Air Cleanliness in a Hybrid Cardiac Catheterization Laboratory

With major contrubution of:

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Challenges of patient safety in a hybrid OR

- Reduction of patient and staff radiation dose
- Excellent image quality
- Air cleanliness (postoperative infection prevention)
- Thermal comfort for staff (temperature and air velocity)
- Acoustic comfort (noise of ventilation systems)

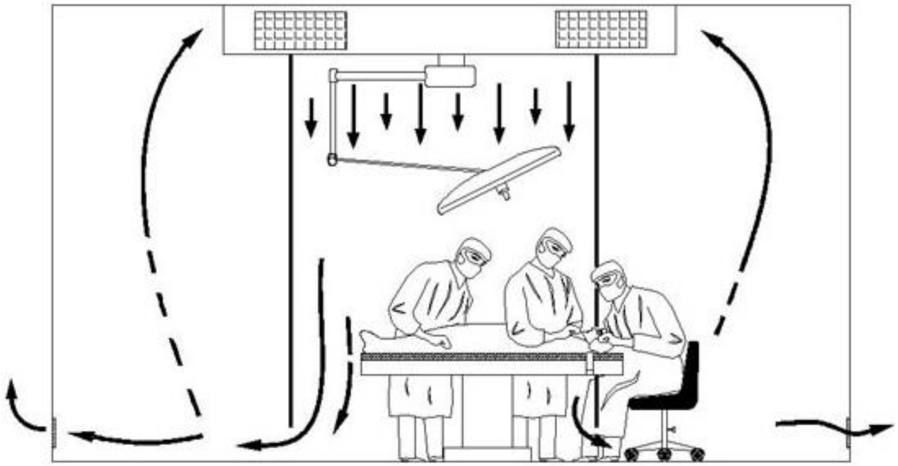
Air cleanliness; at rest and in operation conditions

- Two basic requirements
  - No infection due to pollution during the intervention
  - No infection due to cross contamination
- At Rest conditions*
  - General room cleanliness level ISO 5 (EN ISO 14644)
  - Recovery Time (100:1) < 15 minutes
- In Operation conditions*
  - < 10 CFU /m^3 (CFU, colony forming unit – active sampling)

* CEN TC156 WG18, Hospital Ventilation Working Draft

Assumptions of LAF (golden standard)

- Laminar Air flow
  - Unidirectional low turbulence (Charnley's principle*)
  - No interference of the air currents
  - Full side curtains
  - Only protection under the LAF field
- Are these assumptions fulfilled in state-of-the art hybrid OR?

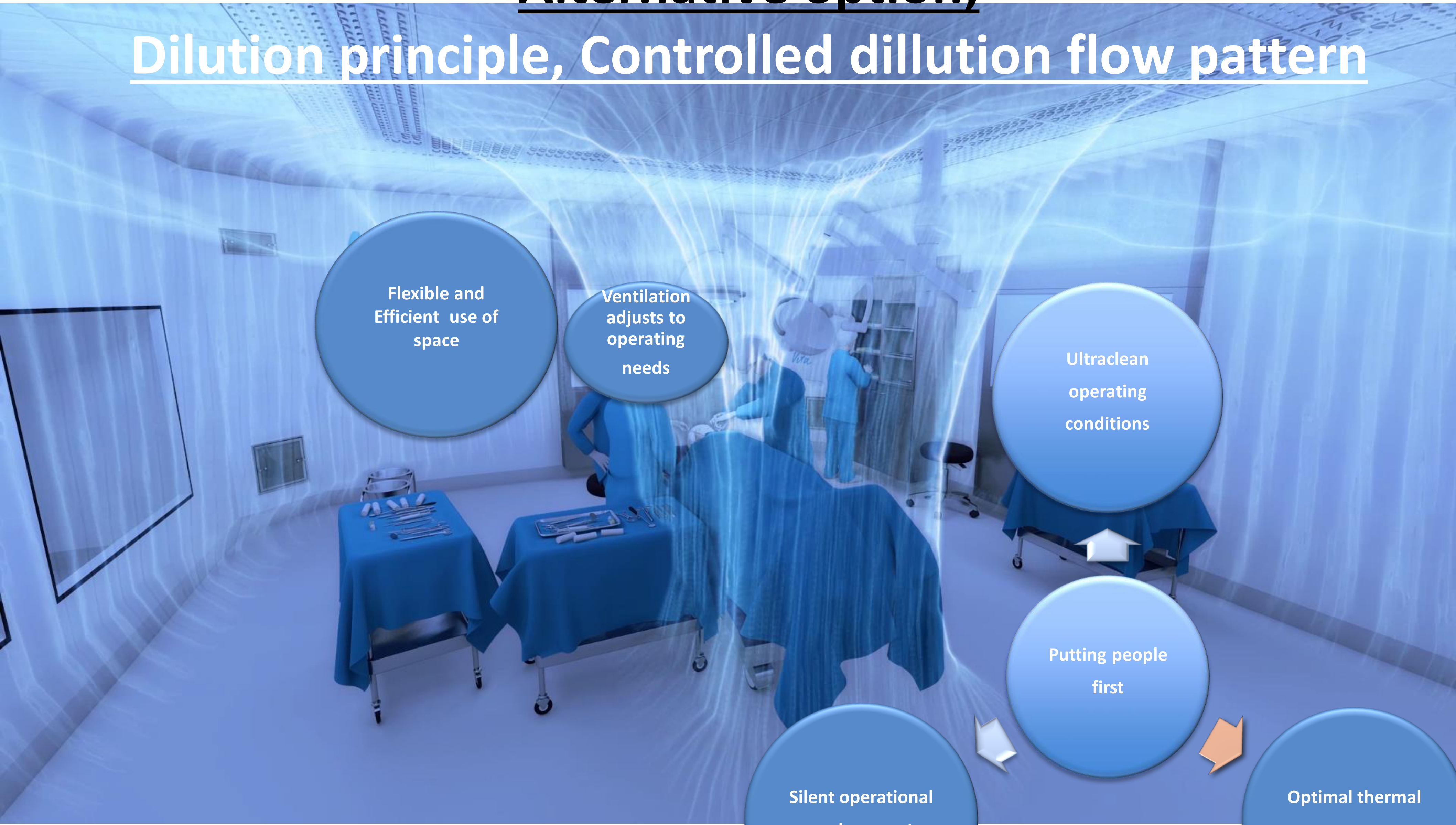


* Br J Surg.1964 Mar;51:202-5

Assumptions of Laminat Air Flow not fulfilled in hybrid OR

Alternative option;

