White Paper

Advancing Aerobiological Quality Standards For Hospital Operating Rooms (ORs)

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Hospital ORs are among the most infection-sensitive environments in healthcare facilities. Undergoing a surgical procedure may expose a patient to pathogens transmitted from surgical personnel, surgical equipment, the air and a patient's own skin flora.

Annually, the United States is affected by 1.7 million Healthcare Associated Infections (HAIs). The CDC reports nearly 99,000 deaths per year resulting from HAIs. According to the U.S. Department of Health and Human Services (HHS), it is estimated that of the more than 290,000 incidences of Surgical Site Infection (SSI) annually, more than 13,000 people die each year due to infections acquired during surgical procedures.[1]

It has been estimated that airborne transmission accounts for 10-20% of HAIs[2], although more recent studies have concluded that the role of airborne transmission may be underestimated due to the difficulty of culturing many airborne organisms and the complexities of assessing the role such pathogens play in the contamination of environmental surfaces and subsequent contact transmission.[3] Landmark studies performed by Lidwell and his colleagues[4,5] along with many other studies[6,7] have indicated a strong connection between contamination in the air during surgeries and SSI rates. Clinical trials carried out in Britain, Europe, and the United States have confirmed that between 80 and 90% of bacterial contaminants found in the wound after surgery come from colony forming units (cfu) present in the air of the operating theatre.[8] With respect to bacteria transmitted to the surgical site through the air, squames (or skin scales) are the primary source of transmission.[9] Approximately 1.15×10^6 to 0.9×10^8 squames are generated in a typical two to four hour surgical procedure.[10] Viral and fungal contamination can also be present in these skin scales.

Quality of care impacts: Public perception

The adverse impact of SSIs has a cumulative effect on the public's perception of a hospital's quality of care. The number of states that mandate reporting of healthcare associated infections (including SSIs) has risen significantly in the past decade, giving healthcare recipients increased access to HAI incidence data at hospitals. Three states had mandated reporting in 2003. As of the beginning of 2011, that number grew to 28 states.[11]

Increasing transparency and public access to hospital performance can also be attributed to additional initiatives and incentives by the Centers for Medicare and Medicaid Services (CMS), the U.S. Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC). In addition to providing oversight, these organizations, CMS in particular, also play a role in the economic costs of surgical site infections.

Economic impacts and where the burdens of added costs fall

"Beginning October 1, 2008, Medicare can no longer assign an inpatient hospital discharge to a higher paying Medicare-severity diagnosis-related group (MS-DRG) if a selected condition is listed on the claim and was not present on admission. That is, the case will be paid as though the condition were not present." [1]

According to the above statement from the HHS *Action Plan to Prevent Healthcare Associated Infections*[1], the

added healthcare costs of treating HAIs (including SSIs) are no longer reimbursed for Medicare patients, placing the financial burden squarely on the shoulders of hospitals. On average, the cost to hospitals per SSI is $25,546.[1] In aggregate, this amounts to $7.4 billion in additional healthcare costs every year.[1]

Rethinking the design of the surgical setting to benefit from cleanroom standards

The purpose of ASHRAE Standard 170-2008 is to define the ventilation system's design and analytical performance requirements that provide environmental control for comfort, asepsis, and odor in surgical suites.[12] Table 1 lists the basic elements applying to operating rooms. While this standard contains airflow requirements such as the number of exchanges and the temperature and humidity of the air, it does not address airborne contaminant levels. The standard essentially reinforces the old adage, "the solution to pollution is dilution." As a result, implementing an airflow system that addresses contaminant levels over the sterile field in a surgical setting is often not considered because it is not required by standards or codes.

Conversely, the standards for airborne contaminant control are extremely well-defined in a cleanroom of a typical semiconductor manufacturer or for other critical manufacturing processes (Table 2). Ranging from Class 1 to 9, cleanrooms are designed to allow no more than a specific number of particles of a specific size to be present in a space at any given time. In meeting these specifications, airflow systems must account for ancillary equipment such as lighting, machinery, people and other elements in the space that could otherwise work against creating the desired environment. Aseptic procedures for personnel entering the space can be equal to or greater than those required for doctors and nurses entering an OR for a surgical procedure.

