HumanIC:CBT3 Stockholm

Operating Room Ventilation Selection, Design and Implementation: From (Need) Concept to Commissioning

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Agenda

- Why Operating Room Projects matter for you
- Requirements and ventilation needs in the OR
- Ventilation principles and solution concepts
- From requirements to solution selection
- From concept to realization: design, installation, commissioning
- Implications for research and innovation
- If time allows: reflection on OR ventilation standards

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Why OR Projects matter for you

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Human IC Objectives

- Reduce infections with 10 %
- Reduce energy use with 30 %
- Improve Thermal Comfort

Compared to what?

- Which OR? Which Solution?
- To worst, To average, to Best-in-Class?
- What baseline year?
- Research concept or design intent or solution in operation?

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Discussion 2-3 minutes

- If you were asked to prove a 10% reduction in infections in operating rooms:
  - What would you compare against?
  - What can you see as problematic in making such a comparison when it comes to reality?

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The Challenge

The outlined Human IC objectives are excellent ambitions, but that they are *undefined until translated into a project context and insignificant until implemented broadly in healthcare and society*.

Requirements → Solution selection → Design → Construction → Validation → Operation

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Avidicare – Opragon – TcAF as the example

- Opragon is a "novel" OR Ventilation Solution based on and supported by research.
- Nearly 20 years of experience in driving innovation to
  - reduce infections,
  - lower energy use and
  - improve thermal comfort
- Experience in moving the market — and in encountering the forces that, for better or worse, slow the adoption of new solutions

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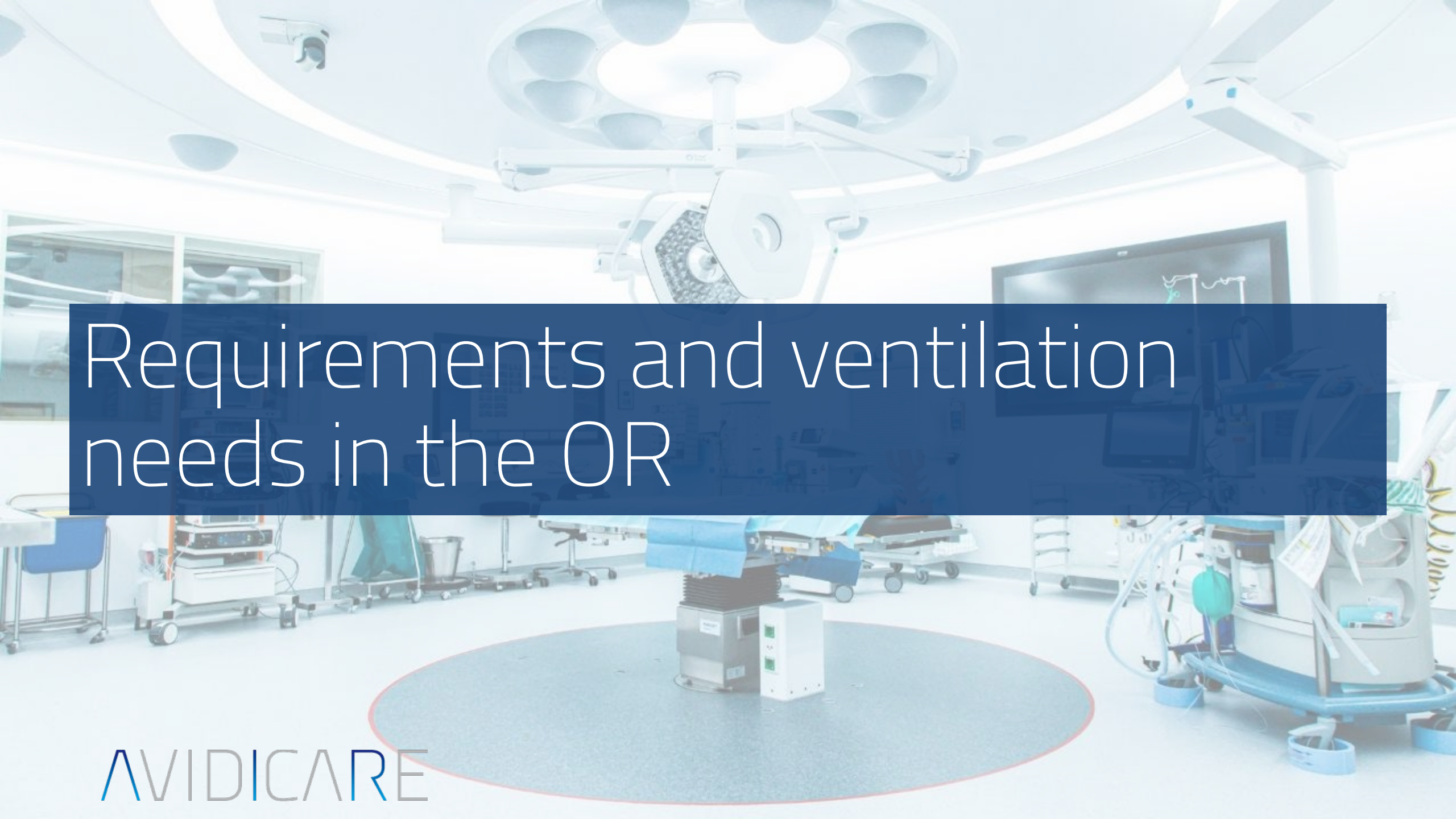

Requirements and ventilation needs in the OR

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Surgical Site Infections (SSIs)

- Surgical site infections (SSIs) are a major global issue, causing significant suffering, fatalities, and healthcare costs.
- A single infection can cost anywhere between $10,000 and $100,000 per case.
- Despite preventive measures like sterile protocols, prophylactic antibiotics, and ventilation, 2–10% of surgeries still result in infection depending on geography.
- The world's best hospitals achieve infection rates below 1%, proving there is massive potential for improvement.

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Reducing Airborne Bacteria Reduces SSI

- Charnley was able to reduced SSI after hip prosthesis surgery from 8,5% to 0,7% by reducing bacteria levels in the air from 600 CFU/m^3 down to <1 CFU/m^3 (1959-1974) in
  - No antibiotics were used
  - Direct correlation between cfu levels and SSI rate
- Confirmed in a prospective controlled multicenter study with 8000+ patients. (Lidwell et al, various publications)
  - Air is main pathway for bacteria to enter the wound (95%)
  - To achieve significant infection reduction in practical terms, the threshold was defined as <10 CFU/m^3 (Ultra-clean air)
  - <1 CFU/m^3 takes infections down to a minimum (Whyte & Lytsy 2019)

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Charnley, J. (1972). Postoperative Infection after Total Hip Replacement with Special Reference to Air Contamination in the Operating Room. Clinical Orthopaedics and Related Research, 87, 167-187.

Lidwell, O. M. (1988). Air, antibiotics and sepsis in replacement joints. Journal of Hospital Infection, 11, 18-40 •

SSI is multi-factoral

- SSI risk is influenced by multiple interacting factors
- Patient-related factors (health status, comorbidities, immunity)
- Procedure-related factors (duration, invasiveness, implant use)
- Environmental factors (air quality, temperature, humidity)
- Human factors (behavior, discipline, compliance, workflow)

Ventilation addresses one *controllable and structural* part of a much larger system.

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The Hospital’s Actual Problem

- Hospitals aim to deliver a certain number of surgeries per day
- Surgical output must meet defined quality and safety expectations
- Infection risk must be acceptable, predictable, and defensible
- Operations must be stable over time, not only on commissioning day
- Cost, reliability, and liability matter alongside performance

Hospitals do not buy airflow patterns. They need predictable surgical capacity with acceptable and defensible risk to a reasonable cost.

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Ventilation principles and solution concepts

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The Role of Ventilation in the OR

1. Contamination Control Through Ventilation
   - Ventilation helps protect the surgical site by:
     - Diluting and removing contaminants
     - Directing airflow from critical to less critical areas for extraction
2. Temperature and Humidity Control
   - Stable indoor climate supports:
     - Infection control
     - Staff comfort and patient safety
3. Pressure Differential Maintenance
   - Positive pressure keeps unfiltered air out by pushing air from the OR into adjacent spaces.

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Operating Room Contamination

- An empty properly cleaned OR stays clean thanks to HEPA-filtered air and overpressure.
- People are the main source of bacteria:
  - Normal clothes: ~1000 CFU/min per person
  - Protective clothes: ~60–300 CFU/min
- Most bacteria/viruses are on larger skin flakes (4–20 µm)
- Large particles fall with gravity unless airflow lift them
- Door openings, obstacles and heat from people and equipment affect airflow.

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CFU = Colony Forming Unit as a measure of bacteria in air and on surfaces

Dilution and Displacement

Dilution

- Clean air is **mixed** with contaminated air
- Goal: reduce **concentration** over time
- Principle used in **turbulent mixing ventilation (TMV)** systems
- Requires very high air volumes, low source strength (tight clothing) to achieve highest cleanliness

Displacement

- Air flows in a controlled direction
- Goal: move contaminated air away from critical areas
- Used in **TcAF** and **UDAF/LAF** systems

In real-world conditions, well working displacement is more efficient than dilution — especially when air volume is limited.
Dilution may outperform displacement if displacement is disturbed

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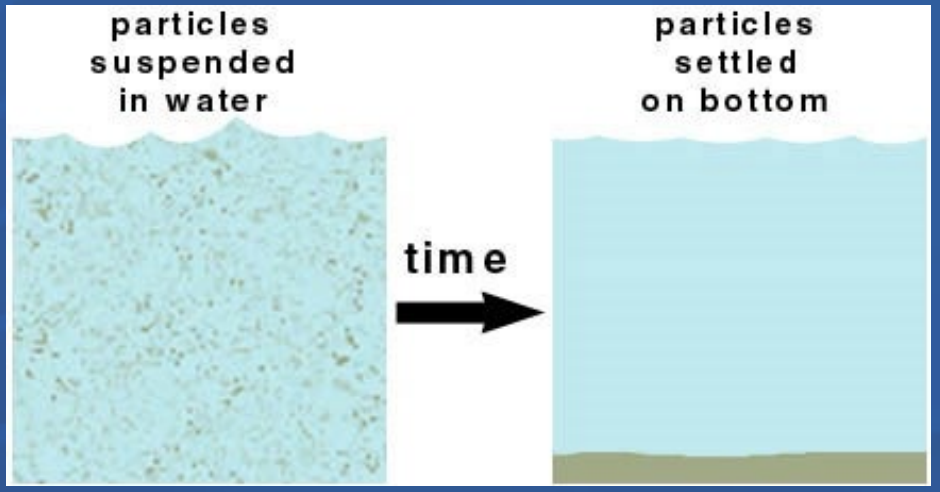
Sedimentation

- Sedimentation means particles slowly fall down — like dirt in still water.
- Turbulence (air moving in all directions) caused by high airflow disturbs sedimentation.
  - If you stir the water, the dirt stays floating.
- If you gently fill a room with clean air from above, and let air exit near the floor, large particles will fall and be removed.
- This principle helps remove contaminants more efficiently – if allowed!



Sedimentation is a passive process.

