BIOLOGICAL SAFETY CABINETS –

Influence of personnel activities

Dipl.-Ing. Thomas Hinrichs
Managing Partner, Berner International GmbH

berner

Introduction:

→Berner International GmbH
→State of the art
→Functions & differences
→Airflows
→Safety functions
→Performance envelope
→Dynamic disturbances

BIOLOGICAL SAFETY CABINETS

Your Speaker

Dipl.-Ing. Thomas Hinrichs

Managing Partner
Berner International GmbH
Elmshorn, Germany

Study at FH Hamburg; Biomedical Engineering, main focus Medical Technology

1995-2000 **Surveyor at TÜV** in Hamburg, Department “Biotechnology Safety”:
Testing & Certification of Safety Cabinets, Fume Cupboards, Centrifuges, Venting Systems,
Auditor for QM-Systems

2000-2011 **Head of Sales & Marketing** Berner International GmbH in Elmshorn:
Product Management, Research & Development, Public Relations, Sales & Marketing

Since 2011 **Managing Partner** Berner International GmbH in Elmshorn
Responsibility: Sales, Marketing, Production, Service, Research & Development

Member of:
DIN 12980; DIN EN 12469; Expert group for laboratory equipment (ELATEC); VDI 2083 Blatt 16
DGOP – German Society of Oncology Pharmacy; ESOP - European Society of Oncology Pharmacy;
EBSA - European BioSafety Association; VDI – Verein Deutscher Ingenieure;
ABSA – American Biological Safety Association

berner

BIOLOGICAL SAFETY CABINETS

Berner International GmbH

Research and development

Training & seminars

Service

Laboratory equipment

berner

Disposables

Personal protective equipment

Isolators

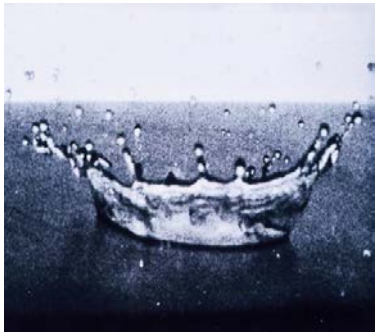
Safety cabinets

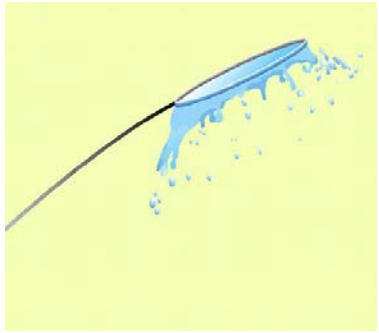
berner

BIOLOGICAL SAFETY CABINETS

Purpose - aerosol formation

Protection against hazardous aerosols





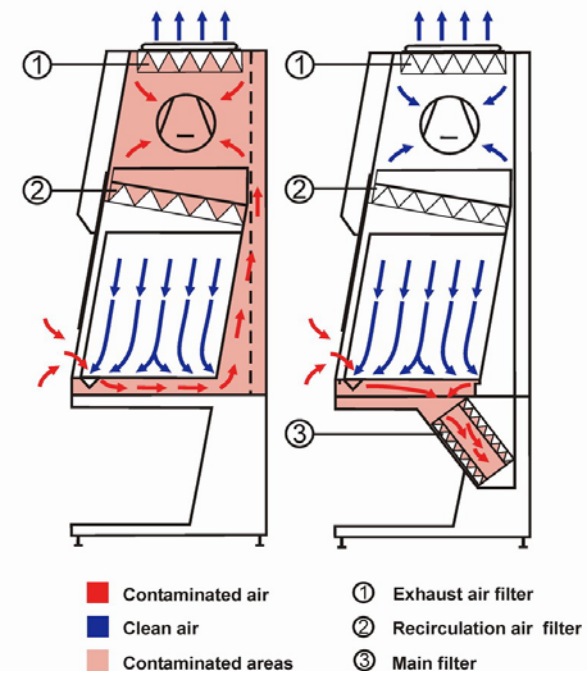
Current state of the art
„Technical possibilities at a certain point in time, based on established findings of science and technology.“

- DIN EN 12469:2000-09
  Biotechnology - Performance criteria for microbiological safety cabinets
- DIN 12980: 2016-10
  Laboratory installations – Safety cabinets and glove boxes for cytotoxic substances and other CMR drugs

BIOLOGICAL SAFETY CABINETS

Functional Principle, class II

Contaminated areas, function and design of a safety cabinet for 2- and 3-filter systems.



- 2- or 3-filter system
- Two air flows: down- and inflow
- HEPA filters
- Personal-, product- and cross-contamination protection

BIOLOGICAL SAFETY CABINETS

Protective function

Personel- and product protection

berner

BIOLOGICAL SAFETY CABINETS
Personal protection

Microbiological testing of personal protection.

Nebulizer and sampler.

The **retention capacity in the workspace** and **personal protection** is the most important function of a safety cabinet.

The safety equipment needs to pass the following tests:

- Dispersal of 5-8 x 10^8 CFU* in 5 minutes.
  * Colony forming units.
- Maximum of 10 CFU in six liquid samplers and 5 CFU in two slit-type samplers.
- 5 or 15 test cycles.
- Air flow settings at the BSC **specific operating point.**

berner

BIOLOGICAL SAFETY CABINETS

Product Protection

Product protection is essential to guarantee adequate manufacturing and experimental conditions.

