2024 Critical Environments Summit

Healthcare Critical Environments, **Solutions for Patient Safety, Decarbonization, and Comfort**

(Course # HCEHD4Z101)

David Rausch

Phoenix Controls

AIA Continuing Education Provider

1/17/24

Upon completion of this course…

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Course Description and Learning Objectives

Abstract: Surgical site infections kill on average 100,000 patients per year, where they perish from a secondary infection contracted after being admitted to the hospital for surgery. Hospital operating rooms are among one of the most infection-sensitive environments within a healthcare facility. Surgery increases a patients vulnerability to pathogens transmitted from surgical personnel, surgical equipment, airflow in the operating room, and a patient's own skin flora. Two of every 100 surgeries in the US result in surgical site infections, according to the Center for Disease Control and Prevention (CDC). During surgical procedures, dust particles, textile fibers, skin scales, and respiratory aerosols containing viable microorganisms are released from the surgical team and to the surrounding air in the operating room. With several research studies relating airborne particulate count to surgical site infections, there continue to be no regulated standards for airborne particulate levels in most health care facilities in the US. ASHRAE 170 does not address airborne particulate levels in operating rooms. However, standards for airborne containment control are extremely well defined for semiconductor and pharmaceutical clean rooms.

Aseptic procedures and requirements for personnel entering semiconductor or pharmaceutical clean rooms are often more stringent than those required for doctors and nurses entering an operating room. Obviously, contaminated semiconductor chips or pharmaceutical drugs can cost billions of dollars in loss to the manufacturer due to lost revenue, warranty costs, back charges and liability due to catastrophic failure resulting from airborne contamination in the clean room. Although not required by codes or law, proven, design solutions/technologies to reduce airborne contamination and improve operating room performance are commercially available in the US, which can reduce the number of SSI deaths per year. These solutions/technologies involve the delivery of air into the surgery suite, proper pressurization control of the surgery suite, and data analytics using real time sensors to understand the indoor environmental quality of operating rooms prior to conducting surgery. Further, if these solutions are properly designed and deployed, the hospital can significantly reduce the energy costs related to heating/cooling/humidifying the air serving these spaces, resulting in a very attractive payback for the investment in such solutions, providing an attractive business case for the executive team to consider.

Course Description and Learning Objectives

Learning Objectives: Part 1

- After this presentation, the audience will leave with an understanding of ….
  - Understand the driving forces for Hospitals to improve hospital acquired infection (HAI) control overall, with a specific focus on surgical site infections (SSIs).
  - Understand the importance of airflow patterns and their effect particle migration using Computational Fluid Dynamics (CFD) models of various laminar flow systems.
  - Understand best practices from other industries requiring "clean" spaces, and how implementing these practices can positively affect airflow patterns and particle migration in an operating room setting.

Learning Objectives: Part 2

- Understand how operating room pressurization can impact surgical site infections and what controls can be implemented to correctly maintain room pressurization to reduce risk of airborne contamination.
- Understand how real time indoor environmental quality (IEQ) "Surveillance Solution" utilizing sensors can be deployed to provide both real time monitoring and risk score on operating room conditions, and use predictive modeling software to "advise" the surgical team when conditions to operate are favorable (clean) or not favorable (higher risk of surgical site infections).
- Understand how to safely reduce energy cost in operating rooms while maintaining indoor environmental quality and reducing the risk of SSIs.
- Understand best practices from other industries in terms of modular design and installation that can be applied to an operating room setting, reducing construction time, improving the quality of systems supporting the operating room environment, and improving room aesthetics and lighting.

The Driving force for improving SSI and HAI Outcomes

If you are admitted to a hospital, you have a 5% chance of contracting an HAI
22
5
Your length of stay in the hospital increases by 17.6 days if you get an HAI
1.7 million
people per year get an infection during a hospital stay
98,987
people in the U.S. die annually from HAIs
HAIs kill more people each year than Breast Cancer and Prostate Cancer combined.
System
$35
Billion/yr
Patient
$1,100
per admission
9.4%
of total
inpatient costs are HAI-related
69%
More than ⅔ of HAIs affect people with Medicare or Medicaid
Prostate Cancer
Breast Cancer 41,115
Heart Failure 56,752
Diabetes 68,504
HAIs 98,987

The Problem we are targeting…

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

Surgical Site Infection (SSI)

A surgical site infection is an infection that occurs after surgery in the part of the body where the surgery took place. Surgical site infections can sometimes be superficial infections involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin, organs, or implanted material. CDC provides guidelines and tools to the healthcare community to help end surgical site infections and resources to help the public understand these infections and take measures to safeguard their own health when possible.

The Problem we are targeting…

While costs of an SSI vary widely based on the degree of infection and the site of surgery, the estimated average cost of an SSI can be more than $25,000, increasing to more than $90,000 if the SSI involves a prosthetic implant.[3] Overall, SSIs cost the US healthcare system an estimated $3.5 to $10 billion annually.[1]

Hospitals faced 'worst financial year since the start of the pandemic' in 2022, Kaufman Hall data show

By Dave Muoio • Jan 30, 2023 04:05pm

Since 2008, the US Centers for Medicare and Medicaid Services (CMS) are no longer reimbursing hospitals for HAIs like SSI.[4] Not surprisingly, SSI prevention has become a critical objective for institutions nationwide.

CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

The Problem we are targeting…

American Hospital Association™

Advancing Health in America

Report: Hospitals could face new normal as financial challenges linger

Feb 28, 2023 - 02:27 PM

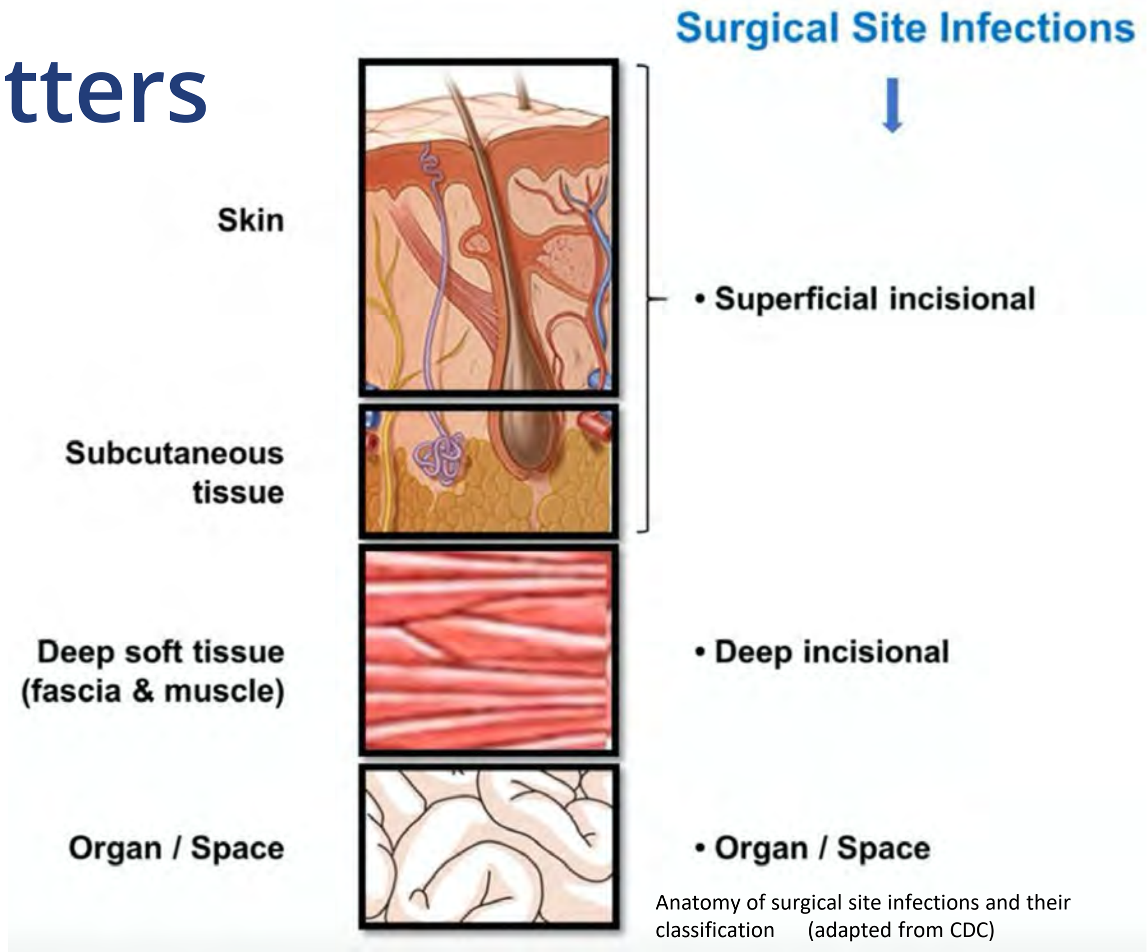
Hospitals continue to experience the same challenges that made 2022 the worst financial year since the start of the COVID-19 pandemic, including higher labor expenses and lower patient volumes, according to the latest report on hospital finances from Kaufman Hall. Hospital operating margins fell from -0.7% in December 2022 to -1% in January 2023, following persistent negative margins throughout last year. Notably, drug expenses have increased 12% compared to YTD 2020.

"While we have seen a stabilization in operating margins over the past several months, the trendline continues to show that hospitals will be in a tough spot financially for the foreseeable future," said Erik Swanson, senior vice president of data and analytics for Kaufman Hall. "With future COVID surges possible and challenging financial months ahead for hospitals, managing cash on hand will be critical to weathering the storm."

Why Surgical Site Infection Matters

SSIs remain a substantial cause of morbidity, prolonged hospitalization, and death:

- Account for 20% of all HAIs,
- Associated with 2-11-fold increase in risk of mortality,
- 75% of SSI-associated deaths directly attributable to the SSI, [1,2]



Anatomy of surgical site infections and their classification (adapted from CDC)

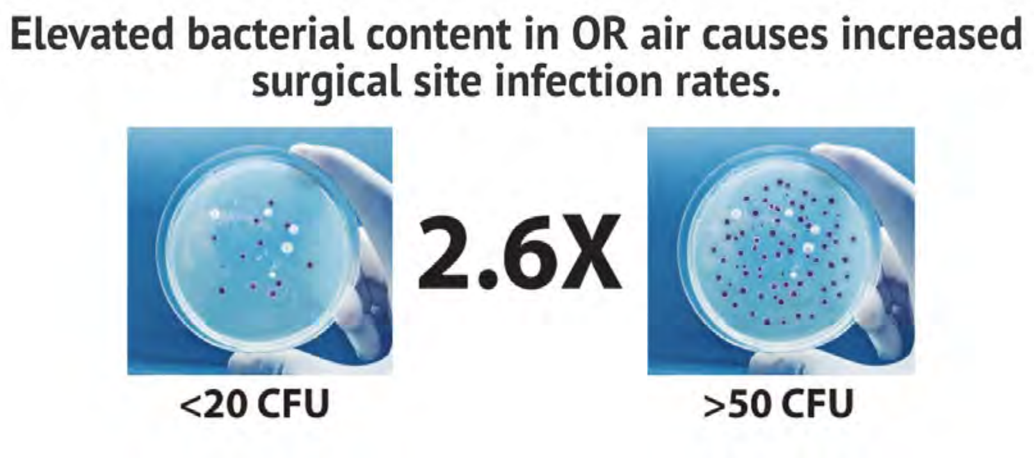
- Most costly HAI: Est. ann. cost $3.3 billion, extends LOS by 9.7 days, increases cost of hospitalization $20,000/admission. [2]

1. Ban, K.A., American College of Surgeons and Surgical Infection Society: Surgical Site Infection Guidelines, 2016 Update. J Am Col Surg 224(1): (2017), 59-74.
2. Awad, S.S., Adherence to surgical care improvement project measures and post- operative surgical site infections. Surg Infect 13(4): (2012): 234-7.
3. Carreira, L. et al. (2020). Surgical blades as bacteria dissemination vehicles in dogs undergoing surgery – a pilot study. Biomed Eng Int 2. 25-29.

