

A critical analysis of “Forced-air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms” by Sessler et al.

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Background:

As the inventor of both Bair Hugger® forced-air warming (FAW) and HotDog® conductive fabric warming, I read the article by Sessler et al, commenting on the relationship between operating room air quality and FAW, with great interest (Sessler D, Olmsted R, and Kuelpmann R. Forced-air Warming Does Not Worsen Air Quality in Laminar Flow Operating Rooms. *Anesth Analg* 2011;113:1416-21). The study, which was funded by 3M/Arizant, purportedly demonstrated that the waste heat from FAW did not rise and, therefore, did not disrupt the integrity of the laminar flow ventilation. I have extensive experience investigating this subject and I immediately concluded that the study was intellectually dishonest. However, after I read the DIN standard that they claim to have used as their study protocol and considered the study design in general, I came to the opinion that this study should be labeled as “research fraud”; the study is a cleverly deceptive and dishonest design, leading to false conclusions and recommendations that knowingly put patients at increased risk of deep joint infections, bought and paid-for by 3M.

Drs. Norman and Jackson, writing for the American Society of Anesthesiologists (“ASA”) Committee on Ethics in the May 2011 issue of the ASA Newsletter, defined “fraud” as “1. A deception deliberately practiced to secure unfair or unlawful gain. 2. A piece of trickery; a trick. 3.a. One that defrauds; a cheat.” Webster adds, “...an act of deceiving or misrepresenting...” Unfortunately, the editors of *Anesthesia & Analgesia*, the medical journal that published this research, do not consider deceptive study design to constitute “research fraud” and thus the article remains published.

Instead of conducting rigorous, intellectually honest research, the authors – all of whom disclose financial and consulting ties to Bair Hugger® forced-air warming (“FAW”) and Arizant/3M — working with Dr. Hansen, Arizant/3M’s VP of R&D, have carefully manipulated the study design to show their preferred conclusion.

The first question one must ask is why did the authors purport to follow the “rigorous DIN 1946-4:2008-12 standard” (“DIN”), a German standard for testing operating room ventilation? Why didn’t they simply explain their testing methods in the “Methods” section of the paper like all other published medical studies do? As you will see, they totally adulterated the DIN, so it would have been much more accurate to simply describe their methods. A proprietary German ventilation-testing standard is certainly not going to be readily available to American readers. Could it be that the authors knew that none of the clinician readers of this study or even the reviewers of the manuscript have any idea what the DIN standard is and they are not likely to special order and pay for a copy simply to interpret this article. If anyone did have access to the standard, what are the chances that they would check this research against the 68 pages of the standard? It’s not by accident that by simply pretending to follow the DIN protocol, the authors were free to obfuscate their research anyway they wanted to with little chance of being found out.

The DIN protocol was highly modified by the authors in order to include the FAW challenge. None of the FAW parts of the study design are included in the DIN standard nor had their modifications to the standard ever been validated. The entire FAW component of this study is a construct of the authors and has no foundation in the DIN protocol. At best, the authors used bits and pieces of the DIN protocol

mixed with their own study designs, yet they continue to refer to it as the following the “rigorous DIN standard,” apparently to give the study credibility that it doesn’t deserve.

Additionally, the DIN standard in question specifically forbids the use of FAW in laminar flow operating rooms; “6.8 ...decentralized heating and cooling devices with a convective effect [FAW] are not permitted.” **Including FAW in the DIN test directly violates section 6.8 the standard.** The fact that FAW is expressly forbidden in laminar flow operating rooms according to this DIN standard also means that the standard was not designed to test for the effects of FAW. **Further, none of the many modifications to the standard test that were invented by the authors were validated in any way. Sessler et al have clearly misused the DIN standard that specifically forbids the use of FAW, by modifying it to their own design to study the effects of FAW.**

Very few people have studied the effects of the 1000 watts of waste heat from FAW on the operating room ventilation. At the time Sessler did this research, there were no published studies on the subject. For these reasons, the reviewers of the manuscript most likely did not understand the subject that they were reviewing. Additionally, since Sessler is a long-time editor, reviewer and publisher in the *A&A* journal, it is highly likely that the manuscript did not receive a thorough review from his friends on the editorial staff.

For anyone who has studied the effects of waste FAW heat, it is very clear that this heat follows the rules of Thermodynamics—the Laws of Nature, in the same way that all heat does: Heat rises! Sessler’s assertion that the waste heat from FAW does not rise is preposterous on it’s face.

Rising heated air naturally coalesces into thermal convection currents of rising warm air, very much like a chimney. Predicting where around the operating table those convection currents of warm air are going to form and rise, can be tricky. However, you can be 100% certain that if FAW is in use, there will be one or more convection currents of rising warm air somewhere around the surgical table because it is a Law of Nature—the heat has to rise. In the alternative, it is easy to understand how you can find where the convection current is located and then measure for convection currents at the opposite end of the table and find no effect. This is exactly what Sessler et al did.

