Ventilation Systems in surgical theatre and minor procedure room

NMA Germany
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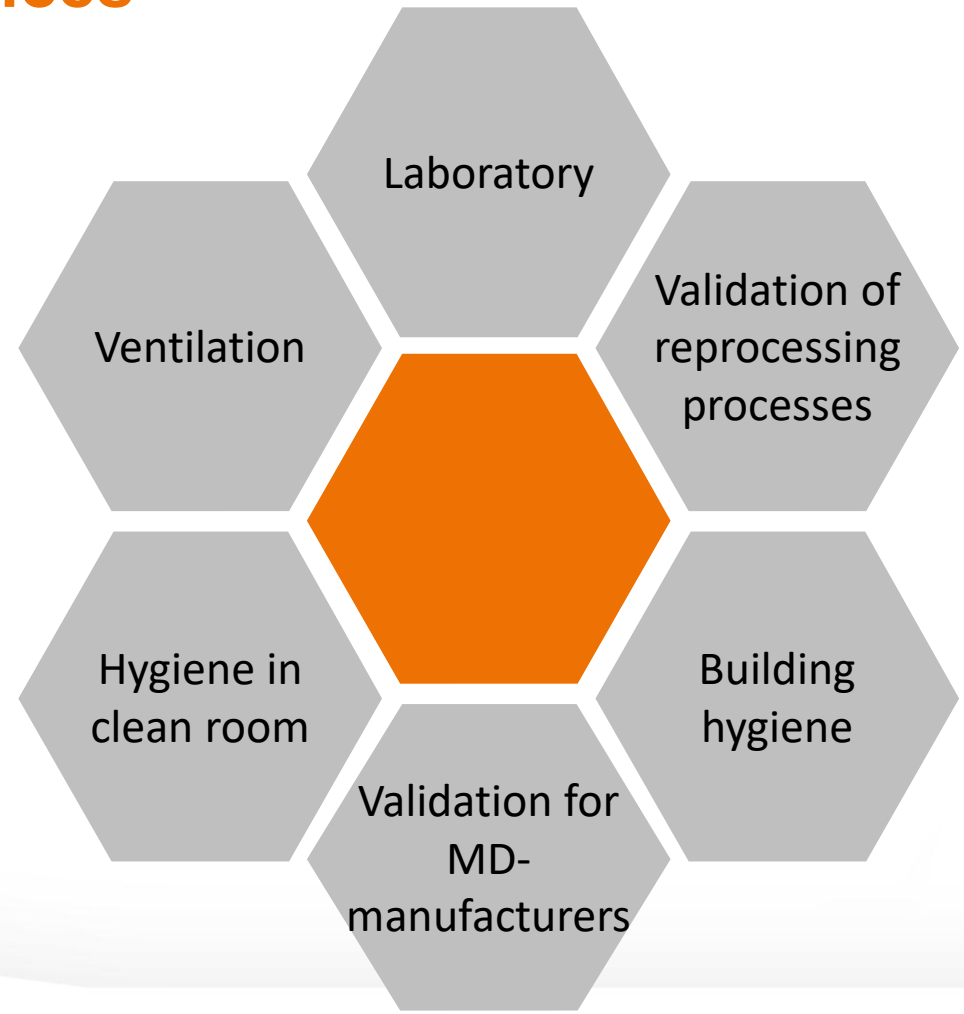
- M.D. Topic: evaluation of low temperature hydrogen peroxide sterilization process (Sterrad System), university of Heidelberg, Germany
- Consultant in Hygiene and Environmental Medicine (Facharzt für Hygiene und Umweltmedizin)
- 20 years work in public health sector on university, state and local health level
- Since 2013: Medical-hygienic management, Normec Hybeta GmbH, Münster, Germany

Normec Hybeta

Services



- Independent microbiological and technical institute of hygiene since 2004
- ISO 17025 accredited testing laboratory for medical devices
- GMP compliance
- > 100 employees in Germany
- Specialist in hygiene and environmental medicine, infection control nurses, biologists, chemists, hygiene technicians, medical technical assistants

Overview

- Technical standards and guidelines - worldwide, Europe, Germany, Nigeria
- Setup of a Heating, Ventilation and Air conditioning (HVAC) system
- Main function of the HVAC system in a hospital
- Air filter stages and Room classes in the surgical theatre
- Ventilation in minor surgical procedure rooms
- Technical validation at implementation of HVAC and maintenance measurements
- Further literature to a new solution for low resource areas

Main Function of the HVAC system in a hospital

- Contribution to patient protection (good air quality with only a low microbial count) or even sterile air
- Provision of thermal comfort for operating room staff
- Removal of harmful particles, e.g. carcinogenic surgical smoke gases or anaesthesia gases
- Assurance of technical process or product requirements for functionality and safety

Technical Standards – Performance and Validation

Worldwide

- ISO 14644- 1: Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration; Part 3: Test methods
- Germany
  - DIN 1946-4 - Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care
  - VDI 6022-1 - Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units (VDI Ventilation Code of Practice)

Technical Standards – Performance and Validation

Nigeria

- Recognizes ISO 14644-1, -3: National Agency for food and drug administration & control (NAFDAC). List of recognized standards for medical devices. Adopted 5th Nov 2004. last update effective 10th Nov. 2024 https://nafdac.gov.ng/wp-content/uploads/Files/Resources/Note_To_Industry_2024/NAFDAC-List-of-Recognized-Standards-for-Medical-Devices.pdf

- In addition, project owner/ manufacturer of ventilation equipment implement British standard (HTM-03; ref. ISO 14644) or American standard (ASHRAE, partly different from ISO 14644)

Technical Standards – Air filter stages

Worldwide

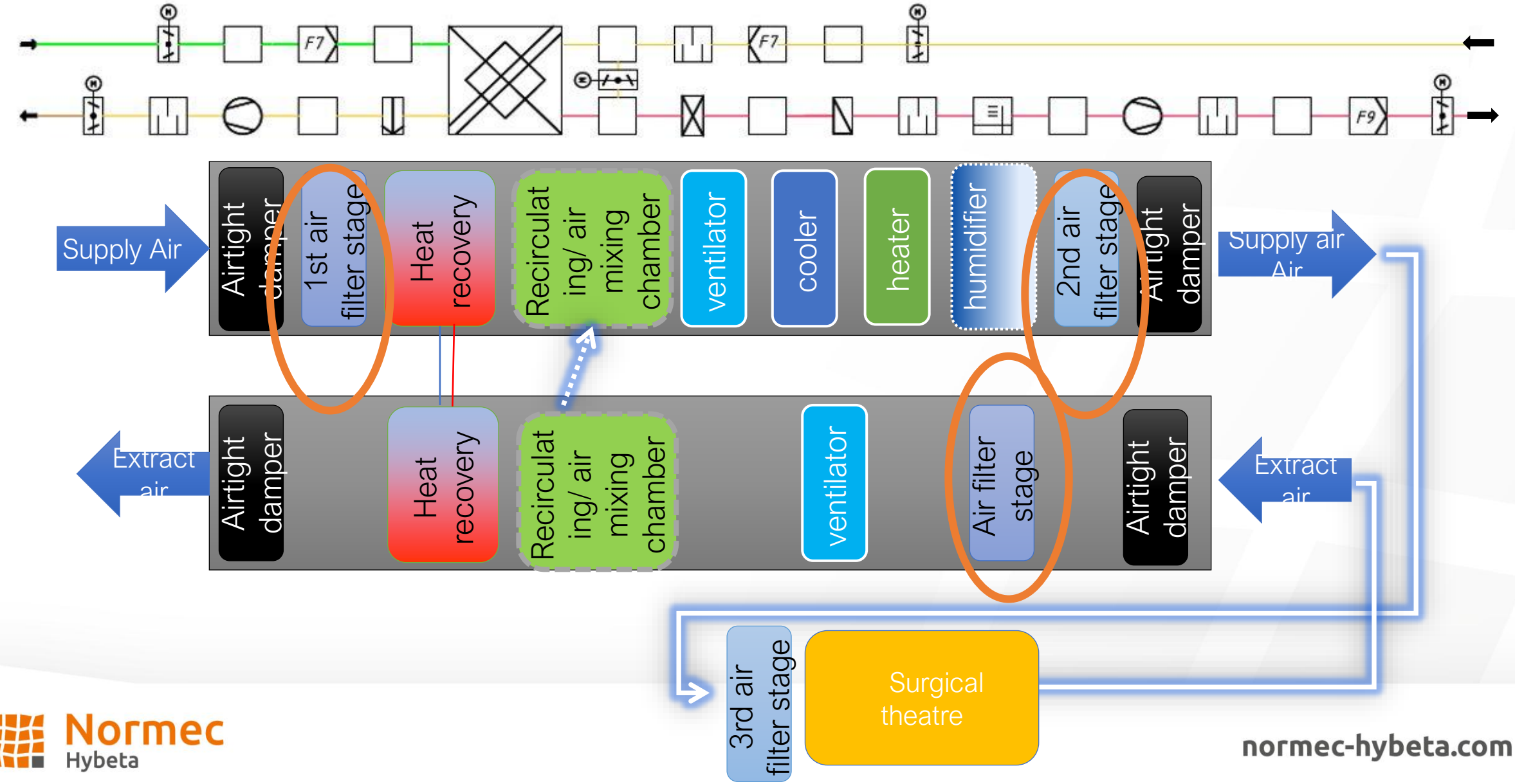
- ISO 16890 : Air filters for general ventilation - Part 1: Technical specifications, requirements and classification system based upon particulate matter efficiency (ePM)
- ISO 14644-3: Cleanrooms and associated controlled environments – Part 3: Test methods (for the Filter integrity test)
- ISO 29463: High-efficiency filters and filter media for removing particles in air