What you don’t want in the OR

- Stagnation zones – no air movement
- Reverse or Uncontrolled Airflows
- Recirculation and Vortex formation
- Insufficient Mixing in Critical Zones
- Poor Air Displacement Due to Obstructions

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OR Ventilation Methods

1. Turbulent Mixing Ventilation (TMV)
   - Uses turbulent airflow
   - Purpose: Mix clean air with contaminated air (dilute) to reduce particle levels
2. Laminar / Unidirectional Airflow (LAF / UDAF)
   - Uses fan-driven vertical airflow (low turbulent) from a ceiling unit
   - Purpose: Create a very clean zone directly under the unit e.g., over the surgical table and instrument table (displace)
3. Temperature-Controlled Airflow (TcAF)
   - Uses gravity-driven downward airflow (low turbulent) by using air that is slightly cooler and also uses peripheral diffusers for full-room control
   - Purpose: Provide a low-contamination environment in both the center and the periphery (displace, dilute and allow natural sedimentation)

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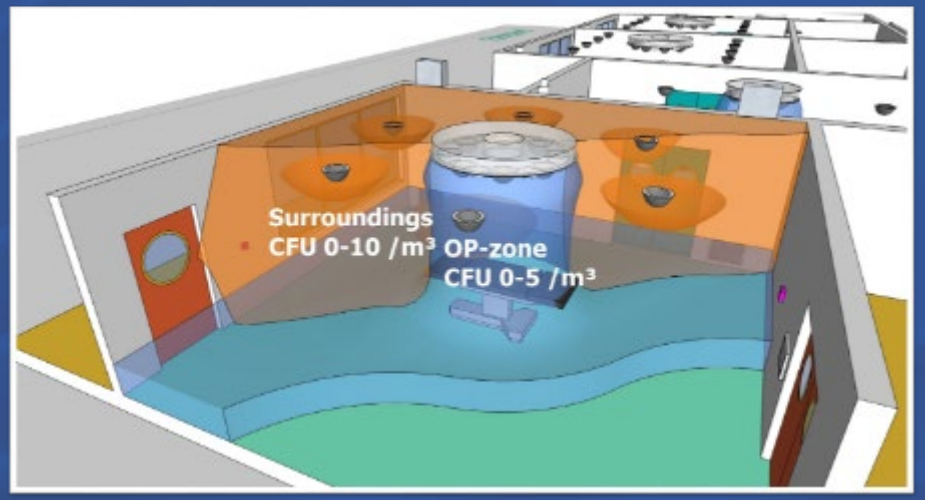
The Example of Opragon TcAF

- Above the Patient
  - HEPA-filtered air is quietly released from a central unit
  - The downward airflow is driven by air that is 1,5-2 °C cooler than the actual room temperature (not fan-driven)
  - This airflow sweeps away contamination in the central zone
- In the Periphery
  - HEPA-filtered air from the ceiling enhance sedimentation of contaminated air toward the floor and out of the room
  - The air temperature is automatically controlled, and the system adapts to heat sources in the room



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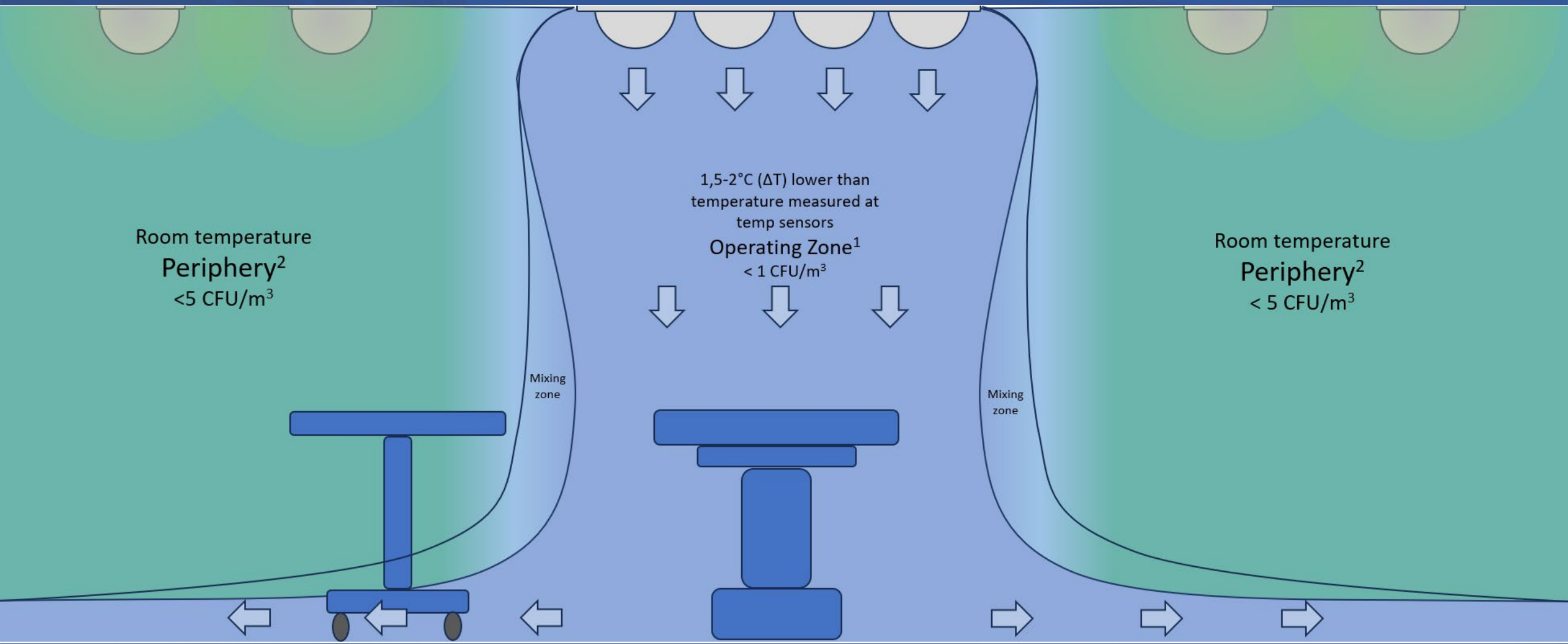
Room temperature
Periphery[2]
<5 CFU/m[3]
1,5-2°C (ΔT) lower than temperature measured at temp sensors
Operating Zone[1]
< 1 CFU/m[3]
Mixing zone
Mixing zone
Room temperature
Periphery[2]
< 5 CFU/m[3]

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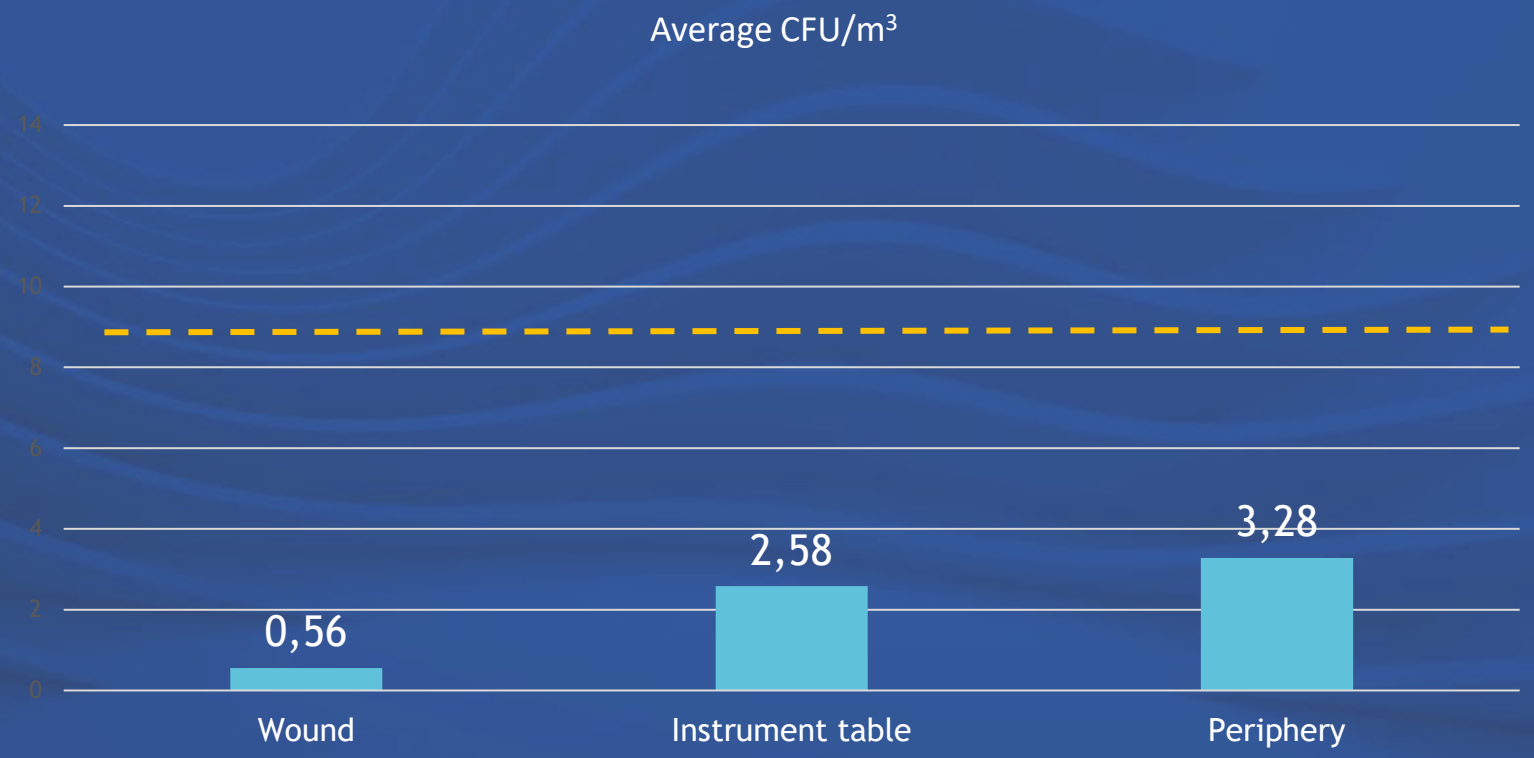
Microbiological Performance

- Internal data on file from more than 800 CFU measurements at customer locations during live surgery and a mix of clothing concepts and number of staff (Opragon 8)
- Results strongly supports the conclusion that the Opragon system is carrying pathogens away from the wound area and away from staff towards the room exhaust vents to create an ultra-clean room.



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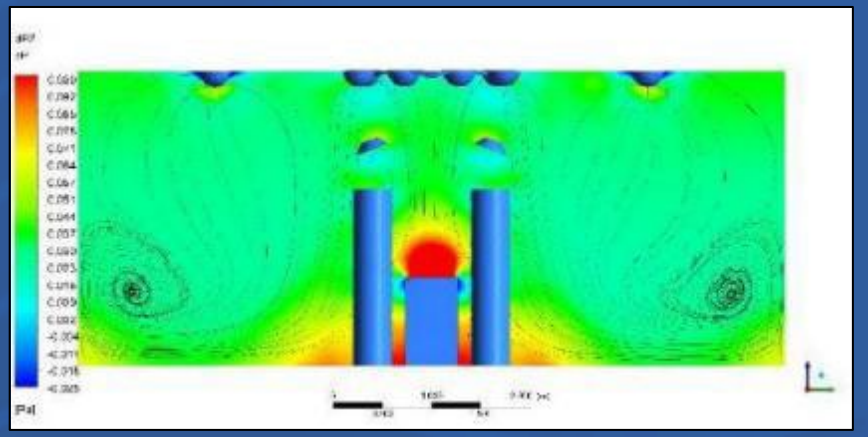
Use of Research

- Royal Institute of Technology in Stockholm
  - Several published articles and doctoral dissertation using Computerized Fluid Dynamics on super-computers proving ultra-clean conditions
- Lund University, Sweden
  - Several published articles and doctoral dissertation from real-world measurements and analysis confirming comparative advantage to other systems
- Weiden University, Germany
  - Several studies, incl an outcome-based study with 2000 patients showing SSI reduction from 3% to 1%
- Extensive database of airborne bacteria measurements proving ultra-clean conditions



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Claimed Advantages

Mixing ventilation

- Simple and well-understood system architecture
- Robust to variations in room layout, behavior, and workflow
- Easy integration with standard building HVAC systems
- Lower design and implementation complexity
- Predictable average air cleanliness in the room

Traditional LAF /UDAF

- Strong, directional protection of the surgical field
- Clear physical separation between clean and less clean zones
- Long clinical history in implant and orthopedic surgery
- High acceptance and familiarity among clinicians and authorities
- Straightforward validation logic aligned with existing standards

Temperature-Controlled Airflow

- Stable, gravity-driven airflow with low turbulence
- Contamination control in both the surgical field and the periphery
- Reduced sensitivity to obstructions and real-world variability
- Lower airflow requirements than high-flow systems
- Improved thermal comfort and energy efficiency
- Flexible to structural constraints

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From requirements to solution selection

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Conflicting Needs and Interests

System and Patient Oriented Needs

- Infection prevention and patient safety
- Staff working environment and comfort
- Budget constraints and life-cycle cost
- Structural and architectural constraints
- Serviceability, maintenance, and uptime
- Flexibility for future use and change

Human and Organizational Drivers

- Personal and professional risk
- Compliance with standards and guidelines
- Accountability and liability
- Established relationships and trust
- Time pressure and project delivery risk

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Project Stakeholders

- **Clinical stakeholders** focus on patient safety, workflow, and perceived risk. Their influence is often strongest early, but not always technically detailed.
- **Infection prevention** tends to be conservative and standard-driven, for good reasons. They often act as risk gatekeepers.
- **Consultants and architects** translate requirements into concrete solutions. Their choices are strongly shaped by standards, precedent, and liability.
- **Contractors** optimize for buildability, cost, and time. Late changes are expensive and therefore resisted.
- **Facility management** cares about serviceability, robustness, and long-term operability — often underrepresented early.
- **Management and procurement** balance budgets, timelines, and compliance.
- **Authorities and standards** define what is acceptable, not necessarily what is optimal.
- **Vendors** contribute expertise, but their input is filtered through trust, familiarity, and perceived risk.

