Infection Prevention and Workplace Safety in Operating Theatres-
Airborne Particles and Bacteria Need a Re-evaluation in Existing Standards

Rupert Mack
Certification for Rupert Mack

Dear Sir or Madam,

We hereby confirm that Mr. Mack is member of the German working group for DIN 1946 Part 4 “Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care” at the Heating and Ventilation Standards Committee (NHRS) in DIN, German Institute for Standardization.

Mr. Mack was fully involved in the development of the national standard named above.

In accordance with the chairman, Prof. Dr. Seipp, Mr. Mack is authorized to speak on behalf of the German working group.

Yours sincerely

German Institute for Standardization
Heating and Ventilation Technology Standards Committee (NHRS)

[Signature]

Christoph Thoma
Head of Technical Group 2.3
Worldwide we differentiate two types of airflow

Unidirectional Airflow
ISO 14644-3 (Class 5)

Turbulent Mixing Ventilation
ISO 14644-3 (Class 7)
Turbulent Mixing Ventilation (ISO 14644-3 Class 7)

(German DIN 1946-4 Class Ib, Dilution Mixing System)
- No protected zone/area
- 20-25 ACH or ≥ 60 m3/m2xh
- Recovery-Time ≤ 25 min (Particles 100:1 recovery)
Turbulent Mixing Ventilation (ISO 14644-3 Class 7)

(German DIN 1946-4 Class Ib, Dilution Mixing System)
- No protected zone/area
- 20-25 ACH or ≥ 60 m3/m2xh
- Recovery-Time ≤ 25 min. (Particles 100:1 recovery)
Unidirectional Airflow (ISO 14644-3 class 5)

(German DIN 1946-4 Class Ia, Laminar Flow, Low Turbulent Displacement Flow)

- Protected Zone System
- 300-400 ACH in protected zone
- Recovery-Time $\leq 0.5$ min (Particles 100:1 recovery)
Unidirectional Airflow (ISO 14644-3 class 5)

(German DIN 1946-4 Class Ia, Unidirectional Airflow, Laminar Flow, Low Turbulent Displacement Flow)

- Protected Zone System
- 300-400 ACH in protected zone
- Recovery-Time $\leq 0,5$ min (Particles 100:1 recovery)
Tasks of a Unidirectional Airflow

Protection of wound area, instruments and sterile clothed personnel (Size of protected zone: acc. Positioning Analyses, min. 3 x 3 m)

Video shows the Unidirectional Downflow:
- the segregation of the protected zone from the periphery area by preventing entrainment of ambient room air.
- Washing out within half a minute (downflow)
Diagram of a modern protected zone system (Unidirectional Airflow)

Benefits:

- Reduction of energy consumption by recirculation
- Reduction of the duct profile coming from the air-conditioning unit
- Air flow rate adjustment possible independently of air-conditioning unit and duct system
- For retrofitting of existing installations
Issue Workplace Safety:
Health risks for surgeons due to surgical smoke

Surgical Smoke:
- Arises from High Frequency (HF) Surgery
- Emerging health risks of surgeons due to increasing numbers of HF-surgeries
Health risks for surgeons due to surgical smoke. Study Netherlands

<table>
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<th>Substance</th>
<th>Formula</th>
<th>Concentration (ppm V)</th>
<th>OEL (ppm V)</th>
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<td>Propanenitrile</td>
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<td>CH₃SCN</td>
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</table>

Table 1. A list of mutagenic and carcinogenic agents that have been analyzed in surgical smoke. (Plast. Reconstr. Surg. 114:458, 2004)

The consistence of surgical smoke is more harmful than cigarette smoke!!
Health risks for surgeons due to surgical smoke. Study China

Breathing in of surgical smoke half a minute is equivalent of smoking one cigarette !!!
Solution: Surgical Smoke Extraction implemented in an a Laminar Flow Canopy

**Benefit:**
- Laminar flow pushes the surgical smoke down to the origin (Turbulent Mixing Flow can not!)
- Odors, aerosols nanoparticles and other hazardous particles are transported into the open (no recirculating)
- Low noise emission as pump is outside the operating theatre
Solution: Surgical Smoke Extraction implemented in an a Laminar Flow Canopy

**Benefit:**
- Optimum protection of surgeons against particles, aerosols, nanoparticles and other hazardous substances
- Clear view thanks to direct extraction and possibility to work independently without additional staff (nurse)
Issue Infection Prevention: Comparison in terms of Airborne Bacteria!

Unidirectional Airflow

Turbulent Mixing Ventilation
Study: Turbulent Mixing Ventilation compared with Unidirectional Displacement Flow

Reduction of Airborne Bacterial Burden in the OR by Installation of Unidirectional Displacement Airflow (UDF) Systems

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Authors’ Contribution:
Study Design: A
Data Collection: B
Statistical Analysis: C
Data Interpretation: D
Manuscript Preparation: E
Literature Search: F
Funds Collection: G

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Source of support: Departmental sources
Study: “Reduction of Airborne Bacterial Burden in the OR by Installation of Unidirectional Airflow “

Result: “Protected Zone Systems“ (Unidirectional Airflow) reduces the bacterial burden by more than 90 %.
Lay-up preparation room/area (for instruments)

„Rooms/areas where sterile packed instruments are opened, stored, checked and arranged on the trollies must have the same air cleanliness as they have during surgery“
Innovation: Continuous Particle Monitoring

Show the cleanliness

Keep an eye on instruments

Quality control and risk management
Diagram of a continuous particle monitoring system (CPM)

Benefit:
- Prevention of infection through the continual monitoring of the air quality
- Light-screen display to show the current air quality
- Increasing awareness among the surgical staff and protection of the sterile chain
- Clean air supply adapted to suit requirements
- Quality management possible for every operation thanks to documentation
Video shows how Continuous Particle Monitoring works
Innovation avoids the risk of collision

The longer the glass pane the larger the protection zone
The longer the glass pane the bigger the risk of collision (lights pendants)
Modern Design of an Operating Theater

- Air curtain system
- Continuous Particle Monitoring
- Unidirectional Airflow Canopy
- Protected Zone
Summery:

- Unidirectional Airflow (Laminar Airflow) only assures a Protected Zone/Area

- Protected Zone/Area has to cover wound (situs), personnel as well as instruments (min. 3m x 3m)

- Protection Zone/Area only meets the requirements referring to nowadays issues Infection Prevention and Workplace Safety (Surgical Smoke)

- Existing Standards are behind and have to be re-evaluated (... as long lasting we can not wait !!)
Thank you for your Attention

Rupert Mack