Dilution principle, Controlled dillution flow pattern



Flexible and Efficient use of space

Ventilation adjusts to operating needs

Ultraclean operating conditions

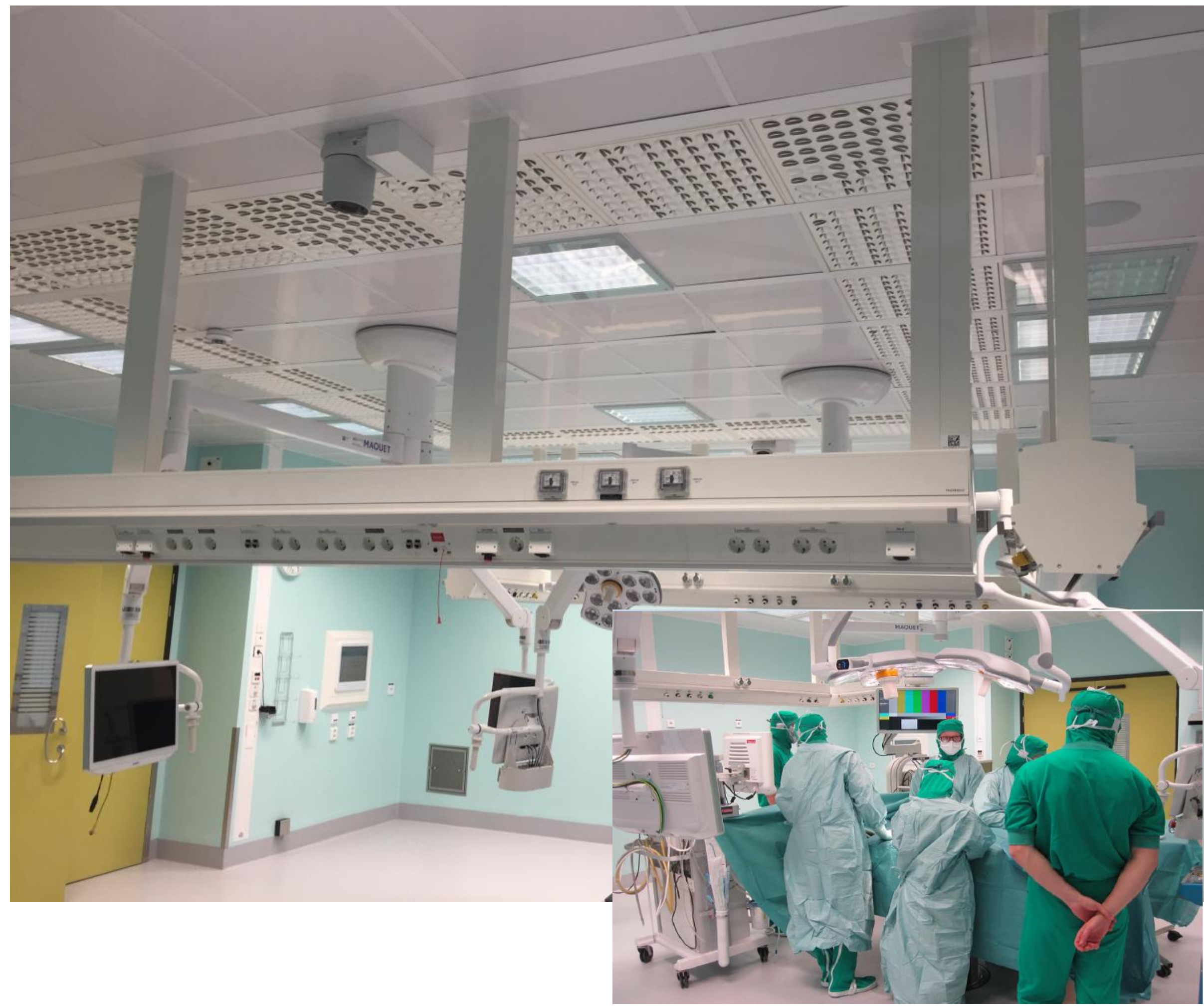
Putting people first

Silent operational environment

Optimal thermal comfort

Nya Karolinska – Independent On-Site Validation

Conducted as a Simulated Operation (after At Rest qualification) at the finished Operation room with Vita OR Space On-Site by Nya Karolinska Hospital and MyAir Qualification company without any involvement by manufacturer



Results:

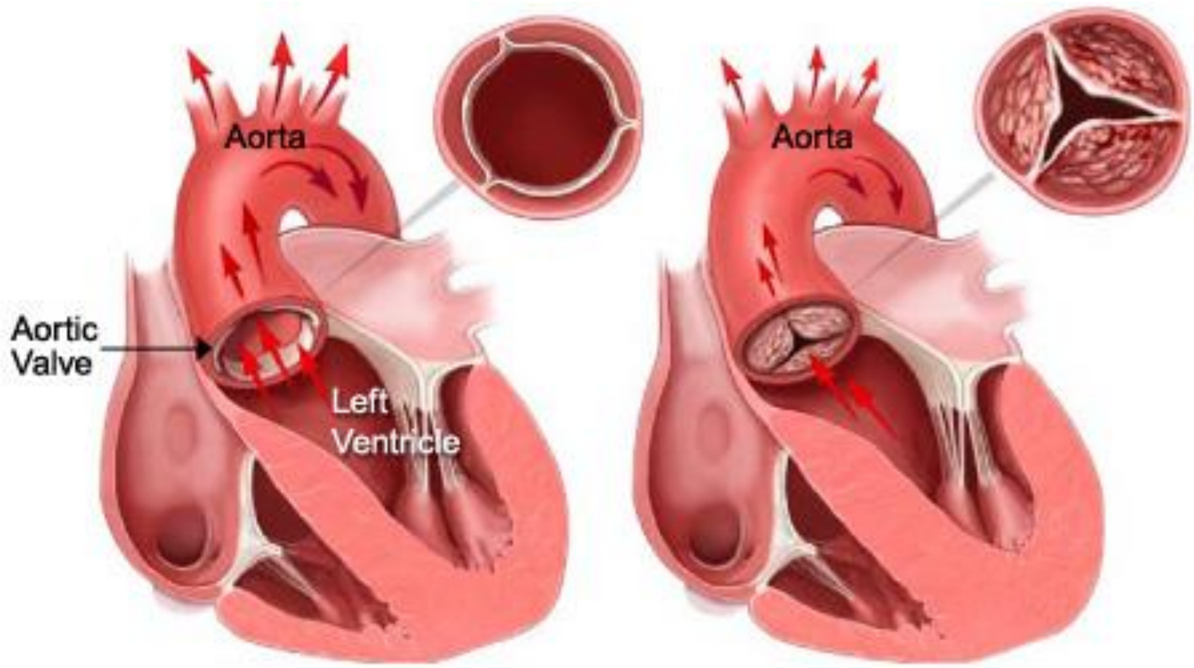
- Average 1,5 CFU/m^3
- Maximum individual reading 4 CFU/m^3

The full presentation may be downloaded from below link:

http://www.r3nordic.org/_project/_private/userAssets/dfeb9598fbfb97cc6bbcc0aff2c785d6/myair_2016_nks.pdf

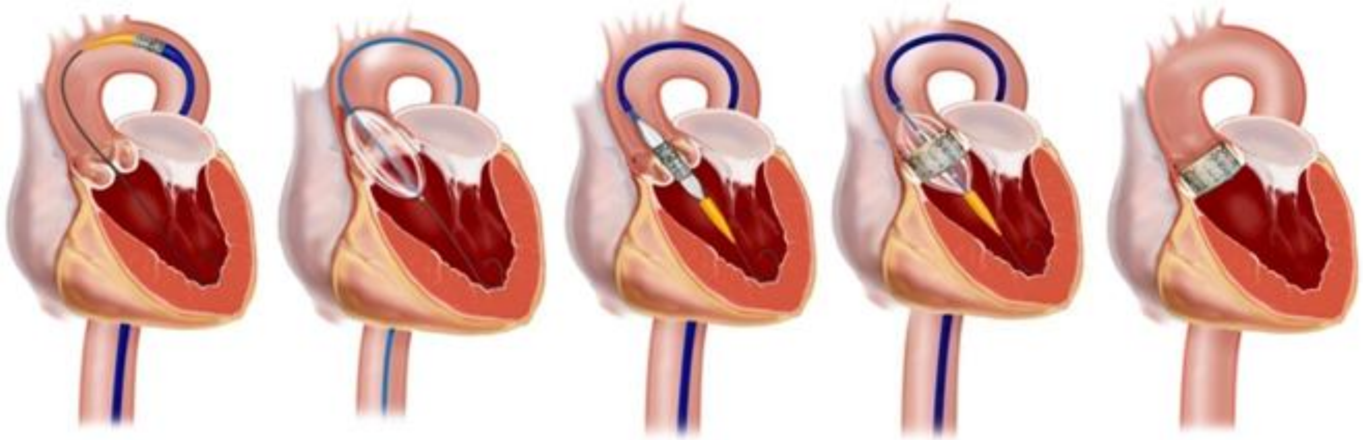
Materials and Methods TAVI

- Aortic valve stenosis = most common cardiac valve lesion
- TAVI = transcatheter aortic valve implantation
- Alternative for open surgical aortic valve replacement in selected patients with high operative risk



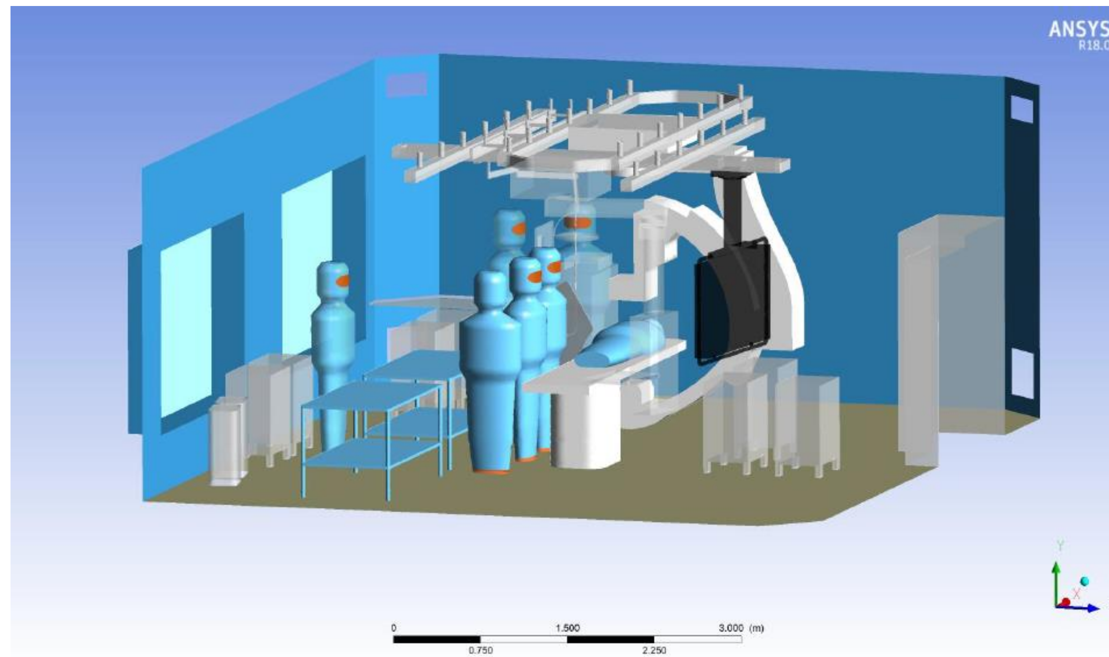
Materials and methods TAVI

- Procedure requires optimal fluoroscopic image quality in a perfectly sterile surgical environment
- Catheter is advanced over the wire from the femoral artery through the calcified aortic valve
- After balloon dilatation of the stenotic valve the new valve is placed inside the native valve
- Positioning of the valve requires rapid cardiac pacing to temporarily stop the pump function of the heart