Airborne Bioburden and Surgical Site Infection: 60 Years of Evidence

- Airborne transmission accounts for 20%–24% of post-operative wound infections.[1]

- 98% of bacteria in patients' wounds, after surgery in conventionally ventilated OR, came directly or indirectly from the air.[3]
  - Rooms with over 50 CFU/m^3 were 2.6x more likely to have postoperative infection than those with 10-20 CFU.



Credit: Aerobiotix

- Large, multi-center study *majority* of bacteria contaminating the wound likely reached it by the airborne route.[2]
  - By reducing CFU level from 600 CFU/m^3 down to <10 CFU/m^3, investigators reduced PJI from 8.5% to 0.7%.

1. Lidwell et al. Bacteria isolated from deep joint sepsis after operation for total hip or knee replacement and the sources of the infections with Staphylococcus aureus. *J Hosp Infect*. 1983;4(1):19–29.
2. Lidwell OM, et al. Airborne contamination of wounds in joint replacement operations: the relationship to sepsis rates. *J Hosp Infect*. 1983;4(2):111–131.
3. Charnley, J., Eftekhar, N. Postoperative infection in total prosthetic replacement arthroplasty of the hip-joint with special reference to the bacterial content of the air of the operating room. 1969. Br J Surg. 1969;56.

Where EQI comes from - Factors Relating to HAI or SSI During Procedure per NIH – 52.3% are used to Calculate Environmental Quality Index (EQI)

*2 out of 11 or **18%** of the environmental factors are covered by code or guidelines

1. **Aerosol and droplet transmission dynamics**
2. **The nature of the dust levels**
3. The health and condition of individuals naso-pharyngeal mucosal linings
4. **Population density**
5. **Ventilation rate***
6. **Air distribution pattern**
7. **Humidity and temperature***
8. Number of susceptibles
9. **Length of exposure**
10. **Number of infected people producing contaminated aerosols**
11. **Infectious particle settling rate**
12. Lipid or non-lipid viral envelope or microorganism cell wall
12. Surrounding organic material
13. UV light or antiviral chemical exposure
14. Vitamin A & D levels
15. Microorganism resistance to antibiotic or antiviral therapy
16. Type and degree of invasive procedure
17. Spatial considerations
18. Contact with a carrier
19. Persistence of pathogens within hosts
20. Immuno-epidemiology
21. Transmission resistance and role of host genetic factors

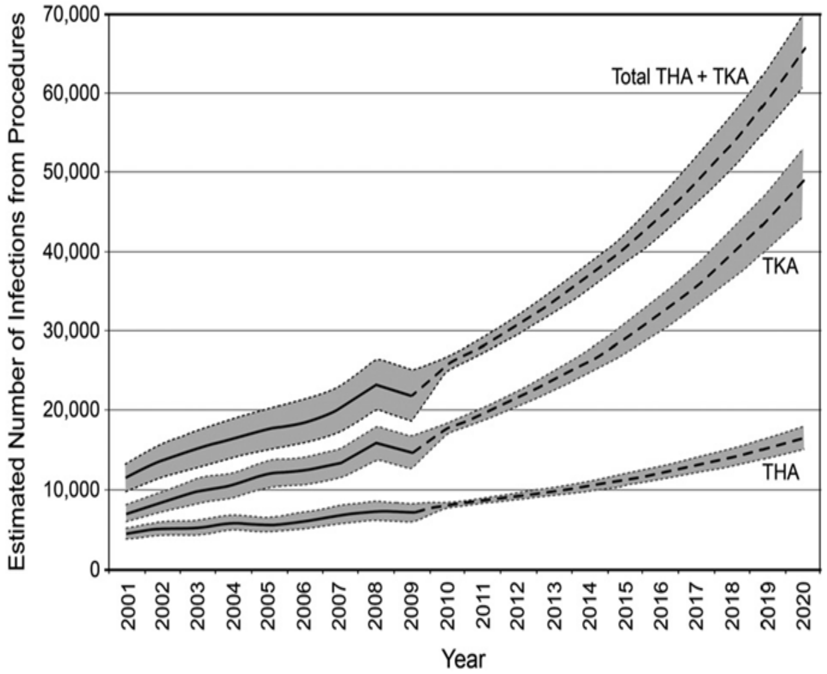
Dr. Farhad Memarazadeh

***Typical BMS Operating Parameters:**

1. Air Changes
2. Temperature
3. Differential Pressure
4. Relative Humidity (not specific)
5. Discharge Air Temp

Prosthetic Joint Infection *Procedural volume and rate of PJI are rising*

- Procedural volume of hip & knee arthroplasty growing *exponentially.*
- 2.18% of hip and knee implants become infected.[1] (2012 underestimate)
- PJI rising, expected to increase to 6.5% (THA) and 6.8% (TKA), respectively, by 2030.[1]
- Cost - $100,000 direct expense, $474,000 cost to society.[2, 3]
- Mortality rate 2–7%. 5-year survival worse than many cancers.[4]



Historical number of infected THA/TKA procedures in the United States [1]

1. Kurtz SM, 2012. Economic burden of periprosthetic joint infection in the United States. J. Arthroplasty 27:61–65.
2.Parisi TJ, What is the Long-term Economic Societal Effect of Periprosthetic Infections After THA. Clin Orthop Relat Res. 2017 Apr 7
3.Tande AJ, Patel R. Prosthetic Joint Infection. Clinical Microbiology Reviews. 2014;27(2):302-345.
4. Jeppe, Chronic Periprosthetic Hip Joint Infection. A Retrospective, Observational Study on the Treatment Strategy and Prognosis in 130 Non-Selected Patients PLoS One. 2016; 11(9).
5. Edmiston Jr, et al. Impact of patient comorbidities on surgical site infection within 90 days of primary and revision joint (hip and knee) replacement. Am J Infect Cont. 2019; 47 (10): 1225-1232.
6. Projected volume of primary and revision total joint replacement in the U.S. 2030 to 2060, Abstract presented at 2018 AAOS Annual Meeting. https://aaos-annualmeeting-presskit.org/2018. Accessed Sept 30, 2020.

The Importance of Airflow Patterns and Mitigating Risk.

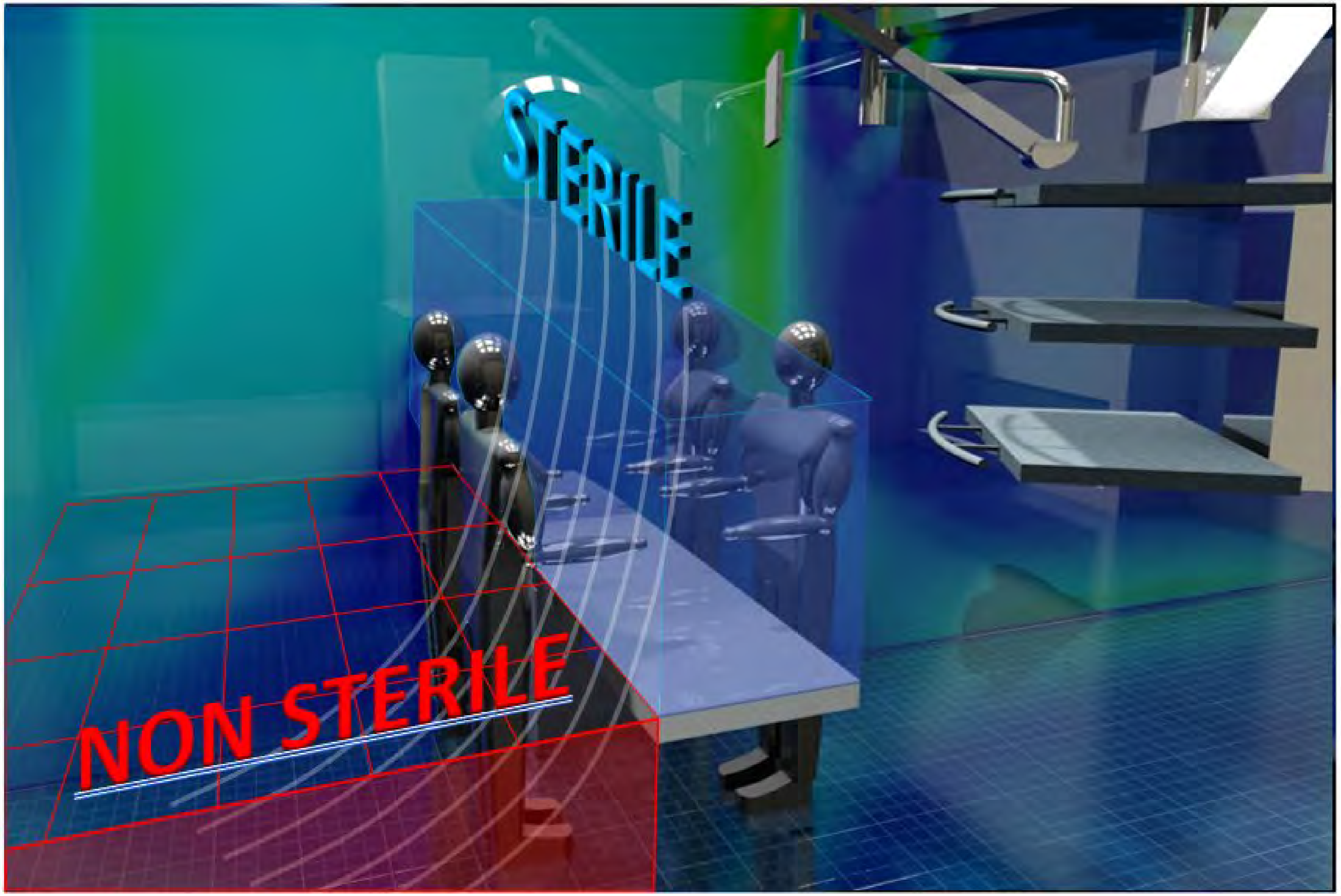
The Impact of Airflow over the table....

The current ASHRAE 170 guidelines define the minimum requirements for OR's:

- 4 ACH (OA) min, 20 ACH (total)
- Rooms positively pressurized to + 0.01" wc
- MERV 14 filtration (HEPA – in ceiling for ortho procedures)
- 20 – 60% RH
- 68 - 75° room temperature
- Laminar airflow diffusers over table (70% coverage)
- Laminar airflow field to extend 12" beyond table

