



Rethinking OR Ventilation Temperature-controlled Air Flow Technology

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Infection Prevention Partners

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Learning Objectives

- Describe the risk factors associated with airborne microbial contamination in the operating room.
- Outline the physics of temperature-controlled airflow ventilation.
- Discuss the differences in design and performance among different ventilation alternatives.
- Characterize the process of assessing a novel ventilation technology

Why change OR ventilation?

Operating Room circa 1960s



Historical Surgery Photo, Operating Room circa 1960
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Operating Room of Today



German Heart Center Munich, Germany, Siemens-Healthineers

Everything has changed except the ventilation!

But does ventilation really matter?

Why OR ventilation matters

- Rooms with over 50 CFU/m³ are 2.6 times more likely to have SSIs than those with 10-20 CFU/m³.¹
- Airborne transmission accounts for 20%–24% of post-operative infections.²
- A large, multi-center study majority of bacteria contaminating the surgical wound likely reached it by the airborne route.³

1. Lidwell OM, et al. Airborne contamination of wounds in joint replacement operations: the relationship to sepsis rates. *J Hosp Infect.* 1983;4(2).
2. Lidwell OM, 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.
3. Charnley, J. and Eftekhari, N. (1969), 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. *Br J Surg*, 56: 641-649
4. Parvizi, J., et al. Environment of care: Is it time to reassess microbial contamination of the operating room air as a risk factor for surgical site infection in total joint arthroplasty? *Am J Infect Cont*, 45(11), 1267–1272.

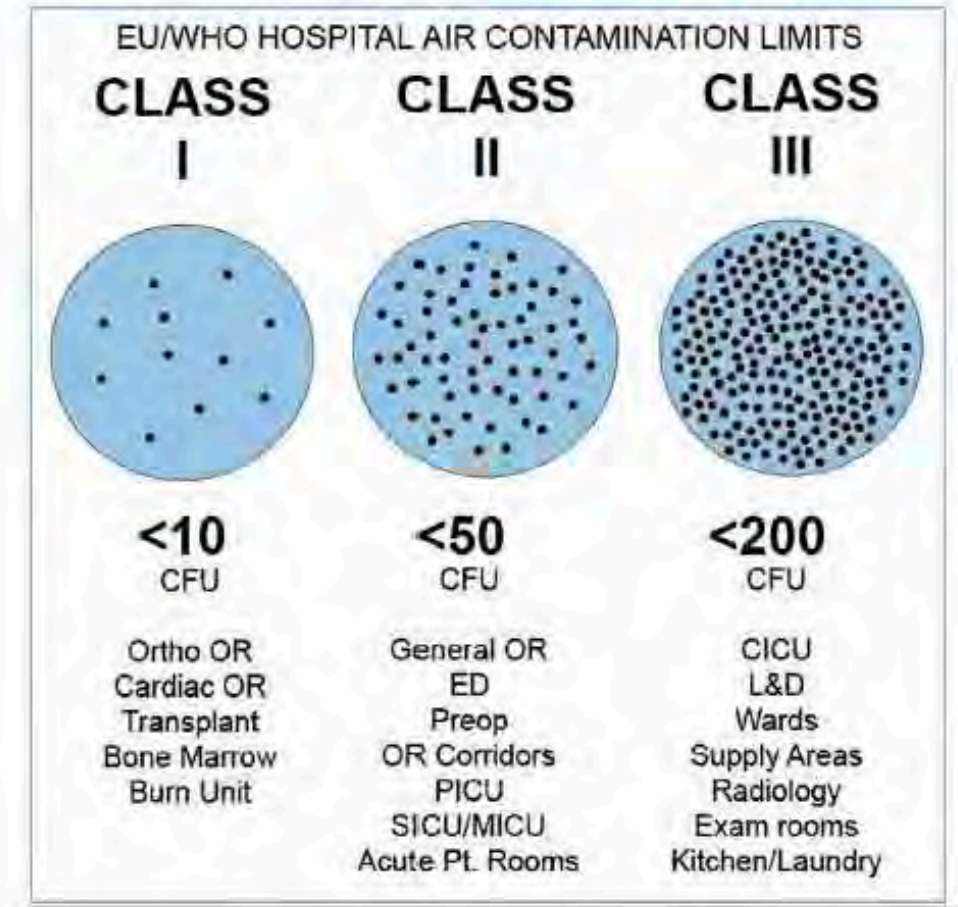
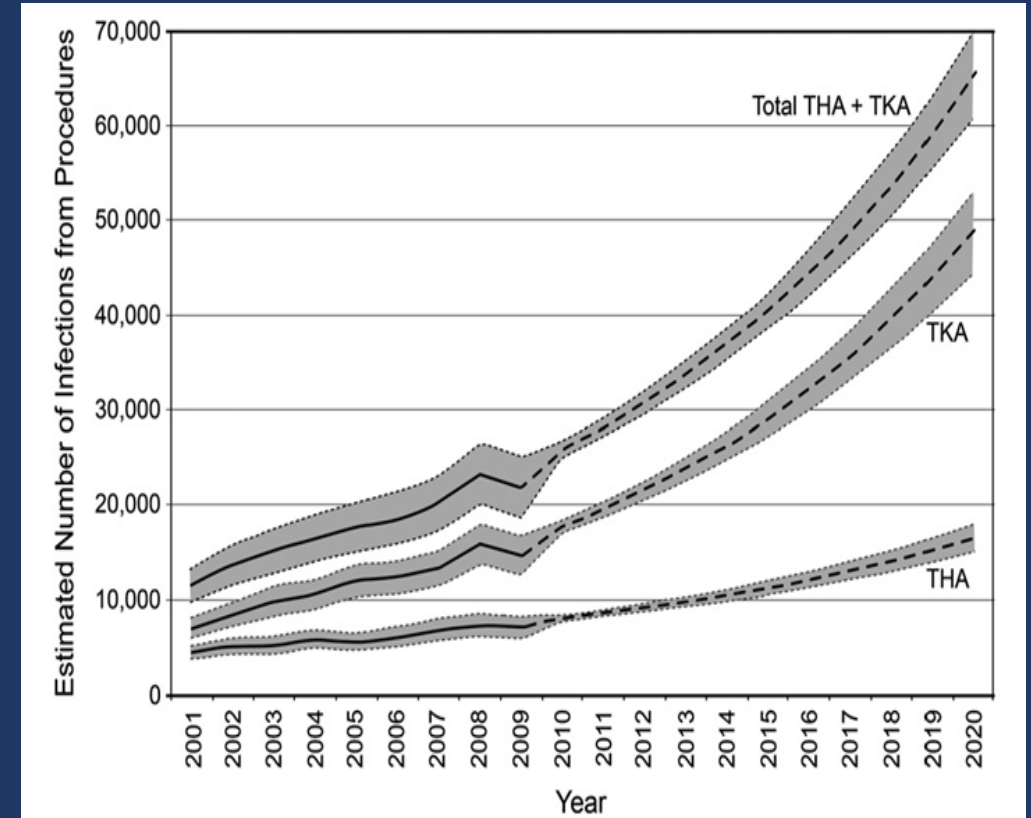


Fig 1. Propose EU-WHO standards for contamination of hospital room air: class I, <10 CFU; class II, <50 CFU; and class III, <200 CFU. Hospital OR fall within class I standards. 39 CFU, colony forming units; ED, emergency department; EU, European Union; Preop, preoperative; Pt., patient; OR, operating room pediatric intensive care unit (PICU); surgical intensive care unit (SICU); medical intensive care unit (MICU); cardiac intensive care unit (CICU) and labor and delivery (L&D). WHO, World Health Organization. 4

Surgical Site Infection is still a problem

- Volume of hip/knee arthroplasties growing exponentially.¹
- 1-2% of hip and of knee arthroplasties become infected (10-20,000) ² **Underestimate!**²
- Cost – Infection in TKA/THA **not reimbursed**. Average \$39-57,000, can be upwards of 100,000+ direct expense.³
- 5-year mortality rate TKA/THA: 25.9% ⁴



Historical number of infected THA/TKA procedures in the United States ¹⁵

1. Shichman, et al. Projections and Epidemiology of Primary Hip and Knee Arthroplasty in Medicare Patients to 2040-2060. JB & JS open access, 8(1).

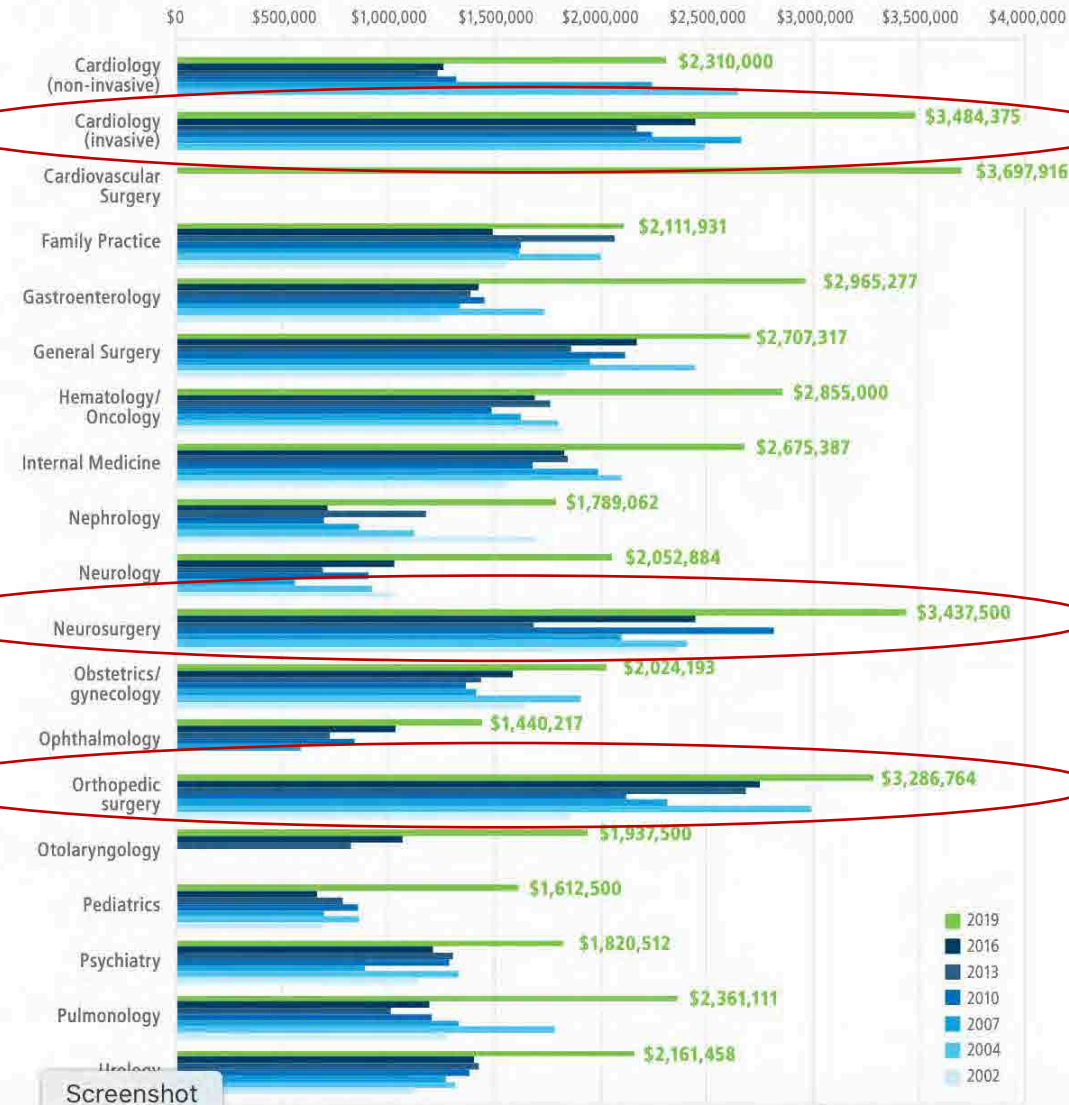
2. Folusakin A, et al. Stat Pearls, Oct 2023. <https://www.ncbi.nlm.nih.gov/books/NBK448131/>

