Clinical Evidence Summary

3M™ Bair Hugger™ Temperature Monitoring System
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<td>Zaballos JM, Salinas U, Guipuzcoa P. Clinical Evaluation of Spot-On(R), a New Non-invasive and Continuous Temperature Monitoring System. ASA Abstracts. 2014;A4270.</td>
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<tr>
<td>Evans M, Davis P, McCarthy D, Van Duren A, Morse DJ, Strom C. <em>3M™ SpotOn™ Temperature Monitoring System versus Nasopharyngeal Temperature Monitoring in Pediatric Surgical Patients</em>. Presented at the Post Graduate Assembly of Anaesthesiology. 2014.</td>
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</table>
The 3M™ Bair Hugger™ temperature monitoring system can non-invasively measure core temperature.


**BACKGROUND**
Current methods to monitor core temperature are invasive. This study compared a new zero-heat-flux thermometer compared to a pulmonary artery catheter.

**DESIGN**
Observational study

**POPULATION**
105 patients undergoing nonemergent cardiac surgery, excluding the period of cardio pulmonary bypass (CPB).

**METHODS**
Core temperature was measured with both a pulmonary artery catheter and a non-invasive zero-heat-flux sensor. Patient core temperature was recorded every minute following anesthesia induction, and for four-hours postoperatively. A bias analysis was used to compare the two devices. Temperature differences of >0.5°C were considered clinically significant.

**CONCLUSION**
Core temperature can be measured non-invasively with zero-heat-flux technology. The 3M™ Bair Hugger™ temperature monitoring system’s core temperature readings were in agreement with pulmonary artery temperature, with a bias of <0.23°C.

Cardiac Trial Data - 105 Subjects; 36,000 data pairs
Mean error (TZHF-TPA) = -0.23°C; 95% LOA = ±0.8 °C
**BACKGROUND**

The goal of this study was to compare core body temperature using a new non-invasive method compared to conventional methods.

**DESIGN**

Prospective, observational study

**POPULATION**

30 total patients: 15 patients undergoing vascular surgery for lower extremities and 15 patients undergoing cardiac heart surgery on cardiopulmonary bypass

**METHODS**

Patient temperatures were simultaneously measured with a non-invasive zero heat flux (ZHF) temperature sensor (3M™ Bair Hugger™ system) on the forehead and esophageal during vascular surgery, and nasopharyngeal and pulmonary artery during cardiac surgery.

*Formerly known as the 3M™ SpotOn™ system.

**CONCLUSION**

This study demonstrated agreement with core body temperatures measured using the non-invasive Bair Hugger temperature monitoring system comparable to esophageal, nasopharyngeal and pulmonary artery with temperatures ≥34°C.

The 3M™ Bair Hugger™ temperature monitoring system is a reliable, non-invasive method to measure deep body temperature.

<table>
<thead>
<tr>
<th>Method Comparison</th>
<th>Mean Difference (°C)</th>
<th>95% Limits of Agreement</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZHF vs. Esophageal</td>
<td>+0.08°C</td>
<td>-0.25 to +0.40°C</td>
</tr>
<tr>
<td>ZHF vs. Pulmonary Artery</td>
<td>-0.05°C</td>
<td>-0.56 to +0.47°C</td>
</tr>
<tr>
<td>ZHF vs. Nasopharyngeal</td>
<td>-0.12°C</td>
<td>-0.94 to +0.71°C</td>
</tr>
</tbody>
</table>

+0.08°C Vascular Surgery
-0.05°C Cardiac Surgery (Off CBP)
-0.12°C Cardiac Surgery (On & Off CBP)
The 3M™ Bair Hugger™ temperature monitoring system was found to provide clinically sufficient accuracy.

BACKGROUND
Pulmonary artery blood temperature is considered the gold standard in core temperature monitoring. This study aims to evaluate pulmonary artery blood temperature compared to a non-invasive zero heat flux thermometry method.

DESIGN
Prospective, observational

POPULATION
20 postoperative cardiac surgical patients in the ICU.

