

# Summary of Research Supporting Air-Free HotDog® Patient Warming



This Research Summary is organized into four sections:

1. **Effectiveness** of the HotDog Patient Warming System
2. **Safety** of Air-Free Warming Versus Forced-Air Warming
  - a. Forced-Air Warming Blowers Contaminated
  - b. Waste Heat Contamination
  - c. Waste Heat Linked to Infection
  - d. Forced-Air Warming Discontinued: Infection Rates Drop
3. **Clinical Benefits** of Intra-Operative Normothermia
4. **Cost** of Hypothermia-Caused Complications

The HotDog® Patient Warming System utilizes a semi-conductive polymer fabric to safely and effectively provide perioperative warming to surgical patients without blowing air. The proprietary technology is most often referred to as Conductive Fabric Warming. Other researchers have called it Resistive-Polymer Warming, Radiant Warming, Conductive Blankets, and Electric Warming.

## HotDog Effectiveness:

### Resistive-Polymer Versus Forced-Air Warming: Comparable Heat Transfer and Core Rewarming Rates in Volunteers.

Kimberger, O.; et al. *Anesth Analg* 2008; 107: 1621-26

| Company Support

**SUMMARY:** The full body HotDog blanket was compared with full body forced-air warming blankets in re-warming anesthetized hypothermic volunteers in a controlled cross-over study. The warming rates of the two technologies were virtually identical.

### Resistive-Polymer Versus Forced-Air Warming: Comparable Efficacy in Orthopedic Patients.

Brandt, S.; Kimberger, O.; et al. *Anesth Analg* 2010; 110:834-8.

| Company Support

**SUMMARY:** 80 orthopedic surgery patients were randomized to forced-air warming (FAW) or resistive polymer warming (HotDog) upper body blankets during surgery. The warming rates were comparable for the two groups. No differences in mean skin and core temperatures. The waste heat from FAW also caused the environment of anesthesia's workspace to be 1.8°C warmer in that group. "Resistive polymer warming performed as efficiently as FAW in patients undergoing orthopedic surgery."

### Relative clinical heat transfer effectiveness: Forced-air warming vs. Conductive fabric electric warming

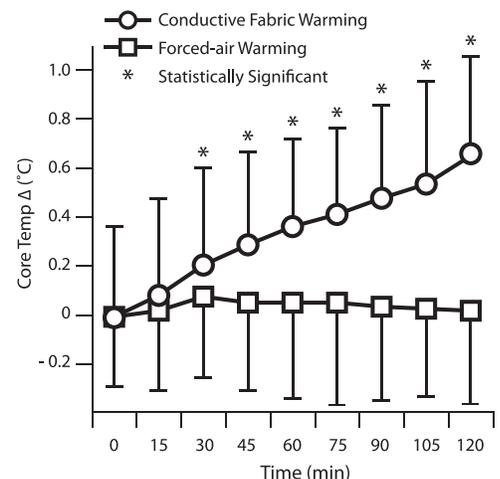
Hayashi, H.; Koizumi, T.; Sumta, S.; Yamakage, ASA abstract 2015. Submitted for publication.

| No Company Support

**SUMMARY:** The heat transfer capability for patient warming technologies is largely determined by two factors: 1.) conductive vs convective; and 2.) surface area of warming. [HotDog] conductive fabric electric warming (CFW) relies on conductive heat transfer and roughly doubles the body surface area in contact with the heat by utilizing over-body blankets and underbody mattresses.

In this prospective randomized controlled trial, conductive fabric warming (Hot-Dog) showed significantly higher warming rates than forced-air warming (FAW) (0.35°C/hr vs 0.02°C/hr), when all other relevant variables were held constant. The temperature difference between the two groups was statistically significant at each data point after 30 minutes.

The authors' conclusion: "We conclude from these data that the clinical heat transfer effectiveness of [HotDog warming] is significantly greater than FAW convection. This is due to the combination of conductive heat transfer and the larger surface area of simultaneously heating from above and below the patient."



## Safety of Air-Free Versus Forced-Air Warming

### Forced-Air Warming Blowers Contaminated:

#### **Forced-air warming blowers: An evaluation of filtration adequacy and airborne-contamination emissions in the operating room**

Albrecht, M.; Leaper, D.; et al: American Journal of Infection Control, 2011; 39:321-8.

| Company Support

**SUMMARY:** 52 forced-air blowers sampled in their operating room environments. Micro-organisms were cultured from the internal air-flow paths of 92.3% of the blowers. 58% of the blowers tested were found to be internally generating and emitting significant levels of airborne contaminants >0.3  $\mu$  m in size (germ size), up to 35,272 particles per ft<sup>3</sup> of air (80 million particles per hour).