To fully appreciate the cleverness of Dr. Sessler’s study, one must understand the variables affecting rising waste FAW heat. The fact that heat rises more or less straight upward dictates that heat escaping from under the operating table is more likely to rise into the surgical site than heat escaping from the anesthesia side of the ether screen. Therefore, the rising waste heat phenomenon is most reliably demonstrated with a lower-body FAW blanket because the waste heat is forced to escape from under the lower edge of the surgical drape near the floor. The heat then rises alongside the surgical table directly into the laminar ventilation airflow and ends up above the table, contaminating the sterile field with dirty floor air.¹⁻⁶

Since Sessler et al are trying to prove a “negative,” to prove that the effect *never* happens, they needed to study the situation where it is most likely to happen and show that it doesn’t. They needed to repeat the experiments known to them at that time¹ and show that the results were wrong. Instead, they concocted a situation where the rising waste heat phenomenon was least likely to be detectable over the surgical site – restricting the heat to the head end of the patient. They did not repeat the experiments but by proclaiming complete safety with FAW, they apparently disregarded the previous experimental results that showed waste heat rising.

Sessler and his co-authors cleverly designed their study to produce what they reported as “negative” results. However, their results were not “negative,” they were “meaningless.” To get a “negative” result requires an honest experiment. It is apparent that the design and execution of this experiment was purposefully deceptive and therefore meaningless.

Study setup modifications to the DIN:

The authors tested an upper-body 522 blanket (arms out) and an under-body 635 “blanket” inflated at the head end, stating, “The forced-air blower was positioned on the floor at the volunteer’s left side, near where the anesthesiologist would normally sit...” Normally a 635 “blanket” would be inflated at the foot end, not the head end, as demonstrated in the attached Bair Hugger advertisement. By inflating the head end of the 635 under-body “blanket,” the outstretched arms of the volunteer “patient” occlude the airflow below the shoulders, preventing all airflow toward the lower body. Why did the authors choose to have a live person as the “patient,” rather than a manikin, which is used in the rest of the DIN protocol? One can speculate that a manikin failed to occlude the air channels of the underbody blanket, allowing some of the air to reach the lower body. With a person acting as the dummy, the shoulders and arms fall backward and will reliably occlude all airflow below the shoulders. Therefore, both of the blankets tested naturally restrict the airflow and waste heat to the head-end of the patient, where it escapes from the anesthesia side of the ether screen toward the anesthesia space, away from the surgical site. The nearly identical results for the 522 and the 635 blankets as shown in Table 1 confirm that the 635 under-body “blanket” was effectively only warming the head and shoulders, as was the upper-body 522.

Referring to Figure 1, it appears that the pretend tubular “surgeons” are directly side-by-side and pressed against the side of the surgical table. The DIN standard specifically calls for a 20cm space between the tubes. The side-by-side arrangement of the tubes not only violates the DIN protocol, but it clearly impacts and invalidates the results of this study.

The side-by-side static tubes (as opposed to live, irregularly shaped, moving surgeons), effectively create the walls of a “canyon” on each side of the table. In the middle of the “canyon,” protected by the tubular walls from any airflow from the sides of the table, is the particle-sampling probe. Thus, the only air that could possibly be sampled in this location is clean air descending straight down from the overhead ventilation system. Even if waste heat were to escape under the table, it would be prevented from rising alongside the table in the vicinity of the air-sampling probe by the tubular “surgeons” that effectively form the walls of a canyon around the surgical site.

Evidence that the tubes were side-by-side is demonstrated in Figure 4. Though invented by the authors and not part of the DIN protocol, visible smoke is selectively introduced into the laminar airflow, approximately one meter above the patient and in the middle of the canyon. The test smoke takes approximately 24 seconds to be cleared. Considering that the laminar airflow velocity should be between 0.3 and 0.5 m/sec, the smoke should traverse the one meter distance and be totally cleared in less than 5 seconds. The prolonged 24 second (vs 5 second) clearance time demonstrates that the canyon walls are effectively preventing the smoke over the table from being cleared. The tubes had to be effectively side-by-side in order to prevent the clearance of the smoke. The same canyon walls that prevent the smoke from being cleared by the laminar airflow also prevent the ingress of waste heat or contaminating particles from the sides of the table toward the sampling probe.