3. Yao, J, et al. Direct Inpatient Medical Costs of Operative Treatment of Periprosthetic Hip and Knee Infections Are Twofold Higher Than Those of Aseptic Revisions. The Journal of Bone and Joint Surgery (2021) 103(4):p 312-318.

4. Yangqi X, et al. Mortality, patient-reported outcome measures, and the health economic burden of prosthetic joint infection, Effort Open Reviews. (2023) Vol 8, Issue 9.

SPECIALTY COMPARISON YEAR-TO-YEAR

The graph below shows average annual revenue generated per specialty for the seven years the survey has been conducted.



Screenshot

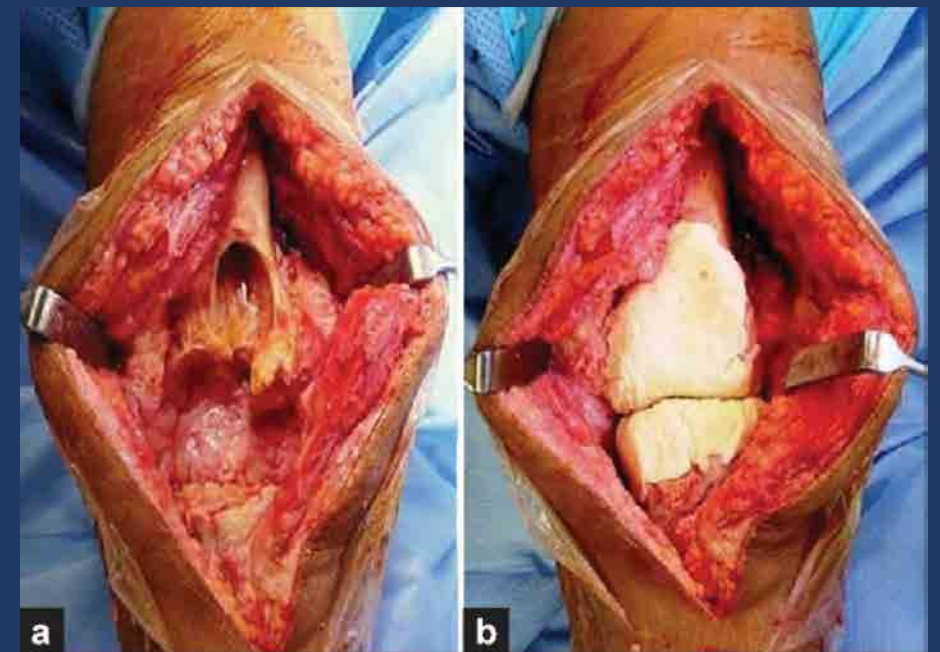
*Ophthalmology included for the first time in 2007, Cardiovascular Surgery included for the first time in 2019

3 of the top 4 generators of health system revenue...

...are infection sensitive surgical procedures.

Airborne factors that contribute to infection

- Number of personnel in the room, *majority of airborne bioburden comes from the people in the room*
- Movement of personnel and equipment
- Door openings and closings
- Length and type of procedure
- Exposure of sterile instruments and implants



Assn of PeriOperative Nurses (AORN)

2024 Sterile Technique Guideline – Expansion of Air Quality Recommendations

- Implement strategies to reduce risk of airborne contamination in rooms where surgical or other invasive procedures are performed. [Recommendation]
- New! - Perioperative air quality management program may be used as a strategy to reduce risk of airborne contamination. [Conditional Recommendation]
 - Elements air quality management program included in guideline
- New! - When an SSI is identified....review of air quality sampling data from the OR and recorded or observed equipment, environment and personnel factors. [Conditional Recommendation]

AORN Sterile Technique – Identifying areas for improvement

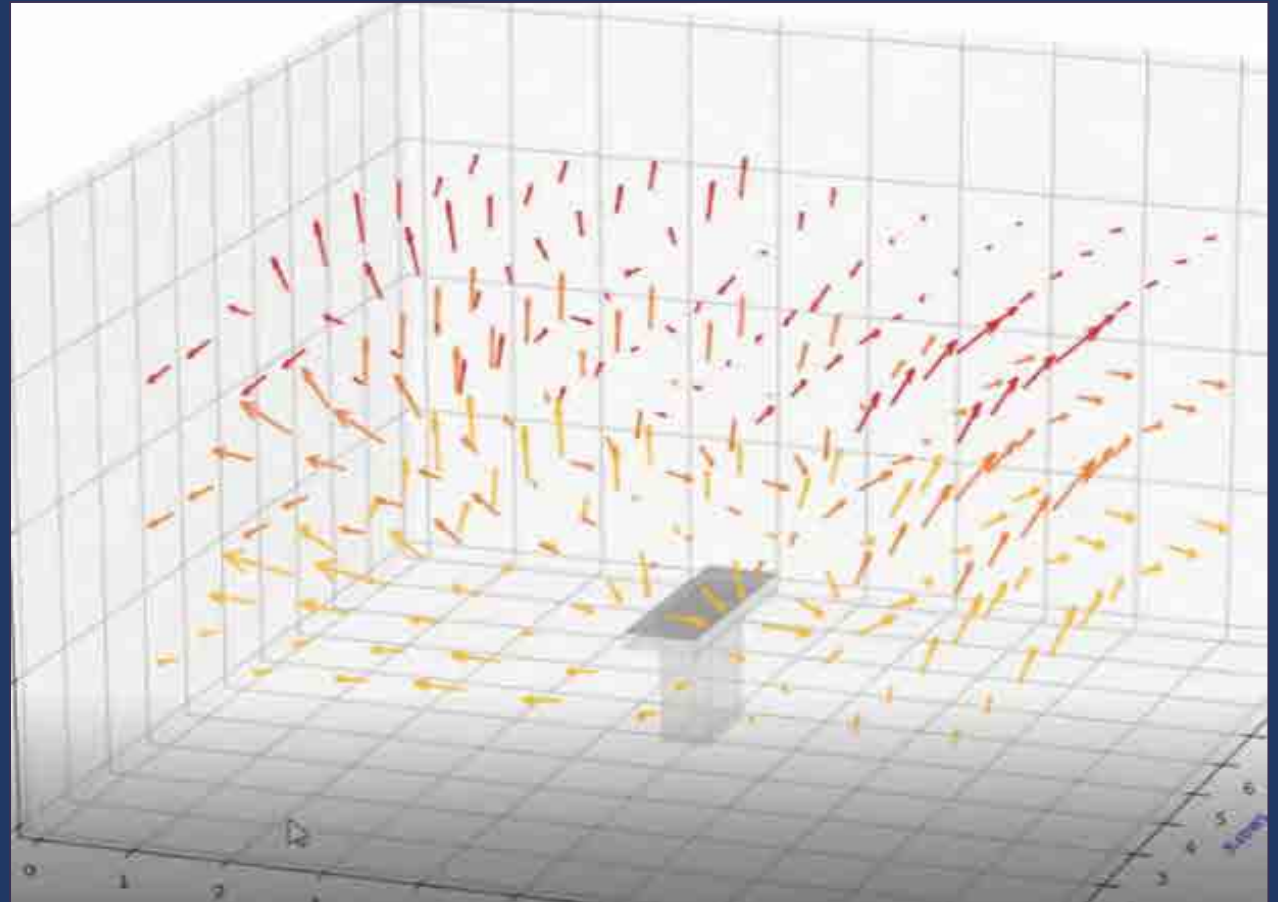
- Verify that HVAC systems meet regulatory requirements and professional organization standards.
- Determine if HVAC system is performing as expected (i.e., unidirectionality, velocity, filtration) based on manufacturer's specifications.
- Verify that recommended HVAC system maintenance has been completed.
- Review HVAC issues identified and addressed during scheduled maintenance.
- Review reports from off-cycle HVAC maintenance processes (e.g., HVAC failure) for root causes and influence on air quality.
- Understand the use and effects of HVAC setback strategies.
- Verify that expected room pressure differentials are present.