In addition in Europe

- EN 1822: High efficiency air filters (EPA, HEPA and ULPA) – proof of conformity with this standard by the manufacturer

Setup of a ventilation system

Setup of a ventilation system (simplified)



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normec-hybeta.com

Facts about HVAC

- Microorganisms in the air can cause infections
- A higher number of microorganisms in the air increase the risk of infections
- The number of microorganisms in the air in the surgical theatre increase with:
  - The number of persons
  - Opening of the doors
  - Speaking of the surgical staff (even with a surgical mask)
  - Activity in the room

- A HVAC should reduce this risk

Release of microorganisms from the human body

Release of microorganism (in 1 hour during little movement)	Normal skin	During a shower	After moisturizing
unclothed	25.000 – 40.000	60.000 – 79.000	1.750 – 36.000
wearing surgical attire	14.000 – 28.000	31.000 – 37.000	1.400 – 2.370
Wearing a cleanroom overall and high-top boots	780 – 2.240	2.900 – 5.400	117 - 340
Christiansen. B. Der kolonisierte Mitarbeiter als Infektionsquelle, 7. Hygiene-Forum Bonn, 2010.			

Humans as a source of emissions

Particle emission	When sitting still	Breathing through the nose	Breathing through the mouth	Speaking	Coughing
	300.000 P / min				
Mean value		1.380 P / min	8.040 P / min	11.700 P / min	822.540 P / min
Maximum value		17.760 P / min	61.080 P / min	37.560 P / min	17.261.820 P / min

P = Particle

Hartmann, A. et al. Emissionsrate and particle size of bio aerosols when breathing, speaking and coughing
https://depositonce.tu-berlin.de/bitstream/11303/11451/4/hartmann_etal_2020_de.pdf

Basis for planning a surgical theatre

- Specifying the equipment for surgical theatre, e.g.:
  - Room size
  - Need of Laminar flow and Size of TAV field (Position analysis) (TAV field with a distance of 1,20 to 1,50 m from the walls)
    - Position of the surgical theatre table holder
  - Surgical lights
  - Type of media supply and with TAV field with flow stabilisers
  - No window ventilation in the OR department

Basis for planning a surgical theatre

- The entire surgical department is under positive pressure relative to the general hospital

- Total supply air volume > Total extract air volume

Determination of room classes

- 3 room classes (Germany)
  - Ia: highest standards
  - Ib: high standards
  - II: low standards
- With respect to bacterial count in the air

Determination of room classes

- Responsibility: Infection Control doctor (Krankenhaushygieniker) and hygiene-engineer
- During planning
  - First, an analysis of the surgical schedule (list of planned operations)
  - Determination of room classes (in some countries total knee or hip joint replacement or organ transplant surgical procedures are done in room class Ia (Laminar flow). Some studies show a beneficial effect for superficial and deep incisional surgical site infections, but not for deep organ infections.

Surial B. et al. Better Operating Room Ventilation as Determined by a Novel Ventilation Index is Associated With Lower Rates of Surgical Site Infections. Annals of Surgery, vol. 276, No. 5, Nov. 2022, 353-360
https://pmc.ncbi.nlm.nih.gov/articles/PMC9534050/pdf/sla-276-e353.pdf

Air filter stages

General HVAC: DIN EN ISO 16890

- Inside a hvac
  - ISO $ePM_1 \geq 50\%$; previously F7 (1st air filter stage and exit filter)
  - ISO $ePM_1 \geq 80\%$; previously F9 (2nd air filter stage)

Explanation ISO $ePM_1 \geq 50\%$:

- e = efficiency
- PM_1: particulate matter with a diameter of **1 micrometer (µm) or smaller** (e.g., combustion particles, viruses, and nano-particles).
- **≥ 50%:** This indicates that the filter is capable of capturing **at least 50%** of these fine PM_1 particles. Filters in this group must achieve a minimum efficiency of 50% for this particle size range to be classified as ePM_1.

Air filter stages

Surgical Theatre: EN 1822 / ISO 29463

- In addion: 3rd air filter stage for the surgical theatre prior to the air inlet into the room:

- High-efficiency Particulate Air (HEPA) filter, minimal requirement in Germany: H13

Explanation:

➢ **Efficiency:** It must have a minimum efficiency of **≥ 99.95%** at the **MPPS** (Most Penetrating Particle Size), which is typically around 0.1 to 0.3 micrometers.

Room classes for surgical procedures

General

German standard DIN 1946-4:2018-09 defines 3 room classes:

- **Room class II**⇒ 2 air filter stages in the HVAC (1st air filter class ISO ePM_1 ≥ 50% (former F 7) and 2nd air filter class ISO ePM_1 ≥ 80%) (former F 9)

- **Raumklasse I** ⇒ 2 air filter stages in the HVAC (see above) *plus* 3rd air filter stage (HEPA-Filter) directly at the air inlet in the surgical theatre
  - **Room class Ib= turbulent dilluting flow**⇒ high air exchange rate (minimum of 60 m³ per m² roomfloor area per hour) *plus* spillage into other rooms
  - **Room class Ia = low turbulence laminar flow**⇒ TAV-field *plus* high air exchange rate (minimum 900 m³ per m² TAV-area per hour) *plus* spillage into other rooms