#### **Forced-air warming design: Evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions**

Reed, R.; McGovern, P.; Guathier R.; et al: JAANA. 2013;81(4).

| Company Support

**SUMMARY:** 23 forced-air blowers were sampled in their operating room environments. Micro-organisms were cultured from the internal air-flow paths of 100% of the blowers. 100% of the blowers were emitting internally generated particles >0.3  $\mu$ m in size, up to 112,000 particles per ft<sup>3</sup> of air (300 million particles per hour). Emitted particle count was 40 times greater than the intake particle count for that blower, and virtually all of the emitted particles were internally generated.

#### **Forced-air warming: a source of airborne contamination in the operating room?**

Leaper, D.; Albrecht, M.; Gauthier, R.; Orthopedic Reviews 2009; 1:e28.

| Company Support

**SUMMARY:** 25 Bair Hugger blowers sampled in their operating room environment. Pathogenic bacteria were cultured from the internal airflow paths of 94% of the blowers. 32% of the blowers tested were emitting internally generated airborne contamination in the size range of bacteria. 24% of the blowers tested were emitting "significant levels of internally generated airborne contamination." "...findings in this study and those of others suggest that bacteria colonize the internal air path surfaces of the majority of FAW blowers. The findings also suggest that a significant percentage of FAW blowers are emitting particulates, which were shown to originate inside the blowers." "Clinicians should be aware that FAW blowers emit more than just hot air..."

#### **Skin Contamination Following use of a Forced-air Warming Device.**

Hamilton KR. Poster Presentation. American Association of Nurse Anesthetists Annual Meeting, 2016.

| No Company Support

**SUMMARY:** In this 30 patient study, 47% of forced-air warming blanket interiors were contaminated (culture positive) by organisms originating in the Bair Hugger blowers. 10% of the patients experienced skin that was contaminated (culture positive) by organisms originating in the Bair Hugger blowers.

#### **Persistent *Acinetobacter baumannii*? Look Inside Your Medical Equipment.**

Bernards AT et al. Infection Control and Hospital Epidemiology. 2004;25:1002-1004.

| No Company Support

**SUMMARY:** The authors reported two multidrug-resistant *Acinetobacter baumannii* outbreaks in their hospital that were genetically linked to organisms growing in several pieces of medical equipment including Bair Hugger forced-air blowers. The first outbreak was controlled by disinfecting the internal airflow path of the Bair Hugger blowers.

### Waste Heat Contamination:

#### **Effect of forced-air warming on the performance of operating theatre laminar flow ventilation**

Dasari, K.B.; et al. *Anaesthesia*. Vol. 67; 2012: 244-249.

| Company Support

**SUMMARY:** Floor-to-ceiling temperatures were analyzed in a laminar flow operating room with different patient warming devices. With forced-air warming, mean (SD) temperatures were significantly elevated over the surgical site vs those measured with the conductive blanket (+2.73 (0.7)0C; p < 0.001). "We conclude that forced-air warming generates convection current activity in the vicinity of the surgical site. The clinical concern is that these currents may disrupt ventilation airflows intended to clear airborne contaminants from the surgical site."

# Waste Heat Contamination (Continued):

## Patient Warming Excess Heat: The Effects on Orthopedic Operating Room Ventilation Performance

Belani, K.G.; Albrecht, M.; McGovern, P.D.; Reed, M.; Nachtsheim, C. Anesthesia & Analgesia. 2013;117(2):406-11.

| *Company Support*

**SUMMARY:** Researchers assessed the effects of waste heat from upper body patient warming devices by releasing neutral buoyancy bubbles into the non-sterile region under the head side of the anesthesia drape and assessing if the bubbles were mobilized to the surgical site. "The direct mass-flow exhaust from forced-air warming generated hot-air convection currents that mobilized 'bubbles' over the anesthesia drape and into the surgical site." Conductive fabric warming had no such affect.

## Do forced-air patient-warming devices disrupt unidirectional downward airflow?

Legg, A.J.; Cannon, T; Hammer, A.J. Journal of Bone and Joint Surgery Br. 2012;94-B:244-256.

| *No Company Support*

**SUMMARY:** The researchers studied the temperature and number of particles over the surgical site comparing forced-air warming, radiant warming (HotDog), and no warming during lower-limb arthroplasty. "Forced-air warming resulted in a significant mean increase in the temperature (1.1°C vs 0.4°C, p<0.0001) and number of particles (1038.2 vs 224.8, p=0.0087) over the surgical site when compared with [HotDog] warming, which raises concern as bacteria are known to require particles for transport."