**When was the last time
you measured the airborne
microbial bioburden
in your operating rooms?**

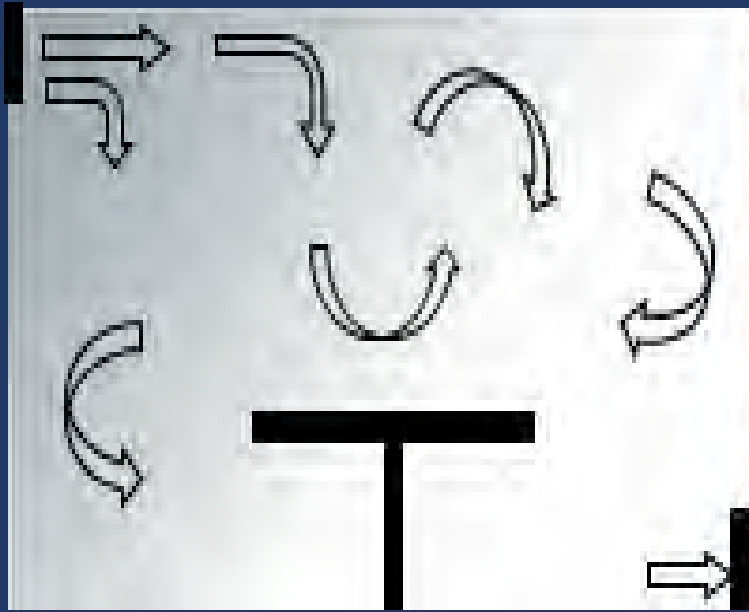
ASHRAE 170 engineering controls

- Rooms that are 170 compliant do not necessarily achieve intent of standard
- Engineering controls do not provide any information on actual level of airborne bioburden.
- Controls are *prescriptive*, not *performance* based.
- No requirements in US for measuring ventilation *performance against airborne microbial contamination*.

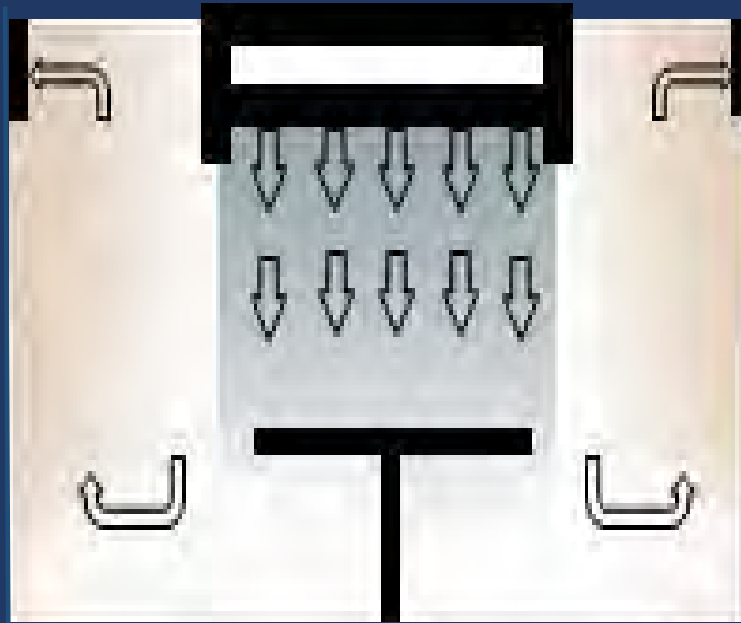


3-D air flow mapping
ASHRAE compliant room, *not unidirectional*

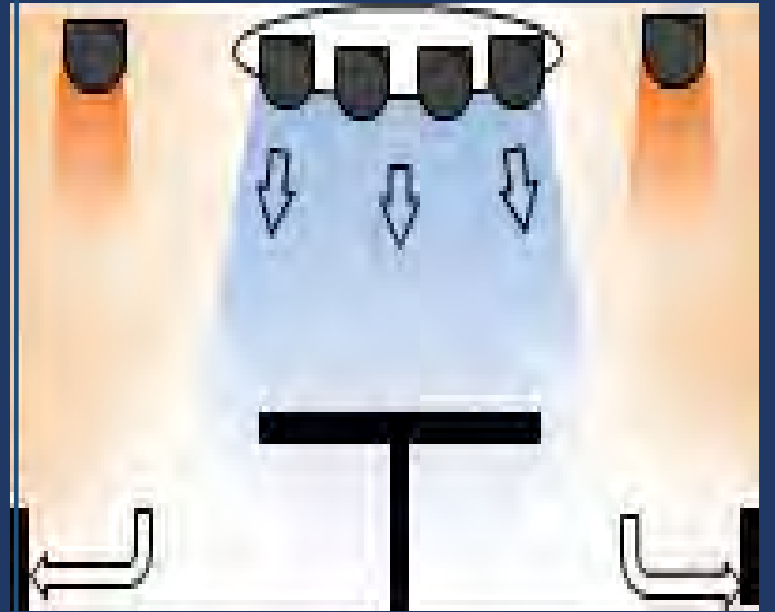
OR ventilation concepts



Turbulent mixed Airflow (TMA)



Laminar Airflow (LAF)



Temperature-controlled AirFlow (TcAF)

Concepts differ in how airflow, direction and velocity are managed.

Conventional Laminar Air Flow (LAF)

- Designed to protect the surgical field *only* (ASHRAE 170 – 12” around surgical table).
- Personnel break air curtain. Free shear mixing layer allows ambient room air to contaminate central sterile jet.

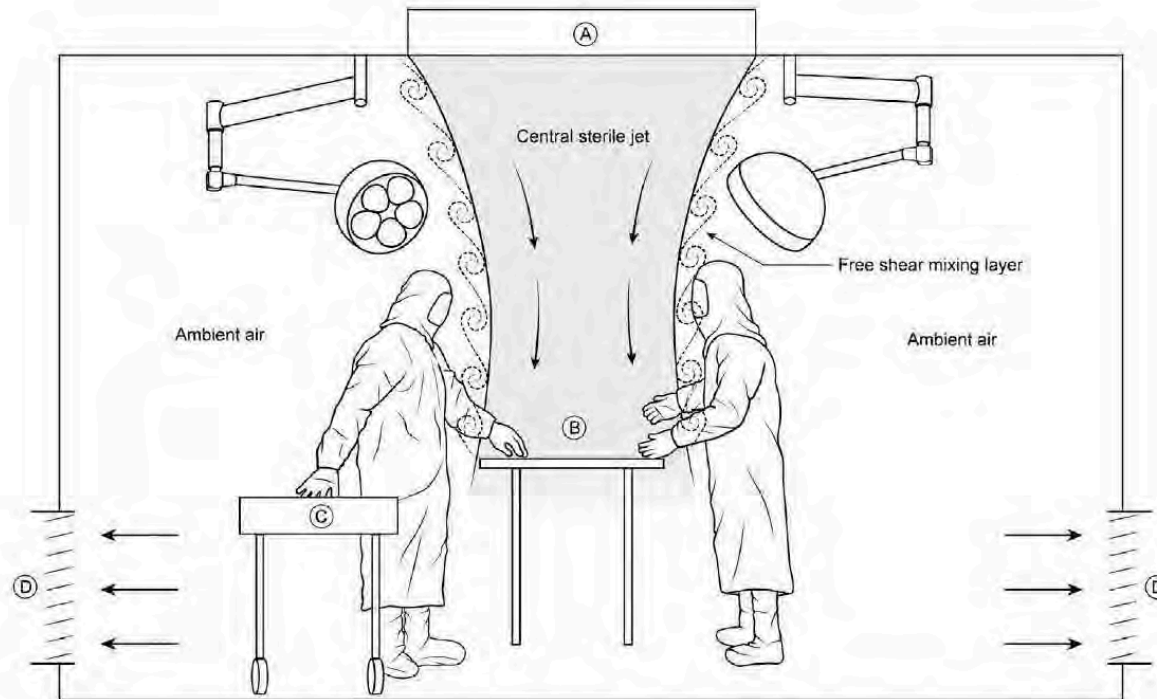
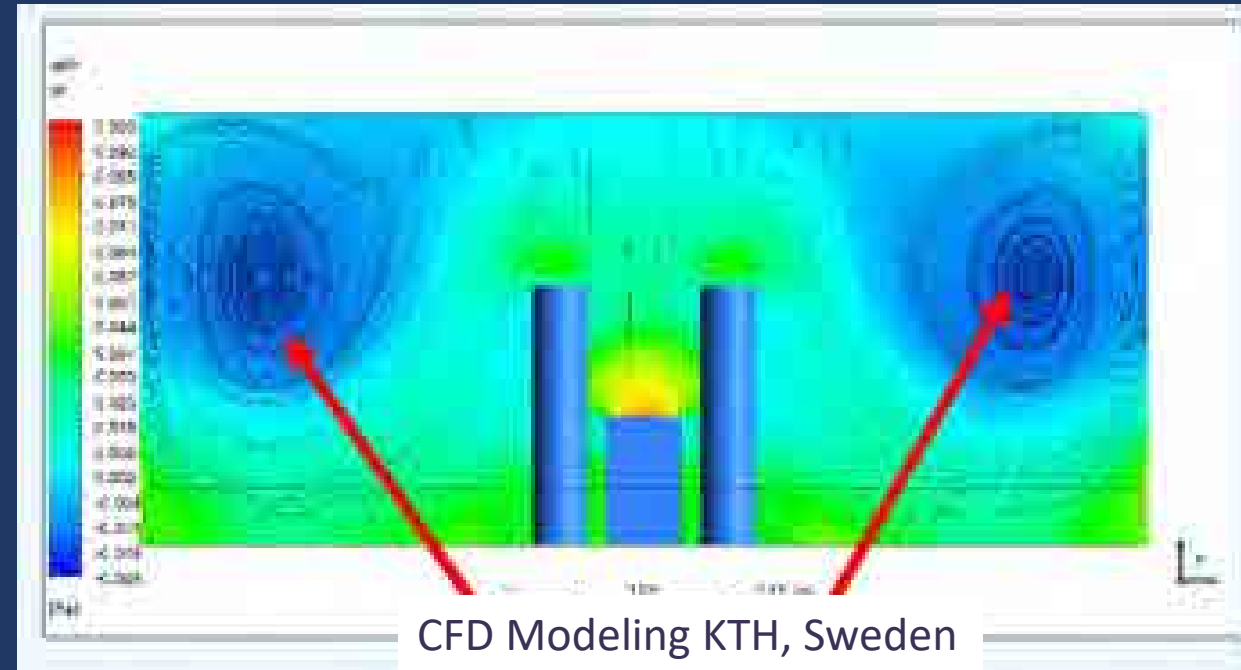
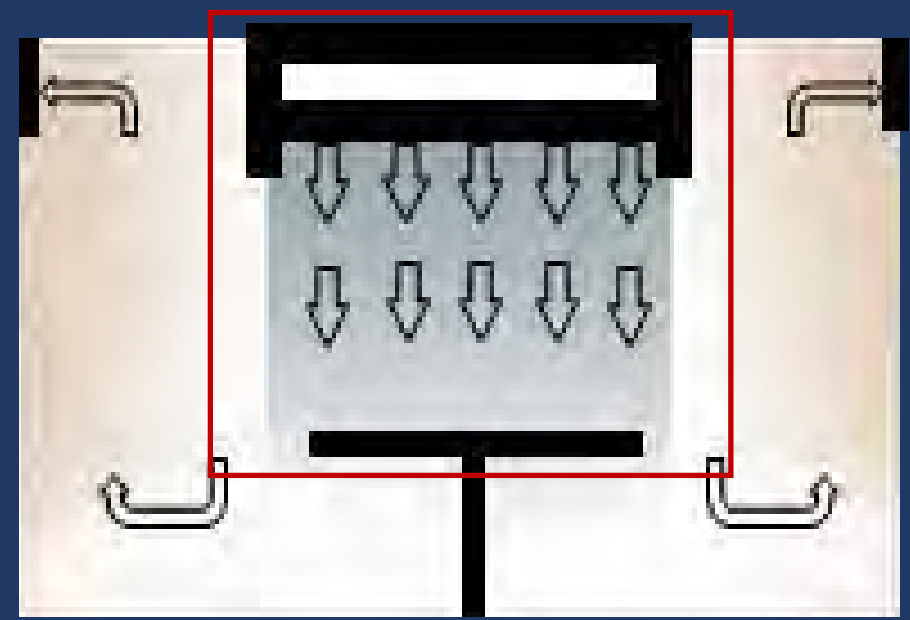