The Nigerian Manual of Infection Prevention and Control

7.3.4 Recommended Infection Control Practice

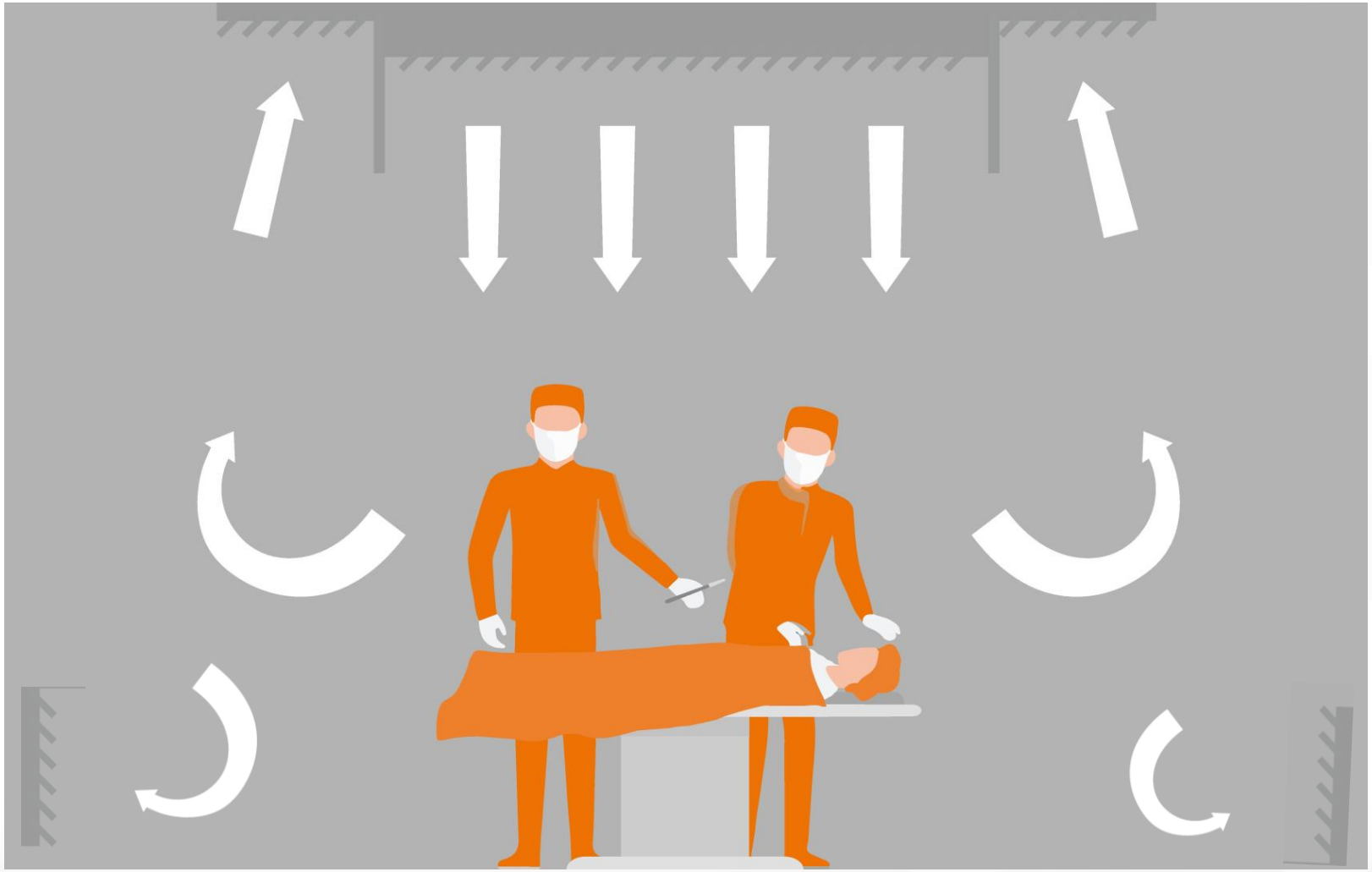
7.3.4.1 Environment

- Modern operating rooms which meet current air flow standards, should be virtually free of particles larger than 0.5 microns when the room is occupied.
- To achieve this, ORs should be equipped with positive-pressure systems to ensure that air travels from ORs to adjacent areas, thereby minimising inflow of air to the room.
- This positive pressure system is challenged every time a door is opened.

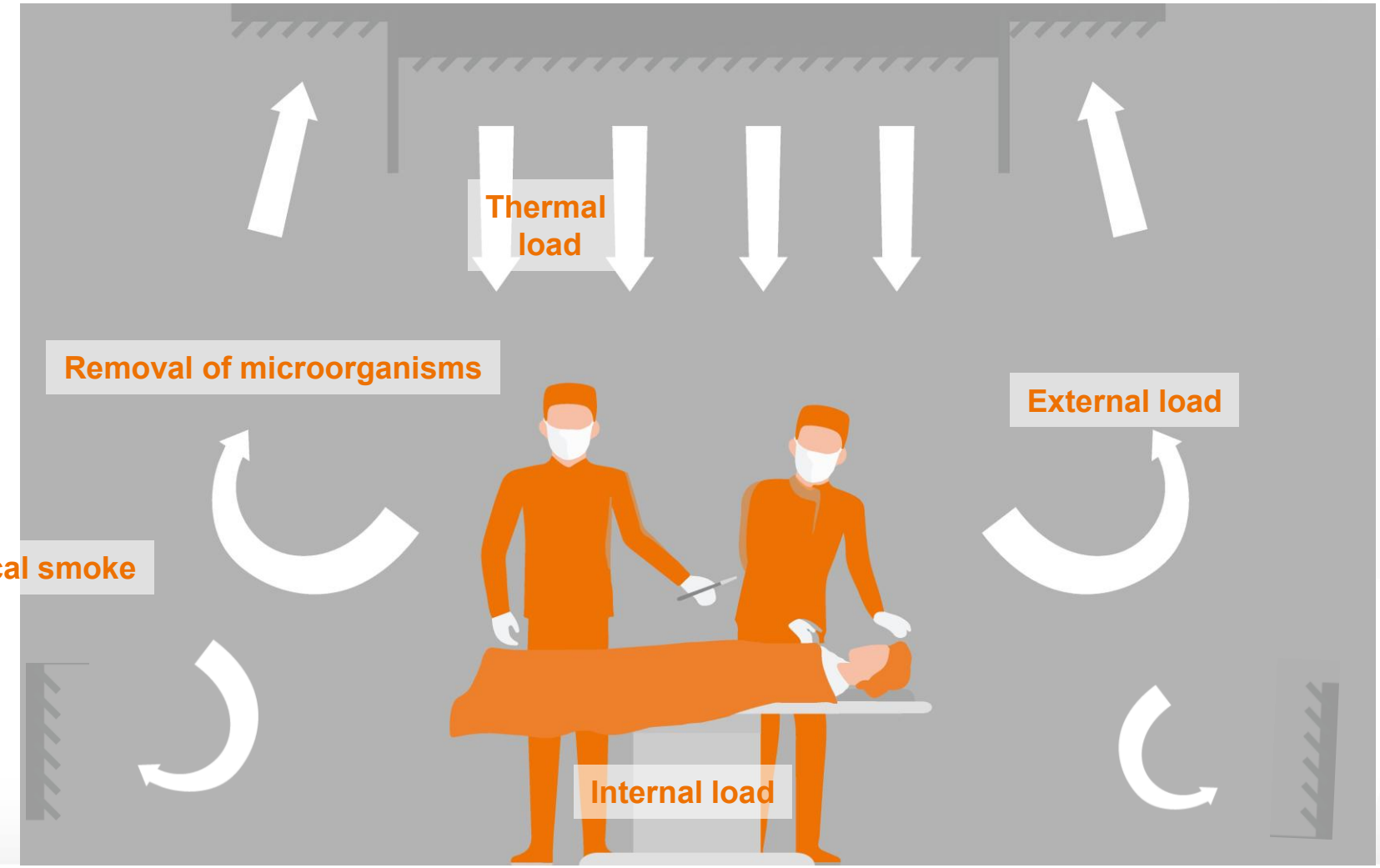
Nigerian Centre for Disease Control (NCDC). Sept. 2021
https://ncdc.gov.ng/themes/common/docs/protocols/296_1649340294.pdf