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Selected Solution

- No single stakeholder designs an operating room. It is the result of accumulated inputs from many actors, each with a legitimate but partial perspective.
- No one has a complete system view.
- The final selected solution is an emergent result of how these inputs interact — not a direct implementation of research findings.

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Why the “best” or “desired” solution is not always selectable

- Architectural and structural limitations (ceiling height, beams, existing structures)
- Hybrid OR requirements (imaging equipment, ceiling congestion)
- Clothing and behavior requirements (tight clothing, discipline, workflow)
- Limited available airflow or HVAC capacity
- Noise, draft, and thermal comfort constraints
- Financial constraints - budget
- Project risk and liability considerations

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Group discussion 5 minutes

- Imagine you are in a real OR project with limited ceiling space, budget pressure, and multiple stakeholders.

- You have decided on a solution.

- What could happen during design or construction that breaks these principles/solutions — i.e. intended performance not achieved — without anyone intending to?

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From concept to realization: design, installation, commissioning

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- In February 2023, our sales department was contacted by an engineering company and a region within the Swedish healthcare system (public hospital).
- They had decided to build two new hybrid rooms in existing facilities at two of their hospitals.
- The X-ray machines were ceiling mounted Philips Azurion Flex Arm
- A pre study was made so there were some drawings available

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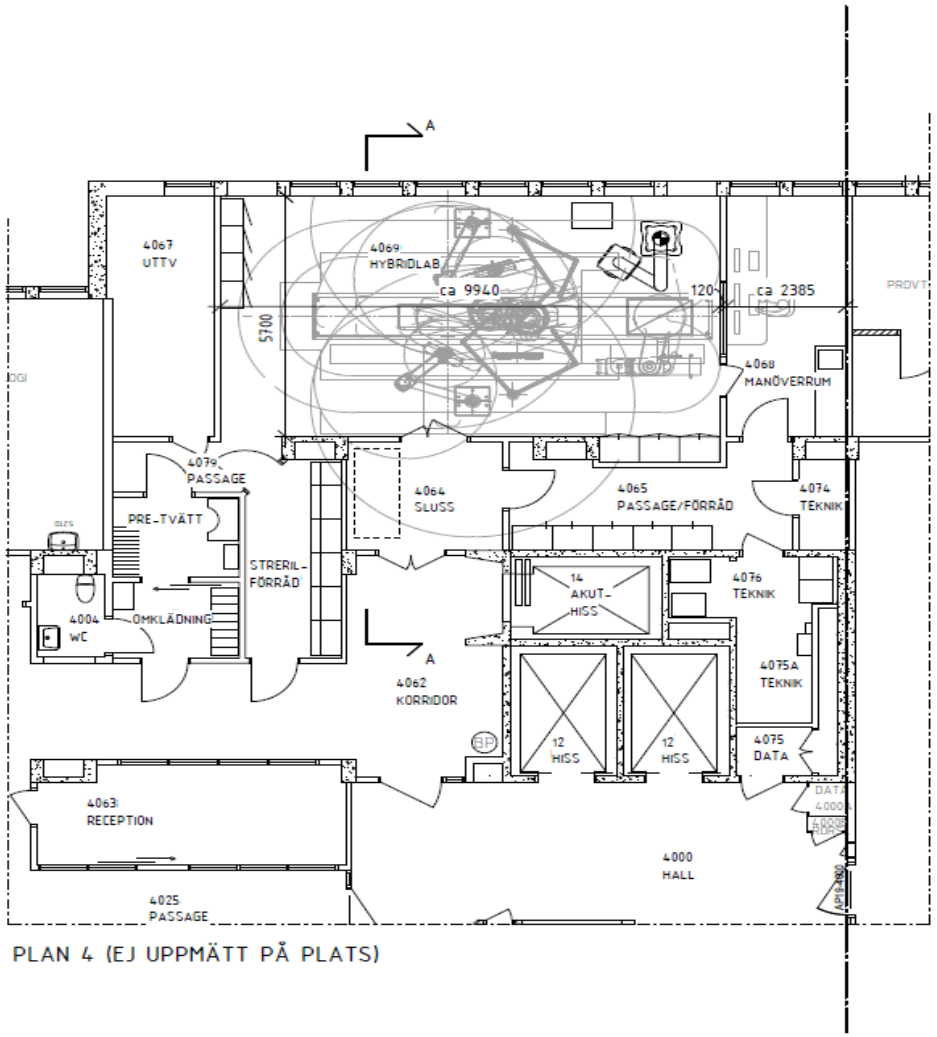
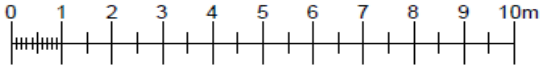
- We first received pdf files…



PLAN 4 (EJ UPPMÄTT PÅ PLATS)

SEKTION A (EJ UPPMÄTT PÅ PLATS)



SKALA 1:100

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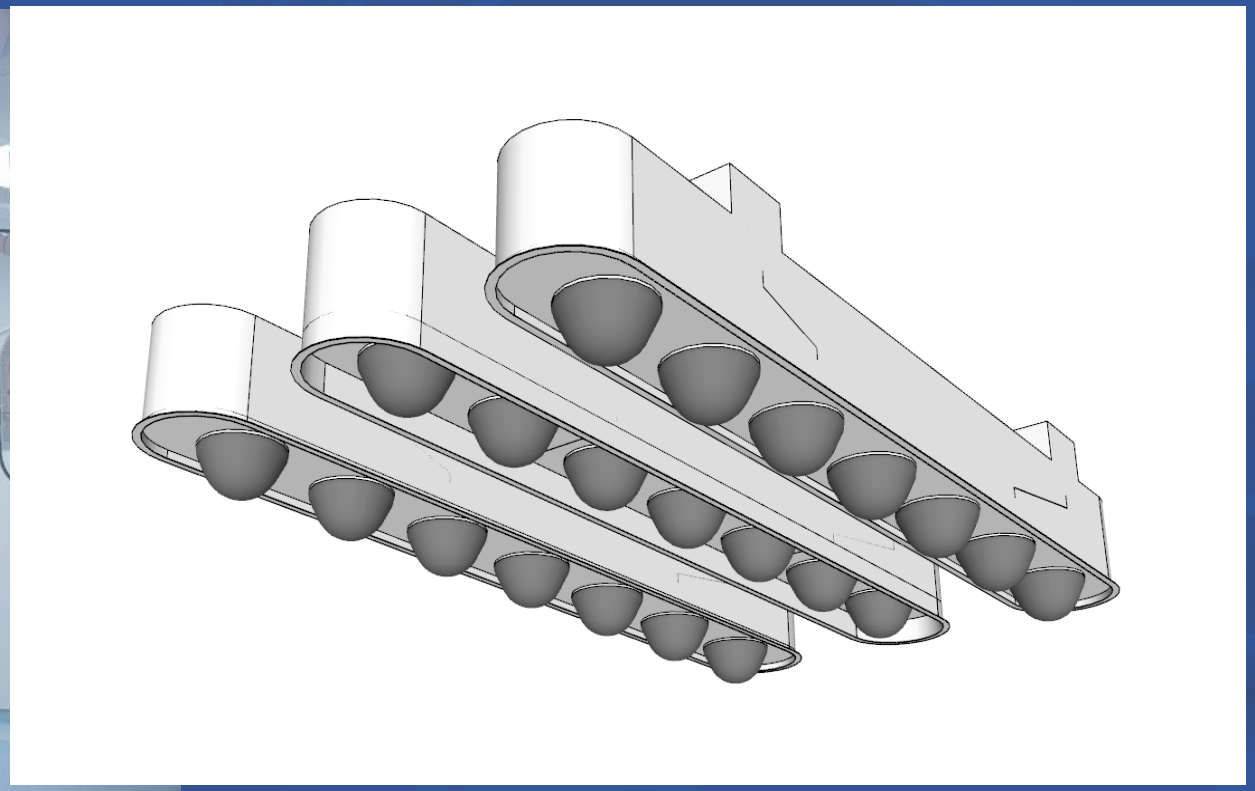
- The Opragon 21 (3x7) is designed to work with Philips Azurion it needs 7350m³/h and air for the external Airshowers (AS)



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Determine air flow and number of air showers

Determine the amount of air ($\mathbf{Q_V}$) to be supplied via external air showers using the following formula:

$$Q_V\ m^3/h = (A_{OP} - A_{TAF}) \times 72 + 0{,}2 \times Q_K$$

Where:

$\mathbf{A_{OP}}$ =Operating theatre area in m^2

$\mathbf{A_{TAF}}$ = Operating zone area in m^2

$\mathbf{Q_K}$ = Air flow Opragon and other devices with under-tempered air in m^3/h

The air flow through the air showers is selected within the range of 300-400 m^3/h per air shower, which makes it easy to calculate the number of air showers to be placed outside the operating zone served by the Opragon.

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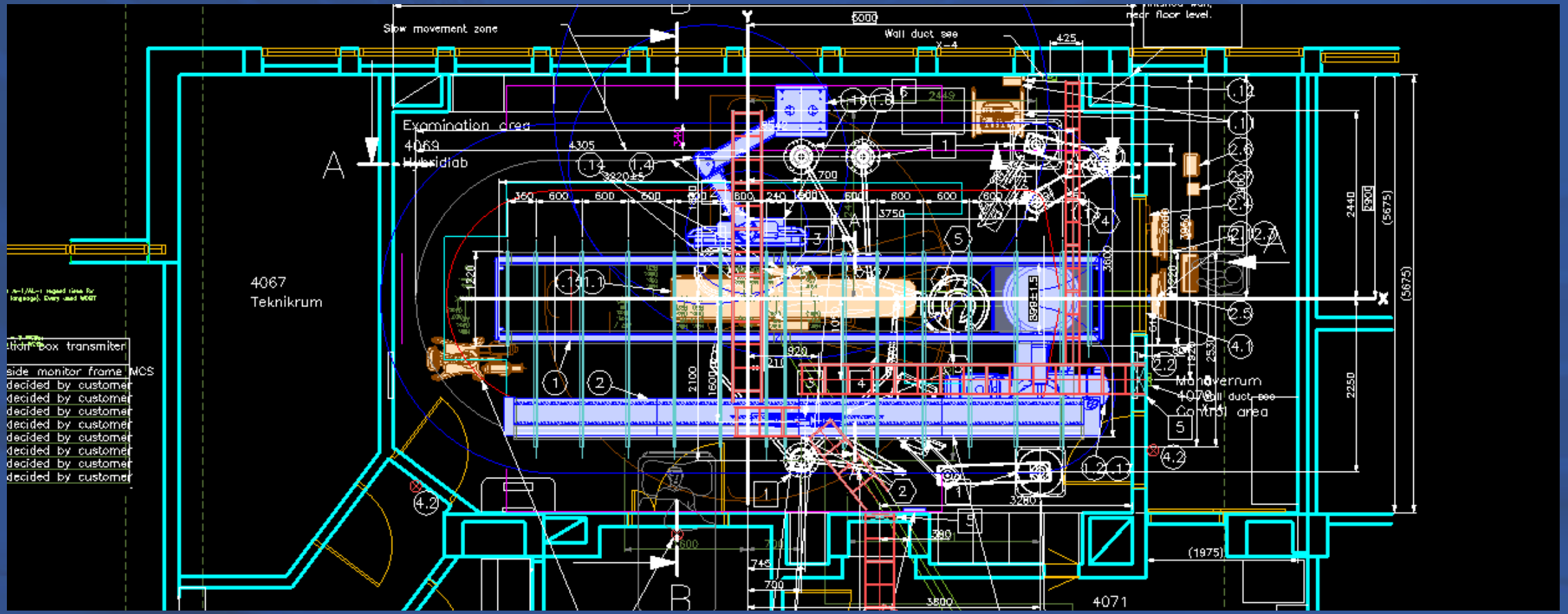
- Total area is 54m²
- Opragon 21 covers ~10m² (7350m³/h)
- That leaves 44m²to the external Airshowers (4600m³/h)