Fig 1. Schematic diagram of airflow in an operating room built to ASHRAE 170 – 2021 standards. (A) Ceiling diffusers supplying HEPA filtered air. (B) Surgical wound zone located in central jet of sterile air. (C) Back table zone for sterile instruments and supplies located in ambient air. (D) Near floor level exhaust grilles. Ambient air surrounds the central sterile jet and will contain variable amount of MCPs from personnel in room. The free shear mixing layer allows ambient room air to contaminate the central sterile jet.

Laminar Air Flow (LAF)

- Airflow easily *disrupted* by objects in pathway
- Challenged by *vortices in the periphery*
- Mean values of airborne CFUs outside protected zone: *55-fold higher* than values inside ¹

Based on a growing body of evidence, LAF is no longer recommended by CDC or WHO for joint arthroplasty.^{2,3}



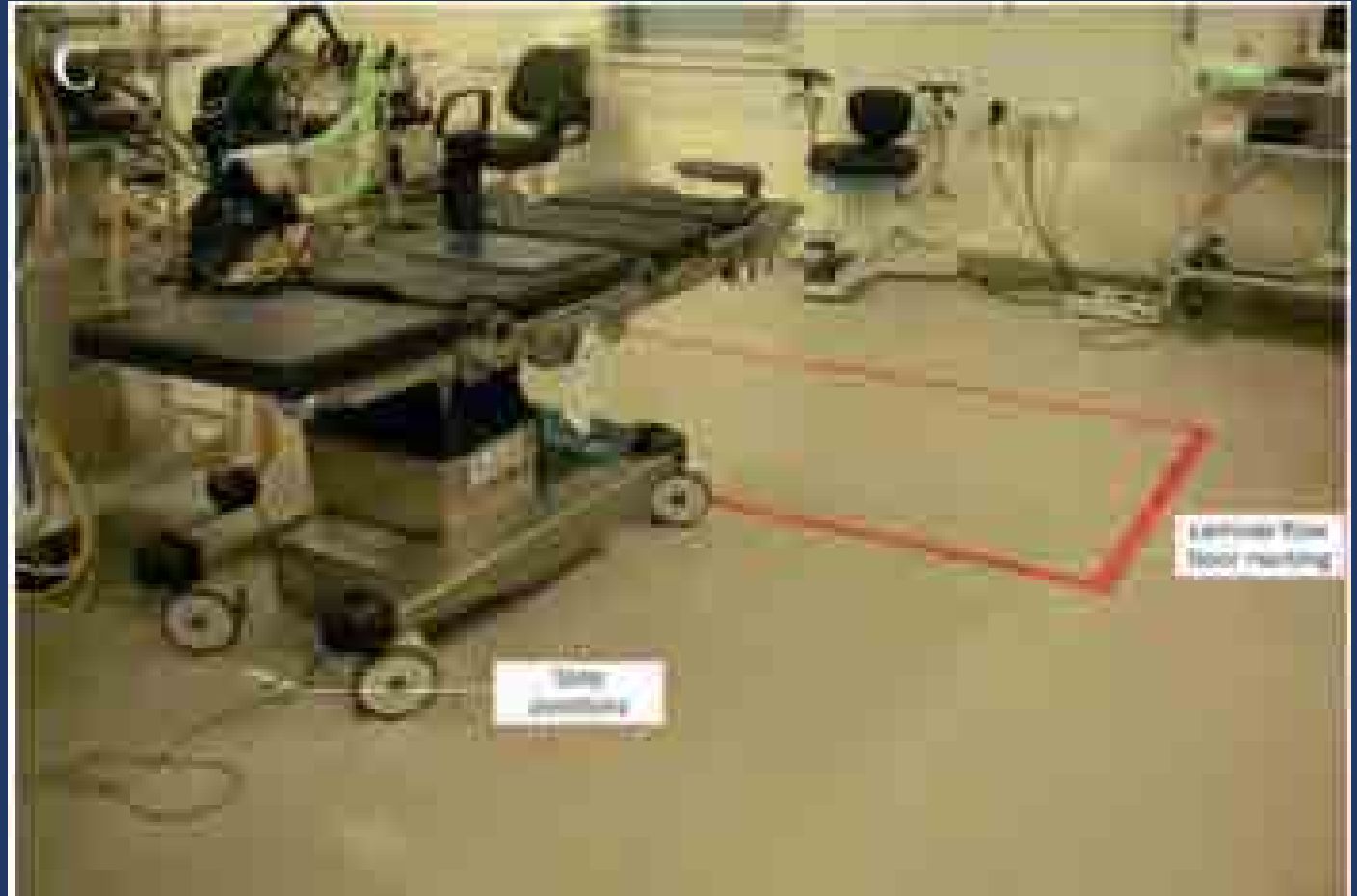
1. Benen T, et al. Influence of different ventilations systems upon the contamination of medical devices. Hyg Med. 2013; 38–41.
2. Berríos-Torres SI, et al. CDC Guideline for the Prevention of Surgical Site Infection, 2017. JAMA Surg. 2017;152(8):784–791.
3. Global guidelines on the prevention of surgical site infection. World Health Organization. 2016. <http://www.who.int>

Why is the periphery important?

Surgical instruments, implants and devices should be placed within the ultraclean zone.
How often is this requirement met?

Safety by design: Effects of operating room floor marking on the positioning of surgical devices

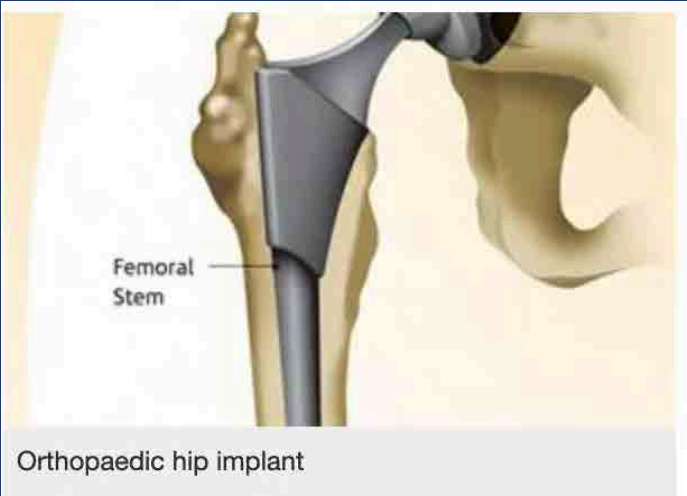
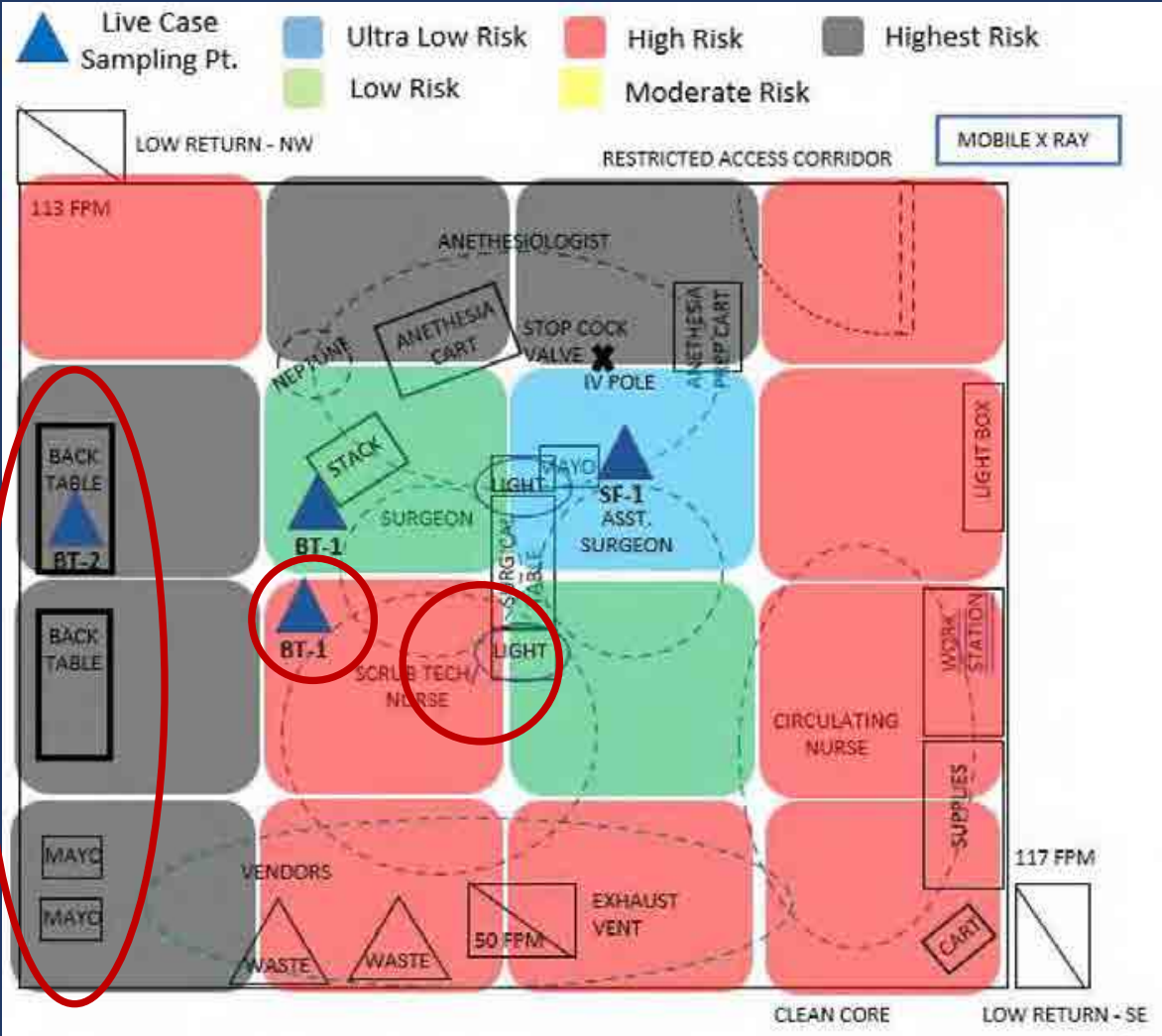
- Before/after study using tape to mark the clean zone.
- Prior to marking, devices in the clean zone in 6.1% of surgeries.
- After marking devices in clean zone 36-52% of surgeries.