Materials and methods

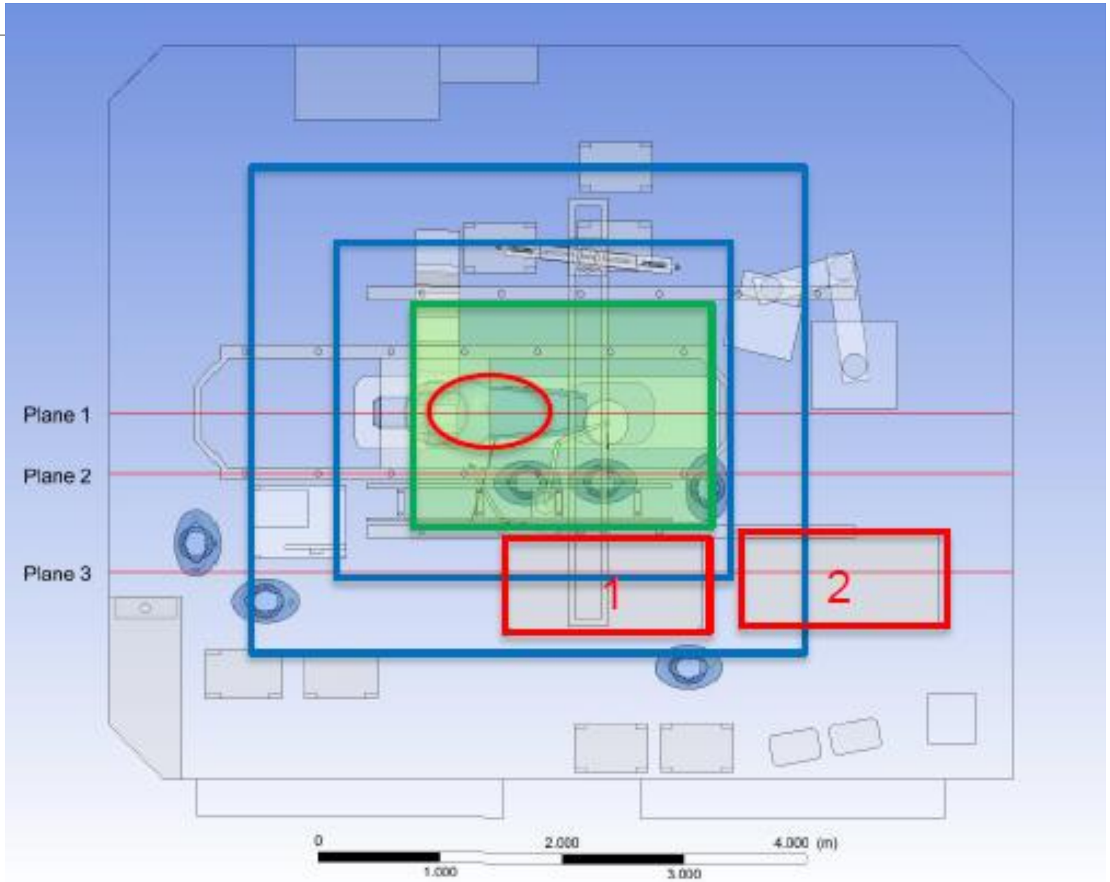
- Computational Fluid Dynamics Simulation using ANSYS* CFD software
  - Steady State analysis with SST turbulence model (shear stress transport)
  - CFUs modeled as solid particles injected from staffs face and feet areas
  - Computational models had approximately 6 million elements



* Ansys, Inc. Canonsburg, PA, USA

Comparison of Laminar flow and controlled dillution system

- Green rectangle LAF 1,8 x 2,4 m
- Blue Ring: air distribution elements for controlled dillution
- Critical zones – Red Areas
  - Wound Area
  - Instrument table 1 and 2
- The Laminar Air Flow corresponding to the same air flow (about 5000 m³/h)