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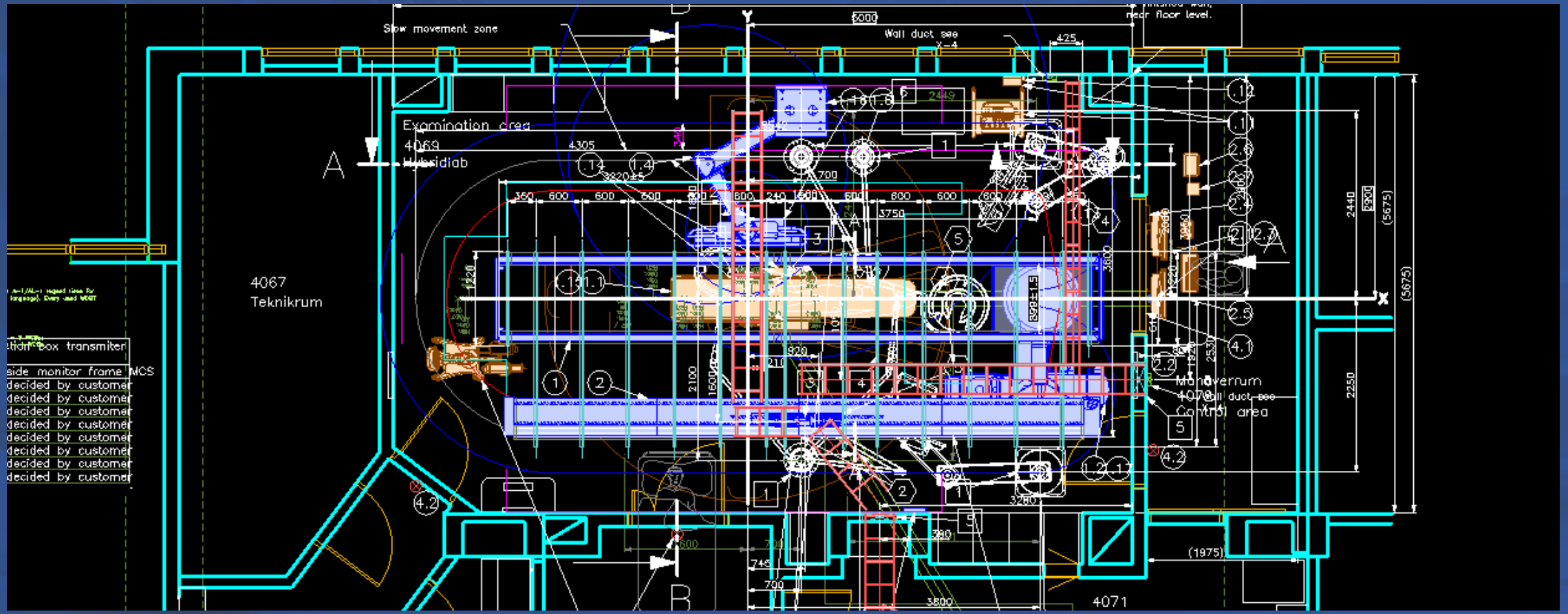
- Available area technical room



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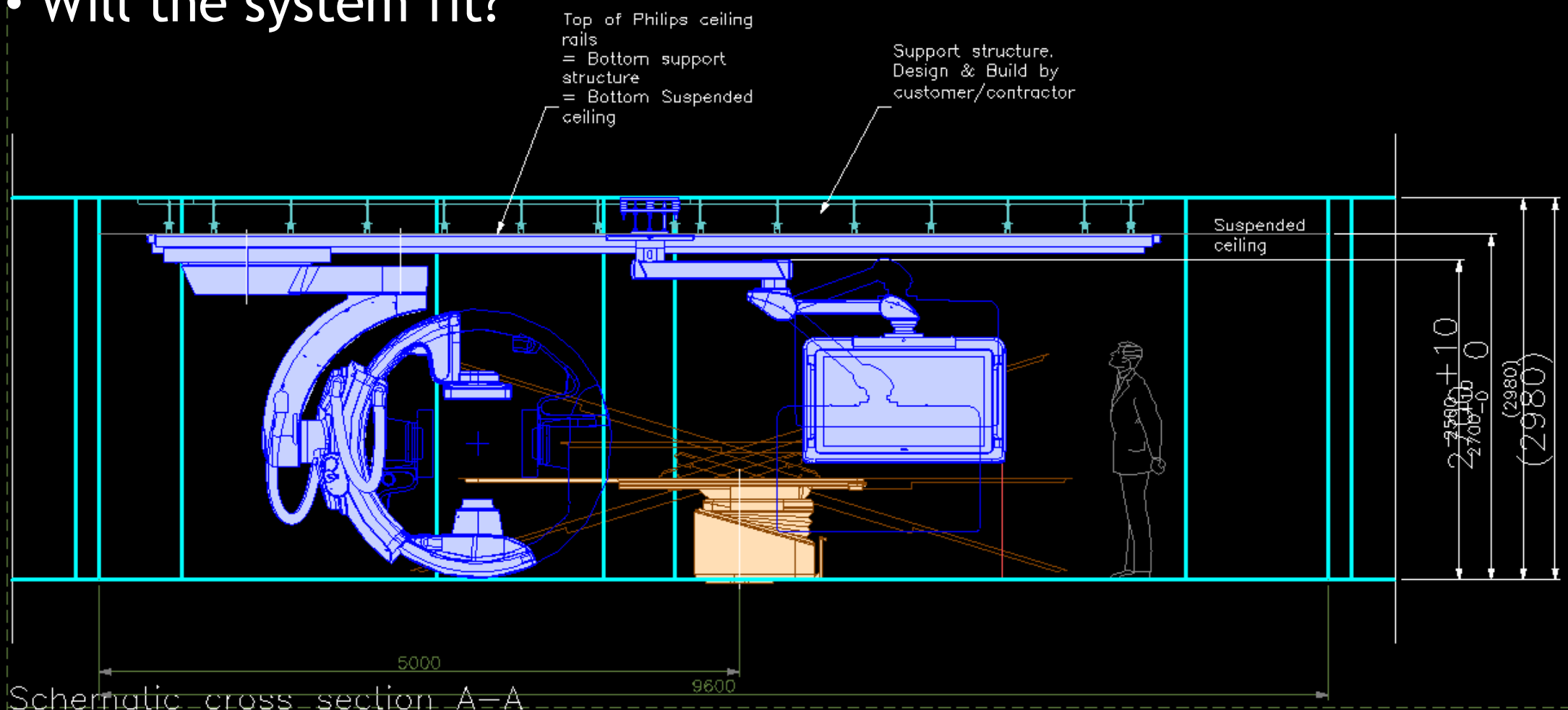
- Distance between floors 2980 mm
- Will the system fit?



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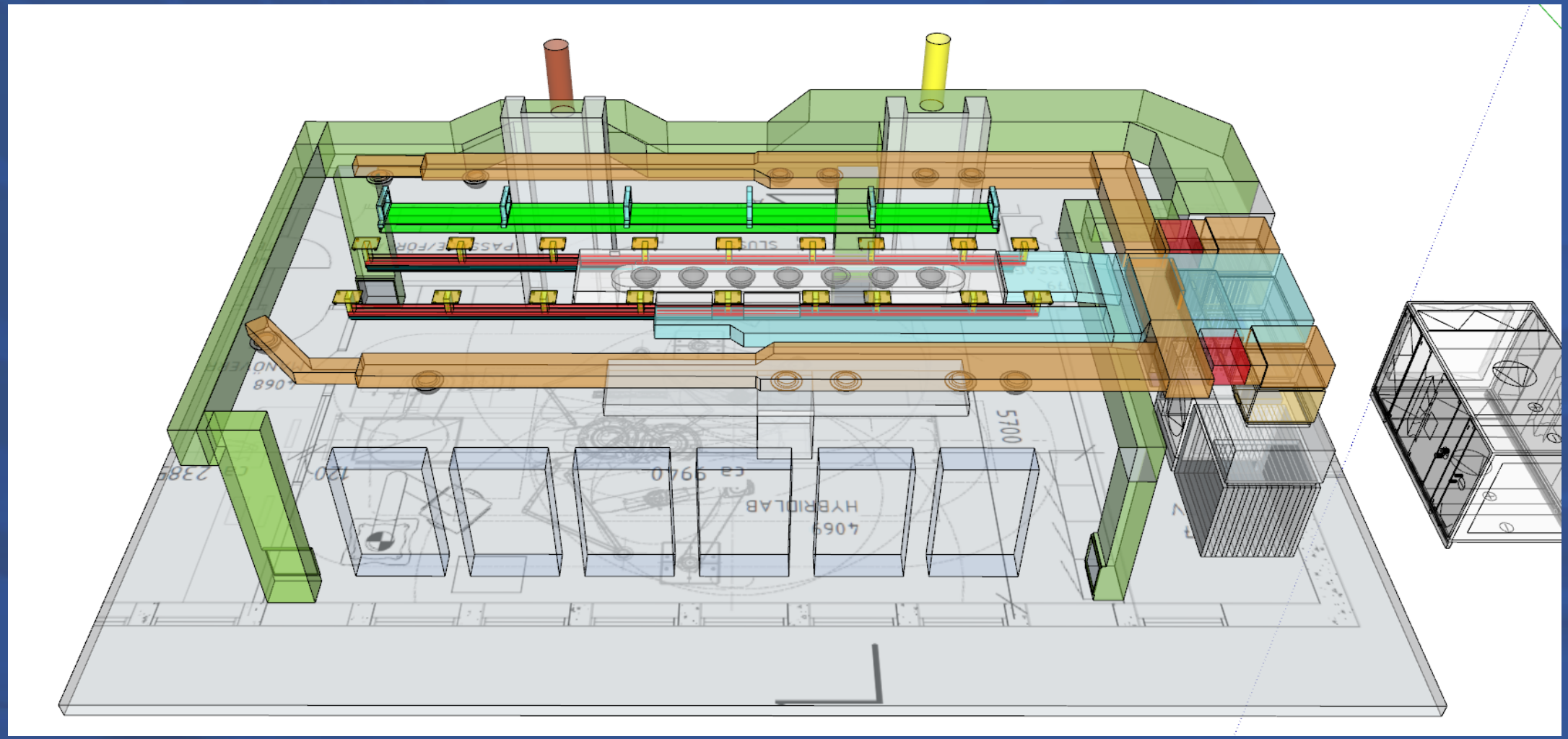
- We presented a system with one Opragon 7 in the center



