intended for use during perioperative care by anaesthetists, recovery room nurses and ward nurses in a secondary care setting. It is used by the same clinical staff who currently monitor a patient's temperature in the perioperative setting.

It can be used for children and adults having planned and emergency surgery. NICE's guideline on [hypothermia](#) states that hypothermia (core body temperature below 36°C) can occur in people having surgery and can lead to a poor outcome including infection. The risk of hypothermia is greater with longer, more invasive surgery, in older people and in those with other illnesses ([Hart et al. 2011](#); [Baquero et al. 2015](#)).

Minimal extra training is needed to use the Bair Hugger temperature monitoring system; this training is provided by the company in person and at no additional cost.

## Costs

**Table 1 Device costs excluding VAT**

Description	Cost	Additional information
Single-use sensor	£7.46 each £186.50 for box of 25	Supplied in boxes of 25, 1 sensor is used per patient operation.

Control unit	£250.00	Includes sensor cable, power pack and 2 monitor cables (if not compatible, additional monitor cables are available at £60 each). Offered at no extra charge if at least 2 boxes of consumables are bought per unit per year.
Calibration verification stick	£65.00	One needed to calibrate the control unit every 12 months.

## Costs of standard care

Electronic thermometers for oral or axilla use (costing around £116 to £276 depending on functionality) are re-useable, minimally invasive devices that are commonly used to directly estimate core temperature. They are normally used with single-use covers, which cost between £0.27 and £0.54 for each temperature measurement taken. Tympanic thermometers (indirect estimate) cost around £18 to £30 per device.

Disposable invasive devices (direct estimates of core temperature) include nasopharyngeal temperature probes, oesophageal probes and rectal probes, which cost between £2 and £7. Re-useable rectal or oesophageal probes cost between £103 and £160.

## Resource consequences

The Bair Hugger temperature monitoring system is currently used by 3 NHS trusts.

If adopted, Bair Hugger would replace existing methods of measuring temperature perioperatively. Significant changes to current facilities or infrastructure are unlikely to be needed.

By accurately and continuously monitoring core temperature, there is the potential to reduce rates of hypothermia which could result in savings through a reduction in associated complications and hospital stay.

## Regulatory information

The Bair Hugger temperature monitoring system was CE marked as a class IIa device in February 2013 and revised in August 2016.

A search of the Medicines and Healthcare products Regulatory Agency website revealed that no manufacturer field safety notices or medical device alerts have been issued for this technology.

## Equality considerations

NICE is committed to promoting equality, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. In producing guidance and advice, NICE aims to comply fully with all legal obligations to: promote race and disability equality and equality of opportunity between men and women, eliminate unlawful discrimination on grounds of race, disability, age, sex, gender reassignment, marriage and civil partnership, pregnancy and maternity (including women post-delivery), sexual orientation, and religion or belief (these are protected characteristics under the Equality Act 2010).

The risk of hypothermia in the perioperative phase is greater in older people. Age is a protected characteristic under the Equality Act 2010.

## Clinical and technical evidence

A literature search was done for this briefing in accordance with the [interim process and methods statement](#). This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting [mibs@nice.org.uk](mailto:mibs@nice.org.uk).

## Published evidence

Seven studies are summarised in this briefing, including over 513 patients (1 study did not report the number of patients and so the exact total is not clear). All studies compared the Bair Hugger temperature monitoring system with either invasive core temperature

monitoring or minimally invasive temperature monitoring. The level of agreement between the devices was high. The manufacturer has re-branded the device since these studies were published but there have been no changes to the technology itself (previously known as SpotOn).

Table 2 summarises the clinical evidence as well as its strengths and limitations.

## Overall assessment of the evidence

The evidence base is developing, both in availability and scope. It is currently focused on measurement accuracy compared with other temperature monitors and not on changes in patient management or outcomes. Only 3 studies have been published in full; others are only available as abstracts which give limited details about the studies.

Studies assessing clinical outcomes would improve the evidence base. These outcomes could include rates of hypothermia, recovery from surgery and length of hospital stay.