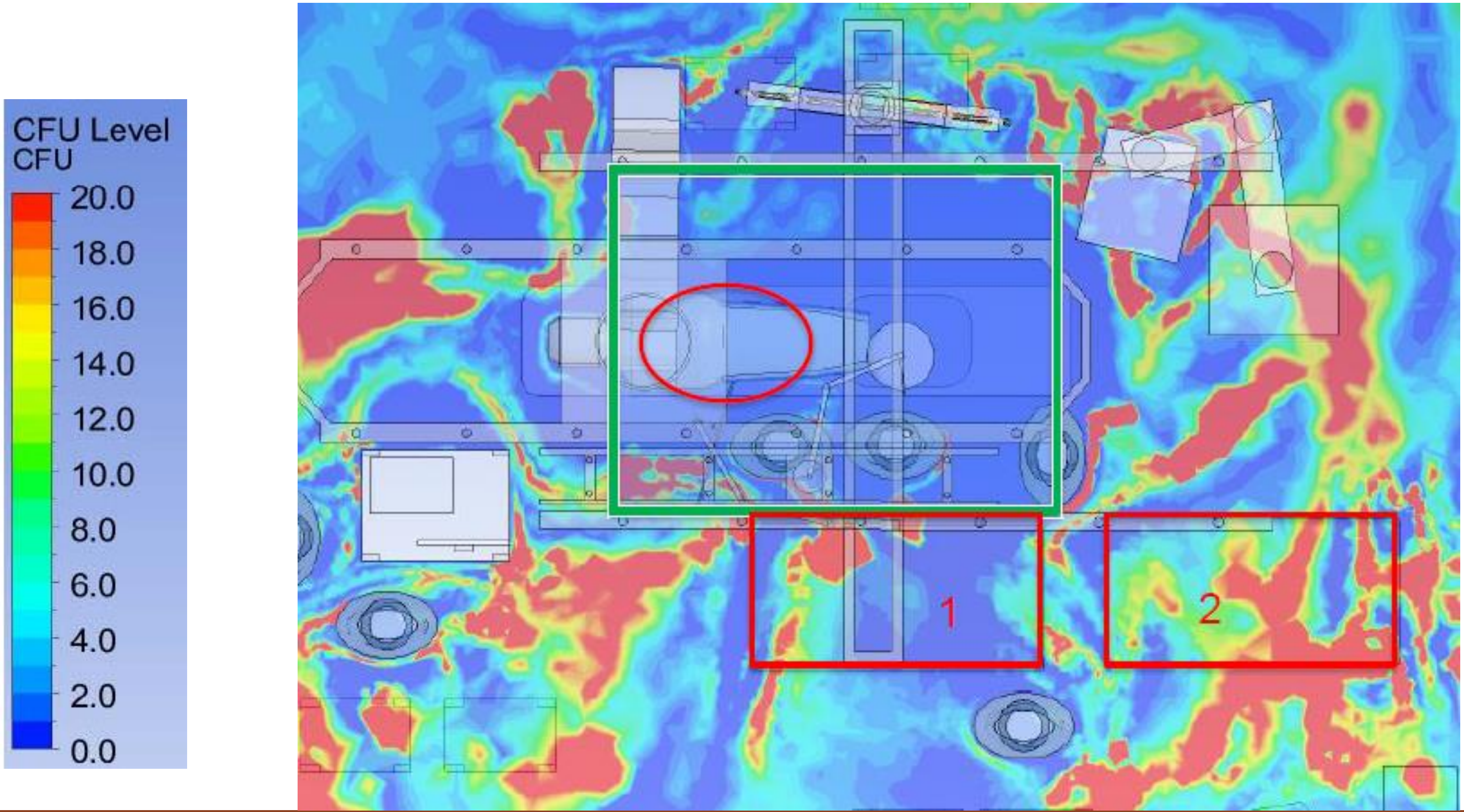
With surface as assumed and obstacles, air distribution is mixing in practice

Results LAF 1,8 x 2,4 m²

- Field 1,8x2,4: no laminar flow in plane 2 (even under the LAF-field) due to C-arm
- Required surface to cover all critical zones = 4,2 x 5,6 m² → airflow 28.000 m³/h: not feasible

Results LAF 1,8 x 2,4 m²

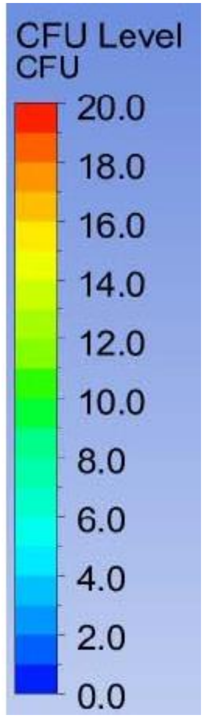
- Microbial Cleanliness 0,9 m plane
- No control of flow **outside** of the LAF-field
- No uniformity

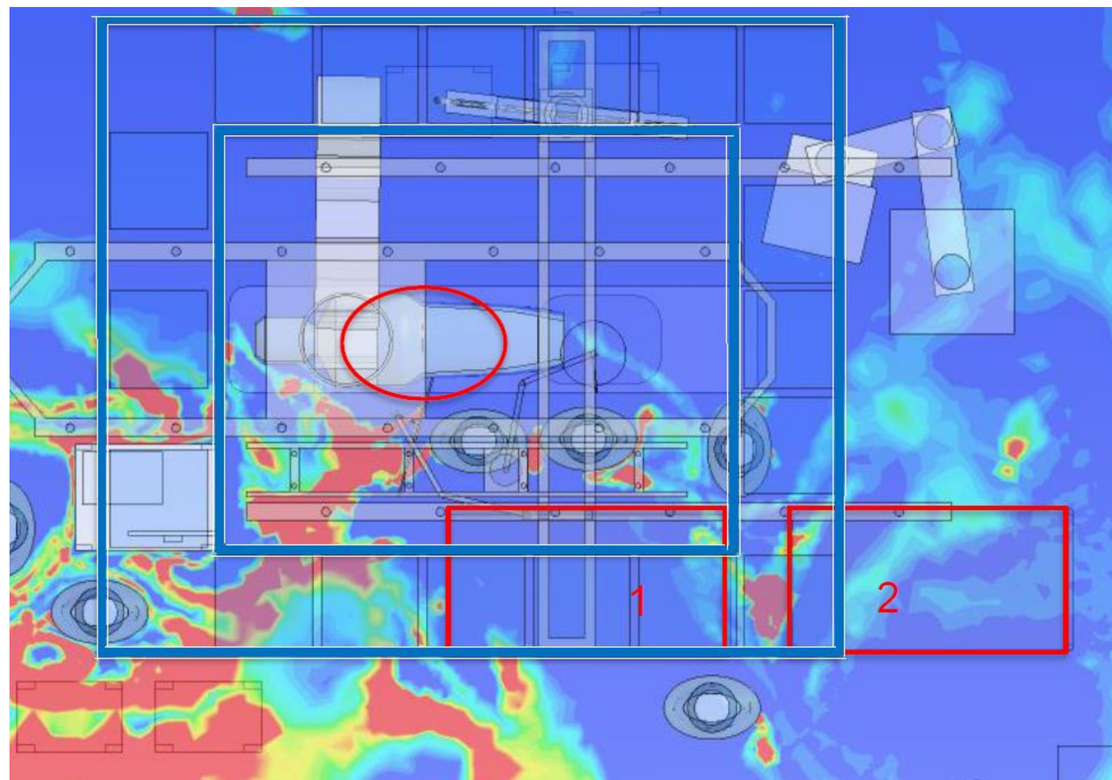


We can control by increasing average air velocity and abandoing „even air distribution" assumption