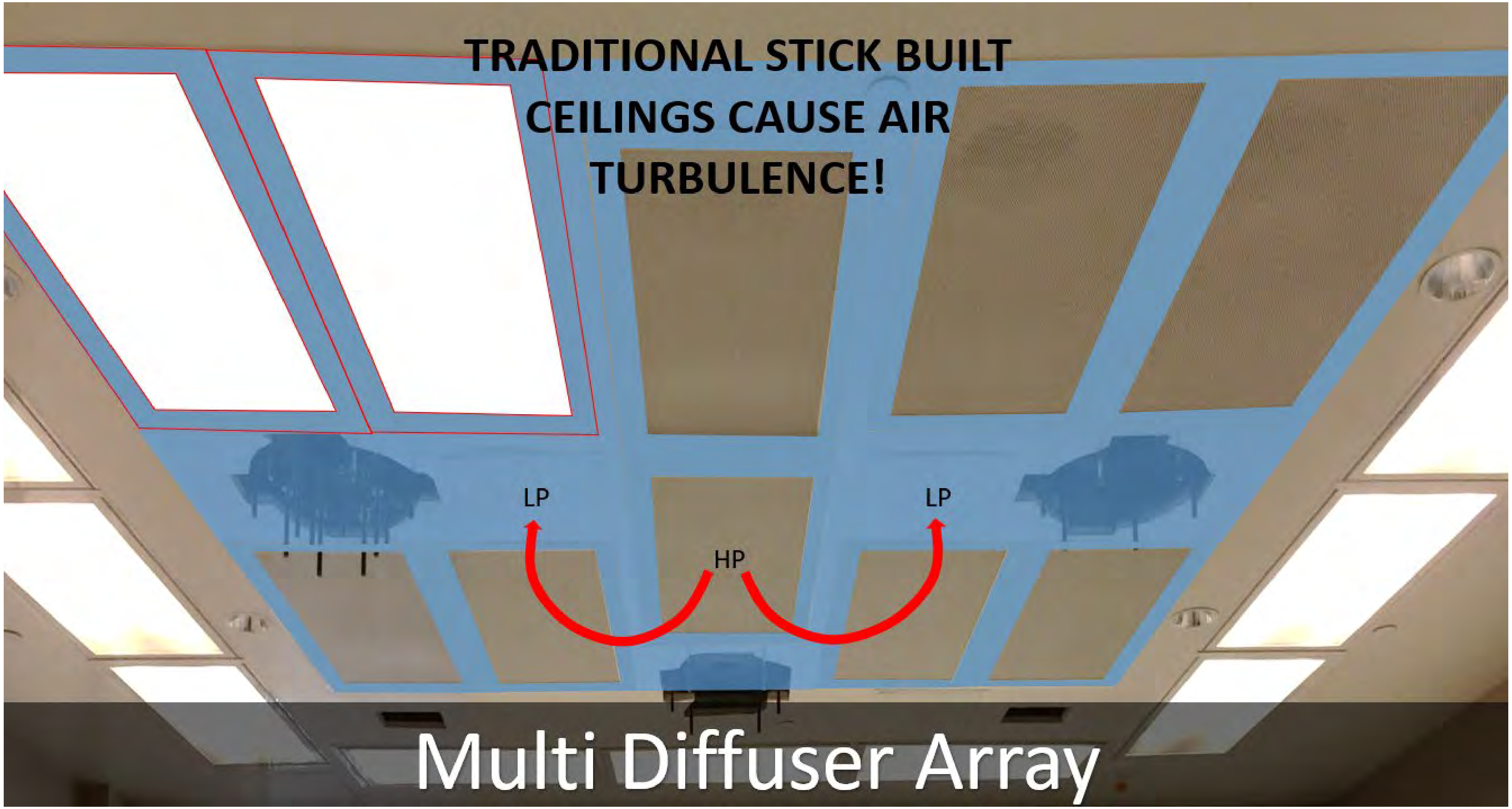
The Impact of Airflow over the table….

The Impact of Airflow over the table….



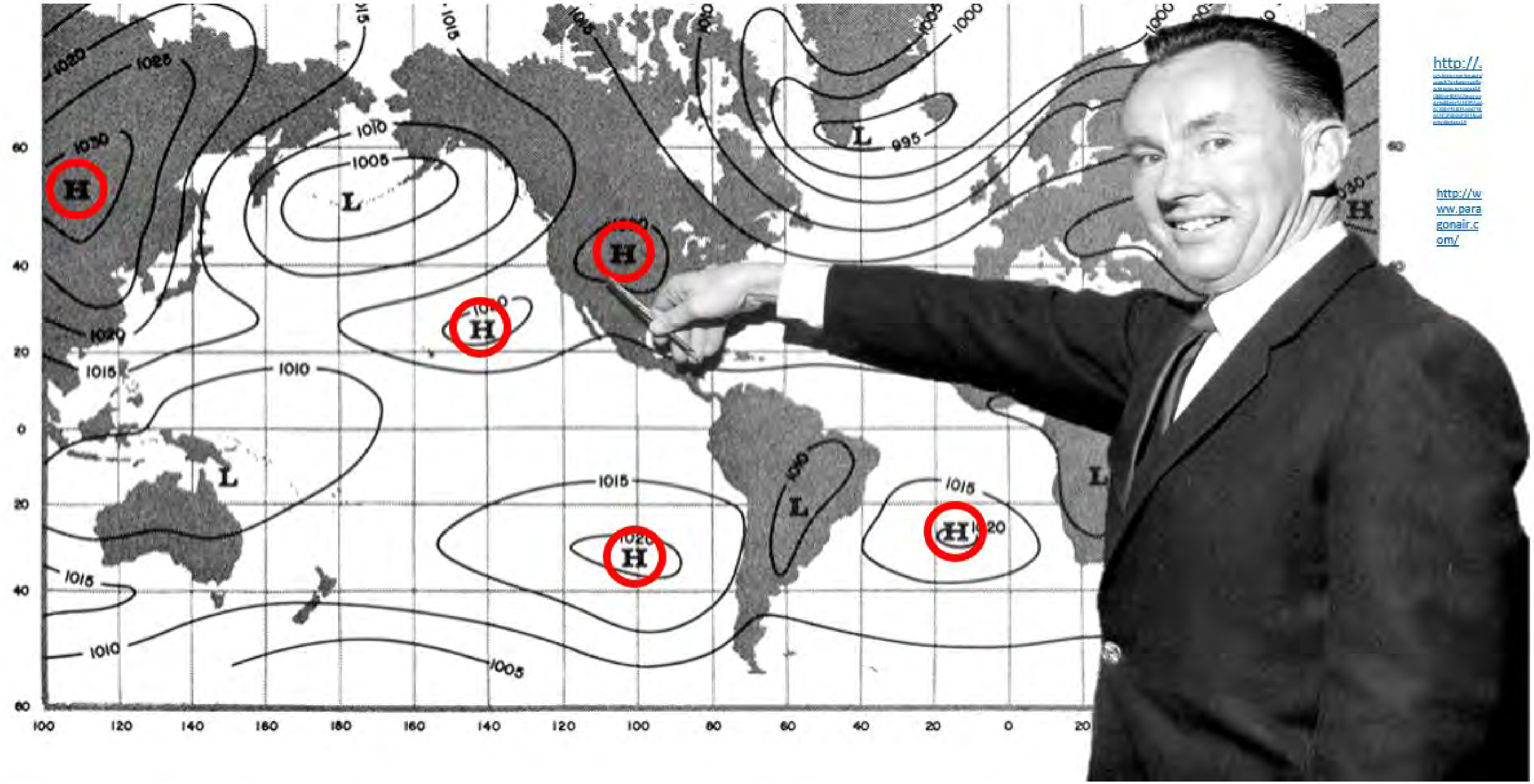
The Impact of Airflow over the table….

ASHRAE 170 allows up to 30% of the ceiling space over the table to have NO airflow…



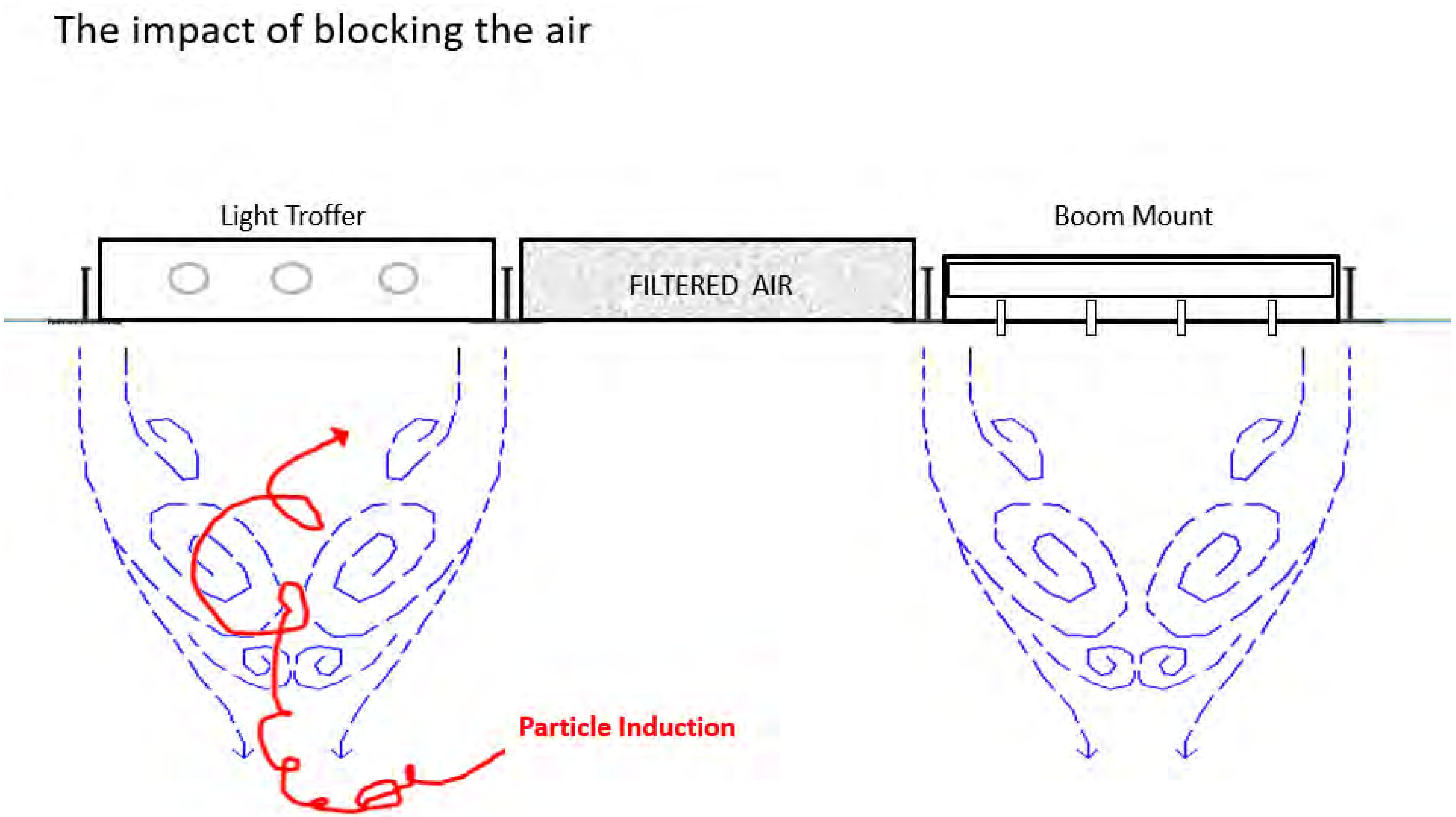
The Impact of Airflow over the table….

Air moves from high pressure to low pressure.

