

Reduced Particle Load in Operating Rooms, Airborne Pathogens Killed, and the Elimination of Infections

A White Paper
Prepared by SecureAire
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Existing hospital, intensive care units, and operating room ventilation systems (including HEPA filtration) do not remove the smallest particles nor inactivate deadly pathogens

Introduction

The human body can last nearly thirty days without food, three days without water, but you will die in three minutes without air. We must continually breathe, every minute of every day. You cannot defer breathing until you're certain to be in a clean air environment. Today 90% of us are spending greater than 90% of our time indoors¹. In many buildings in most cities indoor air quality (IAQ) is now worse than outdoor air. The primary pollutants (indoor and outdoor) and most airborne pathogens are exceeding small in size, less than five microns in diameter. The smallest of these are not removed by traditional filtration methods. The latest research has documented that particulate air pollution (indoor and outdoor) is associated with cardiovascular disease, declining cognitive function, dementia and Alzheimer's disease². Particulate air-pollution is responsible for 14% of dementia worldwide and as in tobacco smoking there is no safe threshold of exposure³. Each and every breath of air contaminated with pollution and airborne pathogens increases your risk of disease. This is no more critical than in hospitalized patients that are at risk for hospital acquired infections (HAI's) with the many who are immune compromised. These HAI's affect millions of patients, kill nearly 100,000 each year, and cost the United States healthcare systems between \$10-30 Billion annually. **Existing hospital, intensive care units, and operating room ventilation systems (including HEPA filtration) do not remove the smallest particles nor inactivate deadly pathogens⁴.**



“Now granted, our infection rate was low ... but, I don't think that you can beat zero!”

— Randy Watson, MD

Methods

SecureAire embarked on the development of a technology platform to address the critical issues of Indoor Air Contamination within the Healthcare Environment. This included laboratory, independent and live operating room studies.

Active Adjacent Operating Room Comparison: Nearly identical and adjacent operating rooms were ventilated using similar air handling units and included different filtration schemes. The first consisting of a pre-filter, MERV 14, and HEPA filter versus the second consisting of a pre-filter and a SecureAire ACS MERV 15 system. Particle counts at ≥ 0.4 microns per cubic foot were measured for two weeks.

Pathogen Killing Study: The Particle Control Technology system (SecureAire ACS) was loaded with > 100 Million viable *Bacillus subtilis* (Anthrax surrogate) cells at a surface loading density $> 10^7$ cells/cm² on the filter surface. Standardized cell viability was measured in triplicate upon exposure to the SecureAire ACS System⁴.

Active Single Operating Room Comparison: In a mid-size community hospital a standard operating room, 20' x 23' x 10' was studied. The ventilation system consisted of a multiple down draft air intake with 16 air exchanges per hour and included HEPA filtration. Operating room airborne contamination levels were measured for a total period of four weeks with two successive weeks of similar surgery activity. The control week used existing ventilation alone. The treatment week was identical with the exception of the addition of the SecureAire ACS portable APS-1000X unit.

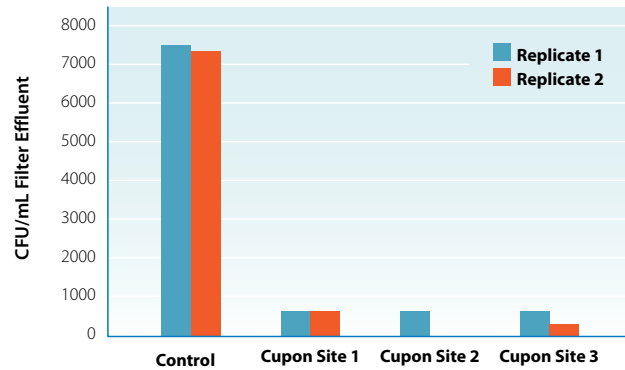
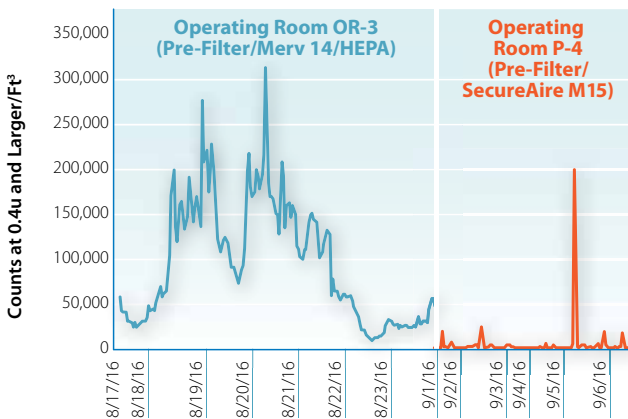
Impact on Infection: In a single out-patient orthopedic surgery center particle contamination loads, measured Total Volatile Organic Compounds (TVOC's), and annual infection rates were compared before and after installation of a SecureAire System.

Results

Active Adjacent Operating Room Comparison: The operating room with a pre-filter and the SecureAire ACS MERV 15 system achieved a 96% reduction in particle counts (> 0.4 microns) for six consecutive days when compared to a pre-filter, MERV 14, and HEPA filtration system.