RK Ib – turbulent diluting flow

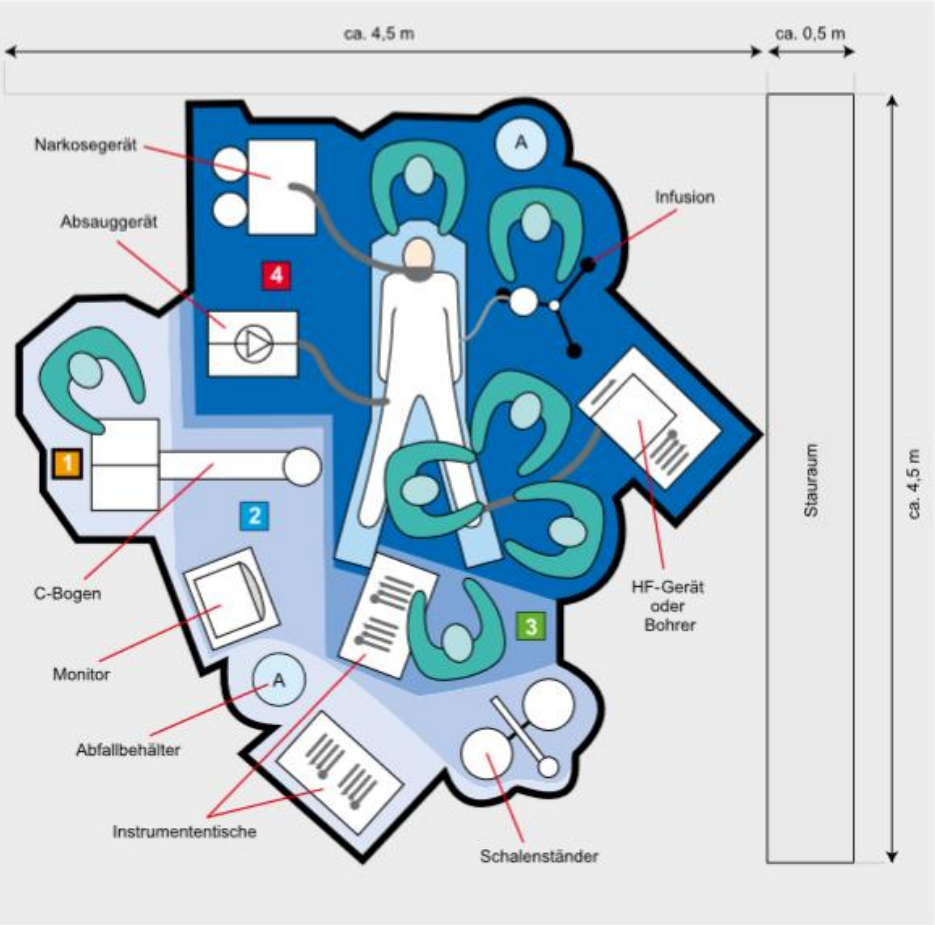
RK Ia – low turbulence laminar flow



Task of a ventilation system

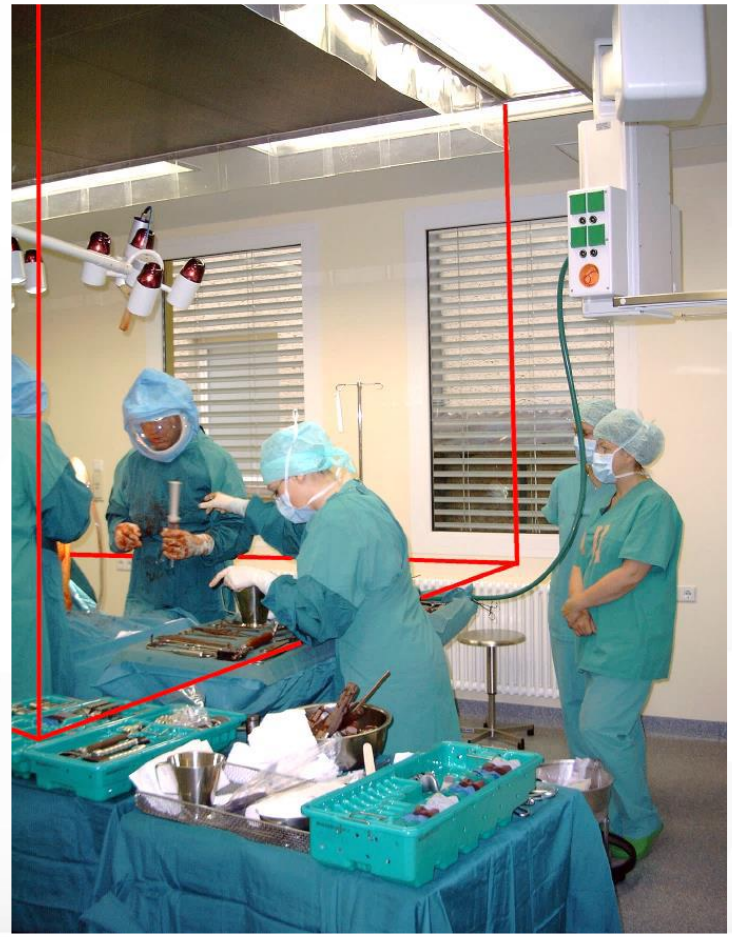


Position analysis



Quelle: https://publikationen.dguv.de/widgets/pdf/download/article/884

TOTAL HIP REPLACEMENT

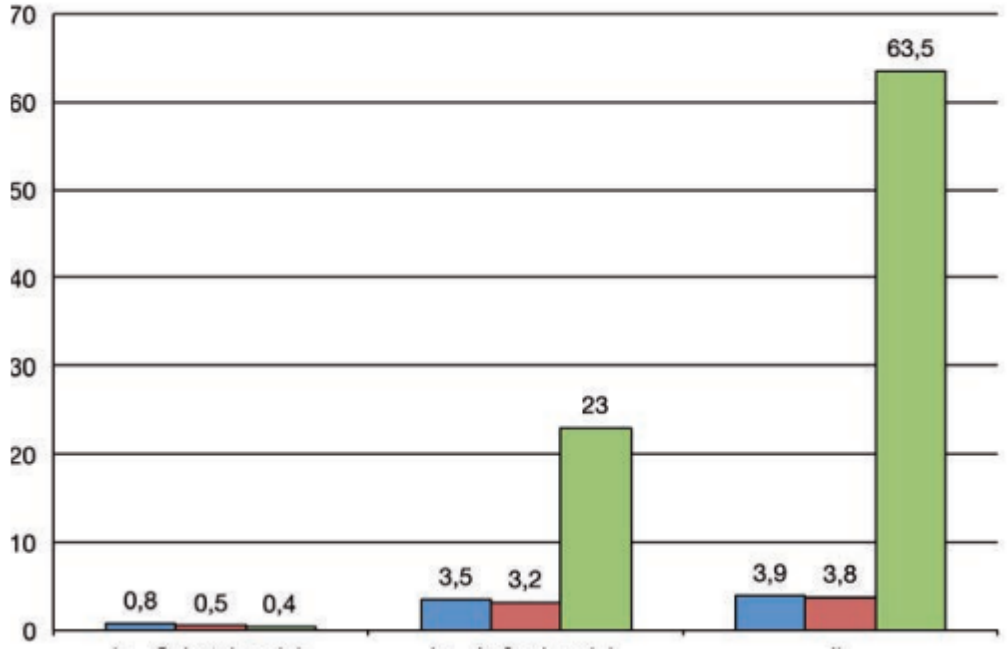


Quelle: Dr. Peter Lüderitz

Influence of different ventilation systems upon the contamination of medical devices

T. Benen, F. Wille, L. Clausdorff.. Hyg Med 2013; 38-4: 142-146
https://normec-hybeta.com/media/2023/06/Einfluss_von_unterschiedlichen_Lueftungssystemen.pdf

Influence of different ventilation systems upon the contamination of medical devices



Legend:
blue: crile clamps (cfu/clamp)
Red: sedimentation (cfu /plate)
Green: air samples (cfu / m^3)

Room class:	Ia: TAV field	Ia – outside TAV field	Ib

Comparison of microbial count from air sampling, sedimentation plate and Crile clamps

T. Benen, F. Wille, L. Clausdorff. Hyg Med 2013; 38-4: 142-146
https://normec-hybeta.com/media/2023/06/Einfluss_von_unterschiedlichen_Lueftungssystemen.pdf

Minor surgical procedure room

Type of surgery

Germany

Operations with low risk of surgical site infection, i.e.:

Minor procedures on the skin or subcutaneous tissue, on the eye, in the oral, maxiallary or frontal sinuses, endoscopy of body cavities, abscess drainage and for interventional radiological and cardiological procedures without a planned change in procedure.

Recommendation of the Commission for Hospital Hygiene and Infection prevention (KRINKO). Prevention of postoperative wound infections. 2018 (not available in English)

https://www.rki.de/DE/Themen/Infektionskrankheiten/Krankenhaushygiene/KRINKO/Empfehlungen-der-KRINKO/Device-assoziierte-postoperative-Infektionen/Downloads/Empf_postopWI.pdf

Minor surgical procedure room (Germany)

Ventilation system

- Room class 2 (DIN 1946-4) if a ventilation ist necessary due to worker safety (i.e. fresh air supply for rooms without windows) or to condition air temperature and humidity

- If ventilation is not necessary, window ventilation in between surgical procedures possible with insect screen on the windows.