METHODS
Each patient was connected to both a pulmonary artery thermistor catheter, urinary catheter thermistor and the 3M™ Bair Hugger™ sensor*. Temperatures were recorded at one-minute intervals following admission to the ICU. The mean duration of temperature measurement was 86-minutes (range, 251-2,283 min), and a total of 16,407 data points were collected for analysis.

The authors in this study found that the 3M™ Bair Hugger™ System, which uses zero-heat flux thermometry, provides clinically sufficient accuracy for measuring core body temperature. However, the accuracy is inferior to that of pulmonary artery catheter.

CONCLUSION
Mean Average Difference of Temperature

<table>
<thead>
<tr>
<th></th>
<th>ZHF vs. Pulmonary Artery Thermistor Catheter</th>
<th>ZHF vs. Urinary Thermistor Catheter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Average Difference of Temperature</td>
<td>-0.28°C</td>
<td>-0.22°C</td>
</tr>
<tr>
<td>79%</td>
<td>95%</td>
<td>of the differences were ≤0.5°C</td>
</tr>
<tr>
<td>of the differences</td>
<td></td>
<td>of the differences were ≤0.5°C</td>
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*Formerly known as the 3M™ SpotOn™ system.

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Zero-heat-flux thermometry is an effective, non-invasive alternative to accurately measure core temperature

BACKGROUND
Core temperature should be measured throughout the perioperative process. However, not all non-invasive devices accurately measure core temperature. The study aimed to determine reliability of core temperature in the OR with the 3M™ Bair Hugger™ system using zero-heat-flux (ZHF) technology and an esophageal temperature probe, and to compare agreement to oral thermometry in pre- and post-op.

DESIGN
Prospective, observational

POPULATION
369 patients undergoing general anesthesia for general, orthopedic, plastic or urology surgery

METHODS
Temperatures were measured with both oral and zero heat flux thermometry (3M™ Bair Hugger™ temperature monitoring system*) starting in pre-op and continuing through post-op. In the OR, temperatures were measured with both esophageal and zero heat flux thermometry.

CONCLUSION
This study demonstrated that the non-invasive Bair Hugger system, which uses zero-heat-flux (ZHF) thermometry, is an effective method to accurately measure core temperature comparable to esophageal and oral temperature.

Absolute Difference of Temperature Pairs
\[ \leq 0.5^\circ C \text{ (% [95% CI])} \]

<table>
<thead>
<tr>
<th>Time</th>
<th>ZHF vs. Oral</th>
<th>ZHF vs. Esophageal</th>
<th>ZHF vs. Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Op</td>
<td>-0.25°C</td>
<td>+0.15°C</td>
<td>-0.22°C</td>
</tr>
<tr>
<td>Intra-Op</td>
<td>68%</td>
<td>84%</td>
<td>70%</td>
</tr>
<tr>
<td>PACU Admit</td>
<td>75%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PACU D/C</td>
<td>70%</td>
<td></td>
<td></td>
</tr>
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The 3M™ Bair Hugger™ system is a clinically acceptable temperature monitoring method

BACKGROUND
There is a clinical need for an accurate and consistent temperature monitoring method for surgical patients under general or regional anesthesia. This study aimed to evaluate zero heat flux (ZHF) thermometry to an esophageal temperature probe.

DESIGN
Prospective, observational study

POPULATION
34 patients undergoing general, thoracic, orthopedic, ear nose and throat (ENT), urology and neurosurgical procedures

METHODS
Temperatures were recorded at 10 minute intervals from anesthesia induction until the end of surgery. The esophageal probe was placed after induction of anesthesia and served as the reference for core body temperature. The ZHF sensor (3M™ Bair Hugger™ system*) was placed on the forehead and allowed to equilibrate for 10 minutes.

CONCLUSION
Overall, the average difference between Bair Hugger system temperatures and esophageal temperatures was 0.03°C (95% limits of agreement of -0.35/+0.41). These results demonstrated that the Bair Hugger system is a clinically acceptable way to non-invasively measure perioperative core temperature.

*Formerly known as the 3M™ SpotOn™ system.