Waste heat rises most efficiently into “dead zones” in the laminar flow ventilation. Dead zones are found under the surgical lights, between the surgeon and the surgical table, under the Mayo stand (missing in this experiment) and along both sides of the ether screen. The authors have likely seen the demonstrations of waste heat rising from an upper-body blanket into the dead zone of a surgical light when it is in the traditional position over the patient near the ether screen.¹ Waste heat and contaminated air then escape from the dead zone under the light on the surgical side of the ether screen, to be propelled into the wound by the laminar airflow. Dead zones interact synergistically with waste heat, forming a chimney into which the heat can rise unimpeded into the sterile field.

In the DIN protocol, the surgical lights are located in very odd positions: lateral to the table. In this unusual lateral location, the chimney-effect created in the dead zone under the lights tends to “suck” rising waste heat away from the surgical field. In contrast, when the surgical lights are in the more

normal position over the patient at the head and foot ends of the table, the dead zones under the lights create a chimney directly into the sterile field. While the DIN may call for lateral light placement, the phenomenon of convection currents forming from FAW waste heat is best demonstrated with the lights in their “normal” positions over the patient.

In summary, this study set-up effectively restricts the waste heat and air to the head-end of the patient and causes that waste heat to escape on the anesthesia side of the ether screen. The side-by-side tubular “surgeons” create protective canyon walls around the periphery of the sampling probe that effectively isolate the probe from all airflow except the overhead, clean laminar ventilation air. The dead zones under the surgical lights of this experiment are strategically located lateral to the table to assure that the waste heat on the anesthesia side cannot get sucked into the dead zone under a light positioned over the head end of the patient.

Deceptive study design:

1. Despite repeated reference to the “rigorousness” of the DIN standard, it must be noted that the authors only reported one of the six tests required by the standard. Two of the three required “flow visualization tests” in Annex B that were not reported would most certainly have demonstrated the rising thermals of waste FAW heat rising from the head-end of the surgical table, disrupting the laminar flow field and violating the standard. They also omitted the “Turbulence Integrity Test” described in Annex D.

In the flow visualization test, aerosol particles (smoke) is released near the ceiling in a grid pattern that covers the entire 3.2m x 3.2m laminar flow plenum. Passing this test requires: “Neither localized disturbances of the emitted test aerosol nor inhomogeneities of the outflow behavior shall be detectable at any position below the Low Turbulence Flow outlet.” (B.2.1.2) These tests are specifically designed to detect the problem of rising waste heat, including heat on the anesthesia side of the ether screen.

The authors failed to detect the rising waste heat because they did not perform the entire testing protocol of the DIN standard. As previously discussed, the authors designed their study so that the waste FAW heat would be vented from the head-end of the patient, on the anesthesia side of the ether screen, and into the anesthesia space. The heat in this location could not be detected by their careful experimental setup loosely based on Part One of Annex C that sampled only over the mock abdominal surgical site. At least two of the three omitted tests in Annex B, would have detected the waste FAW heat rising from the head-end of the surgical table, disrupting the laminar flow field and violating the standard. I have personally done many experiments identical to this situation in our own laminar flow laboratory and can attest that waste heat rising at the head-end of the ether screen is very easy to visualize with smoke particles or neutral buoyancy bubbles, as it disrupts the downward flowing laminar ventilation in that region. The McGovern², Belani⁴ and Heat-rises¹ studies, clearly show that particles originating from the anesthesia side of the ether screen, rise into the laminar flow and then can traverse the ether screen and end up contaminating the sterile surgical field.

Since the German testing company Hybeta GmbH did the testing for this study, either the unreported tests were done by Hybeta but the results were not reported in the study, or Hybeta was told to not do the tests. Either way, the investigators have been purposefully deceptive by claiming to follow the DIN protocol when in fact they only reported one of the six required tests.

2. **Sessler et al did not add detectable particles to the waste heated air at the head end of the table and therefore, it is totally predictable and meaningless that the clean waste FAW air was not detected by the particle counter at the DIN 1946-4:2008-12-mandated monitoring site over the abdomen.** Restated, it is axiomatic that the flow pattern of the waste FAW air cannot possibly be determined without adding traceable particles. It is physically impossible to track the flow path of

clean air...one must add traceable particles such as smoke or bubbles. The failure to add traceable particles to this “experiment” means that the results of this research should be characterized as “*meaningless*” rather than “negative,” as the authors claim.

3. The authors fail to mention that the test that they did perform, Annex C of the DIN standard in question, is itself a two-part test. It appears that they are reporting the results only for Part One: measuring the differential between air outside the laminar flow field and air inside the flow field (“...the overall background level of particles within the room”). However, Part One of the DIN test is totally irrelevant to the question they are trying to answer. Part One tests the ability of the laminar ventilation system to create a differential in the airborne particle concentrations between the interior of the flow field and the exterior of the flow field (“...the overall background level of particles within the room”). Part One reported by Sessler et al., is totally irrelevant to answering the question: does FAW disrupt laminar ventilation with convection currents of waste heat?