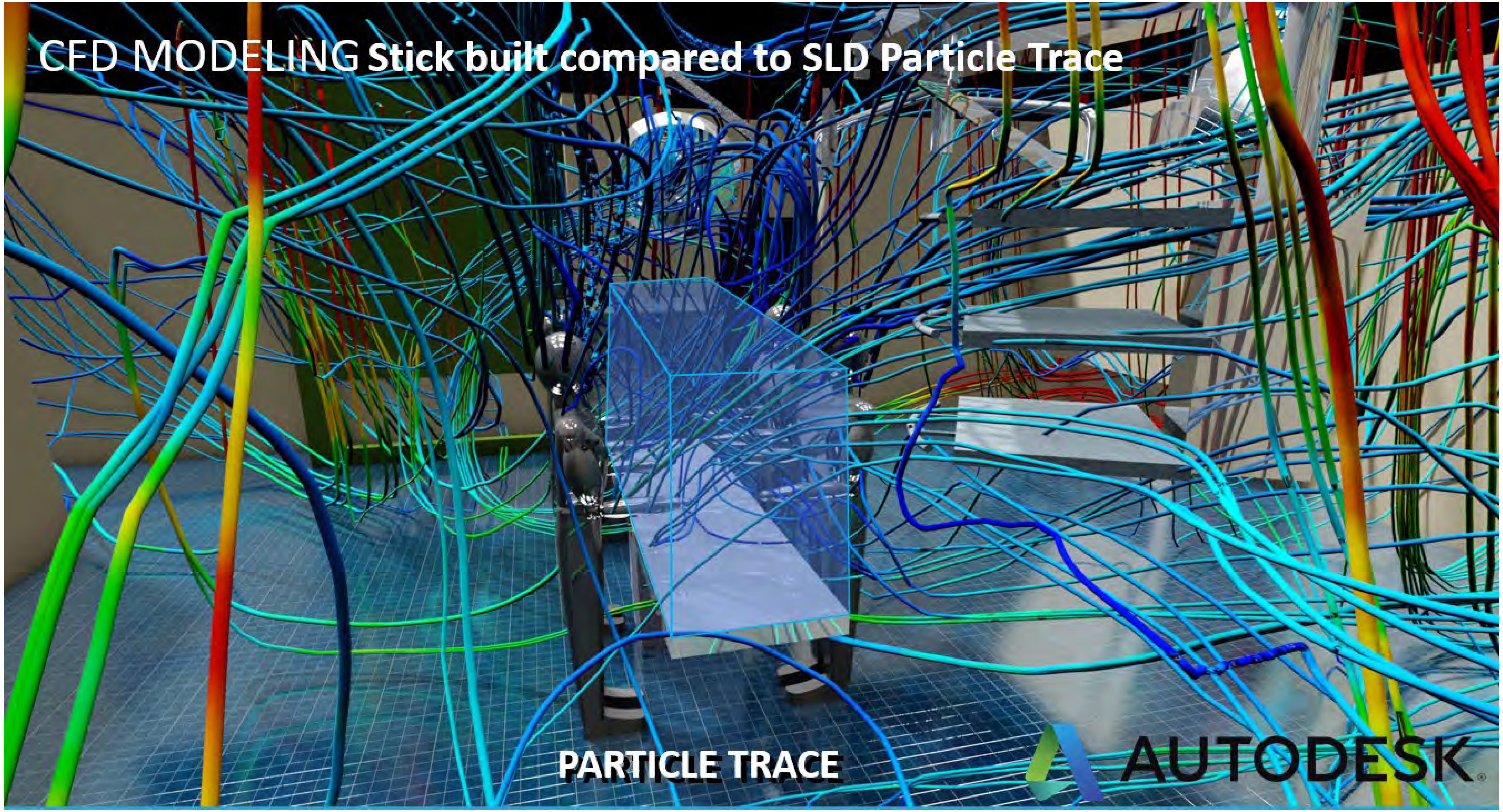


http://www.paragonair.com/

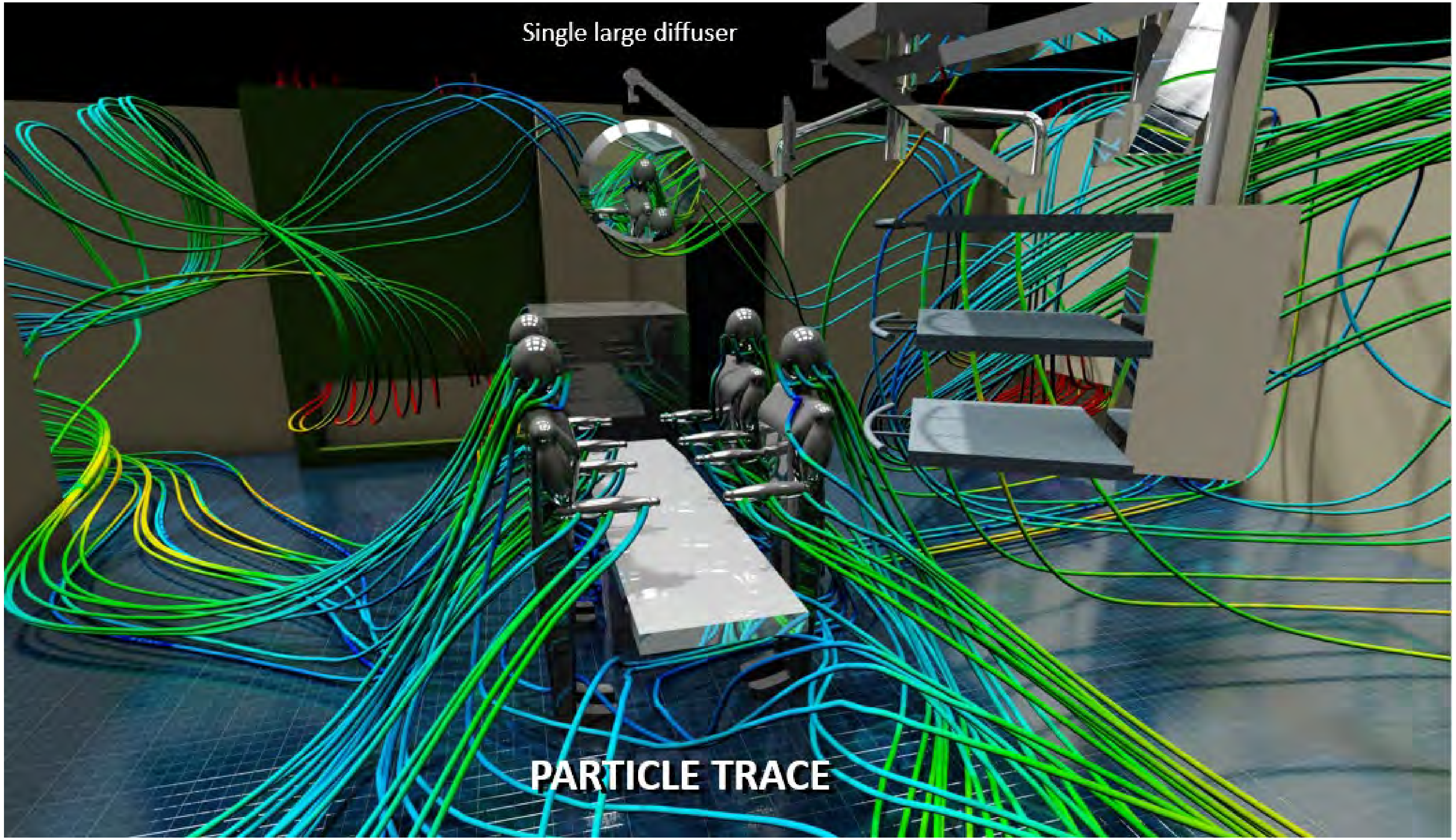
The Impact of Airflow over the table....

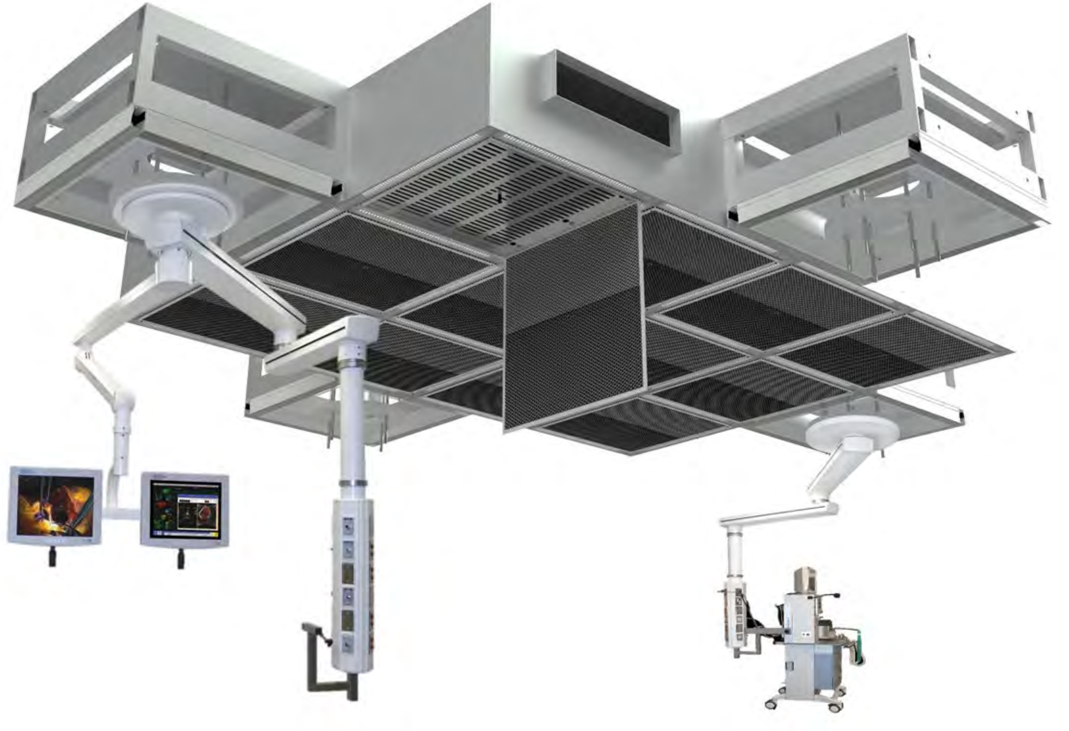


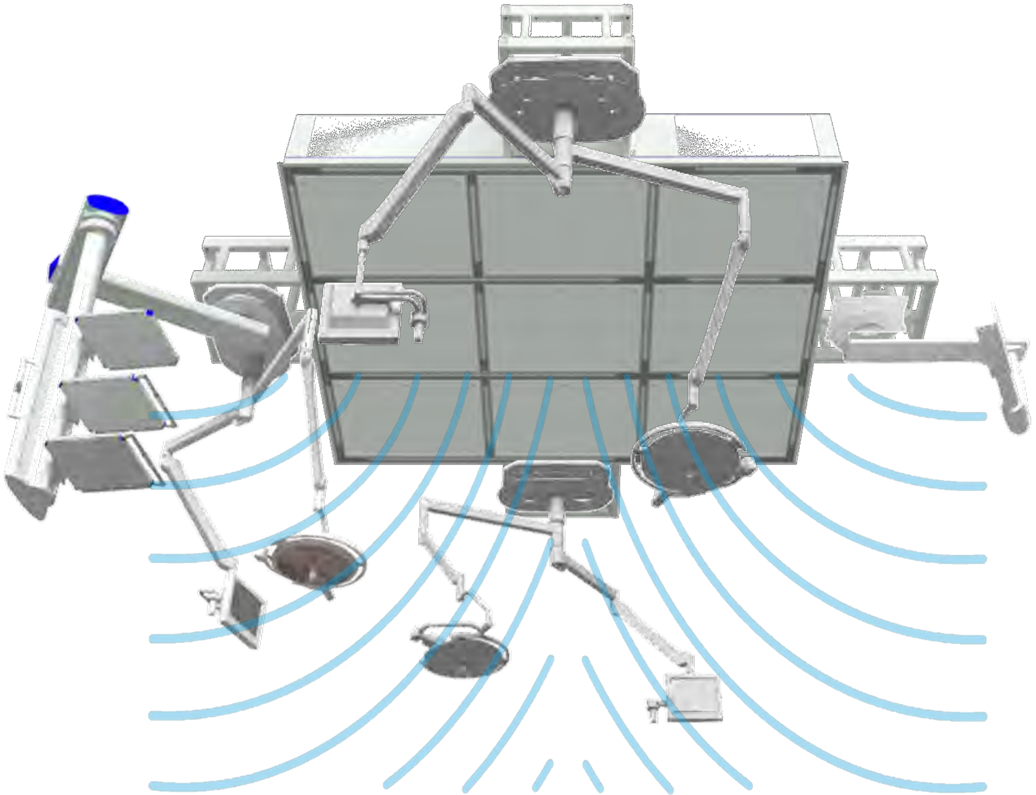
The Impact of Airflow over the table….