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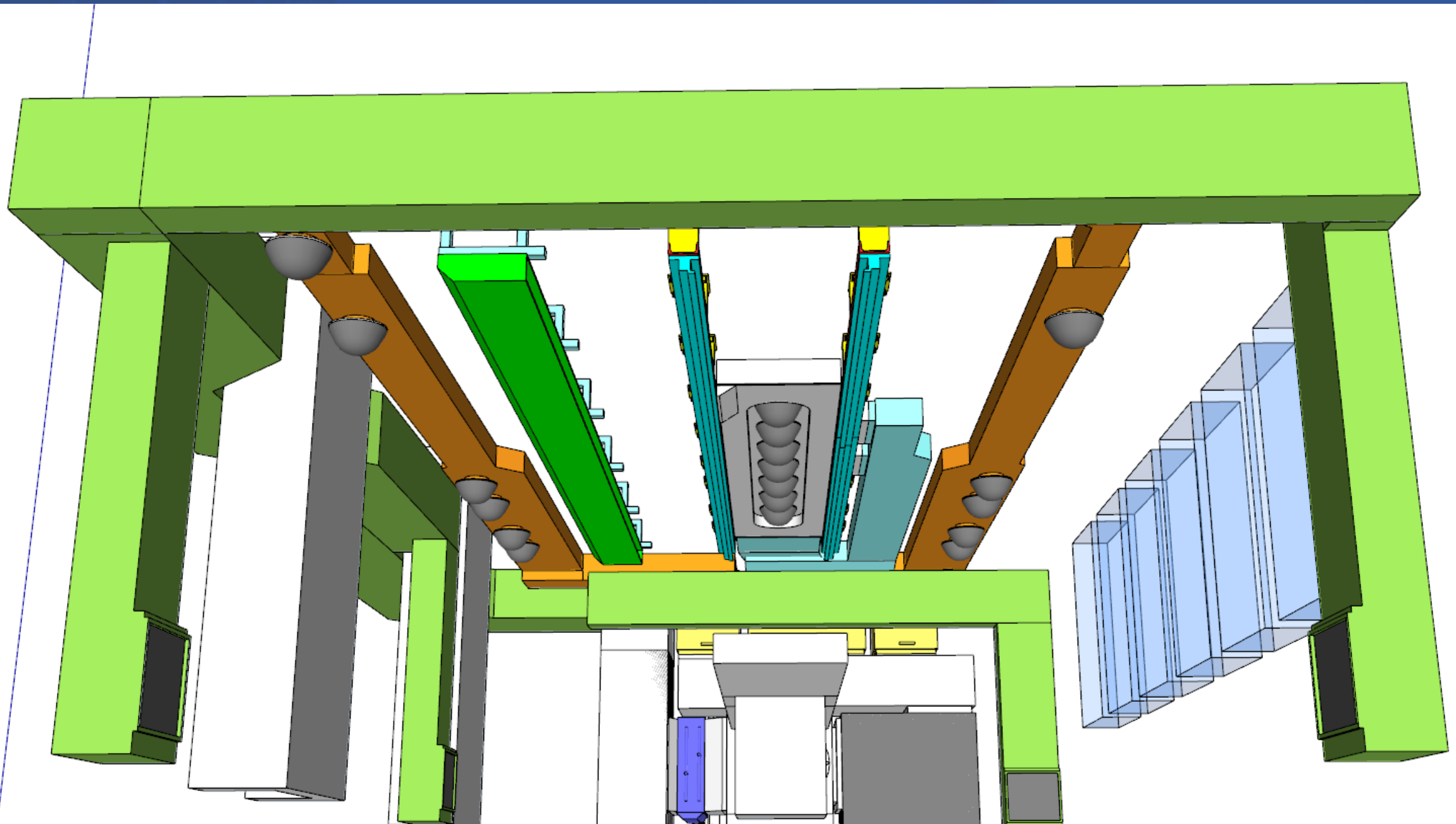
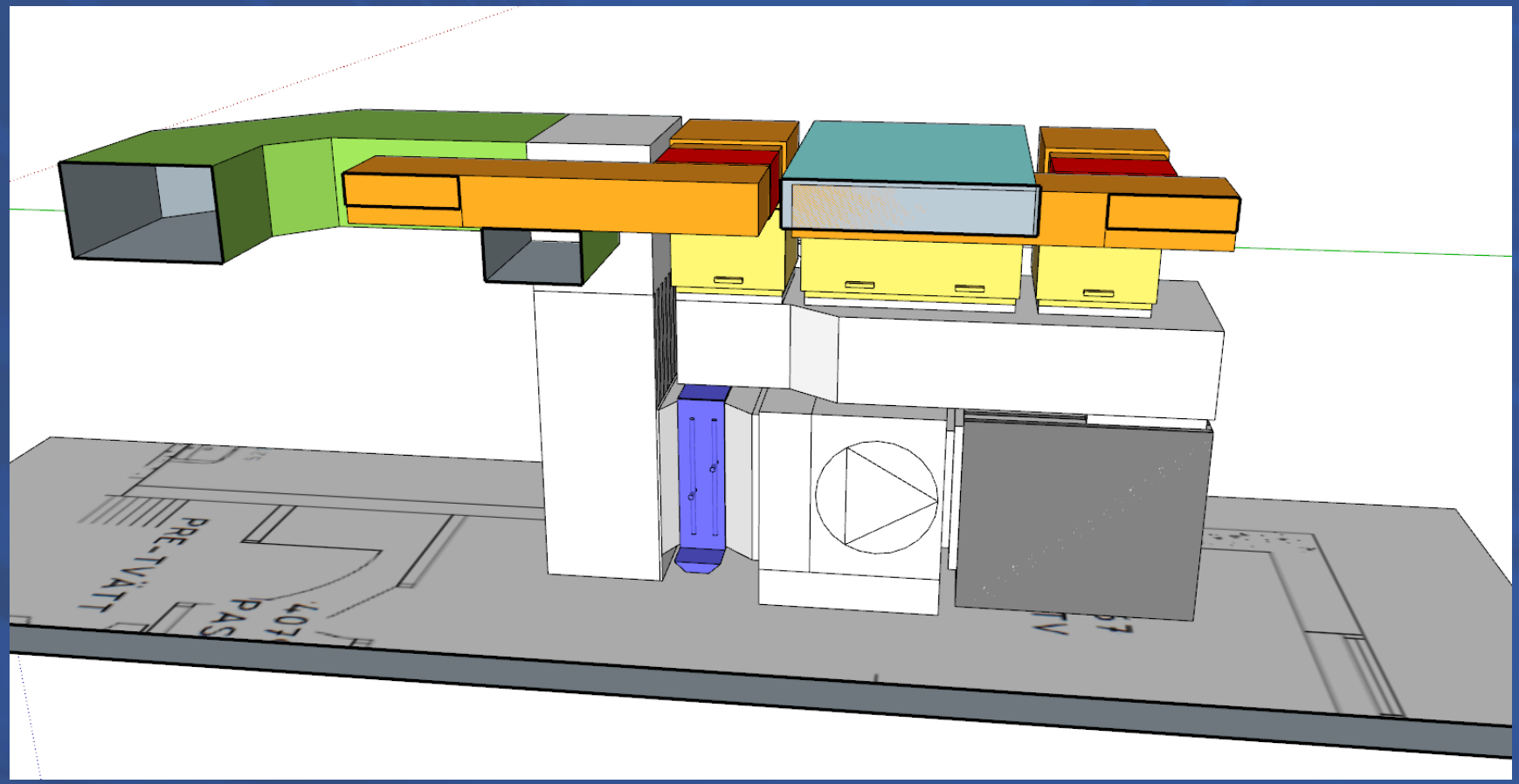


- In order to save space, we suggested a solution for the AHU that we designed for another project



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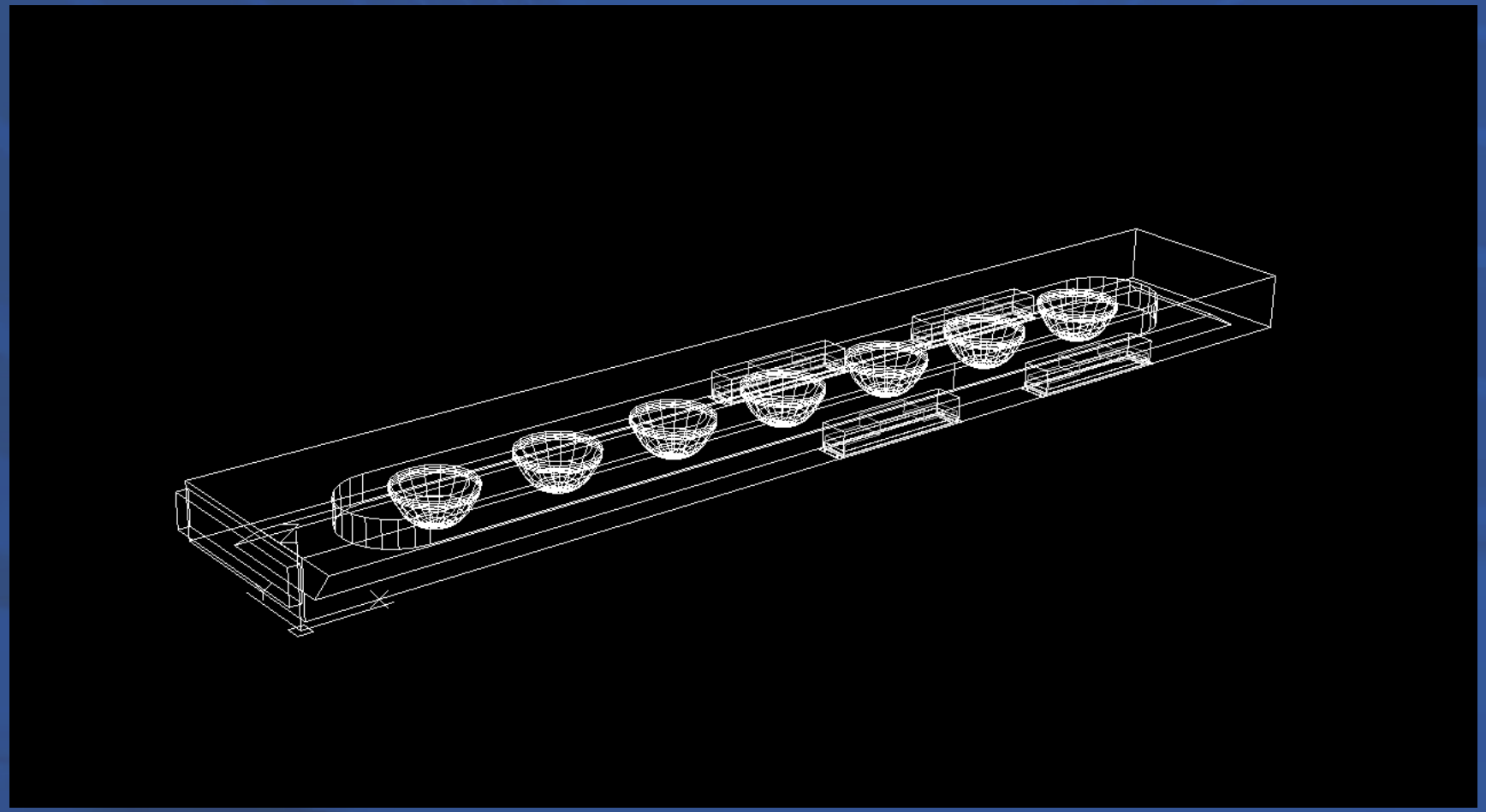
- We supply 3D models and drawings so the project engineers can integrate the Opragon system in the design process



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Iterative communication during design

- Meetings
- E-mails
- Phone calls

- Coordinate and adjust with:
  - Architect
  - HVAC
  - Electricity
  - Structural engineer

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Then we wait…

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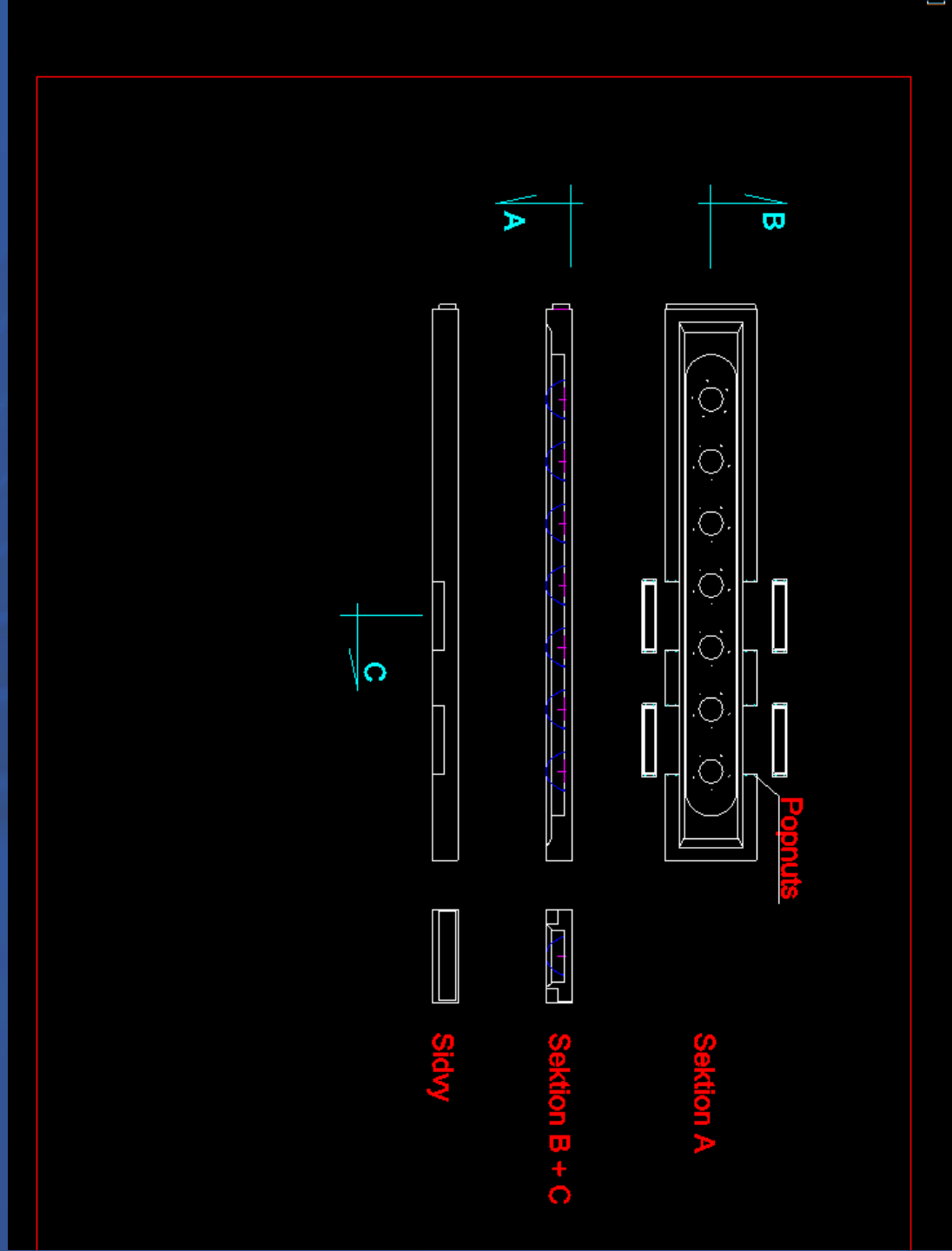
2025 February 4