The core temperature measured by the ZHF method is comparably reliable to esophageal and arterial temperatures measured by a femoral artery catheter.

**BACKGROUND**
Esophageal or arterial temperature monitoring methods are considered reliable, but these devices are invasive. The study aimed to compare accuracy of zero heat flux (ZHF) thermometry to esophageal and arterial temperature using a femoral artery catheter in ICU patients.

**DESIGN**
Prospective study

**POPULATION**
52 ICU and Neuro ICU patients over a 4-month period

**METHODS**
Patient temperatures were simultaneously measured with both an esophageal probe and a non-invasive temperature sensor using ZHF technology. Temperatures were recorded from one to five days, and a total of >62,000 pairs of temperature were collected.

*Formerly known as the 3M™ SpotOn™ system.

**CONCLUSION**
The investigators analyzed >62,000 pairs of temperature to determine that the ZHF method of core temperature monitoring with the Bair Hugger system offers a comparable reliability to esophageal or arterial temperatures in ICU patients.

**Absolute Difference of Temperature Pairs ≤ 0.5°C (% [95% CI])**

- ZHF vs. Esophageal surface: 92.6% (95% CI, 91.9-93.4)
- ZHF vs. Arterial surface: 99.8% (95% CI, 95.3-100.0)
- ZHF vs. Arterial esophageal: 99.8% (95% CI, 95.3-100.0)
BACKGROUND
Measuring core body temperature during surgery is an important way to ensure unintended hypothermia is prevented. Accurate and invasive measurements are not suitable for all patients. The study aimed to evaluate the accuracy of zero heat flux (ZHF) thermometry to sublingual and nasopharyngeal methods.

DESIGN
Observational study

POPULATION
83 patients undergoing elective gynecological or trauma surgeries under general anesthesia

METHODS
Patient temperature was monitored following anesthesia induction, and measured at 15, 45, and 75 minutes using a sublingual probe, nasopharyngeal probe and a Bair Hugger temperature sensor.

CONCLUSION
The Bair Hugger temperature monitoring system is an acceptable clinical method to monitor core temperature compared to nasopharyngeal and sublingual thermometers. Temperatures for the Bair Hugger sensor were nearly identical to nasopharyngeal temperatures (mean difference 0.07°C; \(P=0.1424\)), and slightly lower than sublingual temperatures (mean difference -0.35°C; \(P<0.0001\)).

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The 3M™ Bair Hugger™ system can help reduce or eliminate the disadvantages associated with invasive methods


BACKGROUND
Current methods of temperature monitoring are invasive and offers disadvantages including placement technique, patient discomfort, risk of injury and inconsistent methodologies used in the OR, PACU, or ICU. The Bair Hugger temperature monitoring system was studied to demonstrate accuracy compared to nasopharyngeal.

DESIGN
Non-blinded, non-randomized, comparative research study

POPULATION
20 pediatric patients undergoing non-emergent urology, orthopedic or general abdominal surgery

METHODS
Temperatures were simultaneously measured using both nasopharyngeal and the 3M™ Bair Hugger™ temperature monitoring system*. Temperatures were recorded from anesthesia induction, and every 5-10 minutes in the OR.

CONCLUSION
Overall, the average bias between the 3M™ Bair Hugger™ system and nasopharyngeal temperatures was small at 0.28°C. In addition, the non-invasive method helps to reduce or eliminate the disadvantages associated with nasopharyngeal temperature monitoring including placement technique, patient discomfort, risk of injury, cross-contamination and inconsistent methodologies across departments.

*Bland-Altman Results

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3M™ Bair Hugger™ system is an accurate way to demonstrate early and accurate recognition of hypothermia.


BACKGROUND
Accurate and reliable temperature monitoring methods are important in order to detect unintended hypothermia which is associated with negative outcomes.

DESIGN
Prospective single-center trial

POPULATION
100 patients undergoing surgery for >30 minutes

METHODS
Patient temperatures were simultaneously measured using infra-red tympanic thermometry and the 3M™ Bair Hugger™ temperature monitoring system for a total of 509 paired readings. The mean operative time was 64 minutes and the mean recovery time was 29 minutes.