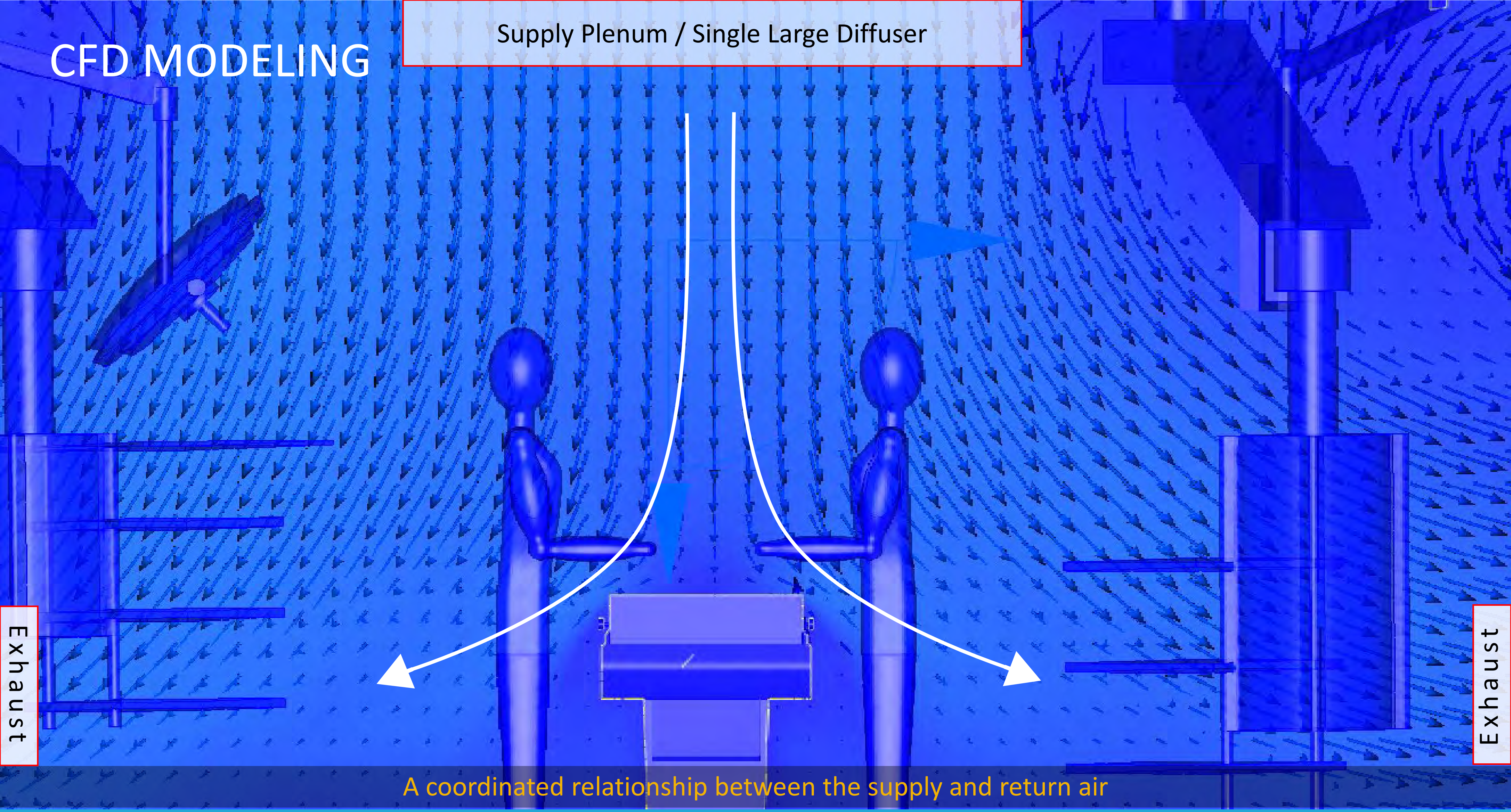
The Impact of Airflow over the table….



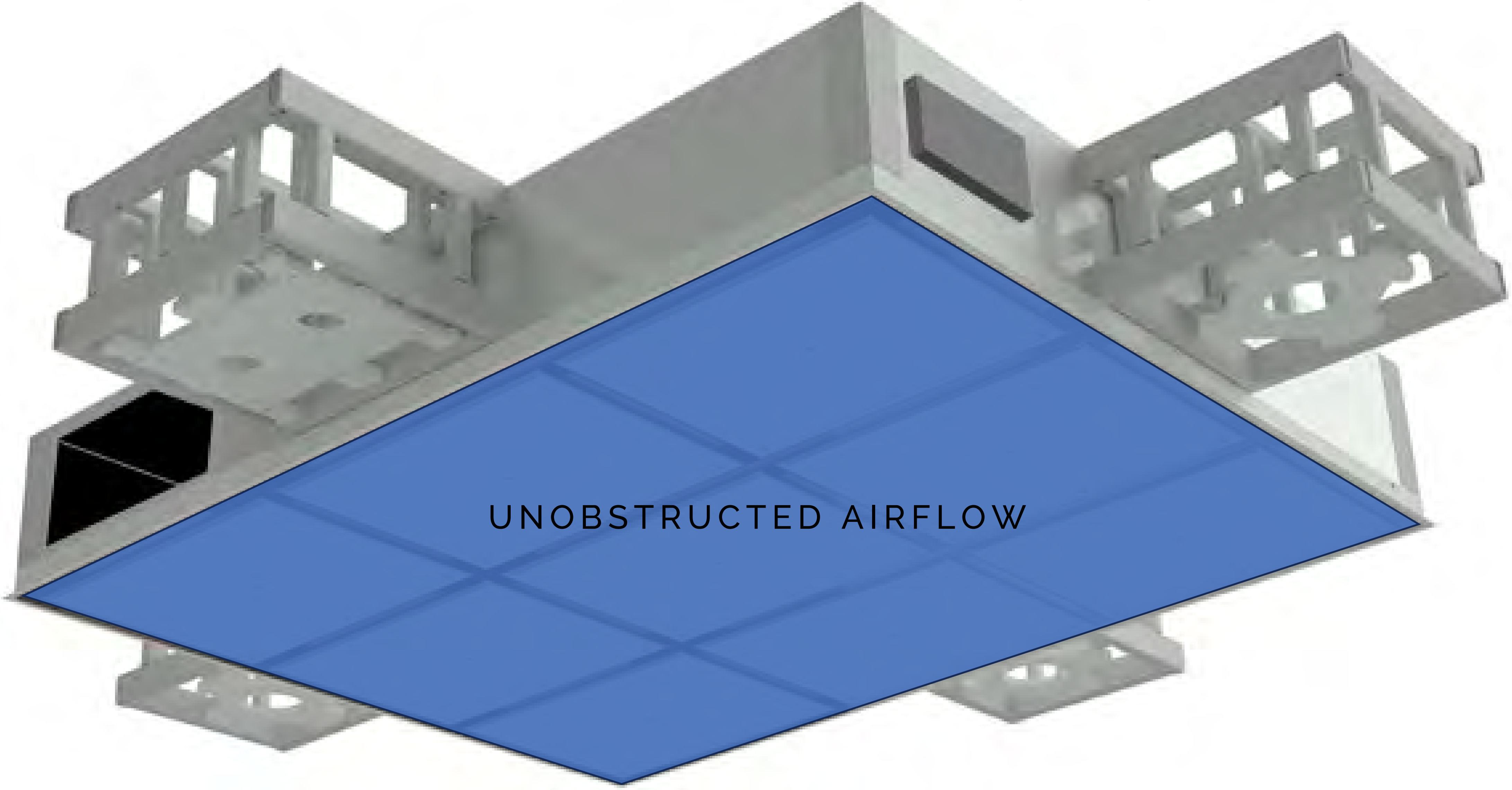




Laminar Airflow Built Into a Moment Frame Manifold


CFD MODELING
Supply Plenum / Single Large Diffuser
Exhaust
Exhaust
A coordinated relationship between the supply and return air

Zonal Pressure Control (ZPC)



Over the entire face area of the contiguous array

Frontloading Coordination of All Ceiling Trades & Vendors

Pre-Engineered MEP Performance

Compression of Construction Timeline

Reduced Risk & General Conditions

Single-Source Responsibility for Infrastructure Over Table

Reduced Site Conflicts & Change-Orders

CONSTRUCTION BENEFITS

The Impact of Airflow over the table….

The study - How we did it

Build full scale surgical suite mockup

Configure space for multiple air delivery methods

Script mock surgical procedure

Train full surgical team

Test multiple contaminants, multiple times, multiple scenarios

Record several thousand points of data

Bacterial, fungal and particulate counts

Submit all samples to the lab

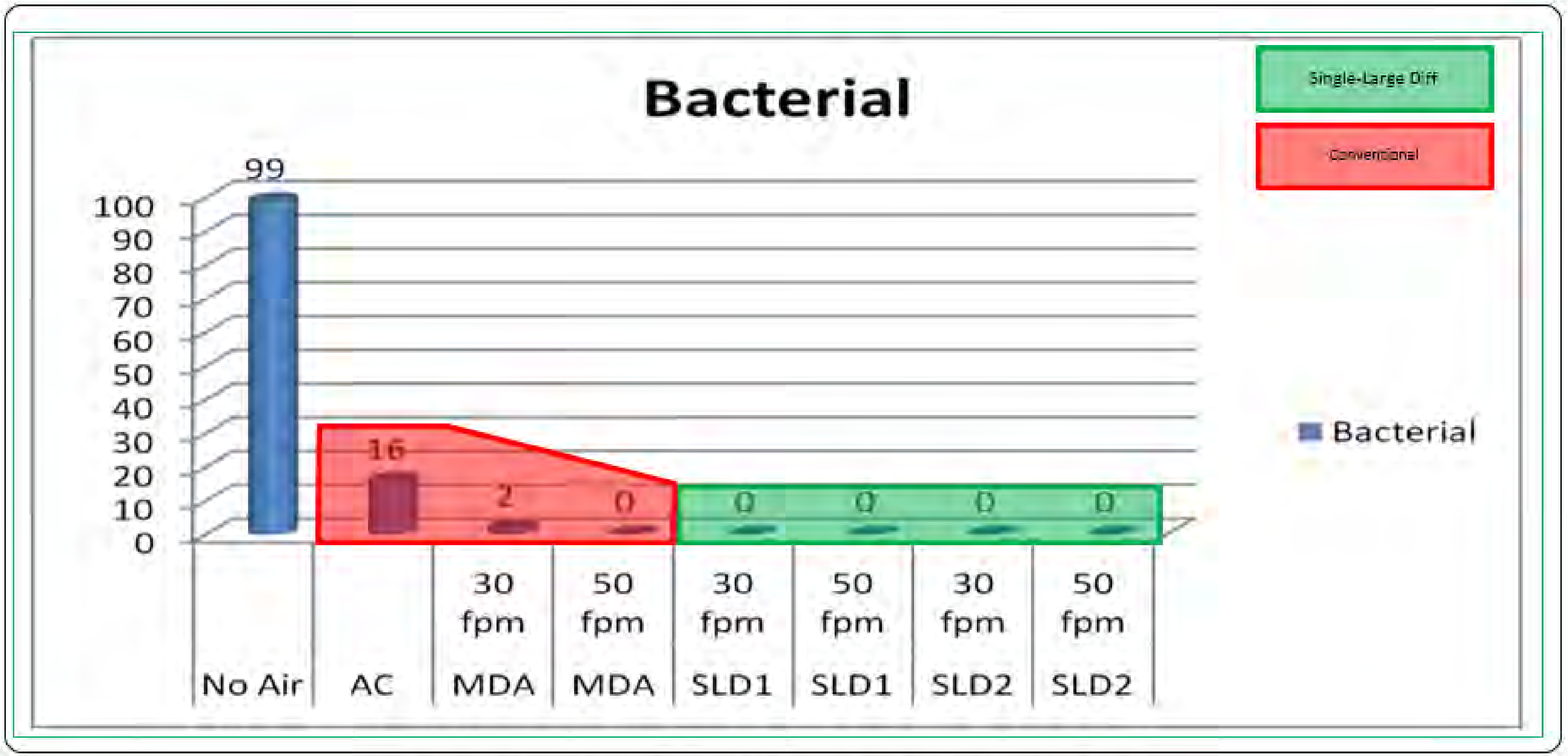
Tabulate results

Independent testing led by Dr. Jennifer Wagner, PHD Microbiologist

Third party validation done by NorthWest Engineering

The Impact of Airflow over the table….