Results Controlled dillution system

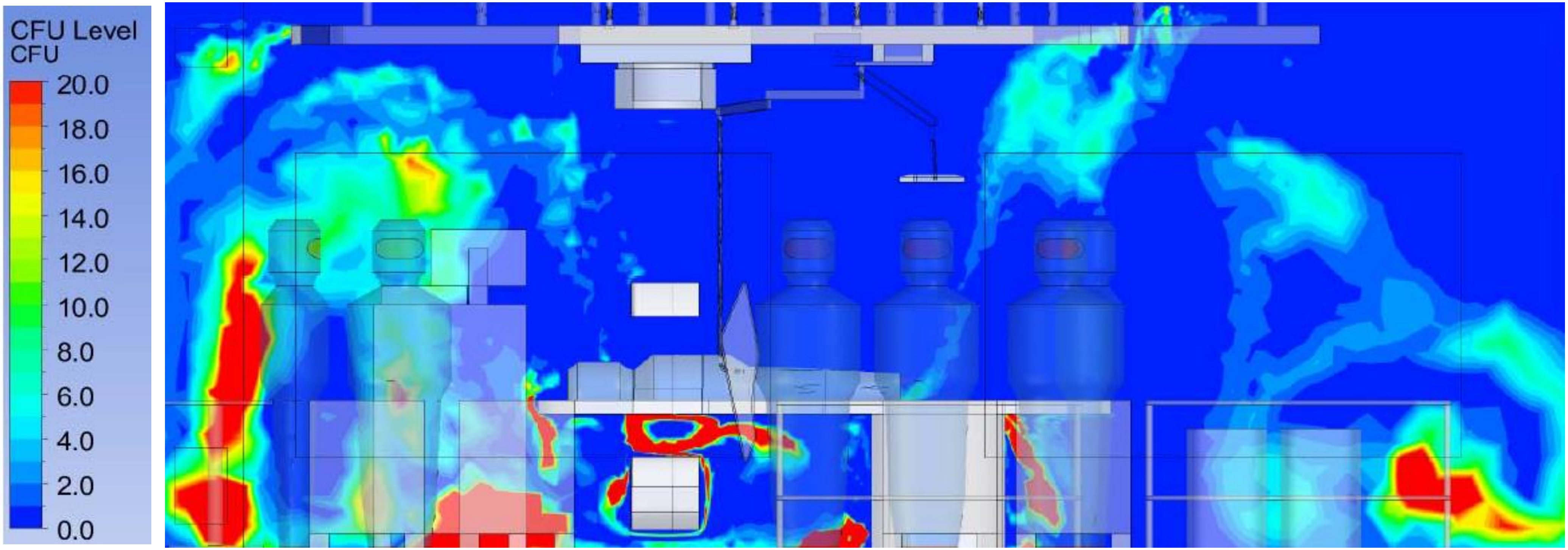
- Microbial Cleanliness 0,9 m plane
- Much more uniform conditions
- All critical zones are covered





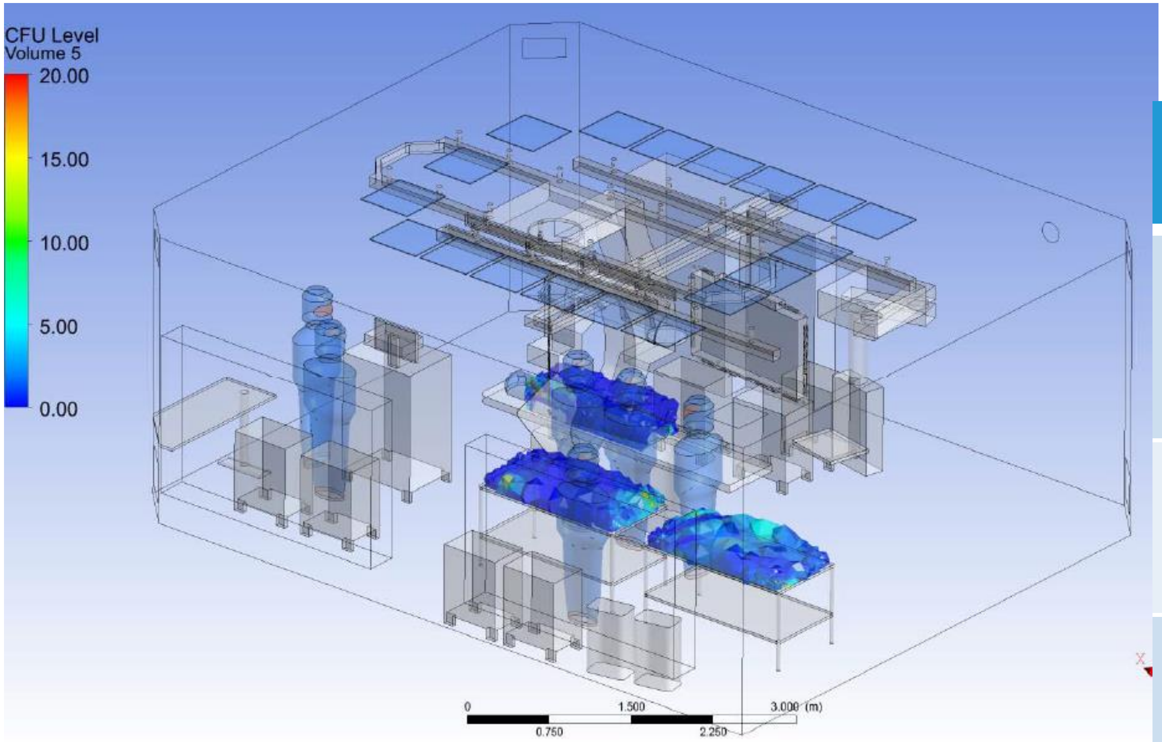
Results for controlled dillution system

- Microbial Cleanliness plane 1 OR table
- Good air quality next to the table, even under the C-arm