Part Two of the test “is performed to detect any updraught of contaminated room air from the floor within the protected area...” (DIN C.2.1). Even though the authors are clearly aware of the many demonstrations of rising waste heat that have been posted on the “Heat-rises” website, the authors do not report data from the second part of the test — the part that could possibly detect that situation.

In fact, even if they had done “Part Two” of the test Annex C, it most likely would have given a negative result due to their modifications of the DIN test setup and their careful isolation of the waste heat to the head-end of the patient.

4. “In response to recent concerns,²³ we asked whether forced-air warming disrupts laminar flow systems...” “A theoretical concern is that warm air released by forced-air covers might disrupt laminar airflow in operating rooms.²³”

At the time this paper was written, the only research that I am aware of showing the effects of waste forced-air heat rising into the sterile operating field was unpublished video-documented research publicly available at www.Heat-rises.blogspot.com and in various HotDog® marketing materials (HotDog® patient warming, Augustine Temperature Management, Eden Prairie, MN). This study by Sessler et al, was commissioned and paid-for by Arizant/3M undoubtedly to disprove the video research on the “Heat-rises” website.

It is axiomatic that the only way to definitively disprove a research study is to repeat the study design verbatim and find different results. Instead of repeating the “Heat-rises” studies to disprove them, the authors designed a study that has virtually no design elements that overlap with the studies supposedly being disproved. The mere fact that they did not study what they said that they studied is “a piece of trickery,” a “deception deliberately practiced to secure unfair...gain.”

Erroneous conclusions:

Even if they had legitimately shown a negative result in this narrow study design, the authors are acting more as marketers than scientists when they proclaim the safety of FAW in all circumstances—a conclusion totally unsupported by the facts. Proving a “negative” is very difficult because it requires that the negative result occur at all times and in all circumstances. A negative proven in one narrow study such as this one cannot be generalized to the myriad of other circumstances that were not tested. For example, this study is very specific, narrow and clinically irrelevant because it was done in an empty operating room.

The irrelevant “straw man” hypothesis of using bits and pieces of a highly modified and non-validated DIN standard and the specific set-up of this experiment could not possibly determine that FAW does not disrupt laminar flow ventilation. Even if this study had been properly designed and executed, the results

could not be generalized beyond the specific conditions of the study. Despite these severe limitations, the authors confidently and broadly proclaim that FAW does not degrade laminar flow performance or reduce operating room air quality, *seven* different times within the study. Such aggressive promotion is more appropriate for marketing literature than for a scientific journal. The bold proclamations of FAW safety during orthopedic implant surgery based on this highly flawed study clearly put implant patients at higher risk of deep joint infections. What makes this proclamation of safety unconscionable is that they did it with the full knowledge of the Heat-rises video data.¹

Considering that laminar flow ventilation is primarily used in orthopedics, the authors are specifically reassuring the readers of the orthopedic infection safety of FAW in their summary statement, “It is reasonable *based on the findings from this investigation* to consider FAW to be safe in laminar flow operating rooms.” (emphasis added) This is a rather bold and reckless statement considering that this study did not even look at the real orthopedic infection safety issues of FAW. The authors have attempted to broaden their own soft tissue (colon surgery) infection study to apply also to orthopedic implant infections that are well known to be caused by airborne contamination. This is nothing more than their personal and unsubstantiated opinions, and they are dangerously wrong.

The authors emphasize the “rigorousness” of the DIN standard as if the standard actually had clinical relevance to the question of orthopedic implant infection risk during FAW. The pathogenic airborne contaminants in deep joint infections are generally bacteria shed from the skin of the surgical staff, *within* the laminar flow air current. The static, empty OR testing of the DIN standard with no living, moving, cell-shedding staff in the flow field may validate a laminar flow ventilation system but it does not test for or assure air quality during orthopedic surgery – the conclusion of this study.

In our opinion, Sessler, Olmsted, Kuelpmann and Arizant/3M have done patients and the anesthesia community a huge disservice by assuring the infection safety of FAW, for all patients, all surgeries and all warming conditions, based on this narrow, intellectually dishonest and deceptive research. FAW clearly disrupts laminar flow ventilation, and recent research now positively links the ventilation disruption to an increase in the rate of deep joint infections. FAW should be contraindicated for use during surgeries that involve implanted foreign materials, especially in orthopedics.

Even if you conclude that this study does not constitute academic misconduct, the exceedingly narrow study design cannot possibly be assumed to apply to all circumstances. The negative results and broad conclusions of safety give false security to clinicians, especially when these results are being aggressively promoted by 3M to protect their Bair Hugger warming franchise. The false FAW safety claims assured by Sessler et al in this study are directly endangering patients undergoing joint replacement surgery.

References:

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