The Results

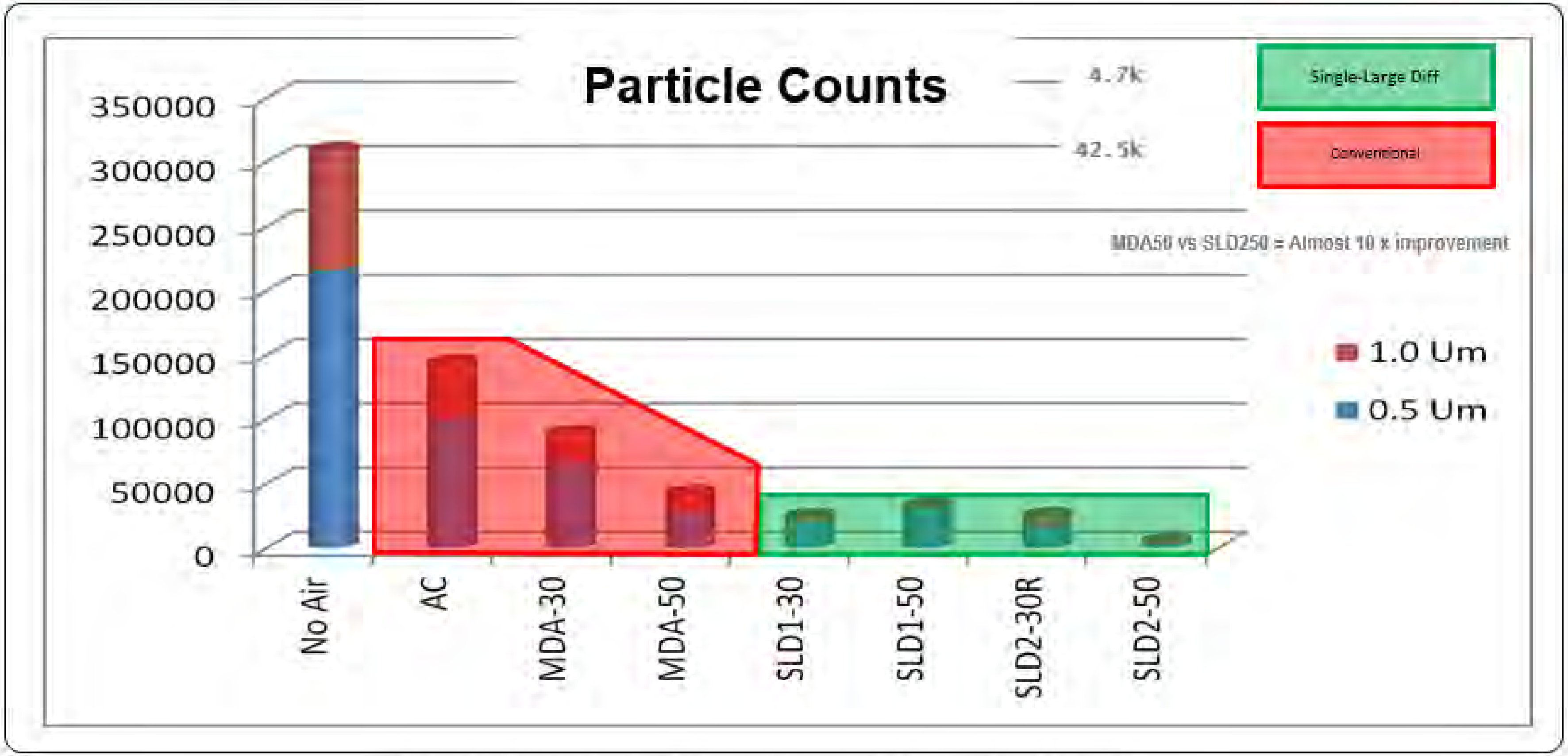


The United States Pharmacopeial Convention. <797> Pharmaceutical Compounding Sterile Preparations. Revision Bulletin. 2008, p.26.

The Impact of Airflow over the table….

The Results

Total particles collected for all tests in triplicate



The United States Pharmacopeial Convention, <797> Pharmaceutical Compounding: Sterile Preparations. Revision Bulletin. 2008, p.26.

The Impact of Airflow over the table….

The Results

Recommended Action Levels for Viable Particles in Air

The United States Pharmacopeial Convention. <797> Pharmaceutical Compounding-Sterile Preparations. Revision Bulletin. 2008, p.26.

The Impact of Airflow over the table….

The Results

ISO 14644-1 cleanroom standards

Class	maximum particles/m³						FED STD 209E
	≥0.1 µm	≥0.2 µm	≥0.3 µm	≥0.5 µm	≥1 µm	≥5 µm	equivalent
ISO 1	10	2.37	1.02	0.35	0.083	0.0029	
ISO 2	100	23.7	10.2	3.5	0.83	0.029	
ISO 3	1,000	237	102	35	8.3	0.29	Class 1
ISO 4	10,000	2,370	1,020	352	83	2.9	Class 10
ISO 5	100,000	23,700	10,200	3,520	832	29	Class 100
ISO 6	$1.0{\times}10^6$	237,000	102,000	35,200	8,320	293	Class 1,000
ISO 7	$1.0{\times}10^7$	$2.37{\times}10^6$	1,020,000	352,000	83,200	2,930	Class 10,000
ISO 8	$1.0{\times}10^8$	$2.37{\times}10^7$	$1.02{\times}10^7$	3,520,000	832,000	29,300	Class 100,000
ISO 9	$1.0{\times}10^9$	$2.37{\times}10^8$	$1.02{\times}10^8$	35,200,000	8,320,000	293,000	Room air

SLD

Conventional

A class 100 cleanroom has **100 particles per cubic foot**. By comparison your typical office space has between 500,000 and 1 million particles per cubic foot.

The Impact of Airflow over the table....

Performance Validation:

TECHNICAL FEATURE

Using Cleanroom Technology

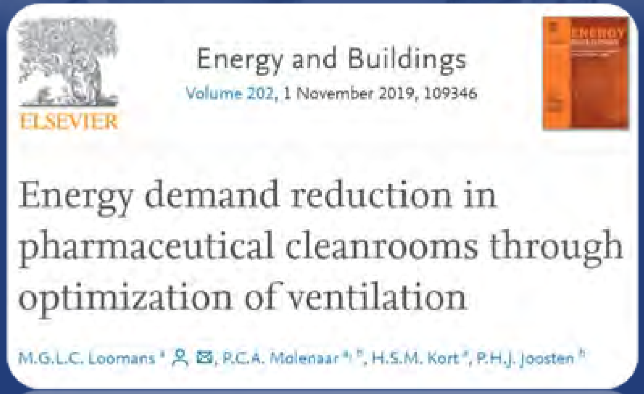
Improving Operating Room Contamination Control

Annually, the CDC reports nearly 99,000 deaths per year resulting from health-care associated infections (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]

Importance of Pressurization Control in a Sterile Environment

Operating Room Pressurization Control

- ORs are allowed to have an unoccupied mode PROVIDED they remain positively pressurized
- OR Room Pressure
  - Minimum +0.01” wg
  - Typically control to +0.02” or greater
- Air Changes per Hour
  - 15 per IDPH
  - 20 per ASHRAE
  - 30 typical at many facilities
  - 8 ACH in unoccupied mode (6 ACH Minimum) (verify this holds room positively pressurized)


ELSEVIER

Energy and Buildings

Volume 202, 1 November 2019, 109346

Energy demand reduction in pharmaceutical cleanrooms through optimization of ventilation

M.G.L.C. Loomans, P.C.A. Molenaar, H.S.M. Kort, P.H.J. Joosten

If Pharma ISO Class 5 can do it… Why not OR’s?

Operating Room Pressurization Control

The Joint Commission

Hospitals are at risk for losing their accreditation if they are not able to achieve and maintain compliance with Joint Commission standards. Losing accreditation could ultimately result in a hospital losing their ability to bill federal payers, creating large financial implications for the institution.

Operating Room Pressurization Control

EC.02.05.01

The hospital manages risks associated with its utility systems.

- EC.02.06.01, EP 1: Interior spaces meet the needs of the patient population and are safe and suitable to the care, treatment, and services provided.
- EC.02.05.01, EP 15: In critical care areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air exchange rates, filtration efficiencies, temperature, and humidity. For new and existing health care facilities, or altered, renovated, or modernized portions of existing systems or individual components (constructed or plans approved on or after July 5, 2016), heating, cooling, and ventilation are in accordance with NFPA 99-2012, which includes 2008 ASHRAE 170, or state design requirements if more stringent.

Operating Room Pressurization Control

Optimizing health care facilities

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Room Pressurization

Note: This information is intended for use during normal operations. If you are looking for information specific to COVID-19, please visit the Negative Pressure Patient Room page.

Certain rooms within a health care building should be positively or negatively pressurized with respect to surrounding areas. Positively pressurized rooms are usually designed to protect a patient, clean supplies, or equipment within the room. Negative pressure is used to contain airborne contaminants within a room. The 2014 FGI *Guidelines*/Standard 170-2013 provides lists of rooms that should be positively or negatively pressurized with respect to surrounding areas. The following are examples of positively pressurized rooms:

Operating Room Pressurization Control

- Operating rooms
- Delivery rooms
- Trauma rooms
- Newborn intensive care
- Laser eye rooms
- Protective environment rooms
- Pharmacy
- Laboratory, media transfer
- Central Medical and Surgical Supply Clean workrooms
- Central Medical and Surgical Supply Sterile Storage

ASHE
Optimizing health care facilities

A room may be pressurized so that it is positive with respect to adjacent areas for several reasons. It may be done to protect patients in operating rooms and protective environment rooms from airborne pathogens that may be present in adjacent areas. It may be done to protect sterile medical and surgical supplies in supply rooms from airborne contaminants that may be present in adjacent rooms. If these rooms are not properly pressurized, airborne contaminants from adjacent areas may be pulled into them. Increased concentrations of airborne bacteria, fungi, and viruses within these rooms may contaminate clean equipment or promote increases in nosocomial infections. Positively pressurized rooms are usually the cleanest environments in a hospital.

Loss of positive pressure compromises the aseptic environment within the room.

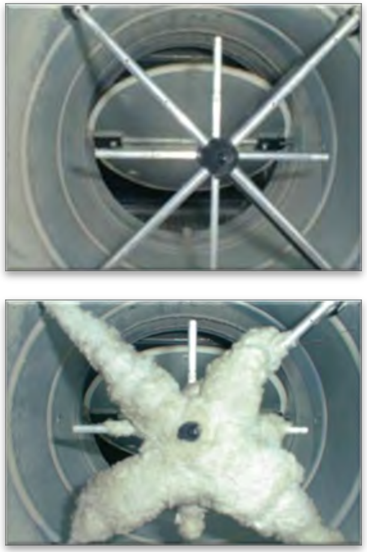
Operating Room Pressurization Control

How is the amount (volume) of air that drives the OR pressurization controlled?

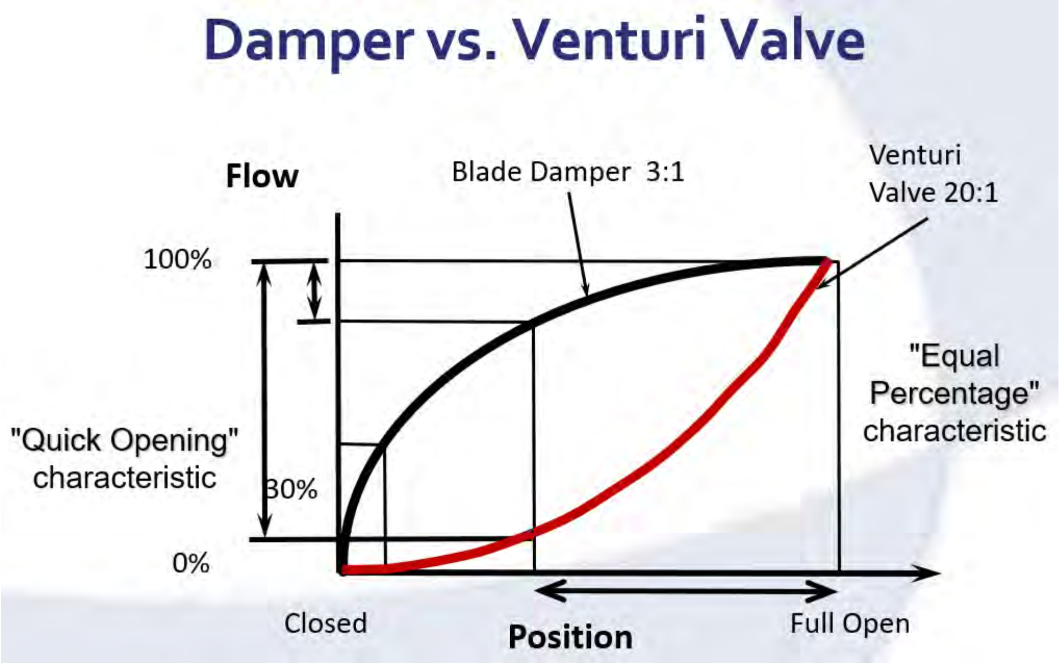
VAV (variable air volume) Box

Venturi Air Valve

MAINTENANCE SAVINGS | VENTURI DIFFERENCE



Transducer drift, lint & debris in exhaust stream, pressure fluctuations, and limited flexibility.