Recommendation of the Commission for Hospital Hygiene and Infection prevention (KRINKO). Prevention of postoperative wound infections. 2018 (not available in English)

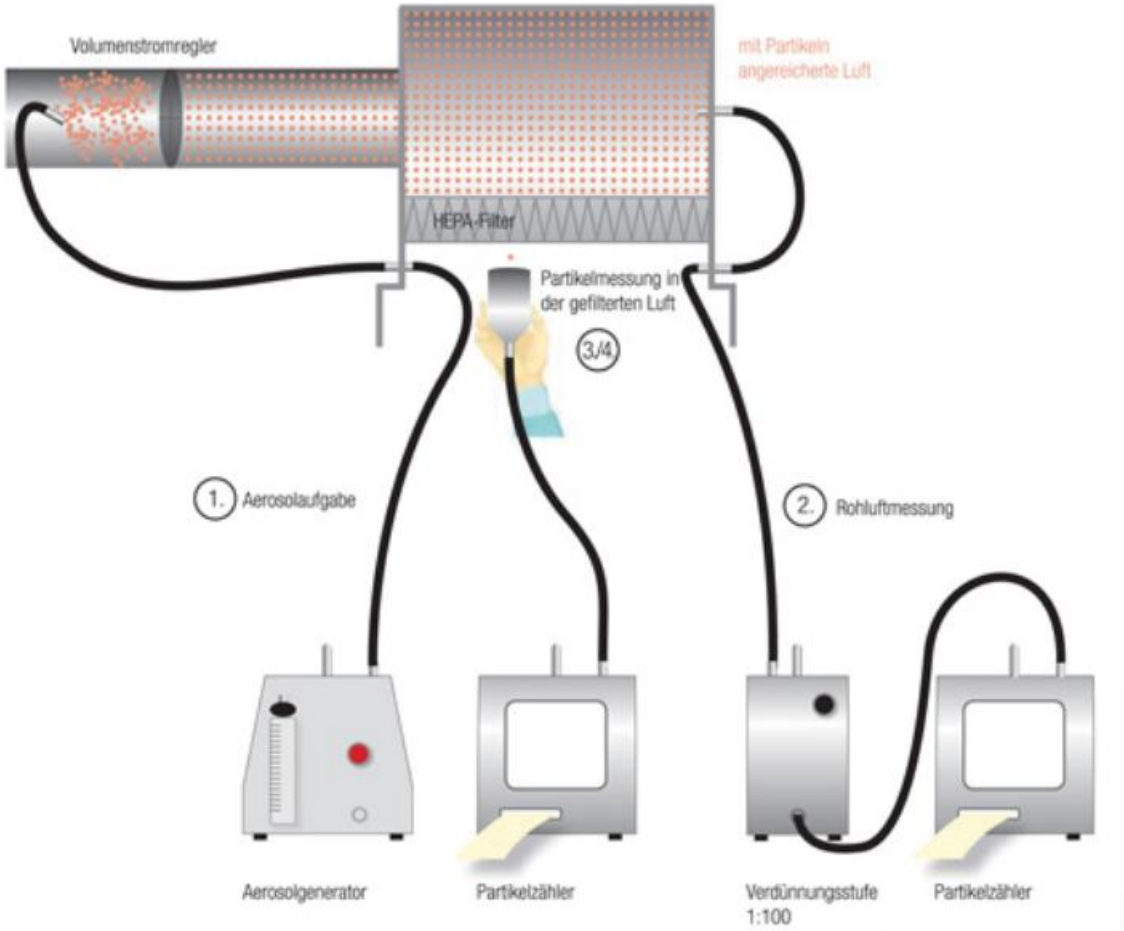
https://www.rki.de/DE/Themen/Infektionskrankheiten/Krankenhaushygiene/KRINKO/Empfehlungen-der-KRINKO/Device-assoziierte-postoperative-Infektionen/Downloads/Empf_postopWI.pdf

Measurement

Air particulate matter

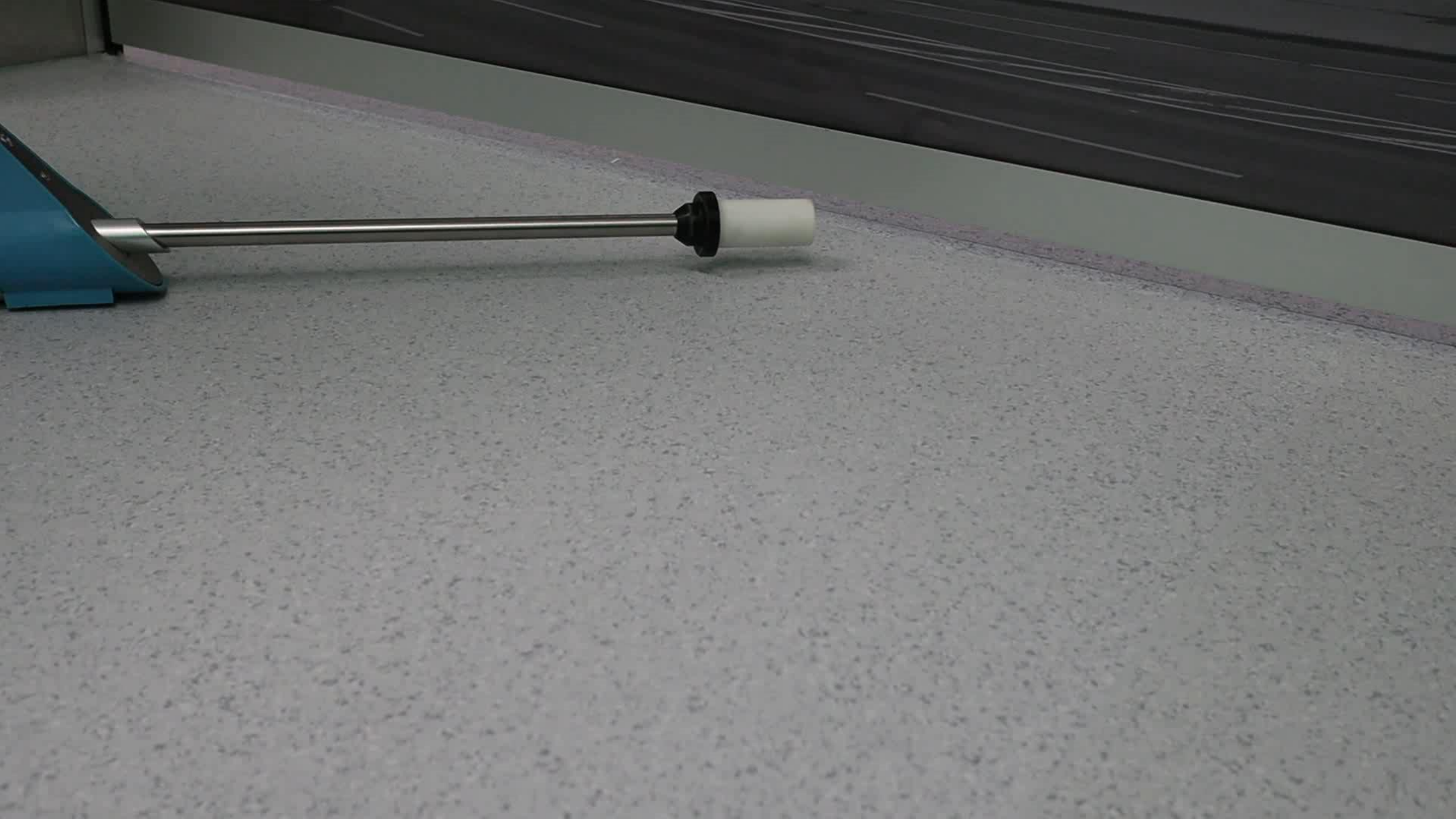
microorganisms

Filter integrity test



Quelle: Fa. Testo industrial services

Visualization of air spillage into other rooms



Recovery test (Room class 1b)

