3M Bair Hugger®* Safety Study: Intentional Deception

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3M has commissioned two scientists to attempt to refute the seven studies and many video-documented experiments showing that the waste heat from Bair Hugger patient warming:[1-10]

1. disrupts operating room airflow and
2. moves contaminated air from the floor to the surgical field.

3M and their experts committed more than a dozen separate infractions—cheating, deception and false analysis--all leading to false results. This document highlights the more egregious deceptions.

General Study Critique:

The Megasonic Fog Generator used for airflow visualization invalidates the entire study.

1. **Unsuitable visualization technique.**
   The Fog Generator aerosolizes microscopic water droplets that evaporate within 2-3 feet of travel and become invisible as water vapor.
2. **Water droplets absorb the waste heat being studied.**
   As the microscopic water droplets rapidly evaporate, they efficiently absorb a large amount of heat from the surrounding air. The fog used in this experiment can cool or neutralize 900 kcal/hr -- 100% of the total heat output of the Bair Hugger heater (1000 watts) -- making the fog visualization technology unsuitable for experiments relating to heated air
3. **Internal fan disrupts visual airflow.**
   The water droplets are propelled out of the fogger nozzle by a fan.

The Megasonic Fog Generator is not only ineffective for visualization, it is the opposite of inert: it interacts with and dominates the experiment, creating its own results. Because the vast majority of waste heat is intentionally drawn from the system by the very method of visualization, in the context of a heat study, and because the authors mislead the audience on this fact, we can only conclude utter incompetence or a clear and carefully realized act of deception.

In contrast, the prior published studies of Bair Hugger waste heat all used theater smoke particles or neutral buoyancy bubbles to track airflow. Both of these visualization technologies are thoroughly validated, are thermal neutral, have no propulsion, and can be visualized over long distances.

Specific Study Critique:

In order to demonstrate the deceptive design of this 3M study, each part will be compared to previously published research. There are three mechanisms by which the waste Bair Hugger heat has been shown to disrupt the operating room ventilation airflow and contaminate the sterile surgical field:

1.) Waste Bair Hugger heat rising from an upper body warming blanket.

3M's experts give the illusion of re-creating the studies by Belani, McGovern, Reed and Augustine, all of which show significant movement of contaminates from the anesthesia side of the screen, over the top and into the sterile surgical field.[2,4-6] However, they changed many key elements in their clever design, making it totally unrealistic and purposefully deceptive.

Operating Set-up Violates Ventilation Standards

- The head end of the surgical table in this experiment is located outside of the operating room ventilation flow field (violating the standard), so the escaping heat was never even in the ventilation airflow field.
- The anesthesia screen is not in a normal location or shape. The opening to the tunnel-like anesthesia screen extends past the head end of the surgical table. With this unrealistic arrangement, all of the waste heat of the upper body warming blanket was effectively vented outside of the experimental airflow field.

2.) Waste Bair Hugger heat radiating and conducting through the surgical drape from an upper body warming blanket.

3M's experts made no attempt to recreate or negate this mechanism of contamination.

Legg, McGovern, Reed, Augustine and Dasari have all shown that the radiant and conductive heat warms the air on the surgical side of the anesthesia screen, causing it to form into a tornado-like vortex in the presence of a downward ventilation airflow.[2-4,9] The vortex literally vacuums contaminants off the floor, sucking them upward and depositing them in the sterile surgical field. Legg reported that this contamination mechanism resulted in 2,000 times (200,000%) more contaminating particles in the sterile field with Bair Hugger warming than with air free HotDog® conductive warming.[3]

3.) Waste Bair Hugger heat from lower body warming of the legs escaping from under the surgical drape near the floor.

3M's experts give the illusion of re-creating this previously studied condition with all of the fog that they blow near the floor and over the surgical site. However, by failing to put the warming blanket on the patient's legs, all of the fog was just illusory. There is no reason to expect heat applied to the arms to have any effect on airflow under the table.

Published research by Belani, Legg, McGovern, Reed and Augustine has shown that heat exhausting from a lower body blanket applied to the patients legs escapes under the warming blanket, vents under the surgical table, heats the contaminated air near the floor, and eventually forms into convection currents that rise with the contaminants from under the surgical drape up and into the sterile field.[1,2,5,10]

Conclusions

For the past six years 3M has insisted that the waste Bair Hugger heat does not rise. Waste heat will always rise in the operating room or anywhere else. It's a law of physics.

To prove a "negative"—as 3M's experts are apparently trying to do—requires that it must be shown to be "negative" in all circumstances. Since 3M's experts failed to re-create any of the three previously published mechanisms of contamination, their study axiomatically fails to refute or negate the previously published research. Not only that, but their heat study is completely invalidated by the very use of microscopic water droplets as a visualization technique, and by cleverly violating operating room standards to manipulate the results.

The only logical purpose of this deceptive research is to give false assurances of safety to the clinicians using forced-air warming—assuring them of the products' safety during orthopedic implant surgery. These false assurances of safety are willfully putting orthopedic implant patients at a significantly higher risk of contracting catastrophic periprosthetic joint infections (PJI)—one of the most serious and devastating surgical complications.

References

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* HotDog is a registered trademark of Augustine Temp Mgmt

3M's videos published on YouTube available at:

- https://youtu.be/xPHGWsp2NGU
- https://youtu.be/QhzeInWlJ54

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