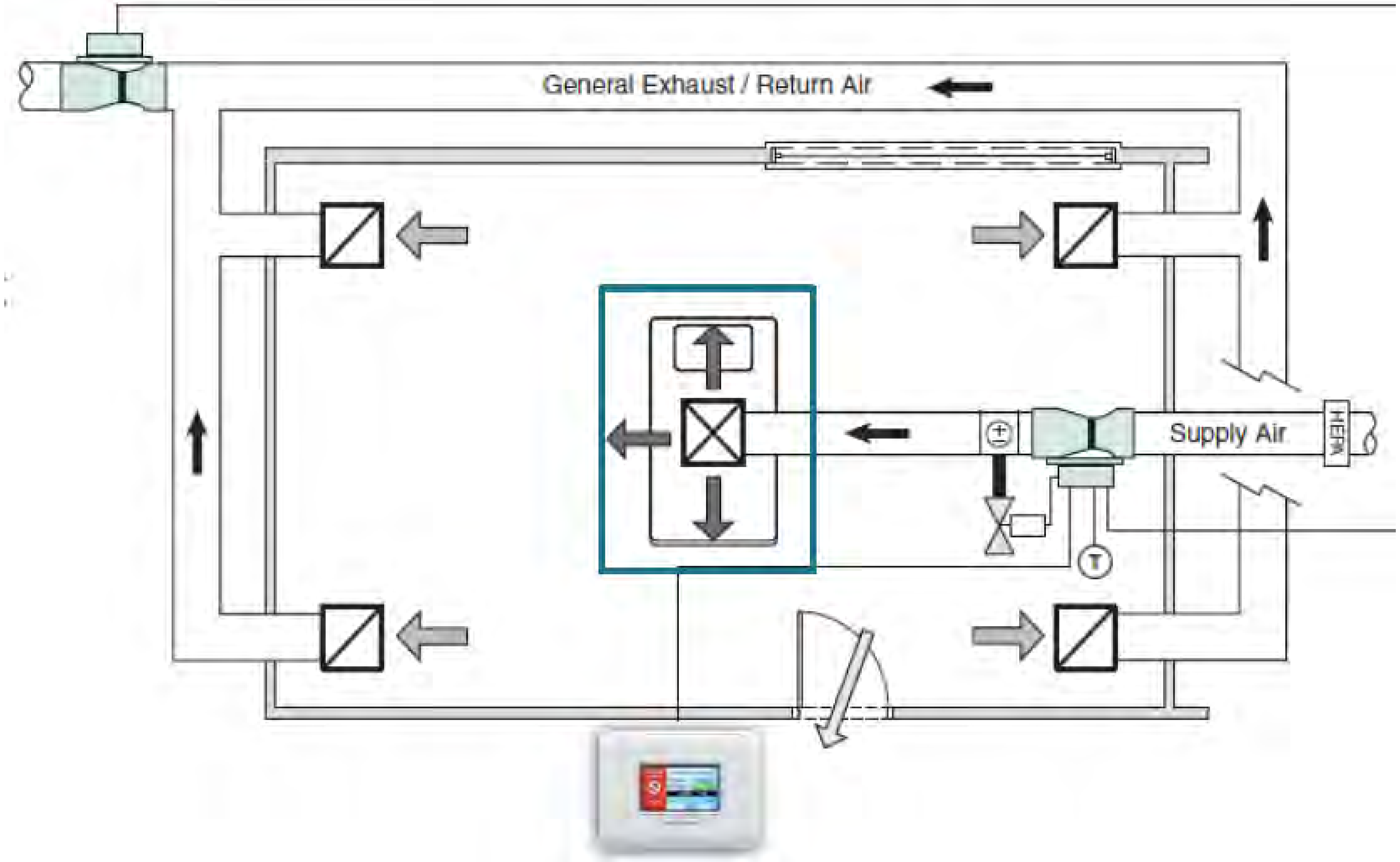


Vs.

Mechanical Pressure Independence

Accuracy at low flows, repeatable, reliable transitions from various room states

Operating Room Pressurization Control



Safely Reducing OR Operating Costs

Operating Room Pressurization Control

Business Case for Venturi Air Valves

Pressure Control for Critical Rooms In-Activity

1. Venturi valve – Std Dev 0.00" w.c., Avg. 0.01" w.c.
2. Control Exh/Ret Damper or CV – Std Dev 0.01" w.c., Avg. 0.02" w.c.
3. Typical OR needs 2 additional ACPH to achieve 0.01" w.c. greater pressure to account for variability (Std Dev) associated with pressure control method #2.

Building Utility Service Type & Climate Zone	Annual Energy Savings per 2 ACPH Reduction*
City Thermal Utilities Climate Zone 5	$4,027
Campus Thermal Climate Zone 4	$2,820
Self-Generated Thermal Climate Zone 4	$2,087

Contents lists available at ScienceDirect
American Journal of Infection Control
journal homepage: www.ajicjournal.org
ELSEVIER
AJIC American Journal of Infection Control
Major Article

Cost-benefit analysis of different air change rates in an operating room environment

Thomas Gormley PhD [a,*], Troy A. Markel MD [b], Howard Jones MD [c], Damon Greeley PE [d], John Ostojic IH [e], James H. Clarke PhD [a], Mark Abkowitz PhD, PE [a], Jennifer Wagner PhD, CIC [f]

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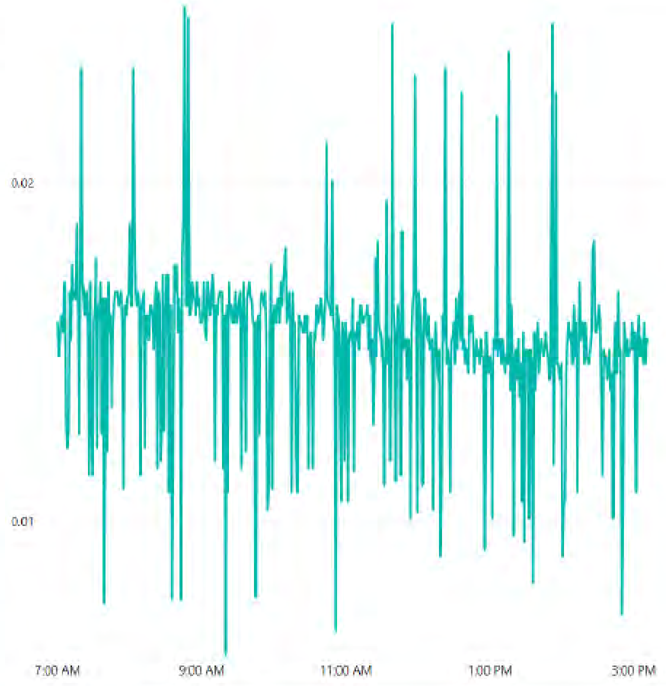
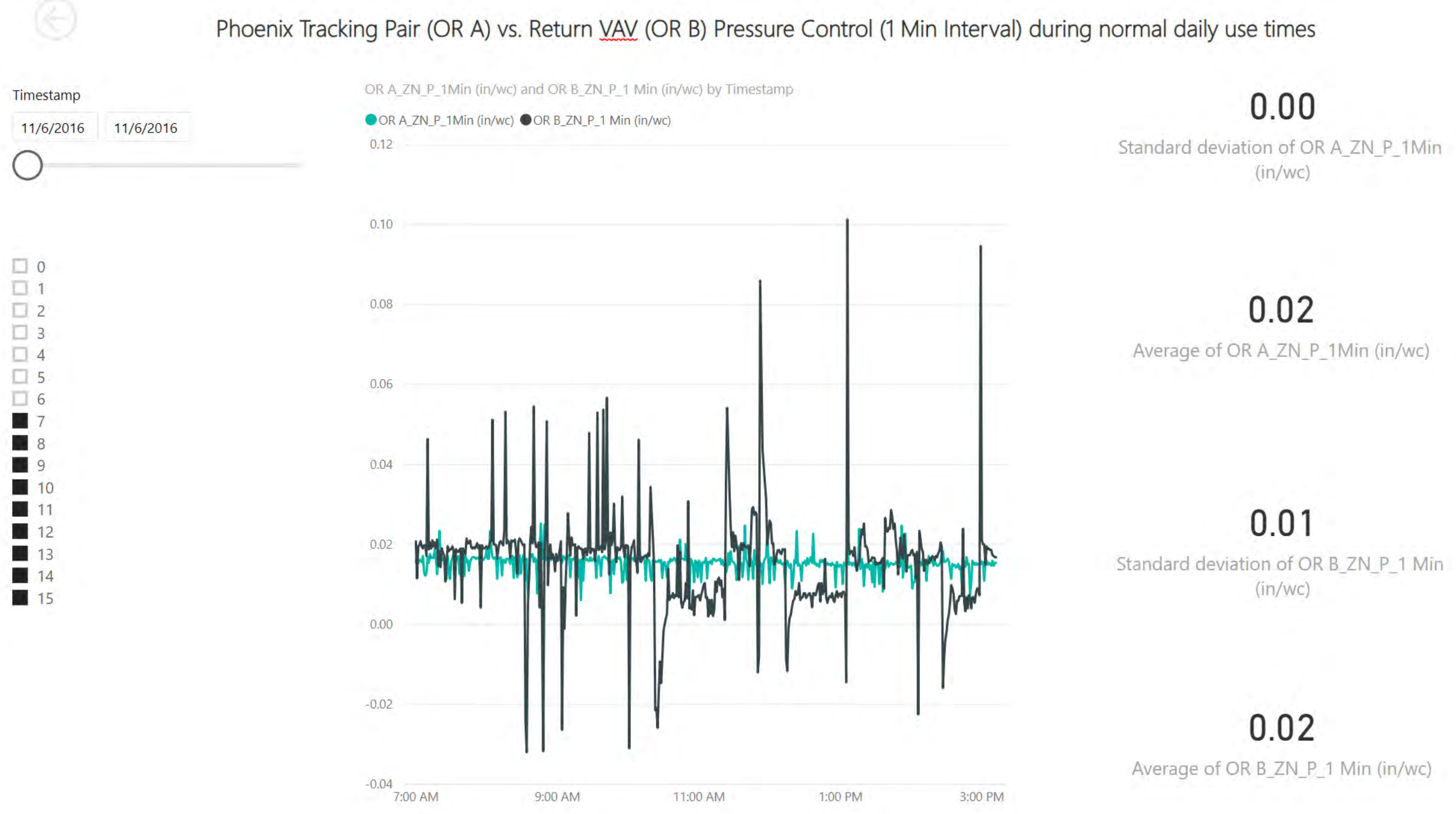
[f] Prism Environmental Health and Safety, Discovery Bay, CA