## Forced-air patient warming blankets disrupt unidirectional airflow

Legg, A.J.; Hamer, A.J.; et al: Bone and Joint Journal, March 2013 vol. 95-B no. 3 407-410.

| *No Company Support*

**SUMMARY:** Knee Replacement: The waste heat from forced-air warming (FAW) torso blankets radiated through the surgical drape to form tornado-like vortexes of rapidly spinning air near the surgical site. The vortexes sucked contaminated air from the operating room floor and deposited it over the surgical wound.

2,000 times more contaminant particles were found in the air over the wound with Bair Hugger warming than with air-free HotDog conductive warming. With HotDog, only 1,000 particles per cubic meter of air were present. With Bair Hugger warming, the particle count was 2,174,000 per cubic meter, an increase of 217,300%.

Conclusion: Waste heat from FAW significantly disrupts unidirectional airflow, drawing contaminant particles to the surgical site. Therefore, a warming device that disperses heat away from the patient should not be used.

### Particle Entrainment Concentration

Warming scenario	Concentration (particles/m <sup>3</sup> )
Control	2000
Radiant warming	1000
Forced-air warming	2 174 000

## Active warming systems to maintain perioperative normothermia in hip replacement surgery: a therapeutic aid or a vector of infection?

Moretti, B.; Larocca, A.M.; Napoli, C.; et al. J Hosp Infect 2009;73:58e63.

| *No Company Support*

**SUMMARY:** This study assessed the risk of contamination of the surgical site correlated to the use of the Bair Hugger blanket during hip replacement surgery. The level of bacterial contamination of the air in the operating theatre was quantified with and without the use of the Bair Hugger, during the course of 30 total hip implant procedures, by measuring the colony forming units (cfu) at three different points around the operative site. In the 20 procedures in which the Bair Hugger was used, the mean bacterial load values were significantly increased in the three points compared with the at-rest conditions (A1 = 41.7 ± 28.1 cfu/m<sup>3</sup> vs. 17.8 ± 14.5 cfu/m<sup>3</sup>, P<0.001; A2 = 42.2 ± 28.6 cfu/m<sup>3</sup> vs. 19.4 ± 17.5 cfu/m<sup>3</sup>, P=0.001; A3 = 42.3 ± 28.2 cfu/m<sup>3</sup> vs. 19.2 ± 17.7 cfu/m<sup>3</sup>, P<0.001). No wound infections occurred in the 20 patients.

## Forced-air Warming and Ultra-clean Ventilation Do Not Mix: An investigation of theatre ventilation, patient warming and joint replacement infection in orthopedics

McGovern, P.D.; Reed, M.R.; et al. J. Bone and Joint Surgery Br, 93B:11. 1537-44. Nov 2011.

| *Company Support*

**SUMMARY:** 1. Hip Replacement: Forced air warming mobilized under-drape air over the anaesthesia/surgery drape and into the surgical site. In contrast, conductive fabric warming did not have a mobilizing effect. Anaesthesia/surgery drape position had a large effect on under-drape air mobilization for forced air warming.

2. Lumbar Spinal Procedure: Excess heat from forced air warming resulted in the development of hot-air convection currents between the surgeon's body and operating table that transported floor-level air upwards and into the surgical site. Conductive fabric warming did not release sufficient excess heat to establish these convection currents.

# Waste Heat Contamination (Continued):

## Hygiene and room climate in the operating room

Scherrer, M.; et al. Minimally Invasive Thermal Allied Technology. 2003 Nov;12(6):293-9.

| No Company Support

**SUMMARY:** “The air emitted from [the blankets of forced-air warming systems] disturbs the ultra clean field and preliminary investigations have shown an increase of bacteria in the operating field when the warming system is on.” Despite laminar airflow conditions, colony forming units (cfu/m<sup>3</sup>) were significantly higher across the four measurements when the warming system was ‘on’ versus ‘off.’

## Effect of Heated-Air Blanket on the Dispersion of Squames in an Operating Room

Elghobashi, S.; March 23, 2017. Expert Report. Available online

<[http://bairhuggerlitigationupdate.org/files/Elghobashi-Expert-Report\\_sm.pdf](http://bairhuggerlitigationupdate.org/files/Elghobashi-Expert-Report_sm.pdf)>

| No Company Support

**SUMMARY:** High fidelity, large eddy simulation (LES) was used to study the interaction of the operating room ultra-clean ventilation air flow and the flow created by Bair Hugger® forced air warming and its impact on the dispersion of squames particles.