### Table 2 Summary of clinical evidence

<u>Cullen (2016)</u>	
Study size, design and location	Audit study, prospective data collection from 2 theatres in the UK. 221 intraoperative temperature measurements.
Intervention and comparator(s)	SpotOn temperature monitoring system compared with bladder or pharyngeal core temperature measurement.
Key outcomes	Paired temperature bias (difference in temperature) was 0.1°C (95% limits of agreement $\pm 0.73^\circ\text{C}$ ).
Strengths and limitations	Abstract only, minimal data given, no details of the patients or surgery type. Temperature values taken at 4 time points only. Funding source not reported.
<u>Maniken et al. (2016)</u>	

Study size, design and location	30 patients Prospective cohort study Finland
Intervention and comparator(s)	SpotOn temperature monitoring system Model 370 (all patients). Mon-a-therm Foley with temperature sensor 400 series, urinary bladder (all patients). Mon-a-therm general purpose temperature probe 400 series inserted into lower oesophagus (during vascular surgery, n=15) or nasopharynx and pulmonary artery (during cardiac surgery, n=15). Swan-Ganz pulmonary artery temperature probe (cardiac surgery, n=15).
Key outcomes	Agreement was good between SpotOn and oesophageal temperature during vascular surgery, between SpotOn and pulmonary artery temperature during cardiac surgery (off cardiopulmonary bypass), and between SpotOn and nasopharyngeal temperature during cardiac surgery (on and off cardiopulmonary bypass). Agreement in 1 patient during induced hypothermia below 32°C was poor.
Strengths and limitations	The study used automated, continuous temperature monitoring and included patients having 2 different types of surgery. However, the sample sizes in the 2 groups were small. Author has links with manufacturer, device supplied by manufacturer.
<u>Jack et al. (2016)</u>	
Study size, design and location	29 patients Prospective cohort study UK
Intervention and comparator(s)	SpotOn Oesophageal temperature probe
Key outcomes	Good level of agreement (difference between devices was 0.024 °C).

Strengths and limitations	Temperature values taken every minute. Small study, published as abstract only, minimal data given, no details of patients. Funding source not reported.
<u>Arunachalam et al (2015)</u>	
Study size, design and location	166 patients Prospective cohort study UK
Intervention and comparator(s)	SpotOn thermometer Tympanic membrane thermometer, no further details provided; assume this is surface temperature.
Key outcomes	Good concordance between temperatures taken by the SpotOn thermometer and tympanic membrane thermometer.
Strengths and limitations	Large prospective study but published as an abstract only. Few details of patients or when temperatures were recorded. Part of a bigger study of perioperative practice. Comparator was not measuring core temperature although the authors state this is their standard practice. Manufacturer helped in data collection, analysis and provided SpotOn recording devices.
<u>Iden et al. (2016)</u>	
Study size, design and location	83 patients Prospective cohort study Germany
Intervention and comparator(s)	SpotOn Nasopharyngeal probe Sublingual probe
Key outcomes	Bias was 0.1°C or less compared with the nasopharyngeal probe and -0.37°C or less compared with the sublingual probe.
Strengths and limitations	Large, powered, prospective study including patients having 2 types of surgery. Temperature was taken at 3 time points only. 3.3% of patients were excluded because of SpotOn failure and 16% because of sublingual probe calibration failure. A further 12% were excluded from the analysis. Funded by the manufacturer.

<u>Eshraghi (2014)</u>	
Study size, design and location	105 patients Prospective cohort study US
Intervention and comparator(s)	SpotOn prototype Pulmonary artery catheter
Key outcomes	The overall mean difference (bias) was $-0.23^{\circ}\text{C}$ . Differences of $0.5^{\circ}\text{C}$ or less were seen between SpotOn and pulmonary artery catheter temperatures in 78% to 84% of measurements.
Strengths and limitations	Large prospective study using continuous temperature monitoring. 2 patients were excluded because of sensor failure. Data from a further 6 patients were excluded because of temperatures indicating sensor or software problems. Relevance of comparator to UK practice is unclear. Funded by the manufacturer.
<u>Searle et al. (2014)</u>	
Study size, design and location	100 patients Prospective cohort study UK
Intervention and comparator(s)	SpotOn Infra-red tympanic thermometer, no further details, assume surface temperature.
Key outcomes	Both methods showed similar averages. SpotOn had lower variability suggesting less random error.  Overall, 25% of patients were preoperatively labelled 'normothermic' by tympanic measures, when hypothermic according to SpotOn.  In recovery, SpotOn showed earlier recognition of normothermia.
Strengths and limitations	Large prospective study but published as an abstract only, minimal data given, no details of the patients. Temperature values taken half hourly. Comparator was not measuring core temperature. Funding source not reported.

