SUMMARY

Reducing Airborne Microbes in the Surgical Operating Theater & Other Clinical Settings: A Study Utilizing the AiroCide™ System

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Introduction

The authors provide a research study examining the airborne microbial killing efficiency of the AiroCide™ Air Quality-Improvement™ System (AiroCide system), a unique photo-catalytic reactor. The study examines baseline bacterial and fungal cultures, commonly known as pathogens, collected at specific clinical test areas.

The primary objective of the study is to determine the reduction of airborne microbial counts as a result of operating the AiroCide system in three clinical settings under control conditions. The three settings are Ear, Nose & Throat (ENT) Day Surgery, Surgical Operating Room (OR) and Surgical Instrument Sterile Preparation Room. 2) The second objective is to determine how/if the AiroCide system complimented existing heating, ventilation and air conditioning (HVAC) and other airflow or filtering systems in reducing airborne microbes. 3) The third objective is to examine statistical evidence related to the cost savings due to lessened risk factors of lower airborne microbial counts involving cross-contamination and nosocomial infections. Healthcare economics and patient comfort will be impacted if lower airborne microbial colonies result from the implementation of the AiroCide system.

The AiroCide Technology

AiroCide is a unique airborne pathogen killing technology that uses a patented combination of ultraviolet light and a proprietary titanium based photocatalyst. The *AiroCide* technology and developing product line is clinically proven and field tested to kill/remove/eliminate airborne pathogenic and non-pathogenic microorganisms in vegetative and spore states (bacteria, mold & fungi, viruses and dust mites), allergens, odors and harmful volatile organic compounds (VOC's) in Medical/Healthcare, Child Care, Consumer Household, Mold Remediation, Athletic and Sports Facilities, Corrections Facilities and Food Preservation applications.

The AiroCide system has advantages that are not present in typical high efficiency filters in HVAC systems. In these systems, spores may germinate within the ductworks and collect on refrigerator compressor coils, which is a common source of *Aspergillus* and *Penicillium* fungi. These types of fungi are often released in the ductwork into clinical and waiting areas of hospitals and can account for up to 80% of indoor fungal spores (as reported by John M. Quarles PhD, Medical Microbiology & Immunology, Texas A&M University).

Air Quality Standards

Several state and national organizations and agencies, as well as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), regulate and recommend standards for hazard control in the healthcare setting. Air quality is assessed based on the lack of hazardous materials contained in a specific area, department or facility and the air surrounding that environment. There is no specific designation for a medical grade of air contained in the surgical operating theater or the healthcare environment in general.

Bioterrorist threats, conceivably exposing the environment to airborne toxic gases and microbes, as well as the annual trend of increasing nosocomial infections in the healthcare setting, create an acute necessity for uniform standards of testing, monitoring and containing a facility's airborne bioburden through active implementation of microcidal devices, especially in the surgical operating theater and other clinical areas.

The Significance of Nosocomial Infections & Airborne Pathogens

Indoor Air Quality (IAQ) is significant in hospitals due to the continuous exposure of bacteria, viruses, and fungi they are confronted with 24/7/365. Some antibiotics used to treat these organisms have become ineffective in recent years due to the adaptation of the organisms survival instincts. This has resulted in microbe mutations known as "super bugs." Since hospitals serve as a receptacle of microbes and fungi from the patients being treated for diseases caused by these organisms, hospitals are a central source of resistant organisms. Visitors enter the hospital virtually uncensored for pathogens on their clothing or exposed surfaces of their body. The authors conclude that in addition to multiple placements of the AiroCide system in strategic areas of the hospital, the public entranceway would be a "must" location and would assist in reducing airborne pathogens thus may have an impact on reducing nosocomial infections. Decreasing opportunities for cross-contamination is a major factor in the vector of nosocomial infections in patient rooms.

Sampling Population

Select diverse clinical areas were sampled using the air sampling method of a "slit" sampler. The sampler has an attached vacuum compressor that samples one (1) cubic foot per minute. The air sampling method is superior to surface sampling, where swabs are cultured from the surfaces of equipment and structures.

In order to maintain a statistically significant sample population, a protocol using "baseline", "active off" and "active on" parameters was established. This allowed for a comparison of airborne microbes in each test area with the AiroCide system activated and not activated. The "active off" and "active on" samples were also compared to airborne microbial levels in each test area while the room was empty, with no surgical procedure in progress, which established the "baseline". The "active on" and "active off" samples were taken primarily within 24-hr intervals. In the case of the ENT Day Surgery sampling, all "active" sampling was conducted prior to "baseline" due to clinical scheduling demands. The samples were delivered to the testing laboratory at Texas A&M University, College Station Texas, College of Medicine, Microbiology & Immunology Testing Labs, without plate sample markings of the settings being sampled, to avoid any bias in the CFU count or microbial expectation. A single blind study was therefore achieved, which promoted preservation, theoretically and statistically, of the clinical normality of the population and reduced variance in the samples tested.