CONCLUSION
The 3M™ Bair Hugger™ system demonstrated significant correlation to tympanic readings in the OR (P = 0.02), and in recovery (P<0.001).

The Bair Hugger system also demonstrated early and accurate recognition of hypothermia compared to tympanic. The ability to provide early detection of hypothermia may help improve patient throughput and reduce costs.

Mean Difference (°C) 0.1°C (95% limits of agreement -1.2 to +1.1°C)

Operating Room
27% of patients listed as normothermic with tympanic were hypothermic when measured with the Bair Hugger system.

Recovery Room
75% of patients listed as hypothermic with tympanic were normothermic when measured with the Bair Hugger system.

*Formerly known as the 3M™ SpotOn™ system.

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The 3M™ Bair Hugger™ system has good agreement with invasive temperature thermometry methods used in the ICU.

**BACKGROUND**
Maintaining normal body temperature of patients in the ICU is important. However, common methods of continuous temperature monitoring are invasive. A recently available non-invasive temperature monitoring system using zero heat flux (ZHF) technology was tested for agreement and precision compared to other thermometry methods.

**DESIGN**
Method comparison design

**POPULATION**
36 febrile (≥38.3°C) patients in the ICU

**METHODS**
Patient temperatures were simultaneously measured over four hours with a ZHF sensor (3M™ Bair Hugger™ temperature monitoring system*) and either rectal (n=28) or urinary bladder (n=8) thermometry methods.

<table>
<thead>
<tr>
<th></th>
<th>ZHF and Rectal</th>
<th>ZHF and Bladder</th>
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<tbody>
<tr>
<td>Bias</td>
<td>-0.24 ± 0.29°C</td>
<td>-0.02 ± 0.20°C</td>
</tr>
<tr>
<td>95% Limits of Agreement</td>
<td>-0.81 to 0.33°C</td>
<td>-0.41 to 0.37°C</td>
</tr>
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</table>

*Formerly known as the 3M™ SpotOn™ system.

**CONCLUSION**
The results of this study indicate that the 3M™ Bair Hugger™ temperature monitoring system has both good agreement with precision to invasive methods, i.e. rectal, urinary bladder, for as a way to non-invasively measure core temperature in febrile ICU patients.

Zero Heat Flux presents the advantage of being noninvasive allowing its use early before anesthesia induction.


BACKGROUND
This study was designed to compare the differences between esophageal, tympanic, and a new non-invasive zero heat flux (ZHF) thermometry method.

DESIGN
Prospective, observational

POPULATION
50 patients undergoing laparoscopic urologic surgery

METHODS
Temperatures were simultaneously recorded eight times per patient with a ZHF sensor (3M™ Bair Hugger™ temperature monitoring system*), an esophageal probe (Philips 21090A) and a tympanic probe (Welch Allyn Braun Thermoscan® PRO 4000). The investigators statistically analyzed temperatures for both correlation and accuracy.

CONCLUSION
The new, non-invasive ZHF method offered by the 3M™ Bair Hugger™ system is a reliable and accurate method for temperature monitoring. In addition, the non-invasive method offers an additional advantage of esophageal as the probe can be placed in advance of anesthesia induction.

There was a high correlation with esophageal thermometry, but a weak to moderate correlation with tympanic. The authors observed low accuracy with tympanic which they suggest may be biased by external surface warming that increases ear temperature but does not accurately reflect core temperature.

Thermoscan® is a registered trademark of Welch Allyn® *Formerly known as the 3M™ SpotOn™ system.

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Degrees matter, beginning with the degree of care you provide before, during, and after surgery.

At 3M, we use science to help you influence the most important aspects of a patient’s experience — the outcomes — with clinically proven solutions that help safeguard them during surgery.

The 3M™ Bair Hugger™ Temperature Monitoring System is an accurate, noninvasive, easy-to-use temperature monitoring system that continuously measures patients’ core body temperature and provides standardization throughout the perioperative journey.

For additional information, please contact your 3M representative, call 800-228-3957, or visit bairhugger.com.