## Recent and ongoing studies

- Central temperature monitoring by zero-heat flux a non-invasive technic compared to two invasive technic during surgery. ClinicalTrials.gov identifier: NCT02869828. Status: recruiting. Indication: major surgery in adult patients. Devices: SpotOn, arterial catheter, oesophageal probe.
- Effectiveness of SpotOn to prevent inadvertent perioperative hypothermia and their consequences. ClinicalTrials.gov identifier: NCT02511080. Status: recruiting. Indication: hypothermia. Devices: SpotOn.

## Specialist commentator comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not represent NICE's view.

One of 3 specialist commentators had used this technology occasionally before.

## Level of innovation

All 3 specialist commentators considered the Bair Hugger temperature monitoring system to be a novel concept for core temperature measurement.

## Potential patient impact

One specialist commentator felt that it was potentially of benefit to all patients having anaesthesia because it is less invasive than other core thermometers, as well as being accurate and user-friendly. One specialist commentator thought that groups of people who may particularly benefit are patients having orthopaedic, colorectal or spinal surgery. This is because there is an increased risk of surgical site infection and, in the case of orthopaedic surgery, the patient is often awake during the procedure so invasive temperature monitoring is inappropriate.

Two specialist commentators suggested that more accurate core temperatures in awake patients may reduce the number of complications from inadvertent perioperative hypothermia. They felt that if used proactively to prevent hypothermia, there could be

improved patient health outcomes by encouraging warming interventions, particularly preoperatively. Preoperative warming of patients reduces the risk of hypothermia during induction of an anaesthetic. Maintaining normal temperature in the perioperative phase can reduce the incidence of surgical site infection, prevent delayed wound healing, and reduce blood loss. These may all lead to a reduction in the length of stay in the recovery room and also reduce hospital stay. Promoting more active warming in the perioperative journey may also increase patient comfort and patient satisfaction.

One specialist commentator felt that it could be used for targeted temperature management as part of post-cardiac arrest care. Currently, the device is only promoted for perioperative care. The specialist commentators did not identify any other groups of people with specific conditions who would particularly benefit from Bair Hugger.

One specialist commentator noted that some patients may find the device uncomfortable and restrictive in the period of monitoring before and after surgery. They noted that it is also unclear whether there are any infection risks or tissue viability issues if the adhesive sensor is attached for a prolonged period of time. The size and positioning of the sensor may be prohibitive in people having head or face surgery, or in children. Two specialist commentators stated that complications from core temperature probes could be reduced, although one specialist commentator noted that the number of these is low.

## Potential system impact

Specialist commentators thought that using the Bair Hugger temperature monitoring system would have minimal impact on NHS services. They also did not believe it would lead to direct cost savings. Two specialist commentators noted that the device is more expensive than current technologies, but that it could make health care professionals more aware of inadvertent perioperative hypothermia. This would help ensure hypothermia is treated appropriately, potentially reducing costs by reducing complications.

## Specialist commentators

The following clinicians contributed to this briefing:

- Mr Tim Baker, practice educator, Adult Intensive Care Unit, University Hospital of South Manchester NHS Foundation Trust. No conflicts of interest.

- Dr Mark Harper, consultant anaesthetist, Royal Sussex County Hospital. Dr Harper has received honoraria for attending advisory panels from the manufacturer and competitor manufacturers, was a member of the NICE clinical guideline on inadvertent perioperative hypothermia; and received loan equipment in order to carry out clinical trials from the manufacturer and competitor manufacturers.
- Ms Joanne Kay, operating department practitioner and deputy team leader, Nottingham University Hospitals Trust. No conflicts of interest.

## Development of this briefing

This briefing was developed for NICE by Birmingham and Brunel Consortium. The [interim process and methods statement](#) sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

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