Manufacturers have adopted ISO requirements for cleanrooms with a single purpose: preventing what could be billions of dollars in lost revenue, warranty costs, back charges and liability due to a catastrophic product failure resulting from contaminants present in a sensitive manufacturing environment.

Table 1. Summary of ASHRAE Standard 170-2008: Ventilation of Healthcare Facilities Requirements for Surgical Suites

Positive pressure differential of +0.01" wc
Individual temperature control
Airflow shall be unidirectional, downwards
Array shall extend a minimum of 12" beyond the footprint of the surgical table on each side
< 30% of the array area shall be used for non-diffuser uses
At least two low side wall return or exhaust grilles spaced at opposite corners
The bottom of these grilles installed approximately 8" above the floor

A common thread between hospital ORs and semiconductor or other sensitive manufacturing environments is the use of a laminar airflow system. These systems are designed to provide uniform, directional airflow that essentially "directs" particles floating in the airstream away from areas that are intended to be contaminant-free (i.e. the sterile field) to where they can be disposed of and contained (through the return ducts and filtration system). Conversely, in a turbulent environment, particles are allowed to float undirected, which eliminates the ability to predict where they may settle.

Benefitting fully from laminar airflow requires proper design

The difference in the design of the laminar airflow systems in hospital ORs and facilities designed to meet ISO requirements can be radical. In ISO Class 1 to Class 4 cleanroom environments, nearly every square inch of ceiling space is utilized, ultimately forming a single large diffuser, to optimize airflow and particle containment. Maximizing the amount of surface area in the space from which supply air is flowing is critical to achieve the ultimate goal of laminar airflow—minimize turbulence to produce predictable movement of particles away from the sterile field.

In comparison, hospital OR systems typically consist of multiple laminar

Table 2. ISO Standard 14644 Cleanroom Class Limits

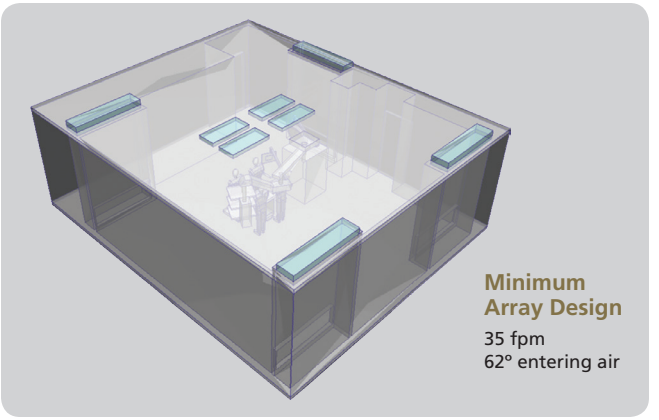
ISO Class	Maximum number particles per cubic meter of specified size					
	Particle size					
	≥ **0.1** µm	≥ **0.2** µm	≥ **0.3** µm	≥ **0.5** µm	≥ **1** µm	≥ **5** µm
1	10	2				
2	100	24	10	4		
3	1,000	237	102	35	8	
4	10,000	2,370	1,020	352	83	
5	100,000	23,700	10,020	3,520	832	29
6	1,000,000	237,000	102,000	35,200	8,320	293
7				352,000	83,200	2,930
8				3,520,000	832,000	29,300
9				35,520,000	8,320,000	290,300

flow diffusers arranged in a variety of arrays intended to optimize airflow, temperature and humidity control in the space (see example in Figure 1). In most cases, the arrangement of these diffusers over the operating table—with large gaps in airflow delivery for light troffers and other components—would be unacceptable by ISO Class 1 to Class 4 cleanroom standards. The gaps produce low pressure areas that the surrounding airflow will flow into, ultimately resulting in turbulence. Figure 2 shows an OR system designed around optimizing the ceiling surface area delivering laminar airflow over the patient.