Results

ENT Day Surgery

Table # 1 – ENT Day Surgery		
Test	Date(s)	CFU/m3
Test 1 - Baseline	6.21.03	228
Test 2 - Active OFF	6.20.03	572
Test 3 - Active ON	6.05.03	179
% Change in CFU's from Test 2 to Test 3		- 68.7%

Test Area Volume	1,424 ft³
HVAC Inlet (1)	80 CFM
HVAC Outlet (1)	140 CFM
Air Exchange per Hour	5.8

The AiroCide system efficiently lowered the number of airborne microbes in the ENT Day Surgery area during procedures by 68.7%, and also reduced the 24-hour CFU count below the baseline count by 21.4% (see Table #1). This would indicate that the AiroCide system was actively eradicating microbes not only in the ENT Day Surgery area, but also along the entire clinical corridor in 4 adjacent offices.

Surgical Operating Room OR#1

Table # 2 – OR #1 Test Area		
Test	Date(s)	CFU/m3
Test 1 - Baseline	6.10.03 - 6.11.03	7
Test 2 - Active OFF	7.28.03	16
Test 3 - Active ON	7.29.03	12
% Change in CFU's from Test 2 to Test 3		- 25.0%

Test Area Volume	6,710 ft³
HVAC Inlet (8)	2,250 CFM
HVAC Outlet (3)	2,603 CFM
Air Exchange per Hour	20.7

There was a 6-unit AiroCide system in OR #1 during the test, which significantly reduced the number of airborne microbes in the operating room by 25.0%. The "Active On" samples were taken during three non-invasive arthroscopic procedures with minimal blood aspiration.

Surgical Instrument Sterile Preparation Room

Table # 3 – Surgical Instrument Sterile Preparation Room

Test	Date(s)	CFU/m3
Test 1 - Baseline	7.18.03	32
Test 2 - Active OFF	7.21.03	207
Test 3 - Active ON	7.22.03	11
% Change in CFU's from Test 2 to Test 3		- 94.7%

Test Area Volume	5,760 ft^3
HVAC Inlet (1)	5 CFM
HVAC Outlet (2)	6 CFM
Air Exchange per Hour	0.5

The single-unit AiroCide system in the Surgical Instrument Sterile Preparation Room lowered the number of airborne microbes by 94.7% with the use of the AiroCide system.

Summary & Conclusion

The authors' research is an attempt to better understand how a photo-catalytic oxidation device, such as the AiroCide system, could lower the occurrence of nosocomial infections in a variety of clinical settings. The AiroCide system was effective in reducing the number of airborne microbes and fungi in all sampled clinical environments. This verifies the first objective of this research study and confirms the original hypothesis as true.

Airborne microbes were reduced by an average of 62.8% (68.7% in ENT Day Surgery, 25.0% in the Surgical Operating Room (OR), and 94.7% in the Surgical Instrument Sterile Preparation Room) with the implementation of the AiroCide system. Empirical correlation of this research data suggests that a reduction in nosocomial infections would follow an exponential decrease in nosocomial rates. The authors base this statement on the fact that MRSA was cultured during an arthroscopic procedure (a surgical procedure that causes very little aspirated fluid and is minimally invasive) in the OR. After the AiroCide system was activated during a similar arthroscopic procedure 45 minutes later, no MRSA CFUs were cultured after sampling. Gram-positive rods (a microorganism, which is highly resilient to antibiotics) were also dramatically reduced with the AiroCide system in the active stage. These facts verify the second objective of the research study, which correlates reduction of airborne microbes to an augmentation and enhancement of risk management in cases of nosocomial infection rates.

The authors conclude that a medical device that does not produce mutants (which have been documented by UV-only systems) or cross-resistance is a very effective means of eradicating or reducing nosocomial and environmental microbial contamination. The AiroCide system both enhances and augments existing facility HVAC systems resulting in lower risk factors for nosocomial infections. It should also be pointed out that the manufacturer recommends that the system be mounted on the ceiling or upper wall for maximum effectiveness. Due to logistical constraints, the authors were confined to placing the AiroCide systems on mobile carts 36 inches above the floor. With the superb and startling results achieved in this research scenario, it can only be concluded that ceiling mounted systems may provide an even more dramatic effect. This would contribute to a more economical baseline for any institution in considering the cost of nosocomial infections and the negative impact of prolonged hospital stays.

In summary, the AiroCide system has the following advantages:

1) An efficiently high destruction rate of pathogens
2) No chemical additives
3) No residual ozone or other byproducts
4) Efficient energy requirements; existing electrical access
5) The ability to oxidize and eliminate VOC's and bioaeorsols (odors)
6) Low maintenance and long product life; no filters to change
7) Not effected by humid conditions
8) Does not effect the HVAC duct flow or pressure drop
9) Enhances air mixing with existing HVAC systems
10) Installation does not require room renovations
11) Size and placement will not obstruct normal clinical processes
12) Quiet does not interfere with communication