“Drastic differences in the trajectories of the squames are observed between the blower-off and blower-on cases.” With the blower-off, the majority of the squames are dispersed by the ventilation air flow and never rise to the level of the operating table (OT). In contrast, with the blower-on, a large number of squames are lifted upwards by the rising thermal plumes. “Large number of squames are seen to be above the OT, several are surrounding the surgeons hands, above the side tables, and some are very close to the patient’s knee and the surgical site.”

“[T]he hot air from the blower and the resultant thermal plumes are capable of lifting the particles and transporting them to the side tables, above the operating table, and the surgical site.”

## Transmission of Mycobacterium chimaera from Heater-Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System

Sommerstein, R.; Sax, H.; et al. Emerging Infectious Diseases (CDC). 2016;22(6):1008-1013.

| No Company Support

**SUMMARY:** Heater-cooler units (HCUs) were recently identified as a source of Mycobacterium chimaera causing surgical site infections. The authors investigated transmission of this bacterium from HCUs to the surgical field by using a thermic anemometer and particle counter, videotape of an operating room equipped with an ultraclean laminar airflow ventilation system, and bacterial culture sedimentation plates in a nonventilated room. Smoke from the HCU reached the surgical field in 23 s by merging with ultraclean air. The HCU produced on average 5.2, 139, and 14.8 particles/min in the surgical field at positions Off, On/oriented toward, and On/ oriented away, respectively. Culture plates were positive for M. chimaera <5 m from the HCU in the test room. These experiments confirm airborne transmission of pathogens from a the exhaust vent of a HCU to an open surgical field despite ultraclean air ventilation. “Efforts to mitigate infectious risks during surgery should consider contamination from water sources and airflow-generating devices.”

# Waste Heat Linked to Infection:

## Forced-air warming and ultra-clean ventilation do not mix

McGovern, P.D.; Reed, M.R.; et al. J. Bone and Joint Surgery Br, 93B:11. 1537-44. Nov 2011.

| Company Support

**SUMMARY:** Forced air warming waste heat transported non-sterile air to the surgical site in both hip replacement procedures and lumbar spinal procedures. Conductive fabric warming did not release sufficient excess heat to establish the same convection currents. “[Forced-air] Patient warming ventilation disruption was associated with a significant increase in deep joint infections, as demonstrated by an elevated infection odds-ratio (3.8, p=0.028) for the forced air versus conductive fabric patient groups (n=1437 cases, 2.5-year period).”

Deep joint infection rates:

9/’08 – 6/’10, Forced-air warming: 3.1% (1066 cases)

7/’10 – 1/’11, FAW discontinued: 0.81% (371 cases); HotDog patient warming used

Discontinuing the use of forced-air warming resulted in a 74% reduction in joint implant infections (p=0.024).

# Waste Heat Linked to Infection (Continued):

## Forced-air warming discontinued: periprosthetic joint infection rates drop

Augustine S.D.; Orthopedic Reviews 2017; 9:6998.

| Company Support

**SUMMARY:** Several studies have shown that the waste heat from forced-air warming (FAW) escapes near the floor and warms the contaminated air resident near the floor. The waste heat then forms into convection currents that rise up and contaminate the sterile field above the surgical table. This study retrospectively compared PJI rates during a period of FAW to a period of air-free conductive fabric electric warming (CFW) at three hospitals. Surgical and antibiotic protocols were held constant. The pooled multicenter data showed a decreased PJI rate of 78% following the discontinuation of FAW and a switch to air-free CFW (n=2034; P=0.002).

## Transmission of *Mycobacterium chimaera* from Heater-Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System

Sommerstein, R.; Sax, H.; et al. Emerging Infectious Diseases (CDC). 2016;22(6):1008-1013.

| No Company Support

**SUMMARY:** The waste heated air from the ventilation fans of Heater-cooler units (HCUs) were recently identified as a source of *Mycobacterium chimaera* causing surgical site infections in several reports. In this study, the HCU produced on average 5.2, 139, and 14.8 particles/min in the surgical field at positions Off, On/oriented toward, and On/ oriented away, respectively. Culture plates were positive for *M. chimaera* <5 m from the HCU in the test room. These experiments confirm airborne transmission of *M. chimaera* aerosols from a contaminated HCU to an open surgical field despite ultraclean air ventilation. "Efforts to mitigate infectious risks during surgery should consider contamination from water sources and airflow-generating devices."

# Forced-Air Warming Discontinued: Infection Rates Drop:

## Forced-air warming and ultra-clean ventilation do not mix

McGovern, P.D.; Reed, M.R.; et al. J. Bone and Joint Surgery Br, 93B:11. 1537-44. Nov 2011.