Pathogen Killing Study: Exposure of *Bacillus subtilis* cells to the electric field of the SecureAire ACS system reduced total viable cell count by 90-99% within three hours. There was no bacterial viability documented beyond three hours.

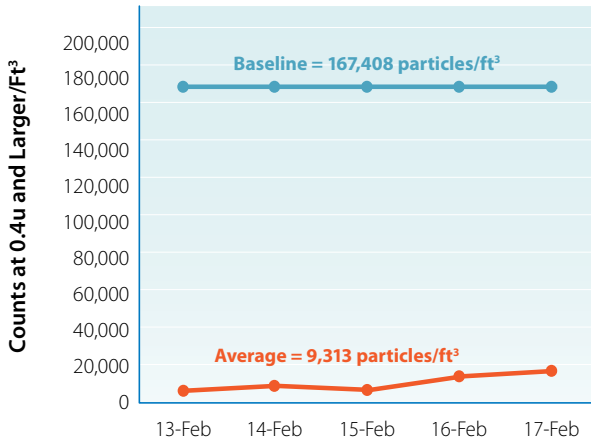
Adjacent Operating Room Results



HEALTHCARE SERIES: Hospital Acquired Infections

Active Single Operating Room Comparison: The addition of the SecureAire ACS portable APS-1000X unit into an active operating room resulted in a 49-94% reduction in airborne particle load at all times and during and after surgery ($p=0.019, 0.056, \text{ and } 0.085$).

Active Single Operating Room Results



Particle Control Technology Data Summary

Item	Baseline Data	Particle Control Technology	Control (HEPA)	Improvement (%)
Average counts (0.4u and larger/ft³)	167,408	9,313	33,936	94.4
Peak counts	629,100	22,600	362,300	96.4
Low counts	4,827	700	1,200	85.4
Surgeries	19	12	12	
Hours	30:03	24:06	22:97	
Pathogen kill rate	0%	99+%*	0%	

* Mark Hernandez, PhD, University of Colorado

References

¹ Environmental Protection Agency

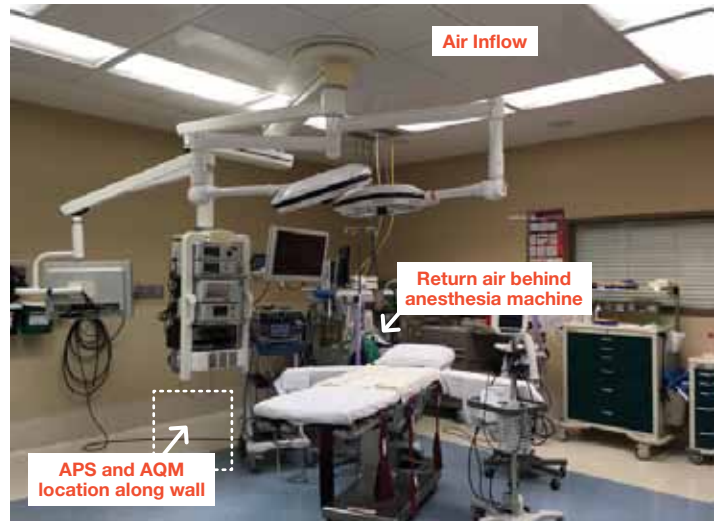
² Fine particulate matter air pollution and atherosclerosis: Mechanistic Insights, Bai & Sun, Biochimica et Biophysica Acta, 2016.

³ Smoking and increased Alzheimer's disease risk: a review of potential mechanisms, Durazzo, et al, Alzheimer's & Dementia, 2014

⁴ A combined Fluorochole Method for Quantification of Metabolically Active and Inactive Airborne Bacteria, Hernandez, et al, Aerosol Science and Technology, 1999

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Impact on Infection: The installation of SecureAire system in an outpatient orthopedic surgery center quantitatively reduced particle contamination loads and significantly reduced TVOC concentrations, which directly translated to an infection rate of a "Zero".

Conclusions

The link between airborne particulate exposure and Atherosclerosis, Alzheimer's Disease, Dementia, Declining Cognitive Function, and Hospital Acquired Infections has now been established. Traditional filtration methods do not have the ability to transfer the critically small contaminants for capture within the environment, however Particle Control Technology provides measurable and impactful results.

The series of laboratory and clinical studies demonstrate that the SecureAire ACS System in both portable and installed air handling unit configurations reduced particle loads in active operating rooms, killed airborne pathogens, and in a single out-patient surgery center eliminated HAI's.

The ability to deploy Particle Control and Pathogen Inactivation Technology exists today and could improve clinical outcomes and reduce the \$20+ Billion annual cost of Hospital Acquired Infections and reduce inflammatory and degenerative diseases.

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About SecureAir

SecureAir is headquartered in Oldsmar, Florida. The Company is the industry leader in Particle Control Technology, which is based upon technologies developed and employed in Semiconductor Cleanrooms. SecureAir has advanced and developed highly sophisticated air purification technologies that make “air flow the dominant transport mechanism for airborne contamination.”

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