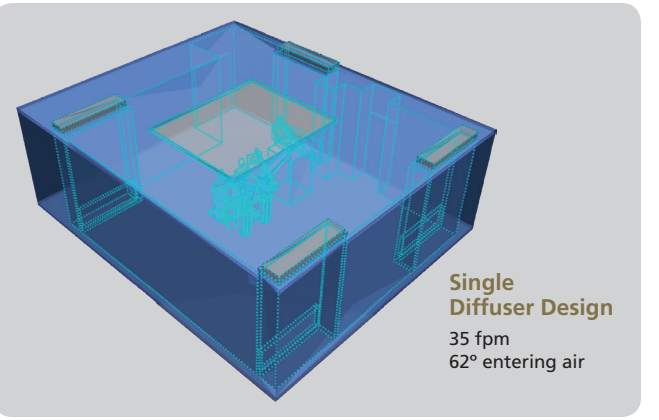
In both cases, ASHRAE Standard 170 and AIA guidelines have been met, but the airflow performance will not be equal. Table 3 provides a comparison of an OR system designed to meet minimum ASHRAE Standard 170 and AIA guidelines, to a system designed to optimize the surface area delivering laminar flow over the patient table. Using Computational Fluid Dynamic (CFD) modeling, this comparison illustrates the difference in how the two systems perform.

Figure 1. Conventional operating room air delivery system (left) and a system designed around optimizing laminar airflow over the patient (right). Note the large gap in airflow delivery over the patient created by the light and equipment booms in the system on the left.

Table 3. Comparison of Laminar Flow Designs



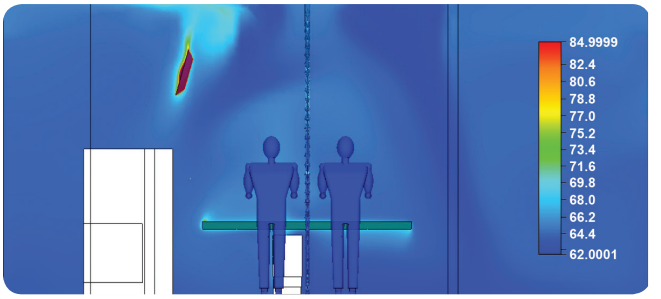
Minimum Array Design
35 fpm
62° entering air

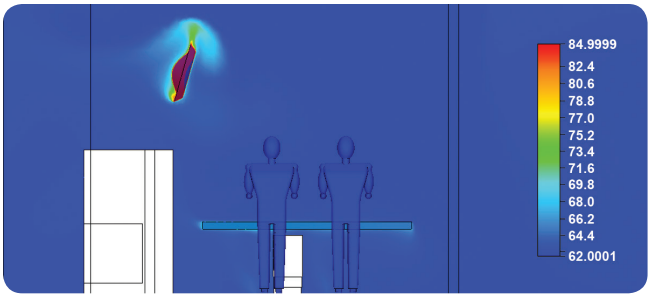


Single Diffuser Design
35 fpm
62° entering air

Thermal Properties:

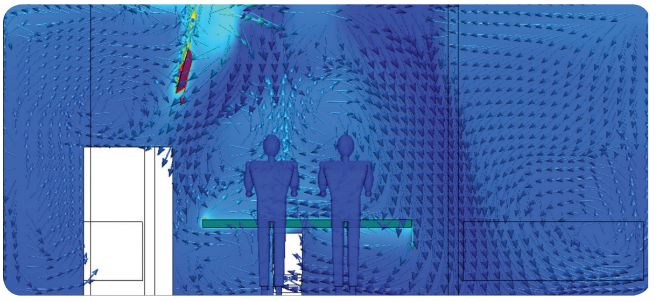
In the minimum array design (left), the temperature varies as much as 10°F due to the thermal effects of lights and people (lighter blue shaded areas). In the single diffuser (right), the temperature remains fairly constant from diffuser to the operating table.