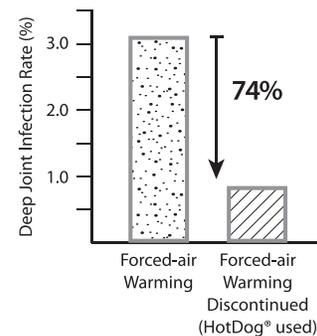
| Company Support

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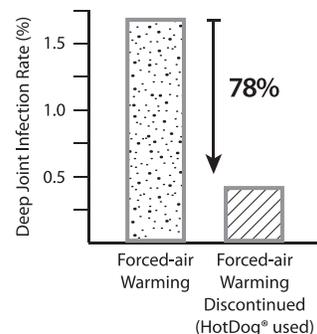


## Forced-air warming discontinued: periprosthetic joint infection rates drop

Augustine S.D.; Orthopedic Reviews 2017; 9:6998.

| Company Support

**SUMMARY:** Retrospectively compared PJI rates during a period of FAW to a period of air-free conductive fabric electric warming (CFW) at three hospitals. Surgical and antibiotic protocols were held constant. The pooled multicenter data showed a decreased PJI rate of 78% following the discontinuation of FAW and a switch to air-free CFW (n = 2,034; p = 0.002). "The 78% reduction in joint implant infections observed when FAW was discontinued suggests that there is a link between the waste FAW heat and PJIs."



# Benefits of Intra-Operative Normothermia:

Complication	N	°C hypothermia	Normothermic	Hypothermic	p value	Author
Surgical wound infection	200	1.9	6%	19%	<0.01	Kurz et al <sup>1</sup>
Surgical wound infection	45,304	0.9	7.5%	12.9%	<0.0001	Scott et al <sup>6</sup>
Duration of hospitalization	200	1.9	12.1 +/- 4.4d	14.7+/-6.5d	<0.01	Kurz et al <sup>1</sup>
Allogenic transfusion requirement	60	1.6	10 +/- 55 mL	80 +/- 154 mL	<0.05	Schmied et al <sup>2</sup>
Intraoperative blood loss	60	1.6	1.7 +/- 0.3 L	2.2 +/- 0.5 L	<0.001	Schmied et al <sup>2</sup>
Intraoperative blood loss	150	0.4	488 mL	618 mL	0.002	Winkler et al <sup>8</sup>
Intraoperative blood loss	60	1.8	1.5 +/- 0.5 L	2.7 +/- 1.0 L	0.01	Hofer et al <sup>7</sup>
Allogenic transfusion requirement	60	1.8	0.4 +/- 0.4 L	1.1 +/- 0.9 L	0.013	Hofer et al <sup>7</sup>
Morbid cardiac events	300	1.3	1%	6%	<0.05	Frank et al <sup>3</sup>
Postop ventricular tachycardia	300	1.3	2%	8%	<0.05	Frank et al <sup>3</sup>
Ischemic cardiac events	45,304	0.9	1.4%	3.1%	<0.0001	Scott et al <sup>6</sup>
Myocardial damage	60	1.0	8 +/- 5 ng/mL	22 +/- 9 ng/mL	<0.01	Nesher et al <sup>9</sup>
AAA mortality	262	2.0	1.5%	12.1%	<0.01	Bush et al <sup>4</sup>
Mortality	45,304	0.9	1.4%	4.8%	<0.0001	Scott et al <sup>6</sup>
Liver transplant CMV infections	100	1.6	4%	17%	0.06	Paterson et al <sup>10</sup>
Duration of post anesthetic recovery	150	1.9	53 +/- 36 min	94 +/- 65 min	<0.001	Lenhardt et al <sup>5</sup>

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## Cost of Hypothermia-Caused Complications:

### Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs

Mahoney, C; Odom, J. AANA Journal. 1999; 67(2):155-164.

| No Company Support

**SUMMARY:** Intraoperative hypothermia averaging only 1.5°C less than normal resulted in adverse outcomes that negatively affected the quality and length of patients' lives. The cumulative adverse outcomes added between \$2,500 and \$7,000 per surgical patient to hospitalization costs across a variety of surgical procedures.

### Clinical Guidelines CG65, Inadvertant Perioperative Hypothermia

National Institute for Health and Care Excellence. September 2016. Available Online.

| No Company Support

**SUMMARY:** The mean net monetary benefit per hypothermia case averted is approx. \$3,000. Hypothermia defined as (<36°C).

### Summary of Research Supporting Air-free HotDog® Patient Warming

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