- 2 years after start
- We recieve the order and OK to start production
- Production dwg is sent to the factory
- 3 weeks later the Opragon is delivered
- Contractor starts building



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2025 April 14

- A possible collision between the Opragon and the Philips C-arm is suspected and we are called to visit the construction site

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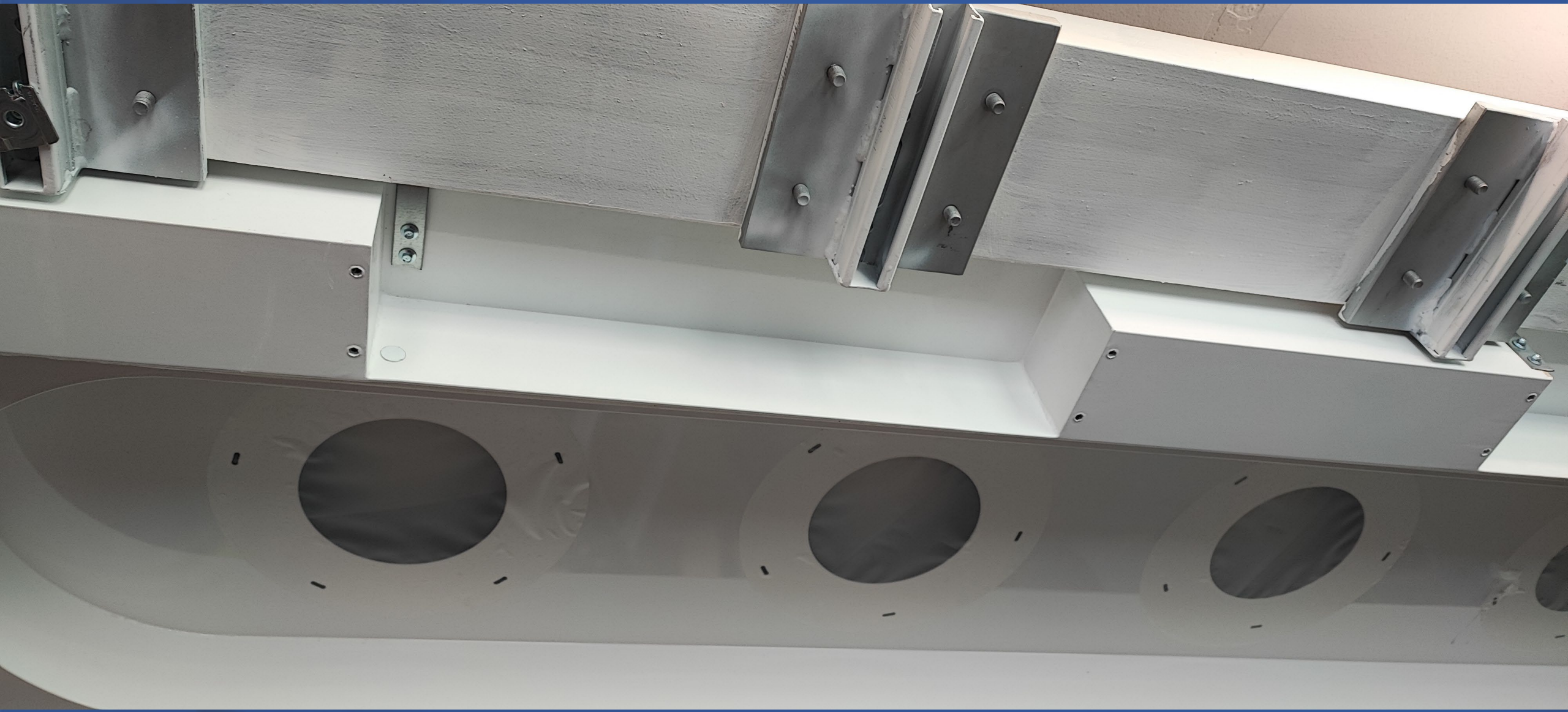

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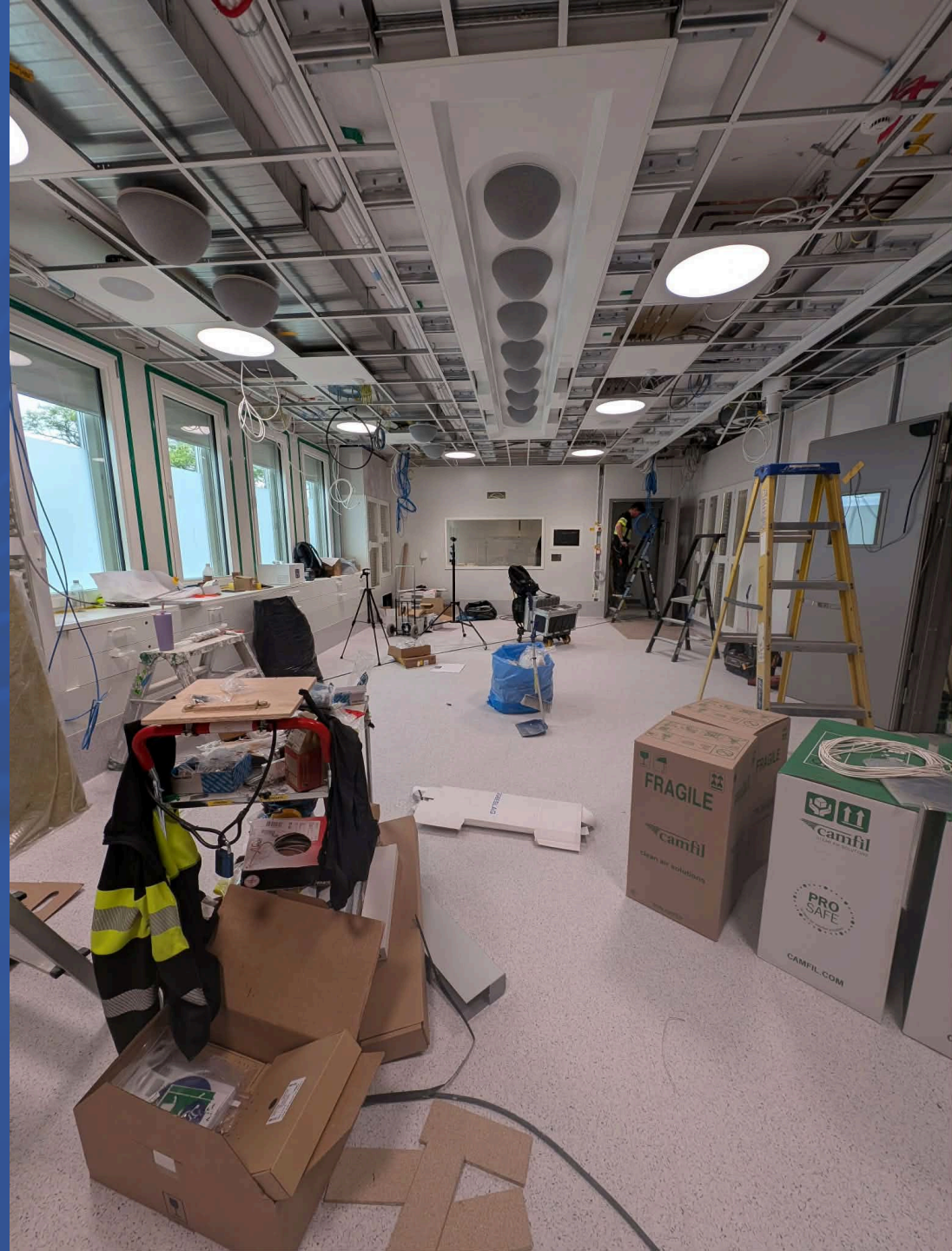
2025 May 14

- Contractor asked us to come and comission the hybrid room



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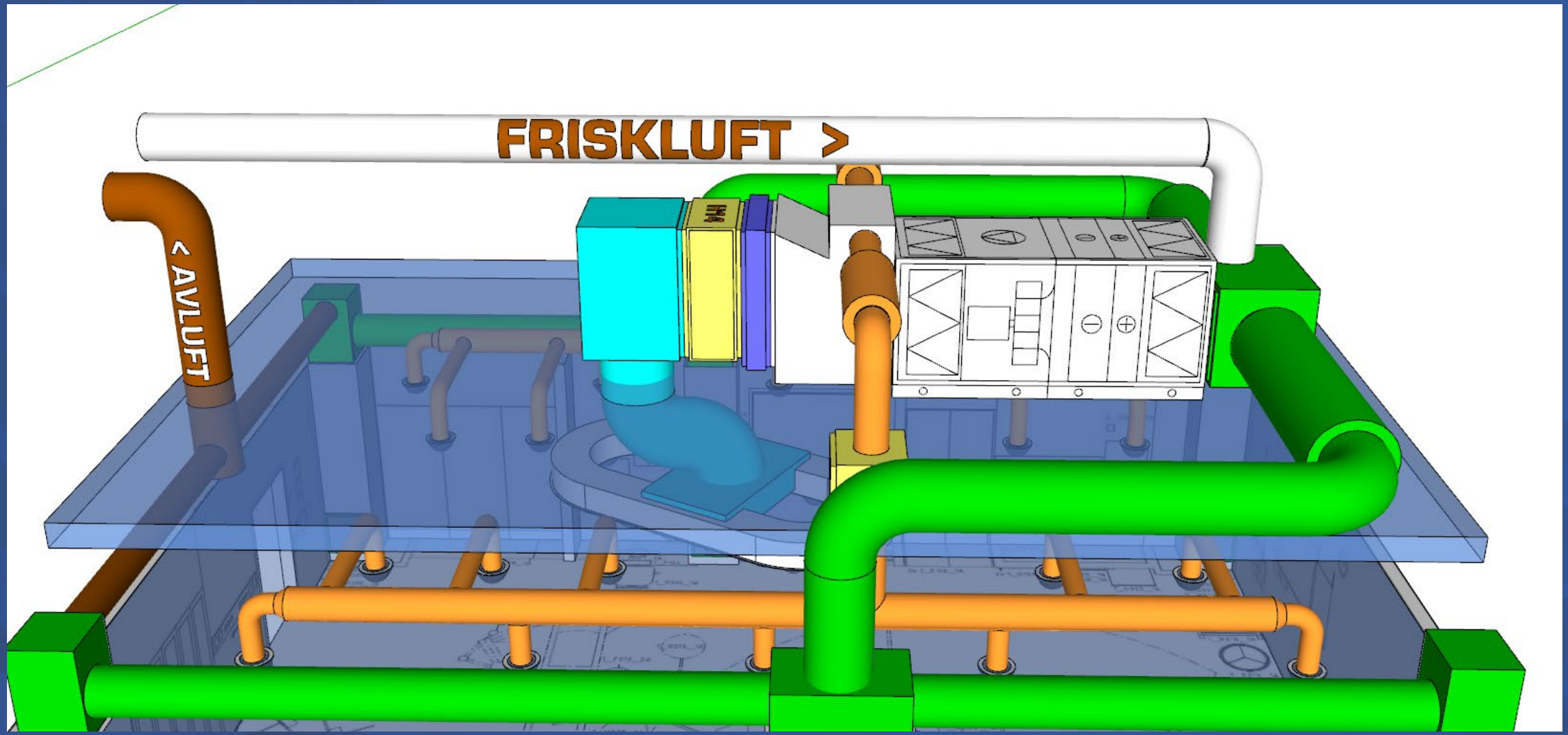