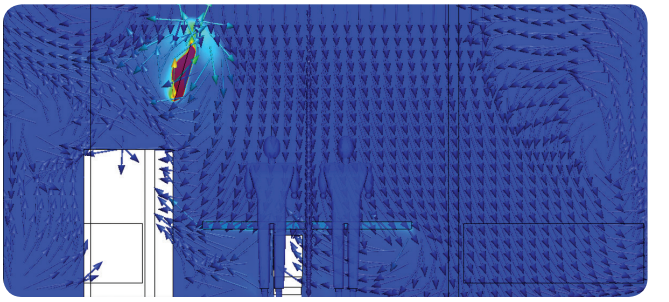




Turbulence:

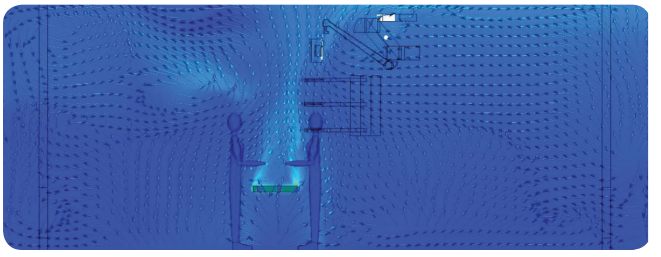
While the minimum array design contains laminar diffusers, it does not create a laminar flow environment in the space (left). The single diffuser design does achieve the desired effect of minimizing turbulence in the sterile field (right).

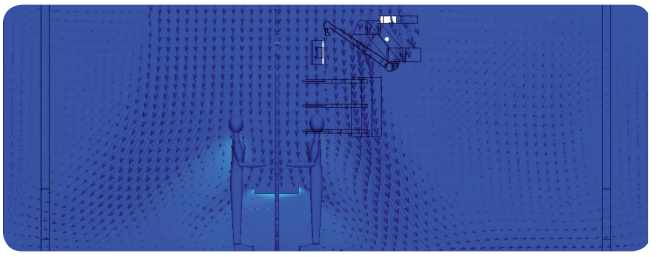




Better Performance As Airflow Is Increased:

Increasing airflow to the space by as little as 15 fpm to 50 fpm in both the minimum diffuser array (left) and the single diffuser design (right) provides improved performance in both systems. This phenomenon is consistent with cleanroom applications where as much as 100 fpm may be required for a Class 1 cleanroom.





Conclusion

Given the quality of care, economic and public relations consequences of SSIs, consideration should be given to rethinking the requirements for the operating room to include some measure of aerobiological quality standards. The technology and design practices have already been successfully implemented by semiconductor, pharmaceutical and other critical-process manufacturers facing similar consequences in a different context. International standards currently exist that identify the size and quantity of particulates allowed in a given space over a given amount of time.

Granted, many obstacles exist within the operating environment that challenge the feasibility of achieving 100 percent laminar airflow. Booms, lights, monitors and other equipment in the operating room can interfere with ideal airflow conditions. But facing these challenges head-on to advance the typical operating room beyond current design standards can prove to be a worthy venture toward improving the quality of patient care and benefitting the financial bottom line of healthcare facilities.

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CLEANSUITE® System: Bringing Cleanroom Technology To The Operating Room

The HUNTAIR® CLEANSUITE system is an all-inclusive, modular ceiling diffuser system, marketed to hospitals as fixtures, that may be built into the facility and hung directly above the patient table in an OR and other facility locations requiring low turbulence, laminar airflow. In operation, CLEANSUITE systems direct airborne particles and contaminants away from the area of the patient on the operating table, bathing the patient in HEPA-filtered air, while at the same time preventing entrainment of room air surrounding doctors, nurses and OR equipment. Ultimately, airborne particles and contaminants are directed away through low level returns.