Results controlled dillution

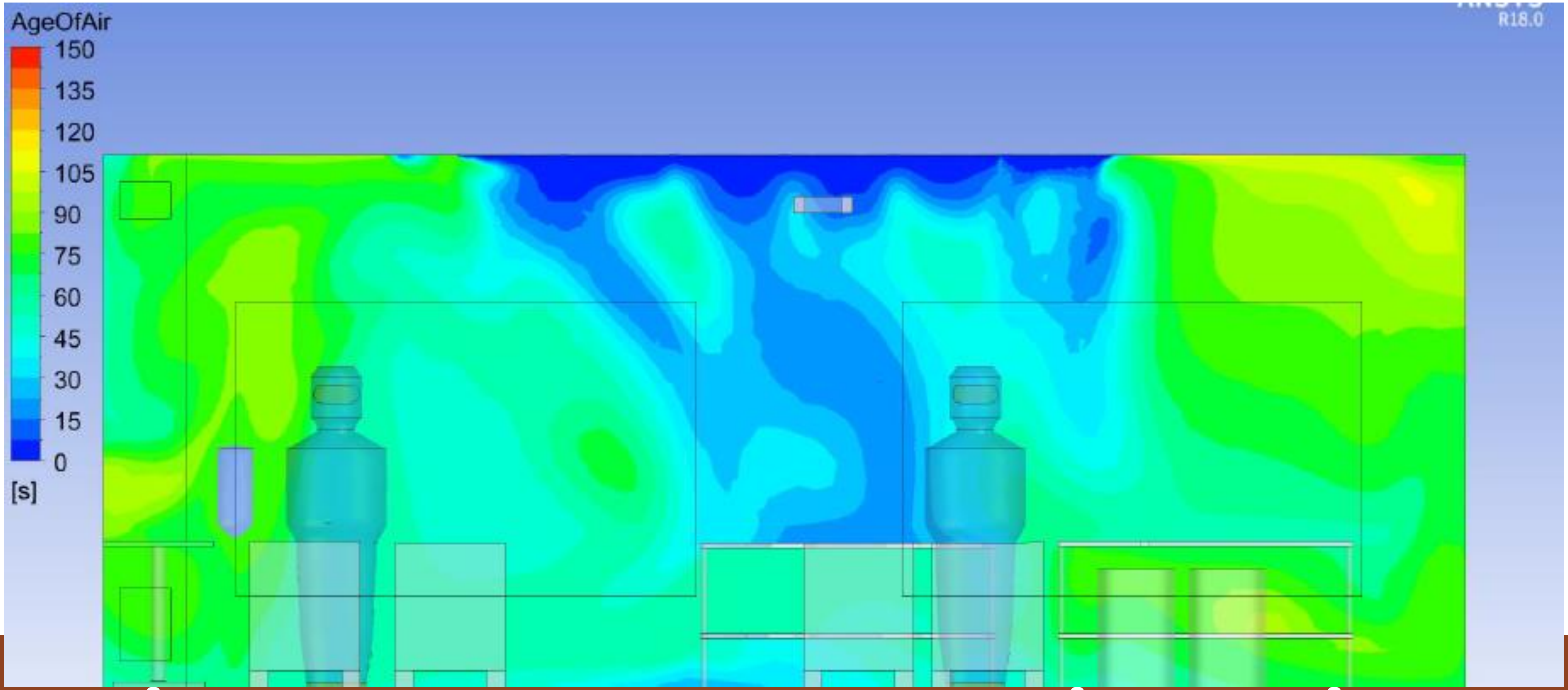
- Microbial Cleanliness critical areas
- Fulfills the requirements of < 10 CFU/m³



CFU	Controlled dillution	Laminar
OR Table	<1	<1
Instr Table 1	<1	12
Instr Table 2	2	19