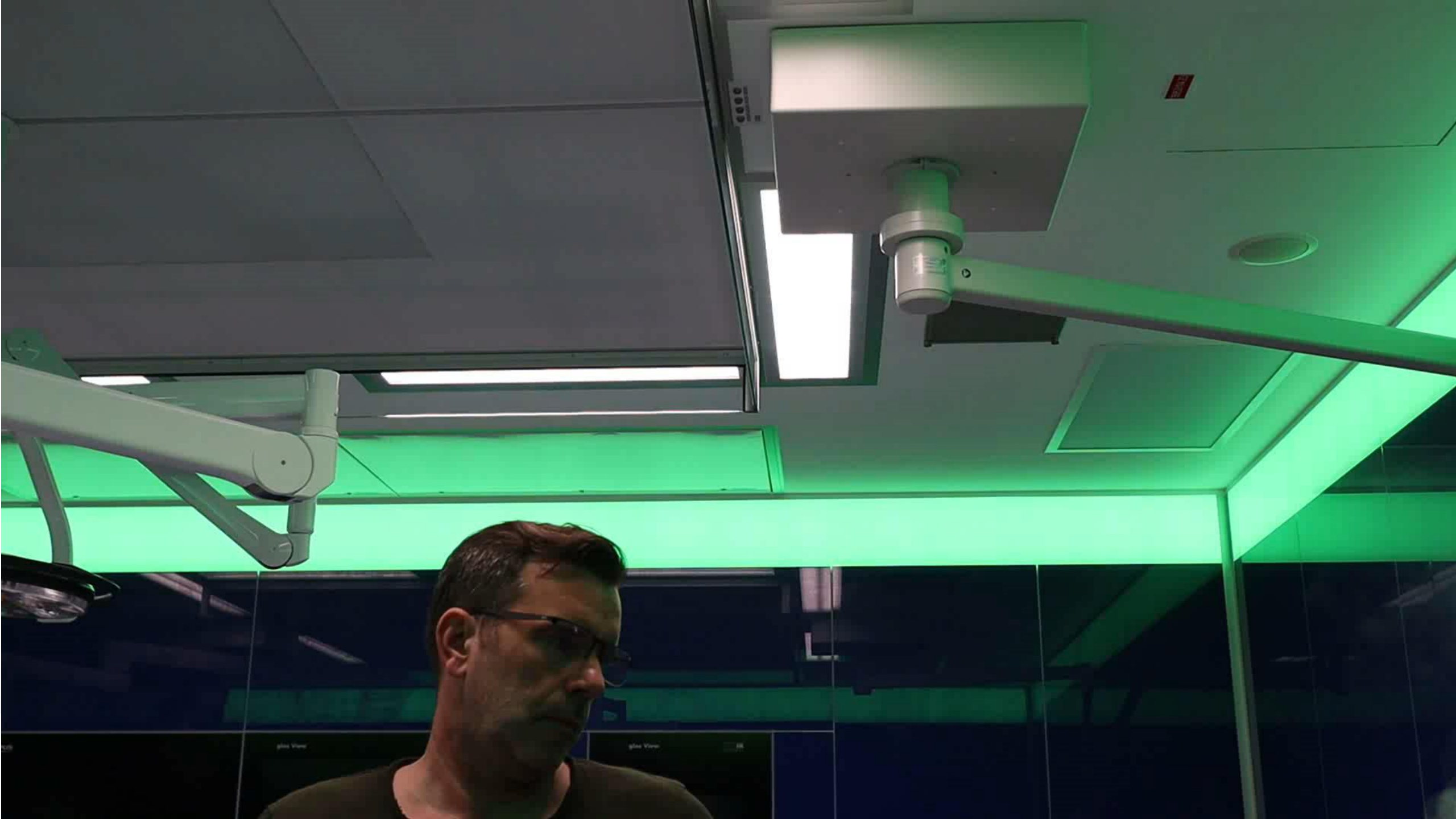
- Basis: ISO 14644
- Measurement of the native baseline (measuring points distributed evenly in the room)
- Objective: Maximum base load: ≤ 100 P/ft³ (P = particle size ≥ 0,5 µm; ft³ = cubic foot)
- The room is contaminated with particles
- Measuring the time taken for particles to be removed
- Aim: 99% reduction in 20 min.

Factors influencing the measurement

- Location of inlet and outlet opening
- Air volume flow
- Protective pressure (positive pressure)
- Air filter quality
- Room size

Visualization of the air flow in low turbulence laminar flow without influence of surgical lights

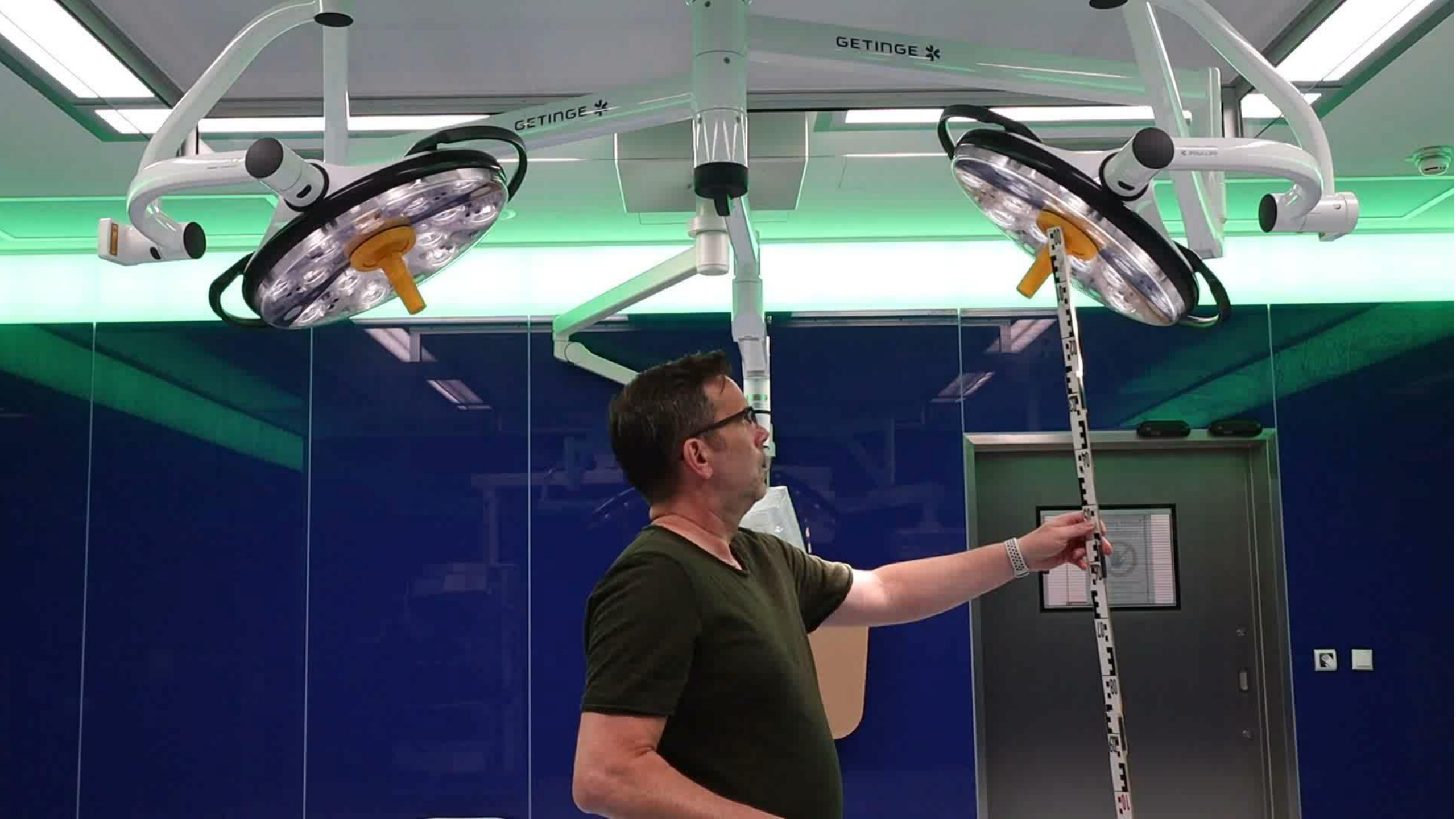
Visualization of the shielding of the protective field in low turbulence laminar flow