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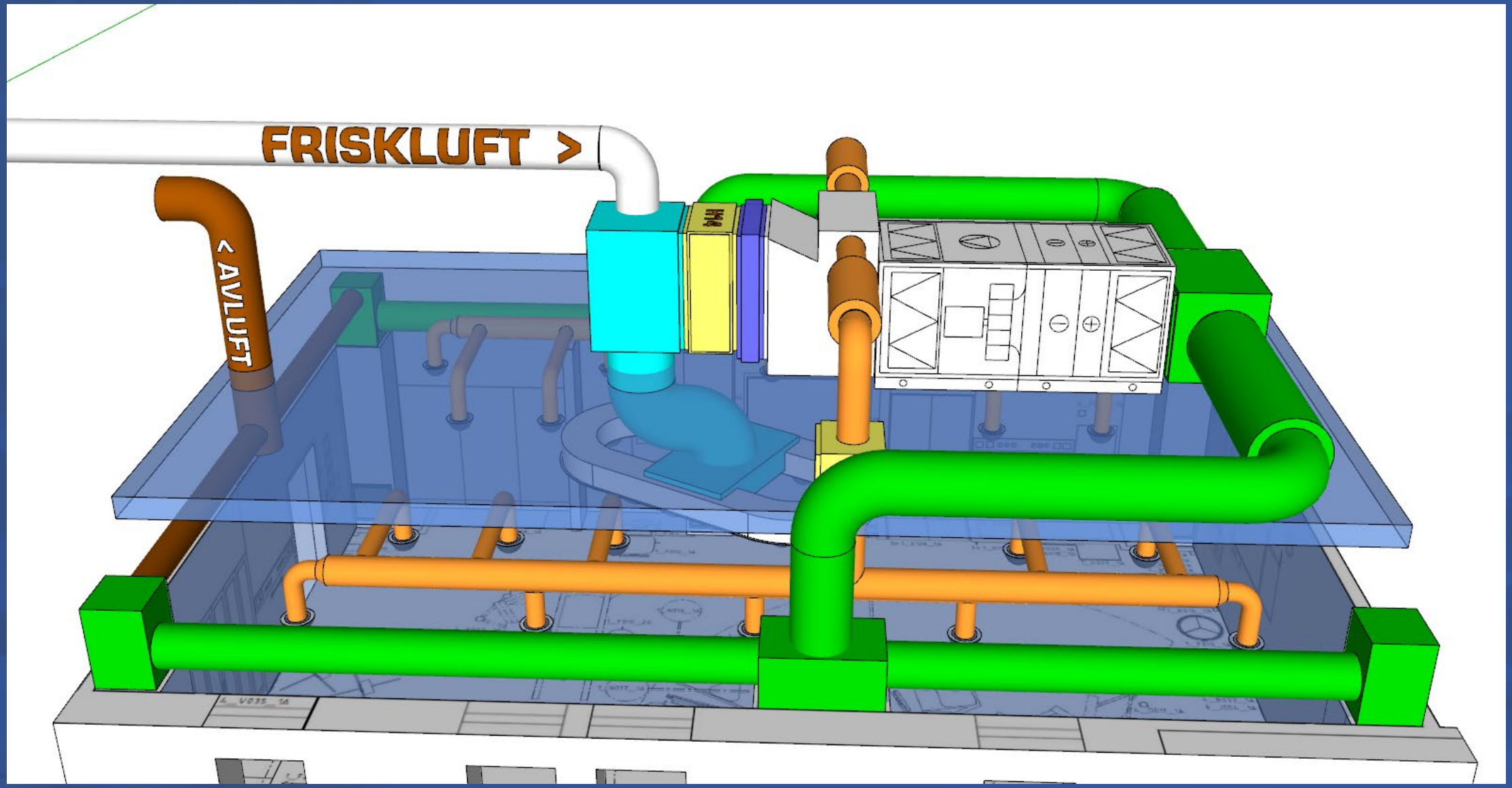

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HEPA Filter integrety test (fail)
EN ISO 14644-3

Belastad partikelmätning						
Rum	Mätpunkt	Punkt för injicering av partiklar	Antal partiklar innan HEPA	Antal partiklar efter HEPA	Kriterium	Resultat
Hybridsal	Opragon	Vid salens frånluftsfilter	858 073	44 011	< 429	⊗
Hybridsal	Opragon	Vid salens frånluftsfilter	858 073	38 964	< 429	⊗
Hybridsal	Opragon	Vid salens frånluftsfilter	858 073	45 391	< 429	⊗
Hybridsal	Periferi	Vid salens frånluftsfilter	858 073	39 342	< 429	⊗
Hybridsal	Periferi	Vid salens frånluftsfilter	858 073	42 223	< 429	⊗
Hybridsal	Periferi	Vid salens frånluftsfilter	858 073	38 131	< 429	⊗

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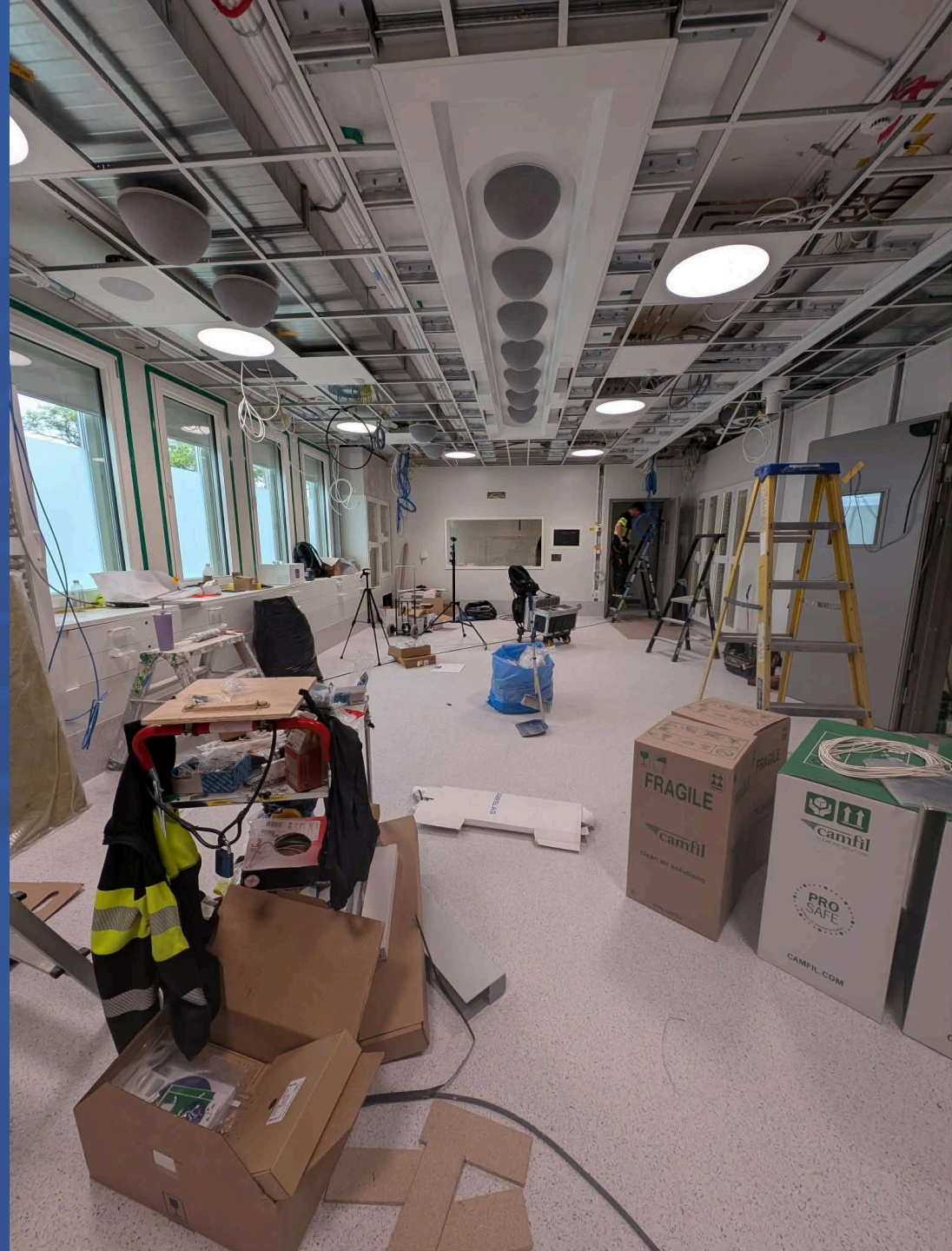
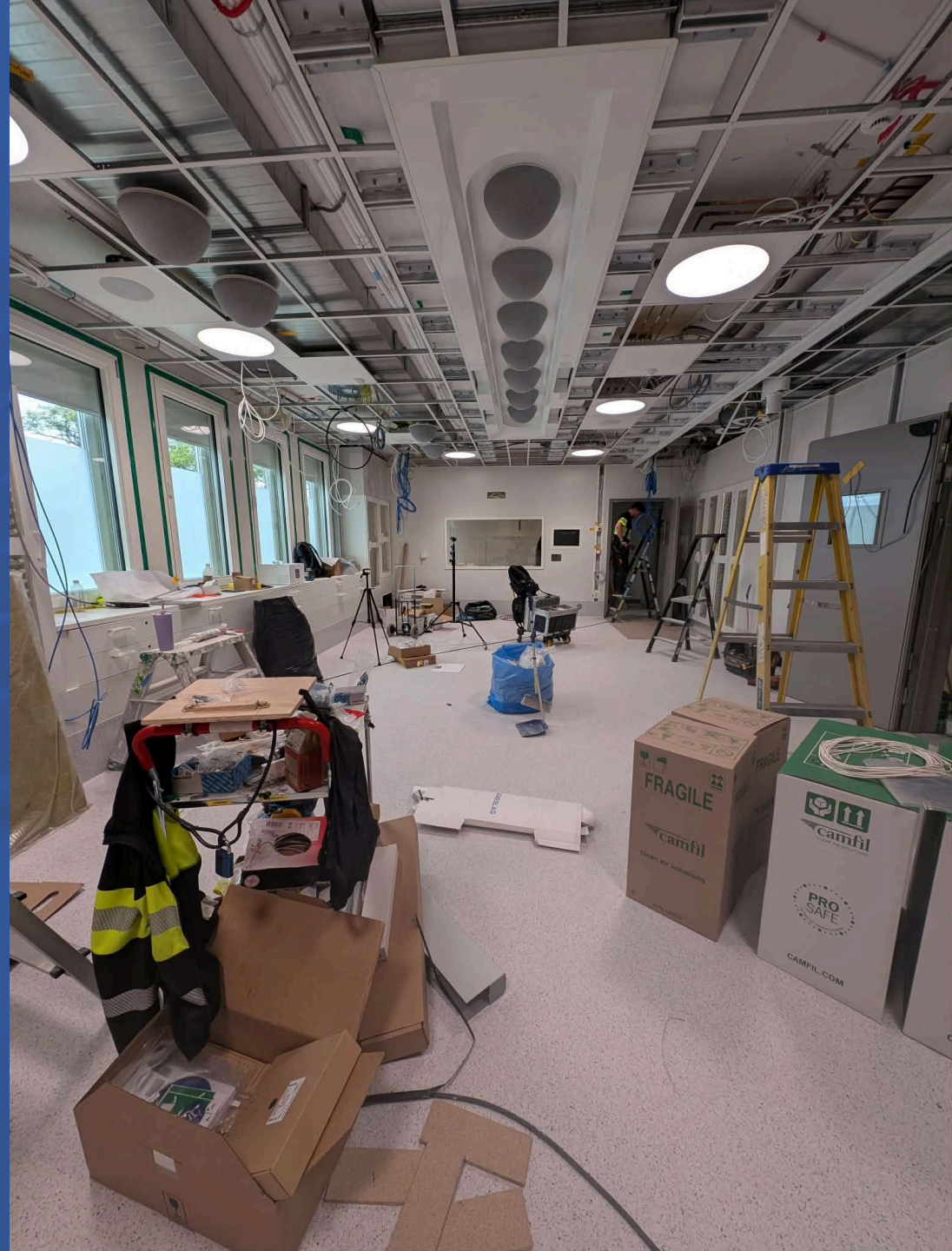
2025 June 25

- Contractor asked us to come and retest the HEPA filters
- Test failed
- No report writen



2025 July 2

- Contractor asks us to come and commission the hybrid room again
- After the HEPA filter manufacturer had been at the site troubleshooting
- This time it passed =)



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HEPA Filter integrety test (pass)
EN ISO 14644-3

Belastad partikelmätning						
Rum	Mätpunkt	Punkt för injicering av partiklar	Antal partiklar innan HEPA	Antal partiklar efter HEPA	Kriterium	Resultat
Hybridsal	Opragon	Vid salens frånluftsfilter	3 531 073	15	< 1 750	✓
Hybridsal	Opragon	Vid salens frånluftsfilter	3 531 073	20	< 1 750	✓
Hybridsal	Opragon	Vid salens frånluftsfilter	3 531 073	11	< 1 750	✓
Hybridsal	Periferi	Vid salens frånluftsfilter	3 531 073	5	< 1 750	✓
Hybridsal	Periferi	Vid salens frånluftsfilter	3 531 073	16	< 1 750	✓
Hybridsal	Periferi	Vid salens frånluftsfilter	3 531 073	19	< 1 750	✓

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What tests are done at commissioning?