CFU heat map, live case with LAF

Measurements taken in 3 locations:

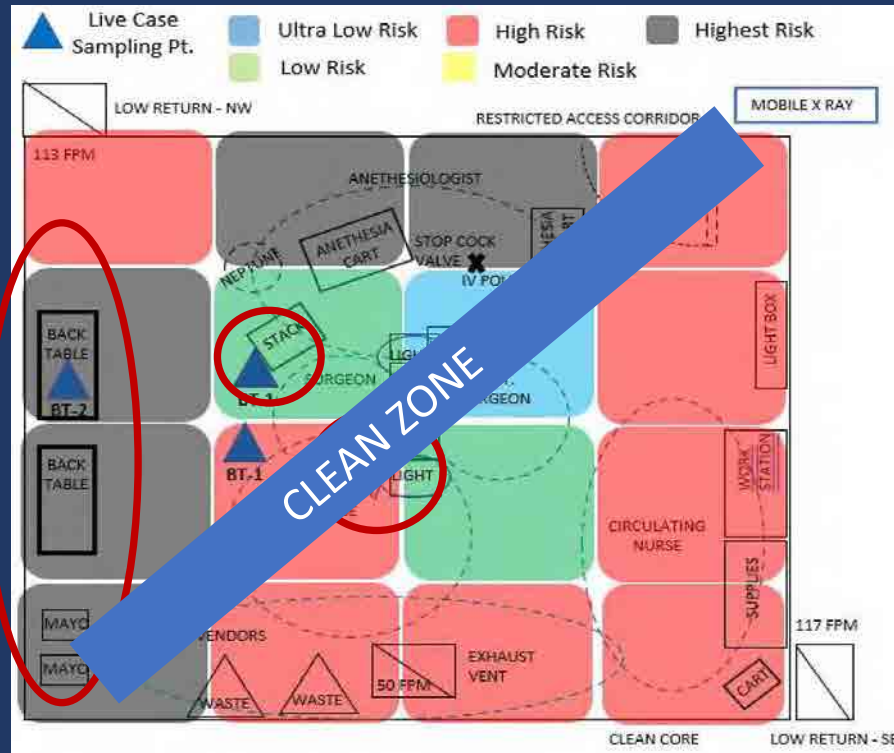
- Wound/surgical field
- Instrument tables
- Periphery (case carts/back tables)



CFU heat maps: Live case comparison Laminar Air Flow (LAF) and Temperature-controlled Air Flow (TcAF)

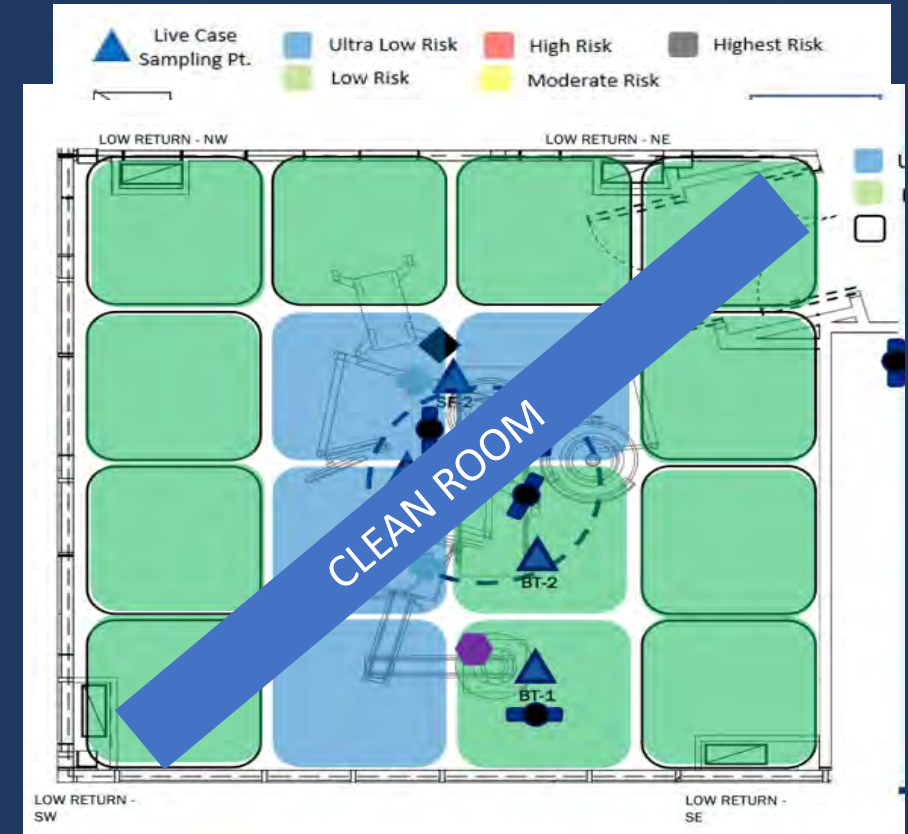


Laminar Air Flow



CFU mapping conducted during active surgery

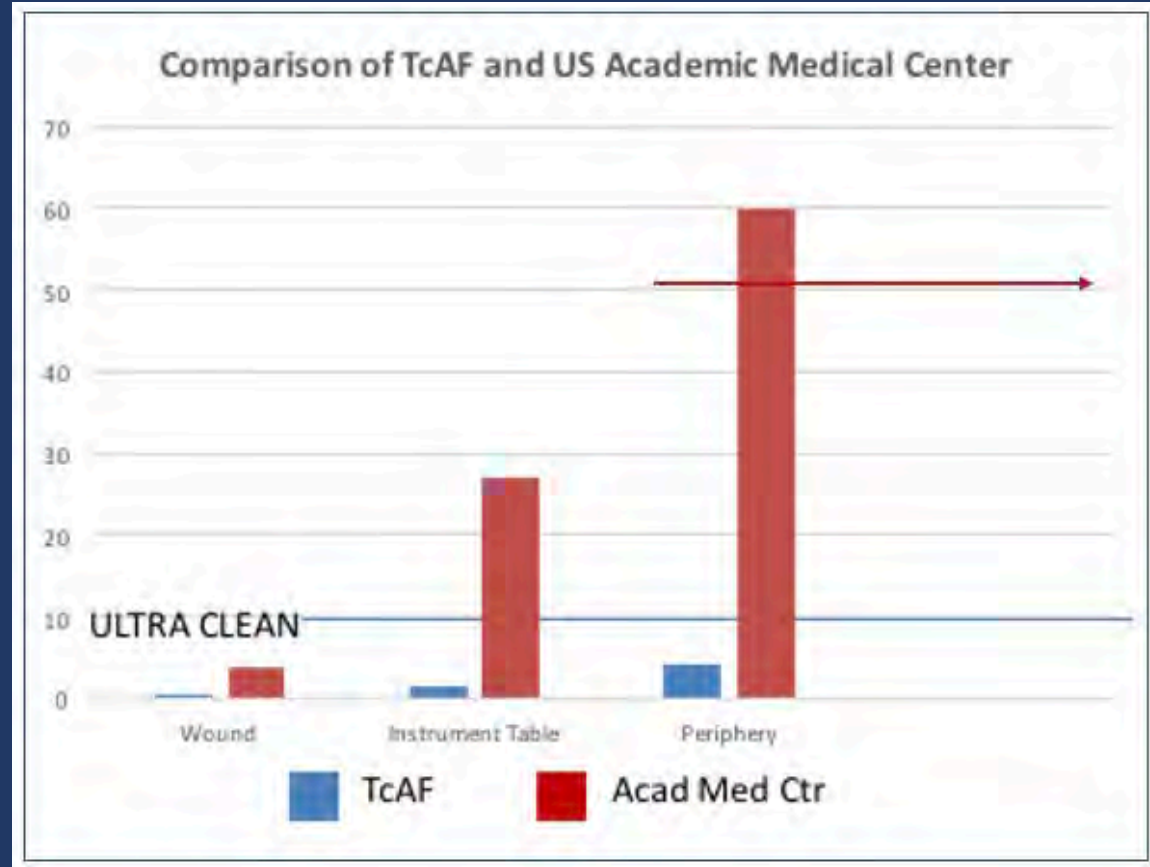
Temperature-controlled Air Flow



“The TcAF technology is effective at providing improved environmental quality... <math><10\text{ CFU}/\text{m}^3</math> inside the sterile field, within the footprint of the TcAF and in the periphery of the OR.”