Visualization of surgical smoke in low turbulence laminar flow

Visualization of differential flow in low turbulence laminar flow

Visualization of low turbulence laminar flow with surgical lights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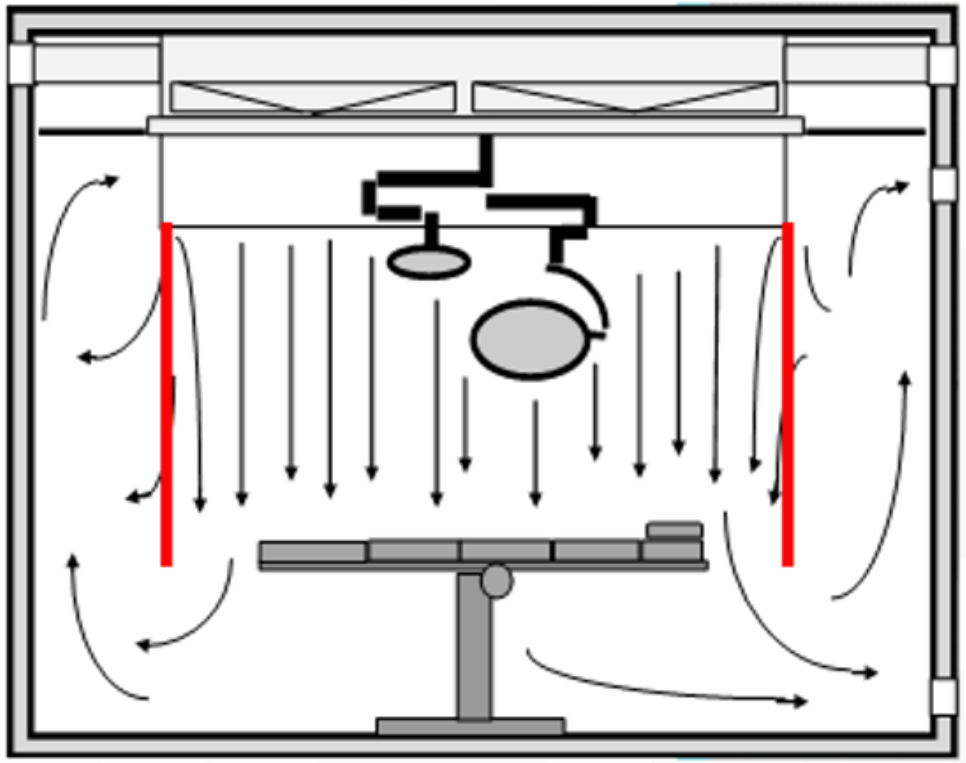
Visualization of air flow on patient table in low turbulence laminar flow

Influence on air flow from installation in low turbulence laminar flow

Media supply bridge



Ceiling supply unit

Surgical lights

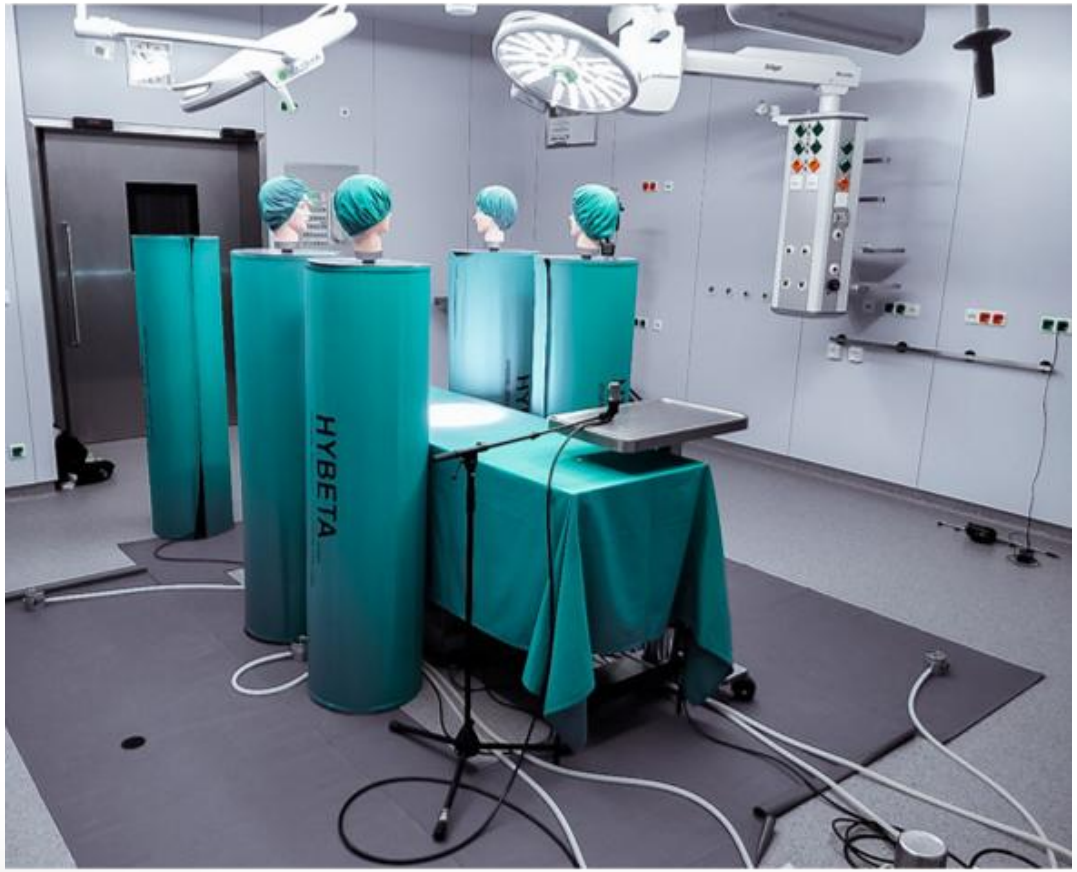
Older model, warm surface

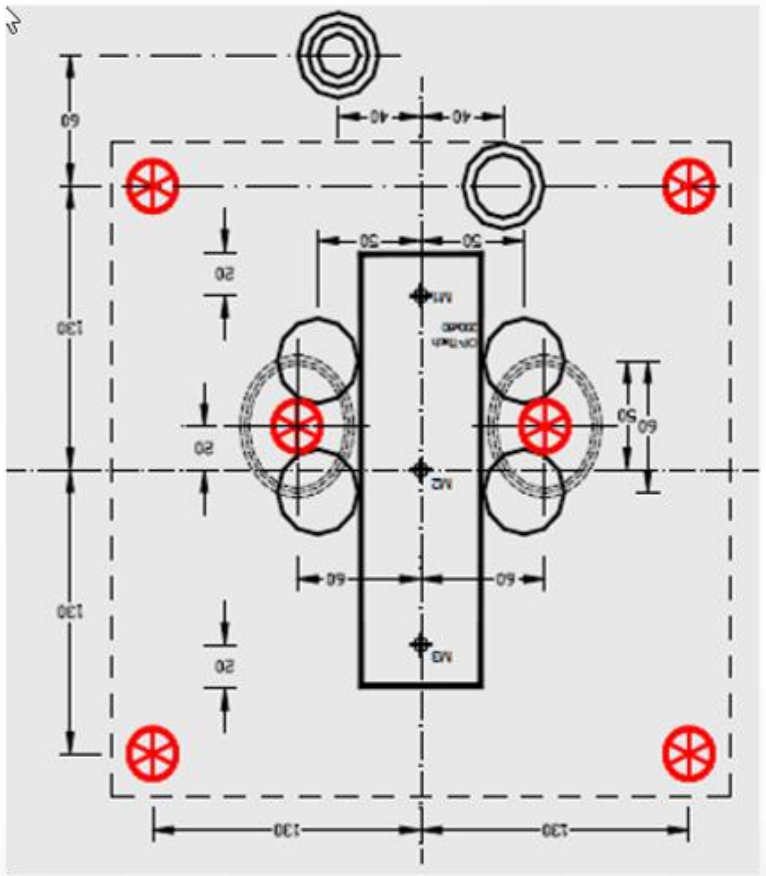
Aerodynamically optimised, LED lights

Degree of protection method (Germany) (Schutzgradmessung)

- Principle
  - Outer load
    - Measurement (particles) of potential contamination entering the TAV area from outside and becoming detectable on the operating table or instrument table
  - Inner load
    - Measurement (particles) of potential contamination arising from people working both inside and outside the TAV area, which can be detected on the operating table or instrument table