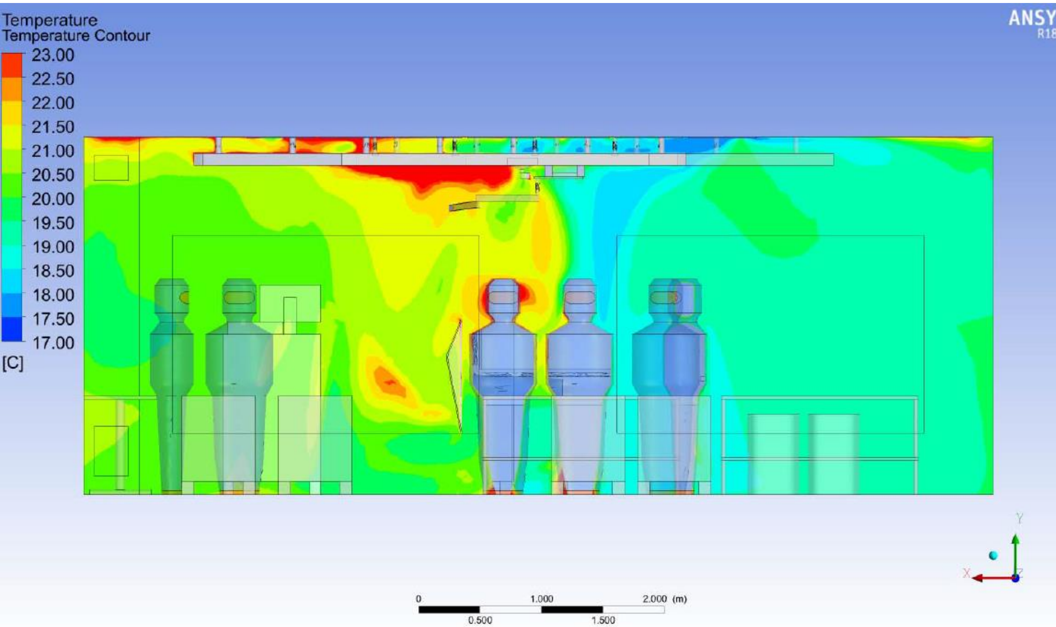
Results controlled dillution

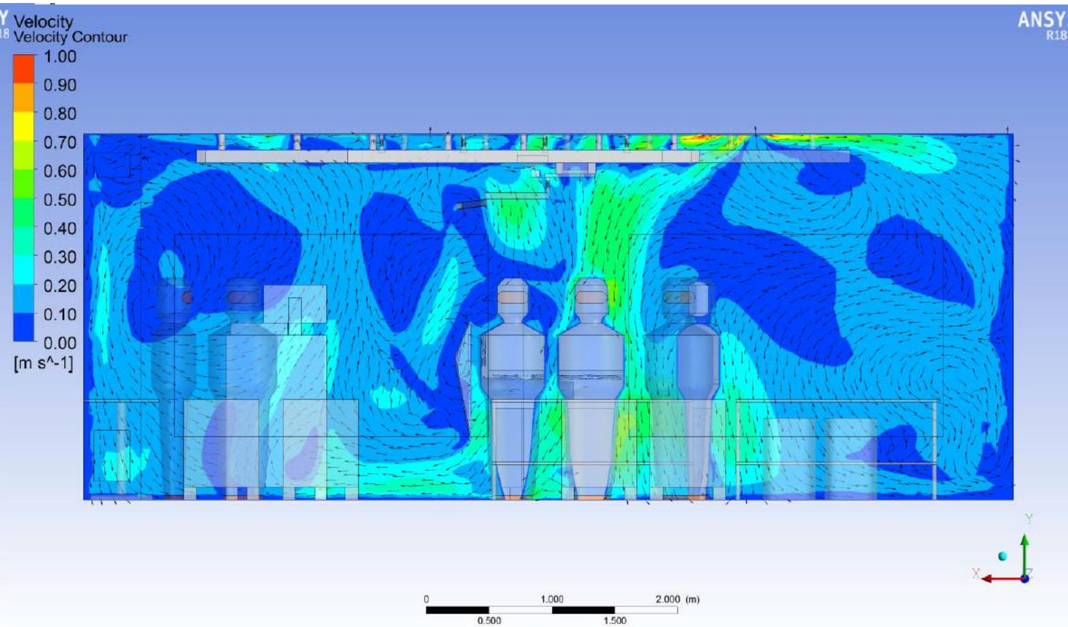
- Average recovery time by design 7 minutes (< 15 minutes)
- Age of Air illustration shows a good flushing of all critical areas (Plane 3 – Instrument tables)



Results controlled dillution

- Thermal environment
- No direct draft of supply air to the operating staff (max 0,5 m/s)
- Air temperature more equalized due to dilution before entering the occupied zone (2 °C higher than supply air (Plane 2 – doctors))

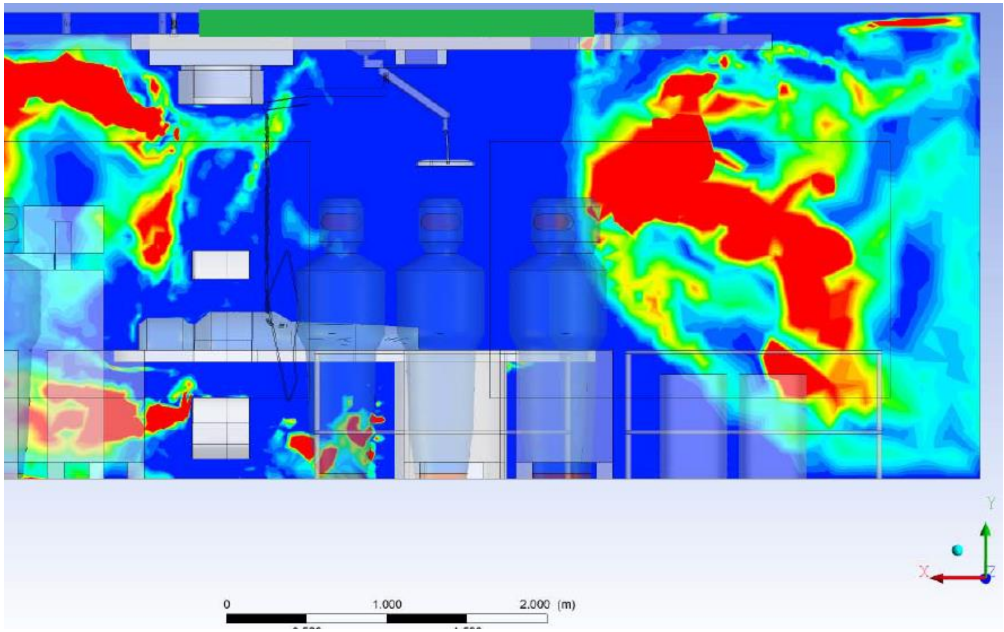




Discussion

- Laminar flow and controlled dillution give good air quality in the wound area
- Only controlled dillution gives good air quality outside the wound area
- Controlled dillution is less energy consuming than LAF 3x3 m (50%)
- Controlled dillution gives better thermal environment due to dilution

Microbial Cleanness, OR Table (Plane 1)
(Laminar Flow 2,4mx1,8m)



Conclusions

1. The ventilation specifications for OR's must modify and take into account modern medical progress
2. New technologies, especially digitalization and drive for minimum intervention require new approaches to OR ventilation, to ensure:
   a. stable airflow through critical areas
   b. leaving space in ceiling infrastructure for medical devices
3. CFD modelling and other contemporary technologies are excellent tools for decision makers in new, changing reality