- Airflow
- Filters
- Downflow (airspeed)
- Control system by:
  - Checking alarms
  - Raise temp
  - Lower temp
- Return air
- Pressure
- Smoke visualisation

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2025 July 3

- Construction finished
- Tech spec fullfilled
- Hospital wants CFU measurements during simulated operation

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Händelse	Kl.	Dörr X	Dörr Y	Dörr Z	Antal	Platta nr	Mät-punkt	CFU/ platta	CFU/ m^3
-	10:37	-	-	1	9-10	1	1	0	<1
	10:37					2	2	1	1
-	10:47	-	-	-	9	3	1	2	2
	10:47					4	2	5	5
Personal nära mätpunkt 1 ~11:01	10:57	-	-	1	8-9	5	1	0	<1
	10:57					6	2	4	4
Personal nära mätpunkt 2 ~11:07-11:15	11:07	-	-	-	8	7	1	1	1
	11:07					8	2	4	4
Personal nära mätpunkt 1 & 2 ~11:17-11:27	11:17	-	-	-	8	9	1	0	<1
	11:17					10	2	2	2
Kontrollplatta	-	-	-	-	-	0	-	0	<1

Mätningstillfälle per operationssal	Mätpunkt 1 (medelvärde)	Mätpunkt 2 (medelvärde)	Medelvärde (totalt)	Högsta värde
1	<1	3,2	1,9	5

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Implications for your research and innovation

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Laminar airflow (LAF): effective in theory — controversial in practice

Review > Lancet Infect Dis. 2017 May;17(5):553-561. doi: 10.1016/S1473-3099(17)30059-2. Epub 2017 Feb 17.

Effect of laminar airflow ventilation on surgical site infections: a systematic review and meta-analysis

Peter Bischoff [1], N Zeynep Kubilay [2], Benedetta Allegranzi [2], Matthias Egger [3], Petra Gastmeier [4]

Affiliations + expand

PMID: 28216243 DOI: 10.1016/S1473-3099(17)30059-2

Abstract

Background: The role of the operating room's ventilation system in the prev
infections (SSIs) is widely discussed, and existing guidelines do not reflect cu
context, laminar airflow ventilation was compared with conventional ventilati
effectiveness in reducing the risk of SSIs.

Methods: We searched MEDLINE, Embase, Cochrane Central Register of Con
regional medical databases from Jan 1, 1990, to Jan 31, 2014. We updated th
the period between Feb 1, 2014, and May 25, 2016. We included studies mos
predefined question: is the use of laminar airflow in the operating room asso
of overall or deep SSI as outcomes in patients of any age undergoing surgica
excluded studies not relevant to the study question, studies not in the selecte
published before Jan 1, 1990, or after May 25, 2016, meeting or conference a
which the full text was not available. Data were extracted by two independen
disagreements resolved through further discussion. Authors were contacted
not available, or if important data or information on the paper's content was

Review > J Hosp Infect. 2019 Sep;103(1):e9-e15. doi: 10.1016/j.jhin.2019.04.021. Epub 2019 May 3.

Ultraclean air systems and the claim that laminar airflow systems fail to prevent deep infections after total joint arthroplasty

W Whyte [1], B Lytsy [2]

Affiliations + expand

PMID: 31059724 DOI: 10.1016/j.jhin.2019.04.021

Free article

Abstract

The World Health Organization published guidelines in 2016 for preventing surgical site infections. The guidelines contained a conditional recommendation that laminar airflow (LAF) ventilation systems should not be used to reduce the risk of infection after total joint arthroplasty (TJA). This recommendation was largely based on a systematic review and meta-analysis of information from hospital infection surveillance registries. The recommendation contradicts information published in earlier major studies carried out by Charnley and the UK Medical Research Council (MRC). The first aim of this article is to revisit and explain the MRC study, and reply to criticisms of it. The second aim

- LAF/UDAF was introduced to reduce airborne contamination in the OR
- Widely embedded in standards and design practice
- Large clinical studies and reviews (e.g. Bischoff et al., 2017) show no consistent reduction in SSI rates
- Interpretation is disputed:
  - "LAF does not work"
  - "LAF works, but not as implemented in reality"
- Are we evaluating the concept — or its real-world performance?

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Advancing technology is not only a technical problem

- Evidence is necessary, but rarely sufficient
- Performance must survive translation into projects
- Implementation matters as much as concept quality
- Real-world variability is not noise — it is the system

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Technology Adoption and Paradigm Shifts in Healthcare

Incremental Change

- Not all innovations challenge the system to the same degree
- Incremental improvements fit easily into existing standards, workflows, and roles

Disrupting Change

- Architectural innovations require coordination across disciplines and stakeholders
- Paradigm-shifting concepts challenge:
  - Established standards and guidelines
  - Professional roles and responsibilities
  - Risk allocation and liability
  - Validation and acceptance mechanisms

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Why new ideas struggle to move forward

- Risk aversion and liability
- Standards that encode historical solutions
- Fragmented responsibility across stakeholders
- Procurement and budget structures
- Path dependency and installed base effects
- Lack of ownership for system-level outcomes

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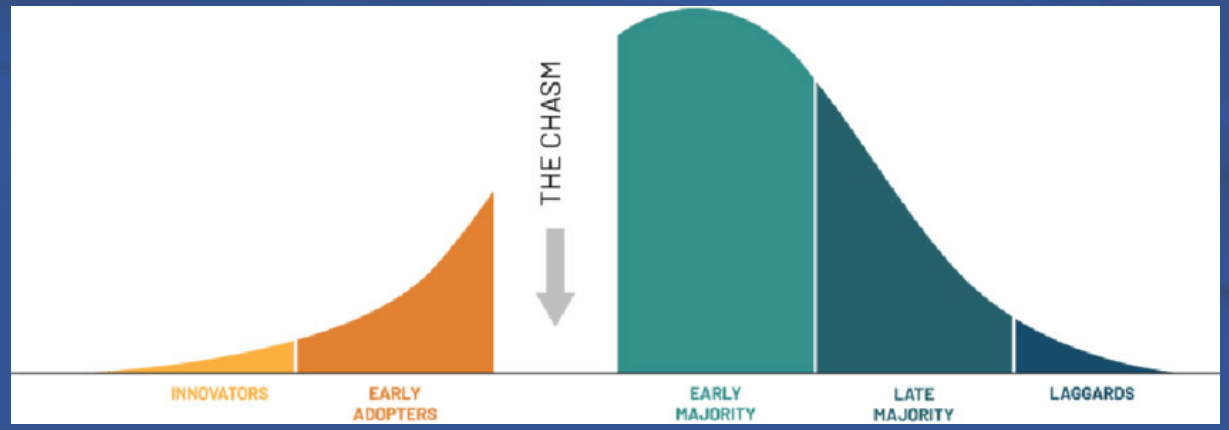
From proven to adopted: the technology adoption gap

Technical proof ≠ adoption

1. Conceptual feasibility
2. Technical validation
3. Project feasibility
4. Organizational acceptance
5. Standardization and normalization



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CFD is a powerful research tool — but only within its assumptions

What CFD does exceptionally well	Why this matters in projects
• Explains mechanisms: airflow, turbulence, buoyancy, heat, particle transport • Allows controlled comparison of concepts before they are built • Reveals sensitivity to geometry, boundary conditions, and disturbances • Makes invisible phenomena visible and discussable • Supports development of new concepts and challenges legacy assumptions	• Ventilation systems operate as systems, not components • Small deviations accumulated during design and construction can invalidate modeled behavior • A solution proven in CFD can become experimental in practice when real-world performance no longer matches the design intent. • Validation tests the project, not the concept
What CFD cannot guarantee	**What this means for PhD students**
• That the modeled system will be implemented as designed • That boundary conditions will remain valid throughout a project • That human behavior, workflow, and maintenance match assumptions • That mixed or hybridized solutions still follow the intended principles	• CFD does not validate reality — it validates assumptions • Impact depends on how well those assumptions survive translation into projects • Robust concepts tolerate imperfection; fragile ones do not • Engaging with designers, standards, and implementation early increases real-world impact

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Reflection

Think about your own research.
At what point could it fail to translate into practice — even if the science is sound?

Can you improve your research in any way to prevent this?

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Advice on advancing new ideas

- Define baselines explicitly
- Understand the project environment your results will enter
- Identify where decisions are actually made
- Design solutions that tolerate imperfect implementation or they remain practically unachievable
- Engage with standards, not just publications
- Expect having to be patient and strategic to make an impact

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Standards

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The Purpose of Standards

- Standards exist to ensure patient safety, infection control, and operational consistency.
- They offer minimum performance and/or technical requirements, not necessarily optimal solutions – intended to allow some level of competition, variation of solutions within certain varying boundaries.
- Key functions:
  - Define cleanliness levels (particles, microbes).
  - Set design and performance requirements for airflow, pressure, and filtration.
  - Provide a basis for validation and compliance.
- Standards are recommendations and not law in most cases. Hence, there is room for customers to deviate.

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Cleanroom and Building Standards

- Cleanroom Foundations (ISO 14644 Series)
  - Origin in semiconductor industry, later adapted to healthcare.
  - Define air cleanliness classes based on particle concentrations, not microbiological performance.
- Important: Cleanroom class ≠ infection risk control.
- ISO 14698/EN 171141: Addresses biocontamination, a less consistently applied layer of control.
- EN 16798-3: Adds an energy performance lens—sometimes overlooked in surgical contexts.

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Key Standards

- DIN 1946-4 (Germany): Mandates unidirectional airflow (UDAF), high air change rates (e.g., 60 ACH/>10000m3/h). Used by many other countries.
- HTM 03-01 (UK): Focus on airflow design and balancing energy, cleanliness, and comfort. Primarily advocated High Flow UDAF with specified coverage.
- FMS/NOV/VCCN (NL): High Flow UDAF for most sensitive surgery only. Open to TcAF with separate validation methods.
- SIS TS39 (Sweden): Microbial outcome focus. This allows many systems while still ensuring validated protection by CFU/m3 thresholds.
- ASHRAE 170 (US): Technical. Specifies minimum ventilation rates, pressure relationships, filter efficiencies, and airflow direction for patient care areas. Maximum airflow defined to prevent pushing contaminants into wound.

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Shared Requirements

1. Pressure Control and Zoning
   - Operating rooms must be maintained at positive pressure relative to adjacent spaces.
   - A pressure cascade must be established: OR → prep/scrub rooms → corridors, ensuring air flows from clean to less clean areas.
2. Air Change Rates (ACH)
   - Minimum airflow volumes required (typically ≥20 ACH, and up to 60+ ACH for systems with unidirectional flow).
   - Varies by standard, but all agree on sufficient airflow volume for contaminant dilution and removal.
- 3. HEPA-Filtered Supply Air
   - High-efficiency filtration (H13/H14 or MERV 17+) required for supply air.
4. Airflow Directionality and Pattern
   - For infection sensitive surgery air must flow from clean to less clean areas and sweep across critical zones (e.g., surgical field, instrument table).
5. Temperature and Humidity Control
   - Indoor climate must support both comfort and infection control.
   - Typical ranges:
     - Temperature: ~20–24 °C
     - Relative humidity: 30–60%

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Shared Requirements

6. Alarm and Monitoring Systems

- Continuous monitoring of:
  - Room pressure
  - Filter status
  - Temperature and humidity

7. Validation and Testing

- Periodic testing of:
  - Airflow volume and velocity
  - Particle concentration (ISO 14644-1)
  - Pressure differentials
  - HEPA integrity (DOP/PAO testing)
  - CFU/m3 levels

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Notable Differences between Countries

- Differ in ambition of achieving the highest cleanliness levels
  - High: e.g. DE, UK, SE, FR, NL* (High flow UDAF, TcAF)
  - Low: e.g. US, NL, DK, NO (Low flow UDAF or mixing)
- Low-flow (15-20 ACH) vs High-flow (+60) UDAF
- Accepting Mixing ventilation or Not
- CFU vs Particle focus
- Performance (CFU/m3) vs technical (validation) requirements

*NL highest class for orthopedics only

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Problematic Requirements

- Terminal HEPA-filter placement (in the ceiling unit)
  - From the cleanroom standards and is a design feature of UDAF
- Require a certain air velocity by the supply diffusers
  - Required to sustain velocity at table in UDAF
- X % of ceiling shall be covered by diffuser array (UDAF)
  - To ensure UDAF ceiling does not get occupied with other installations and ensure enough coverage
- Segregation test (protect center from periphery) with small particles
  - UDAF optimizes protection of centre, which TcAF does not

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How standards are created and changed

- Developed in technical committees within bodies such as ISO, CEN, ASHRAE and national institutes
- Written by mixed groups: engineers, clinicians, researchers, industry, and authorities
- Translate existing knowledge and consensus into minimum requirements and test methods
- Change slowly through evidence, experience, and committee revision — not disruption

Standards do not lead innovation. They consolidate it.

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