Setup for measurement for inner load





Influence on air flow from old surgical lights with low turbulence laminar flow

HYBETA GmbH
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Influence on air flow without the old surgical lights with low turbulence laminar flow

Influence of short flow stabilizers on air flow in low turbulence laminar flow

Influence of longer flow stabilizers on air flow in low turbulence laminar flow


Standby

Pictures from on site inspection of HVAC according to VDI 6022

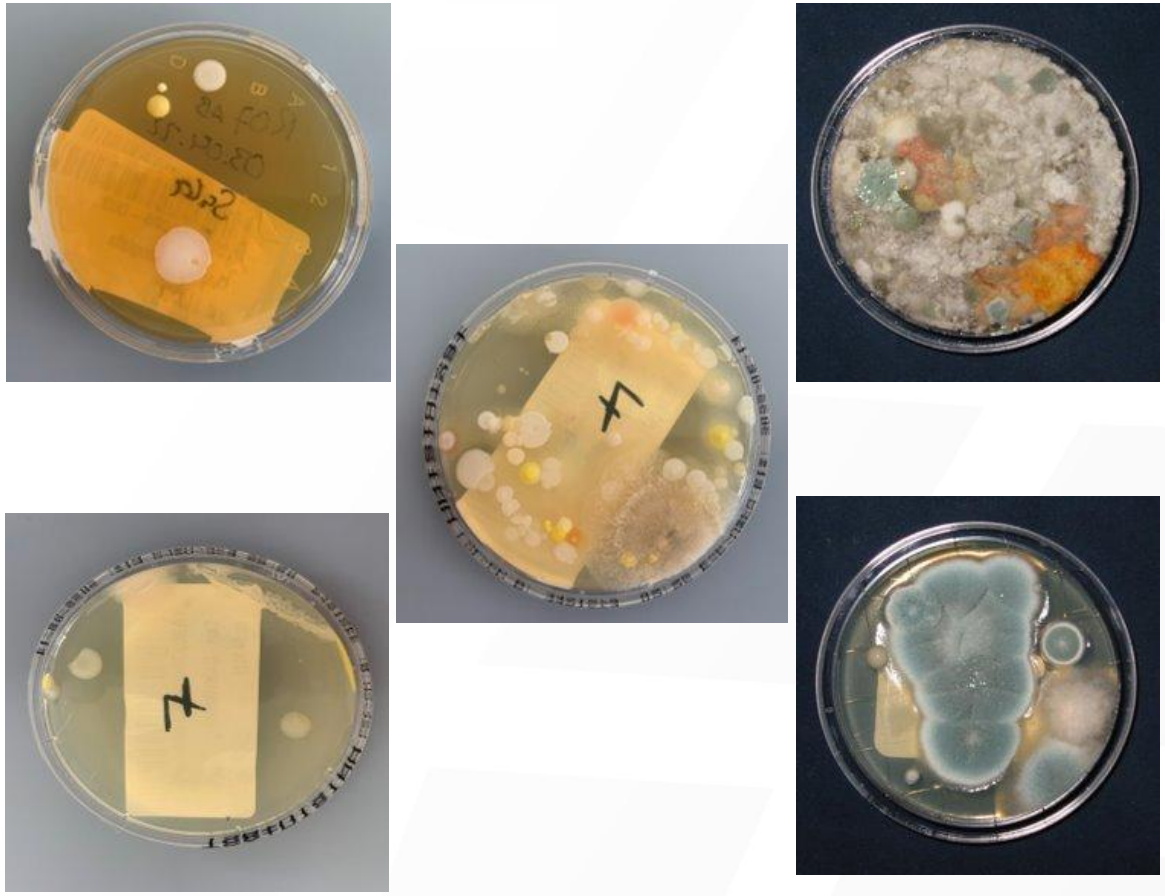
1. Visual inspection

1. Visual inspection

2. Contact plate sampling

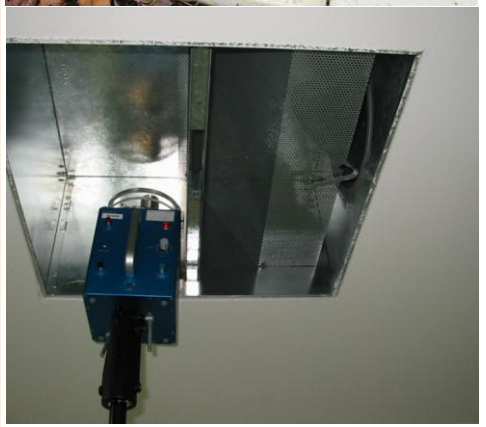
- Assessment of microbial contamination inside the device
- Material: RODAC-Platte (replicate organism detection and counting)
  - Tryptic soy agar (Bacteria)
  - DG 18/ malt agar (mould)

Assessment values [CFU/25cm²]	Assessment
<25	Good or very good
25 bis 100	borderline
>100	insufficient



3. Microbial air count

- Comparison outdoor to indoor air
- Material:
  - Tryptic soy agar (bacteria)
  - DG 18/ malt agar (mould)
- Assessment criterion: There must be no deterioration in the quality of the supply air



Further literature:
Pilot study for an affordable high-efficient air filtration ventilation system for operating theatres in a low-resource setting

District hospital in Mbouo, Cameroon

Leonhard c. et al. How to get cheap clean air? GMS Hyg Infect Control. 2026 Jan 12; 21:Doc06.
Sources for free download including construction plans:

https://journals.publisso.de/en/journals/hic/volume21/dgkh000615

https://pmc.ncbi.nlm.nih.gov/articles/PMC12914505/

Figure 1: Large operation theatre

Figure 2: Outside fresh air collector (red circle)

Leonhard c. et al. How to get cheap clean air? GMS Hyg Infect Control. 2026 Jan 12; 21:Doc06. https://pmc.ncbi.nlm.nih.gov/articles/PMC12914505/

Figure 3: Air system box, with closed maintenance doors

Figure 4: Air system box, with open maintenance doors; H13 filters and radial ventilator visible

Leonhard c. et al. How to get cheap clean air? GMS Hyg Infect Control. 2026 Jan 12; 21:Doc06. https://pmc.ncbi.nlm.nih.gov/articles/PMC12914505/

Table 2: Technical data of the ventilation system of the present study, in comparison to selected DIN 1946-4 requirements and to the window-based ventilation

Characteristic	Requirements for class Ib OT according to DIN 1946-4 [13]	Ventilation system of the study	Window based "natural" ventilation of the study
Three-stage filtration with HEPA filter	yes	yes	no
Turbulent mixing airflow	yes	yes	yes (similar to)
Particle count ≥0.5 µm at rest	max 3,500/m³	101,000/m³ after three hours	13,181,000/m³
Air changes per hour	15–20	9.6	unknown (lower/worse than ventilation system)
Total air flow	at least 60 m³ per m² and hour	47 m³ per m² and hour	unknown (lower/worse than ventilation system)
Air cleanliness at air inlet at least DIN EN ISO 14644-1 class 5	yes	yes, significantly better than class 5 (0 particles)	no
Outside air proportion	at least 1,200 m³ per hour	more than 1,200 m³ per hour	unknown (lower/worse than 1,200m³ per hour)
Positive differential pressure between OT and neighbouring room	yes	yes	no
Temperature and humidity control	yes	no	no

Leonhard c. et al. How to get cheap clean air? GMS Hyg Infect Control. 2026 Jan 12; 21:Doc06. https://pmc.ncbi.nlm.nih.gov/articles/PMC12914505/

Pilot study for an affordable high-efficient air filtration ventilation system for operating theatres in a low-resource setting

- Price: 3,500 € HEPA system
- Device was working properly after 4 years of regular use without any maintenance.
- The air filtration system reduced particles in the OT by >97%.
- The microbial contamination in the OT air was reduced by 72% after starting the device.
- Although not fully compliant with all DIN/ISO requirements, the ventilation system greatly improved the cleanliness of the OT air compared to ‘natural’ window-based ventilation

Conclusion

A well-planned and properly monitored surgical theatre ventilation
is a crucial factor in patient safety
and
quality of care in the surgical setting.

Thank you very much for your attention!

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