Comparison of TcAF and U.S. academic medical center

Airborne contamination 10x higher than TcAF



> 50 CFU/m³

2.6X more likely to have post-operative infection

- TcAF: 700 measurement events, live surgery, 30 procedure types
- Academic Medical Center: Live neurosurgery, average of multiple ORs

Introduction to Temperature-controlled Air Flow Ventilation



Physics of Temperature-controlled Air Flow (TcAF)

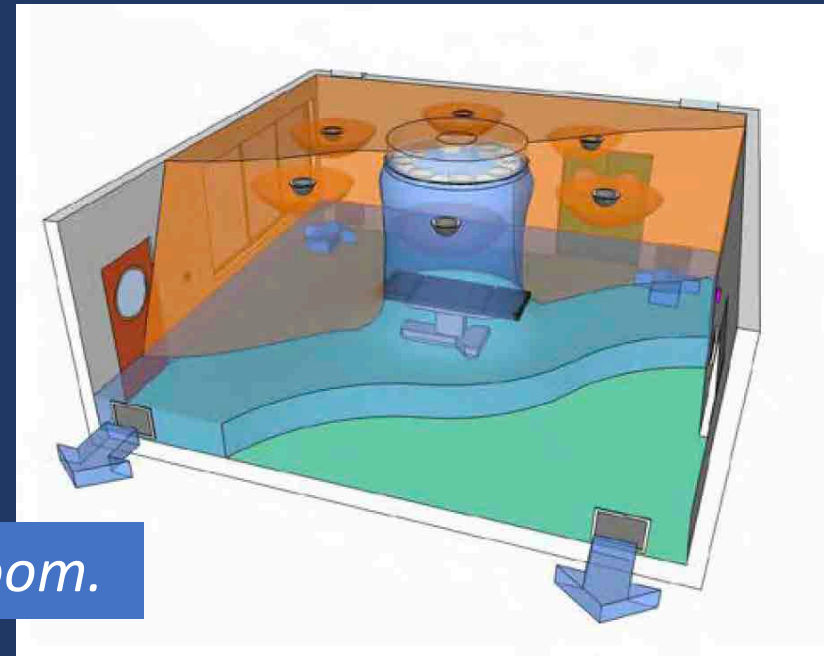
Central Zone

- HEPA filtered air released through diffusers mounted in circular platform above OT
- Air is 3-4°F cooler than ambient room temp
- Temperature differential creates gravity-driven down-flow.
- Air speed *accelerates* with gravity (cooler air is denser).



Periphery

- Warmer air dispersed through additional diffusers
- Creates a low turbulent environment, prevents air from periphery returning to center



Creates ultraclean conditions ($<10\text{CFU}/\text{m}^3$) throughout *entire room*.

TcAF meets the engineering parameters of ASHRAE 170

- ✓ **Positive pressure:** Prevents airflow from contaminated areas into adjacent areas
- ✓ **Direction:** Consistent, perpendicular, downward flow (unidirectional)
- ✓ **Velocity:** Driven at speed that ensures
 - ✓ uni-directionality
 - ✓ high enough to overcome, obstacles and heat convection
 - ✓ minimize turbulence
- ✓ **Temperature & Humidity:** Also influence transmission

TcAF diffusers (air showers)

- Aluminum and steel frame
- Honeycomb structure is polypropylene
- UV resistant
- Tested for compatibility with standard hospital disinfectants
- Removable (twists off)
- Microbial testing after use indicates HEPA filtered air flowing through air shower keeps interior free of CFUs



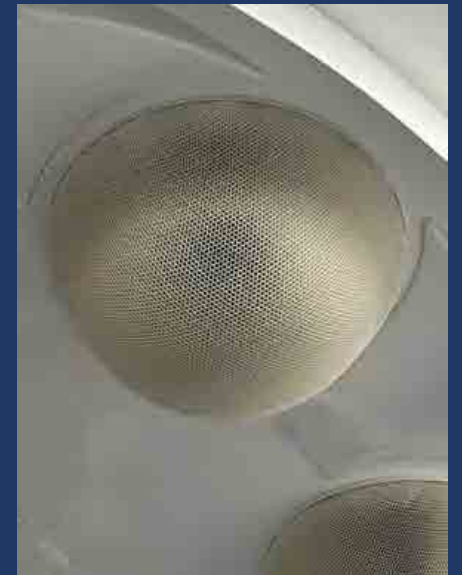
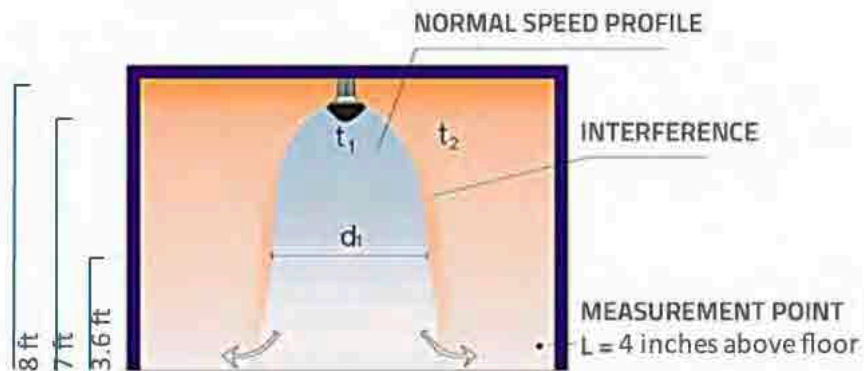
Diffuser coverage

- Parabolic shape creates airflow **wider in diameter than the diffuser itself**
- Airflows in central unit overlap to create a unidirectional downflow
- Overlapping air from multiple diffusers creates **coverage beyond footprint of central unit**
- Diffusers in periphery prevent turbulence, allow for sedimentation
- Gravity takes over, air speed accelerates (Velocity: 25-35 ft/min. at table height)

FIGURE 1: AIR DISTRIBUTION AT ISOTHERMAL AIR SUPPLY ($T_2 - T_1 = 0^\circ\text{F}$)



FIGURE 2: AIR DISTRIBUTION AT SUBSET AIR SUPPLY ($T_2 - T_1 \geq 1.8^\circ\text{F}$)



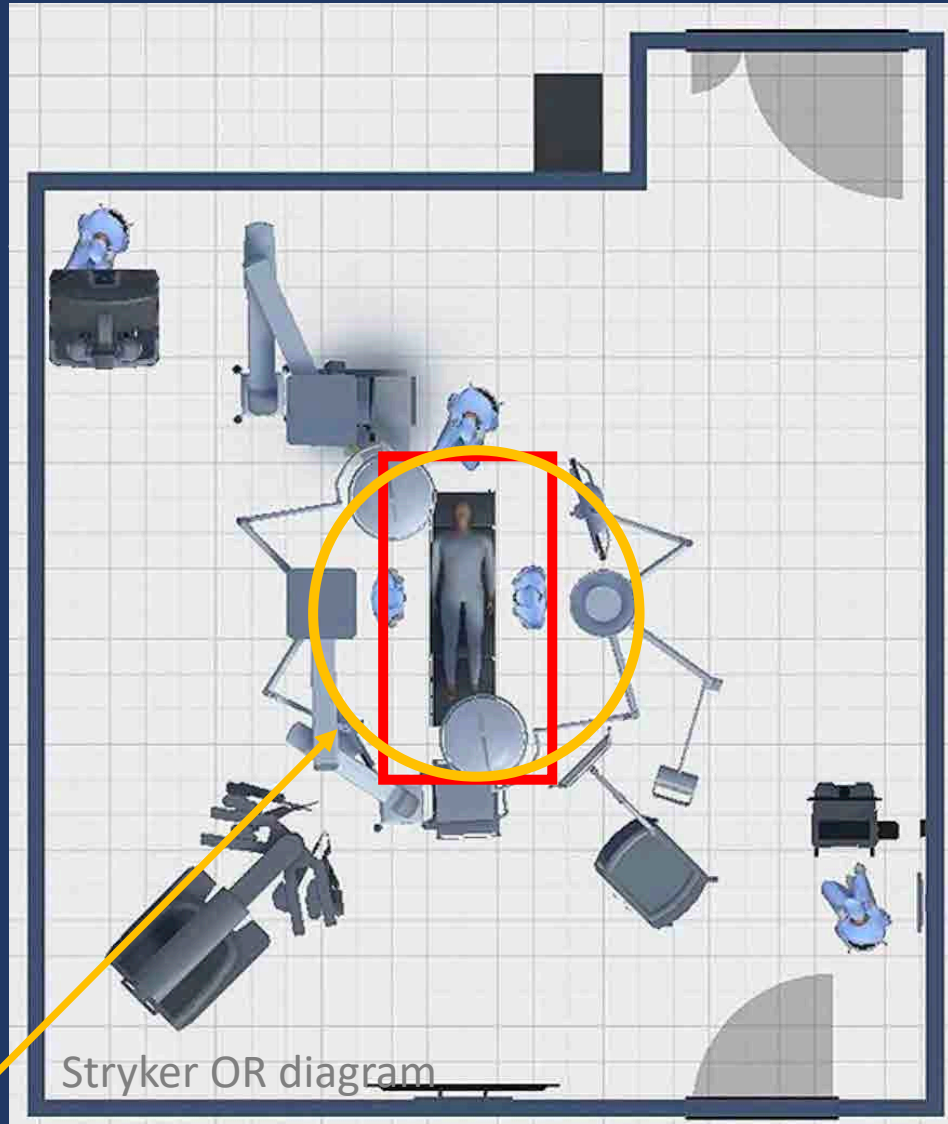
TcAF surgical area coverage and ASHRAE 170



ASHRAE 170-2021:
“Coverage area of primary supply diffuser array shall extend 12 in. beyond surgical table on each side....no more than 30% of primary array shall be used for non diffuser uses.”

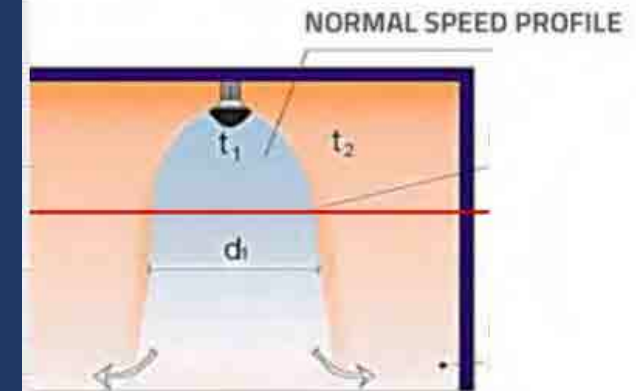
Standard table, plus 12 in. on all sides yields a coverage area of 32 SF x 0.7 (70% non-diffuser area) = **22.4 SF min. required coverage area.**

TcAF coverage area = 31.8 SF



Parabolic Diffuser Shape

AIR DISTRIBUTION AT SUBSET AIR SUPPLY



Air coverage broader than diameter of diffuser. The horizontal plane where the air develops fully is the practical TcAF coverage area.