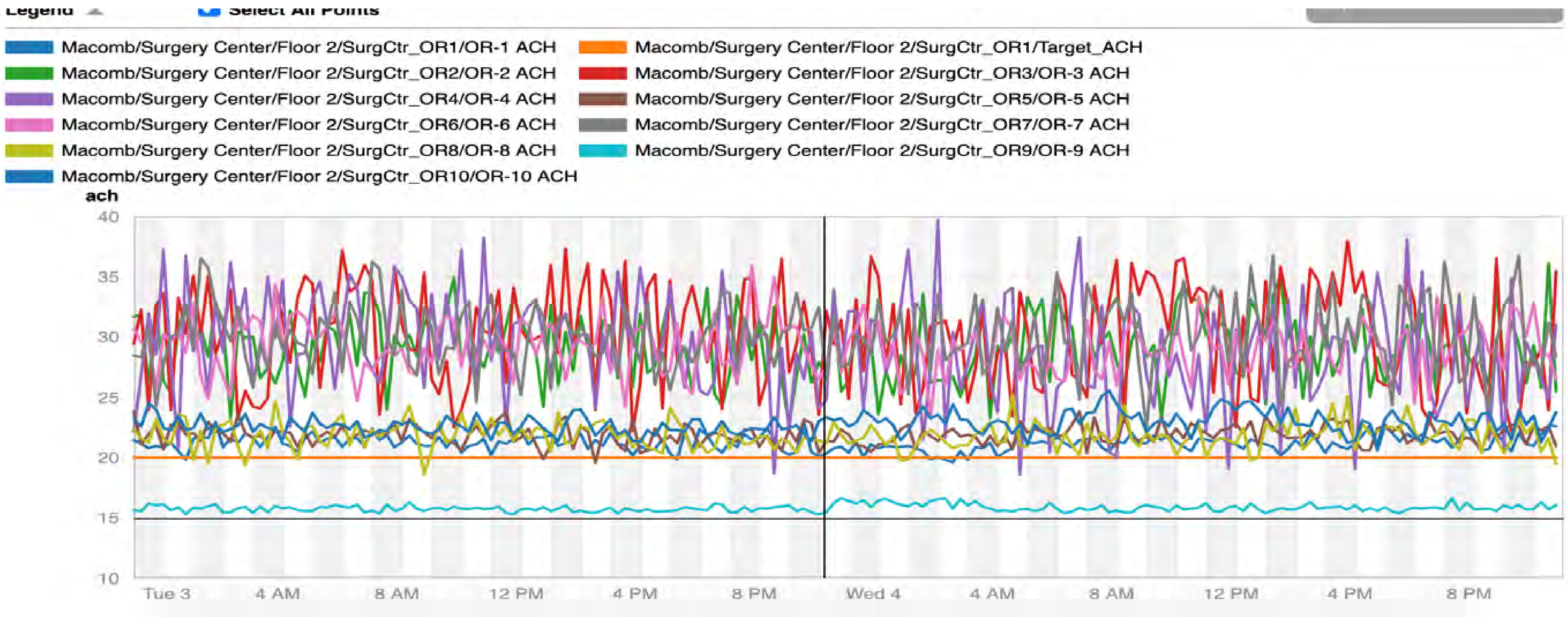
*Energy calculations were based upon ~ 20 ACPH for a 550 SF operating room that included electrical energy from fans, pumps, cooling systems, thermal energy for preheating and terminal unit reheating, and steam humidification. The model also included the appropriate seasonal utilization hours for cooling, heating, economizer, and dehumidification/sub cooling modes of operation. The air handling system was ~40% outdoor air.

Room Differential Pressure Comparison – Venturi Air Valves vs. Return VAV Terminal



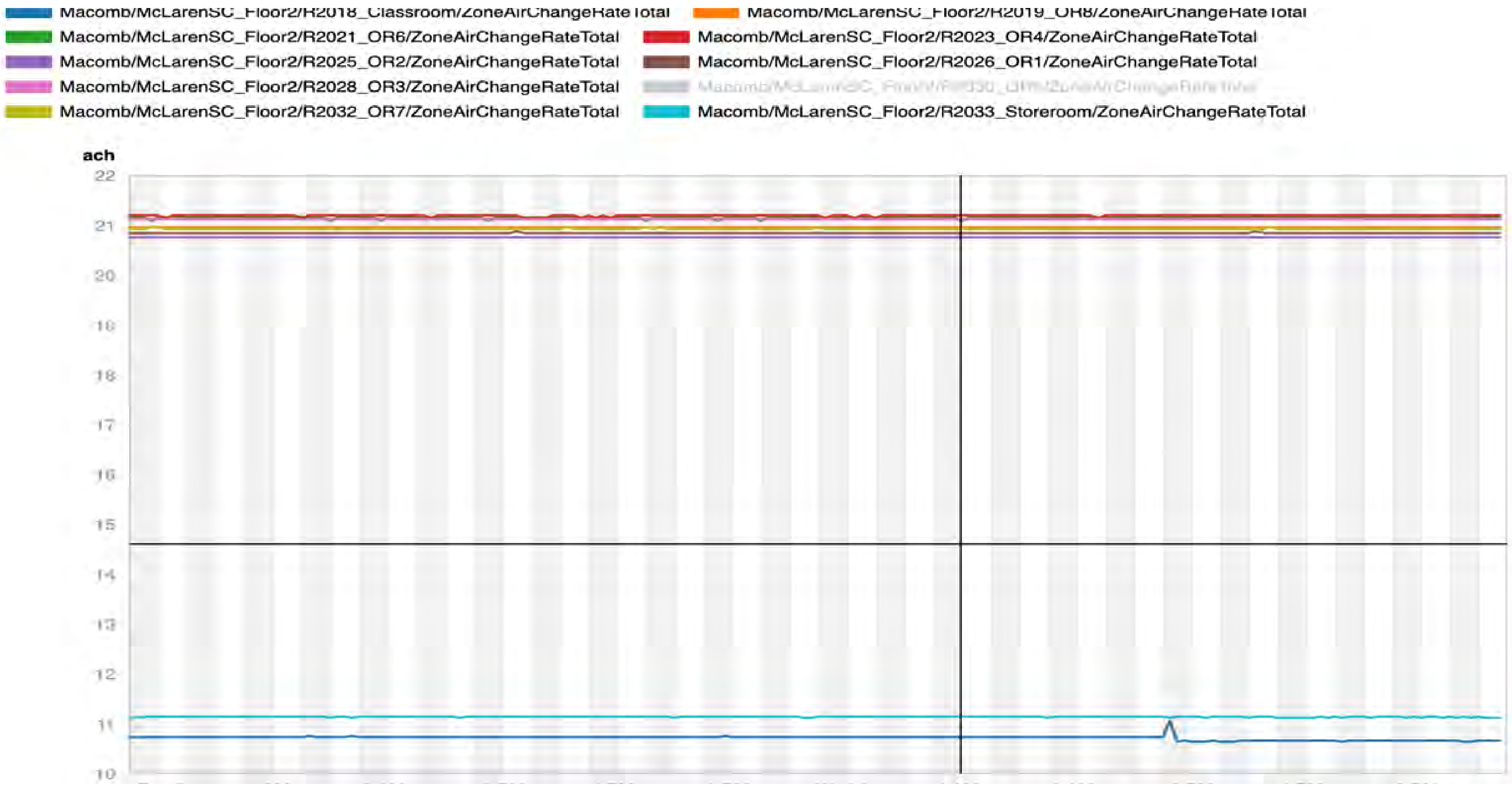
Operating Room Pressurization Control

OR Airflow Control stability with VAV Boxes



Operating Room Pressurization Control

OR Airflow Control stability with Venturi Air Valves

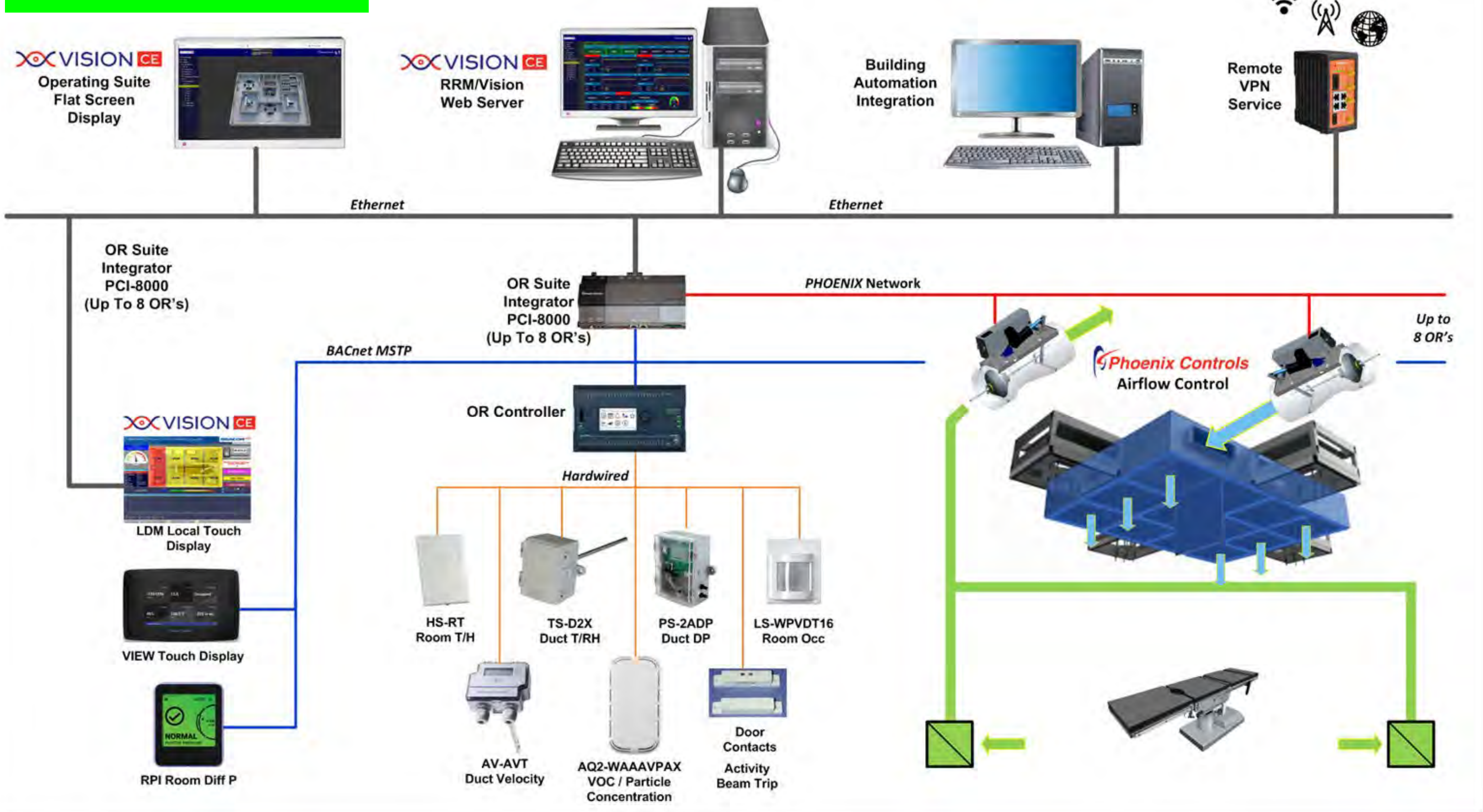


Realtime SSI Risk Assessment for OR's

In-Room Contamination Risk Monitoring and EQI Surveillance Dashboards

> "If you can't measure it, you can't improve it."

Sensor Suite



In-Room Contamination Risk Monitoring and EQI Surveillance Dashboards

IEQ (Indoor Environmental Quality) Surveillance

Phase 1

Define, Measure, & Analyze to Establish Baseline Assessment (3-5 days),

Phase 2

Implement & Augment Technologies to Improve Integration (1-2 Months),

Phase 3

Training, Analytics, and Reporting to Control Monthly or Quarterly,.

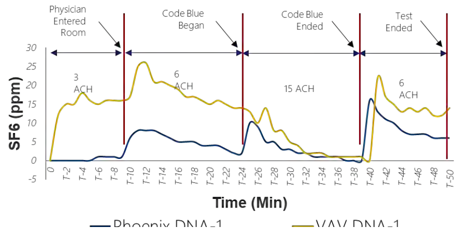
Case Study | IU Methodist

What They Had

- Constant Volume VAV Boxes

What They Achieved

- 3.9 to 0.5% Reduction in SSI = ~87% reduction



*Infection Prevention and Control Compliance Surveillance System**

	Average Number of Procedures/Day	Number of days in the year	Number of Procedures/Annum	Revenue per OR per year	Reduction in liability payouts	Avoided Costs	Reduction in HAIs
	4	365	1,460	$51,100,000	**79%**	**-$4,117,201**	**86.84%**
Average cost of procedure	$35,000	Number of infections @ 3.8%	55	-$5,215,120			
Average cost of Infection	$94,000	Number of infections at 0.5%	12	-$1,097,920			

*Cost projection model utilizing generalized data on US Govt. Average Patient Procedure Costs and Average cost per Hospital Acquired Infection

Medical Research Archives

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European Society of Medicine

2024 Critical Environments Summit

For more information, please reach out to me:
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Thank You!

Questions or Comments?

This concludes The American Institute of Architects Continuing Education Systems Course

Phoenix Controls