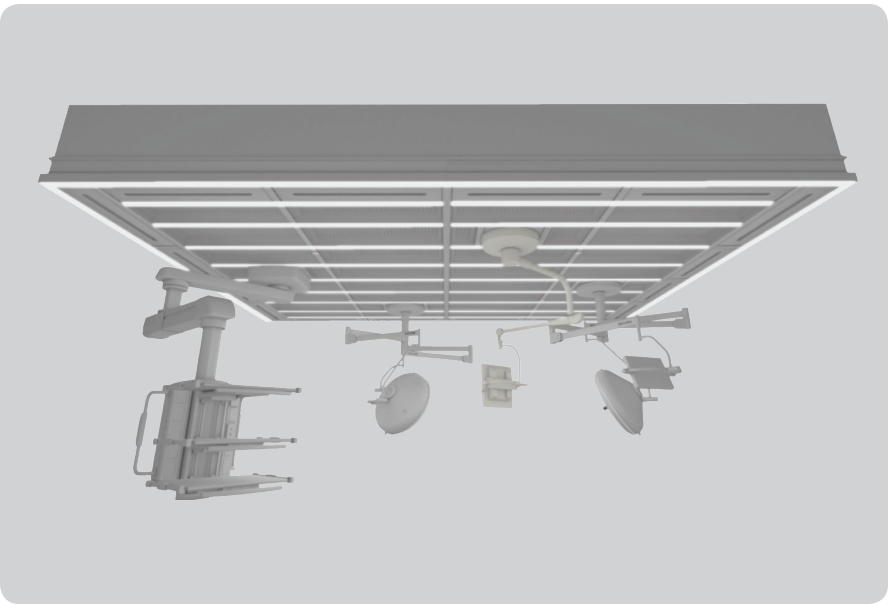
CLEANSUITE systems evolved from manufacturing environments for semiconductors, pharmaceuticals and other sensitive products where particulate levels are strictly controlled by Federal and industry standards. Currently, ASHRAE Standard 170 includes airflow requirements, but does not address specific particulate contaminant levels in the space. An ISO Class 1 cleanroom, by contrast, is required to maintain particulate levels at less than one 0.5 micron sized particle per cubic meter of space. CLEANSUITE systems can help you bridge this gap and create a cleaner environment that exceeds ASHRAE Standard 170 requirements using proven technology and design practices from thousands of operating Huntair cleanroom applications worldwide.

Huntair's reputation for providing the highest quality systems for airflow and aerobiological quality has been earned over 20 years of experience in serving mission-critical applications. We are experts in providing aseptic design details with HEPA filtration, antimicrobial coatings and laminar flow for cleanrooms and other sensitive environments. The CLEANSUITE system is a natural extension of these capabilities and can be custom-designed for the unique requirements of your operating room setting.

CLEANSUITE System (top) and cleanroom system (below): Taking advantage of the similarities in both design and function provides a unique opportunity to better achieve low turbulence, laminar airflow in operating rooms and other sensitive healthcare applications.

CLEANSUITE® Systems: A Different Approach Offering Sole Source Responsibility

CLEANSUITE systems are pre-designed and fabricated at Huntair, arriving at your facility in fully integrated modules that can be navigated through standard doorways and service elevators, lifted into place and connected to the building structure. Each all-inclusive module is custom-designed and can include integral boom mounts, lights, filtration, air balancing, sprinklers, medical gas connections and more. Single point connections can be provided for all services including controls, communications, electricity, water and/or medical gas.



Traditional plenum systems for operating room environment control are field-built and require significant coordination between trades representing structural, mechanical and utility services (electrical, plumbing, sheet metal and specialty services such as medical gas). The modular design and sole source responsibility offered by CLEANSUITE systems provides several benefits over the traditional approach:

- Dramatically reduces the design phase and jobsite coordination of trades while providing a custom-designed system for your operating room environment control.
- Provides tremendous installation cost savings by eliminating most jobsite labor and costly field workarounds associated with field-built systems.
- Installs in 1/6 the time typically required for a field-built system, providing the opportunity to accelerate the timeline from construction to a fully functional, revenue-generating facility.