TcAF meets the ASHRAE 170 diffuser velocity requirement of 25-35 FPM.

Conventional Laminar Air Flow

- Turbulence
in periphery
- Obstacles
disrupt
airflow



TcAF

- Navigates obstacles
- Maintains downward airflow throughout the room, including the periphery



TcAF

- Manages heat convection more effectively
- Robust downflow pushes air away from breathing zone



TcAF

- Protects periphery of room, back tables, case carts



Independent Validation of TcAF

Control of CFUs in-use

Live case instrument set-up

CFU measurements at wound, instrument table, periphery

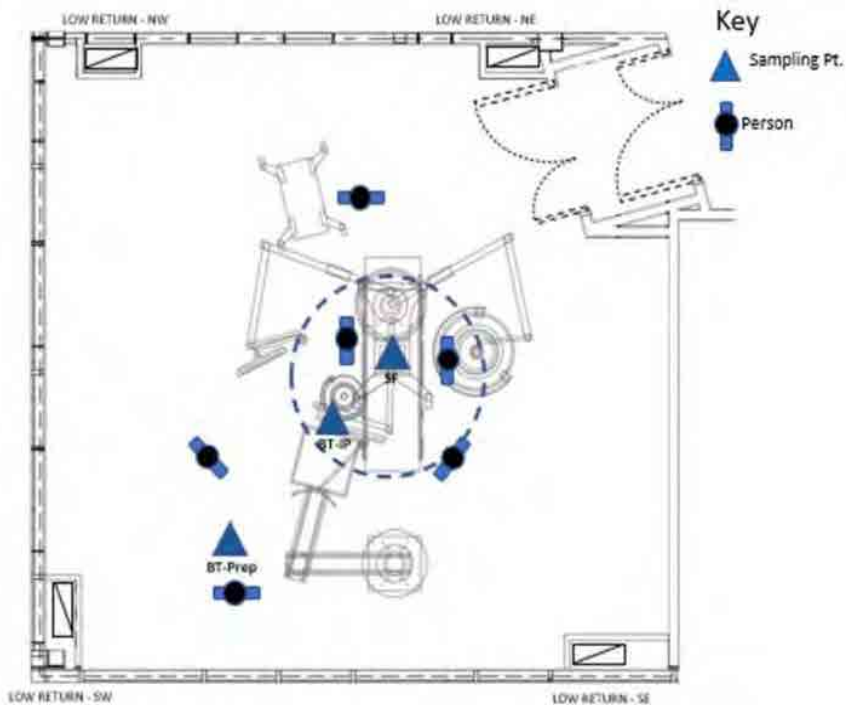


Figure 6 – Locations of Instruments to Measure EQI in the Live Cases

Sample #	Sterile Field	Back Table - Procedure	Back Table - Prep
1	2	4	2
2	0	0	0
3	0	0	0
4	0	1	0
5	0	0	0
6	1	1	0
8	0	1	2
9	0	1	1
10	0	0	0
11	0	0	0
12	0	6	0
Median CFU/m³, IQR	0/1	0/1	1/1

Table 1 - Live case colony forming units per cubic meter of air (CFU/m³) for eleven samples collected (sample #7, the air pumps failed) within the sterile field at the surgical site, at the back table position during procedure, and at the location where the back table would be prepared prior to the start of the case. The medians and interquartile ranges were not significantly different between the three locations, p>.05.

Stress testing TcAF

- Leeuwarden Medical Center: 640 bed teaching hospital, specialization in cardiovascular and neurosurgery
- Building project: 12 new ORs, with 2 hybrid rooms



Purpose of study

- Measure performance of TcAF against new Dutch standard for OR air quality
 - Requires ≤ 10 CFU/m³ for “infection-prone surgery,” mean value of ≤ 5 CFU/m³
- To “test the limits” of TcAF, gauge robustness

Stress-testing TcAF: Results

Upper Leg Trauma Procedure

- 13 surgical personnel
- 2 instrument tables, 2 lamps
- Anesthesia machine, suction unit, Bair Hugger
- Equipment switched on, maximum heat loads
- C-arm brought into OR, drawn up
- Considerable movement “*not quiet*”
- 36 door openings
- Duration: 50 minutes

Results

- Average CFUs wound: 0.75 Average CFUs instrument table: 7.0



“This procedure... was an extreme example....maximum efforts were made to defeat the system.”

R. Noor MSc., CTO, Maximuse B.V.

TcAF and SSI Reduction

Clinical validation and efficacy of a temperature-controlled ventilation system (TcAF) in the OR to reduce surgical site infections

■ Objective

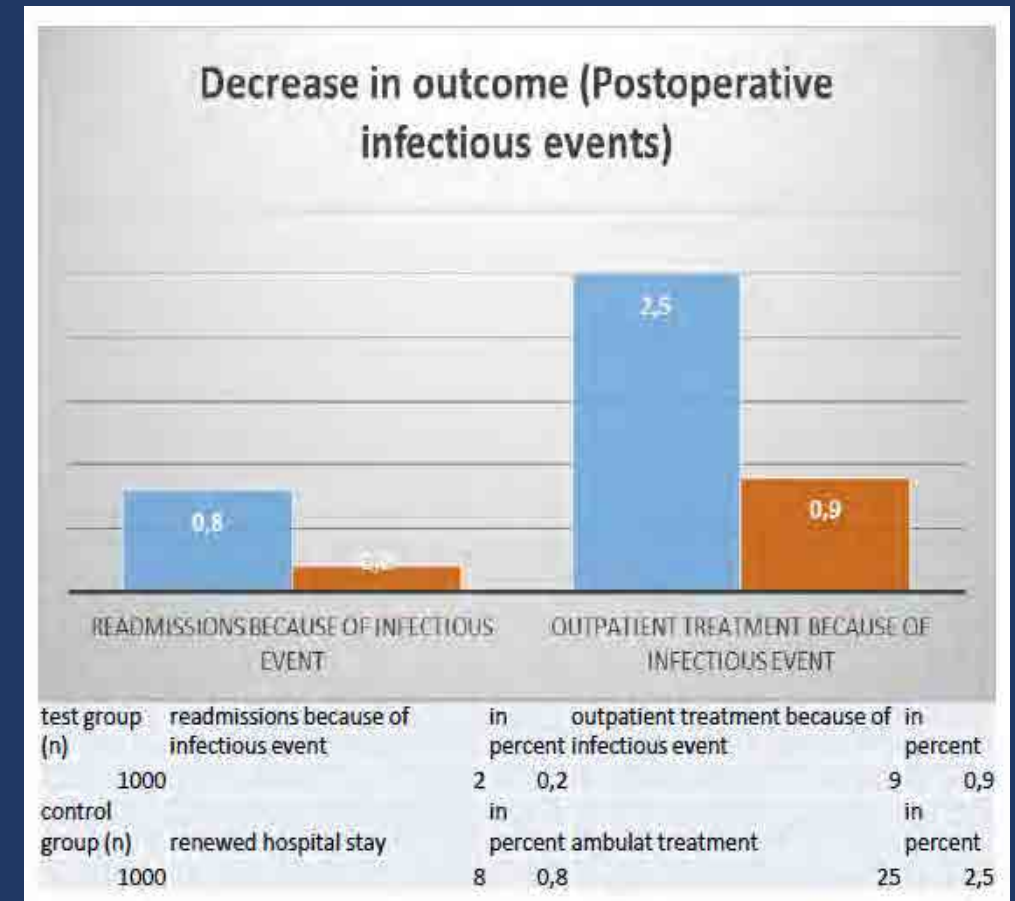
Evaluate efficacy of TcAF under routine conditions, assess impact on PJI.

■ Methods

Retrospective analysis: 1,000 consecutive cases of total joint arthroplasty before, 1,000 consecutive cases after retrofit.

■ Results

Surgical site infection rate decreased 3.1% to 1% . (OR - 0.3259 (95%CI, 0.16-0.65, $p < 0.05$).



Decrease in PJI before (blue) and after (orange) TcAF

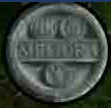
Global movement to performance-based standards for OR air

Country	CFU Limits	ISO Clean Room	Document	Comments
Australia	Class 6, ISO 14644-1	ISO Class 6	ANZ/NZS ISO 14644-1	
Sweden	≤ 10 CFU/m ³ for procedures utilizing implants	TcAF designed to meet most rigorous standards	Standards Institute Teknisk Specification SIS-TS 39	
Netherlands	≤ 10 CFU/m ³ for procedures utilizing implants			Mean value of ≤ 5 CFU/m ³ targeted, to ensure ≤ 10 CFU/m ³
Germany	Recommended < 4 CFU/m ³ , limit of < 10 CFU/m ³		Standard DIN 1946-4-2008 Standard VD 2167	3 classes of rooms
Switzerland	$< 10, 50$ & 200 CFU/m ³ depending on risk			3 classes of rooms by risk
France	≤ 20 CFU/m ³		NF S 90-351	2 classes of rooms
UK	≤ 35 CFU/m ³ rooms at rest, < 10 for ultraclean rooms, not to exceed 180 CFU/m ³ for more than 5 min		British Standard 52-95-1	
Wales	< 10 CFU/m ³		HTM 03-1	
Italy	< 180 CFU/m ³		ISPESL 2010	
Russia	< 5 CFU/m ¹ at OT, < 20 CFU/m ¹ periphery		GOST R 52539	5 classes of rooms including CFU limitations in ED
South Africa		Class 5, ISO 14644-1	Design of mechanical installations (Core Standards 2006)	



University of
Rochester
Medical Center

Experience



UR Medicine's new Center for Orthopaedics and Physical Performance

Univ. of Rochester Advancement



URMC
02:23 ATORRY ORTHOPAEDICS



University of Rochester *Orthopedics & Physical Performance Center*

Selection/Assessment process



- A new facility with an opportunity to consider different approaches to design.
- Recognition of EU standards and different approaches in addressing microbial contamination and system design.
- Early exposure to the physics of temperature-controlled airflow ventilation. This was logical to everyone involved.
- Demonstrated differences in ventilation technology.

Why TcAF?



- Lower CFU measurements with TcAF ventilation technology.
- ISO 8 vs. ISO 6 measurements at rest.
- Reviews of reputable studies and “owner” recommendations.
- Over 300 verified installs and 900+ Microbial measurements.
- Quicker delivery of system components with superior “upfront” product engineering support.

TcAF installation at URMC OR 5

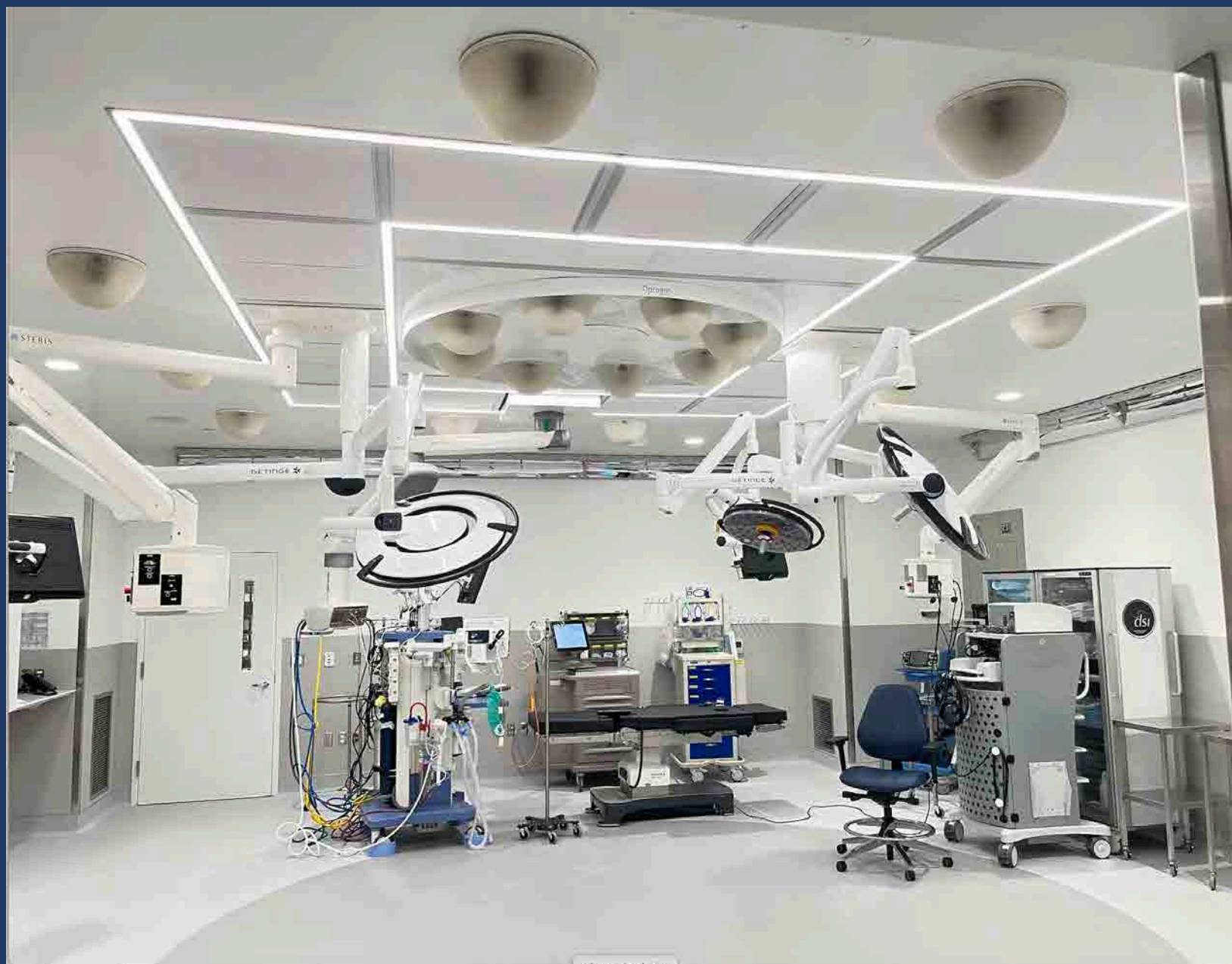


Particle testing of new operating rooms



- 8 newly constructed rooms, OR 5 with TcAF
- Rooms were “broom cleaned” only prior to testing.
- Significantly lower counts in OR 5.
- “A testament to the physics of the design.”

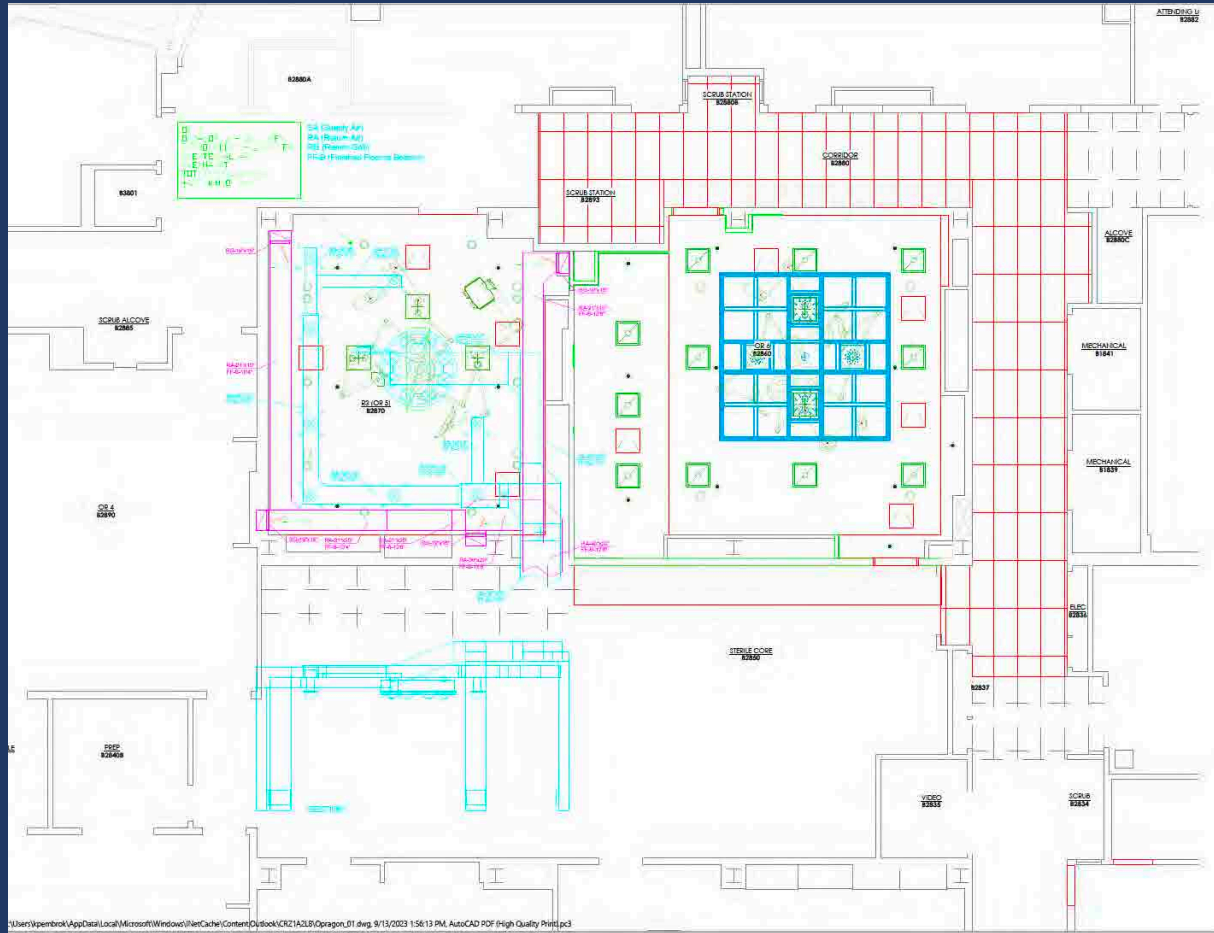
AVG PARTICLES @ 0.5 μ and larger (PPCM)								
NUMBER	OR-1	OR-2	OR-3	OR-4	OR-5	OR-6	OR-7	OR-8
1	2,189	8,934	1,447	953	36	2,754	7,239	14,125
2	1,165	9,994	1,589	4,977	103	6,286	6,815	12,889
3	1,059	10,947	4,873	6,601	138	5,932	7,592	11,300
4	1,483	4,202	3,354	6,778	703	4,273	7,204	9,640
5	918	4,873	1,518	1,553	197	2,860	4,379	7,062
6	388	1,165	776	177	274	1,094	35	1,377
7	211	3,520	35	0	38	1,024	0	35
8	494	9,570	5,791	2,506	62	2,154	2,472	6,886
9	105	2,295	1,765	4,413	117	2,966	3,637	7,486
10	0	1,342	317	71	39	317	423	70
11	35	600	35	35	191	317	812	565
12	1,059	4,343	1,907	1,942	37	1,342	1,306	8,016
13	1,488	635	847	35	39	529	1,695	8,722
14	388	565	4,237	2,400	88	211	1,200	3,919
15	247	529	494	3,318	68	776	3,496	4,061
16	706	1,271	988	1,447	79	1,483	2,789	4,449



OR 5

**Orthopedics &
Physical
Performance
Center**

Strong Memorial retrofit



Strong Memorial retrofit



Temperature-controlled Air Flow ventilation for the OR

Designed for the modern operating room:

- ✓ Achieves ultraclean (<10 CFU/m³) throughout the *entire space*
 - ✓ Improves comfort
 - ✓ Optimizes energy use
-
- 350+ installations
 - Independently validated
 - Outcomes reinforced by microbial measurements during active surgery after each installation
 - Approved for installation in NY (DOH) & CA (HCAI)



What we covered

The risk factors associated with airborne microbial contamination in the operating room.

The physics of temperature-controlled airflow ventilation.

The differences in design and performance among different ventilation alternatives.

One institution's process of assessing a novel ventilation technology.

A photograph of an operating room, dimly lit with a blue tint. In the center, a surgical table is surrounded by various pieces of medical equipment, including monitors, IV stands, and anesthesia machines. Large, circular surgical lights are mounted on the ceiling. The room appears clean and professional.

Rethinking OR Ventilation

Temperature-controlled Air Flow Technology

QUESTIONS??