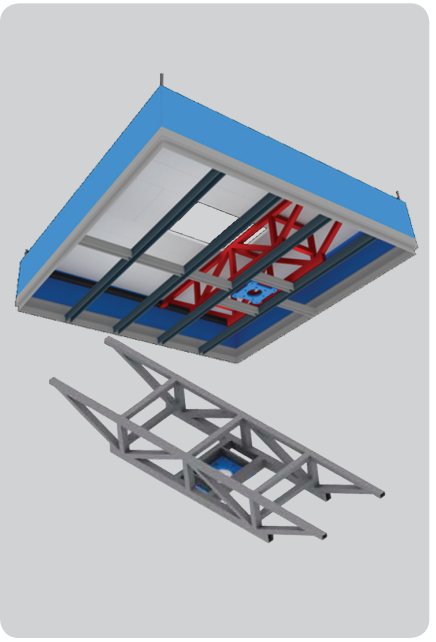
CLEANSUITE Systems: Custom-designed For Your Application

The anatomy of a CLEANSUITE system begins with Advanced Space Frame technology that provides a high strength-to-weight ratio capable of supporting the most demanding loads—including radially extending surgical booms, imaging equipment, robotics, etc., supplied by others—while performing to the strictest seismic requirements. Each module is pre-plumbed and wired with quick connects for electrical, water and other specialty services such as medical gas. Facing down at the operating room, each module includes a grid that incorporates flush-mounted lighting, sprinkler heads and room-side air balancing equipment. The grid includes accommodations to bottom-load gel-sealed HEPA filters (optional) and patented Clean-Screen® laminar diffusers. All metal surfaces are powder coated or stainless steel, with or without anti-microbial treatments.

The CLEANSUITE design results in smooth surfaces facing the operating room and allows the maximum possible surface area to be devoted to delivering laminar airflow over the operating table.

The degree to which your CLEANSUITE module is customized is ultimately determined by your requirements. Highlighted custom features include:

- Variable height (18" to 72") and width (24" to 120") allow you to match space and move-in path requirements.
- Virtually limitless configurations and options for boom mounts and other ceiling-hung equipment within each CLEANSUITE module provides the flexibility to optimize their function while minimizing their impact on laminar airflow.
- Flexible placement of wiring, medical gas, audio/video feeds and other specialty items that are required to run through each CLEANSUITE module. Items are encased outside the airstream and provided with quick-connects to simplify field connections.
- Flexible side or top placement of supply air connection(s) to match application requirements.



HUNTAIR® Air Handlers: Benefit From Sole Source Responsibility For Your Entire Air Delivery System

For seamless integration of your entire air delivery system and its controls, consider HUNTAIR air handlers with FANWALL TECHNOLOGY® to complement your CLEANSUITE® system. Huntair is a leading supplier of custom air handling solutions for the most sensitive mission critical applications in the healthcare, semiconductor and pharmaceutical industries.

Since 1993, Huntair has reengineered how we move air with innovative solutions, including FANWALL TECHNOLOGY®, arguably the first true innovation in the air handling equipment industry in years. Based on replacing large fans with a modular array of smaller fans, FANWALL TECHNOLOGY allows for a significantly smaller footprint, redundancy for improved reliability, high energy efficiency, low operating costs, very low sound and significantly reduced maintenance requirements. All of these benefits are ideal for new construction and retrofit applications for healthcare facilities—particularly the critical application of serving operating rooms.

The experience, attention to detail, quality and innovation of Huntair provide you with the assurance that you are getting the most advanced, capable and reliable air handler—custom-made for your requirements.

For more information on how Huntair CLEANSUITE systems and air handlers with FANWALL TECHNOLOGY can benefit your next application, contact your local Huntair representative. To locate your representative, visit www.nortekair.com.

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