Microbiological testing of product protection.

The product protection equipment has to pass the following tests:

- Dispersal of 5 - 8 x 10^6 CFU* in 5 minutes.
  * Colony forming units
- A maximum of 5 CFU on all sedimentation culture plates.
- 3 test cycles
- Air flow settings at the BSC **specific operating point**.

berner

BIOLOGICAL SAFETY CABINETS

Cross-contamination protection

Cross-contamination protection: Product or experiment to protect against cross-contamination from the workspace.

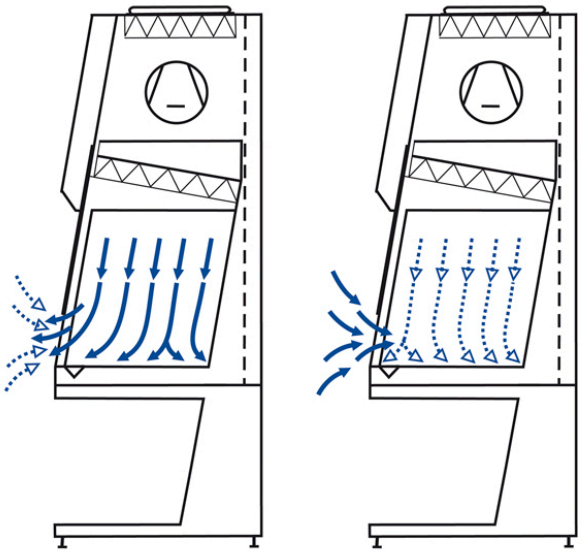
Microbiological testing of cross-contamination protection.

The strict adherence to these conditions is documented by the following tests:

- Dispersal of 5-8 x 10^4 CFU* in 5 minutes.
  *Colony forming units
- No more than 2 CFU on all sedimentation culture plates.
- 6 test cycles.
- Air flow settings at the BSC **specific operating point**.

BIOLOGICAL SAFETY CABINETS

Interaction of in- and downflow



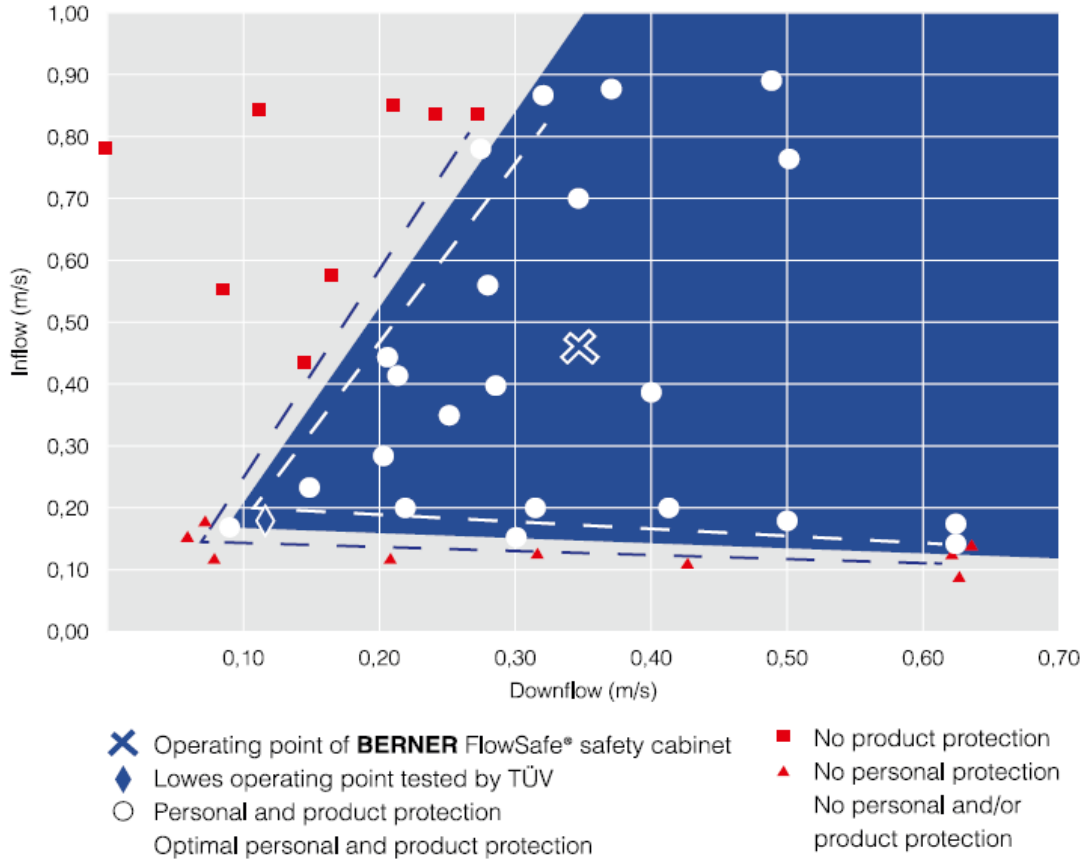
Interaction of air inflow and downflow

Air flow		Protective functions	
Inflow	Downflow	Person	Product
↓	↓	?	?
↓	↑	?	✓
↑	↓	✓	?
↑	↑	✓	✓

berner

BIOLOGICAL SAFETY CABINETS

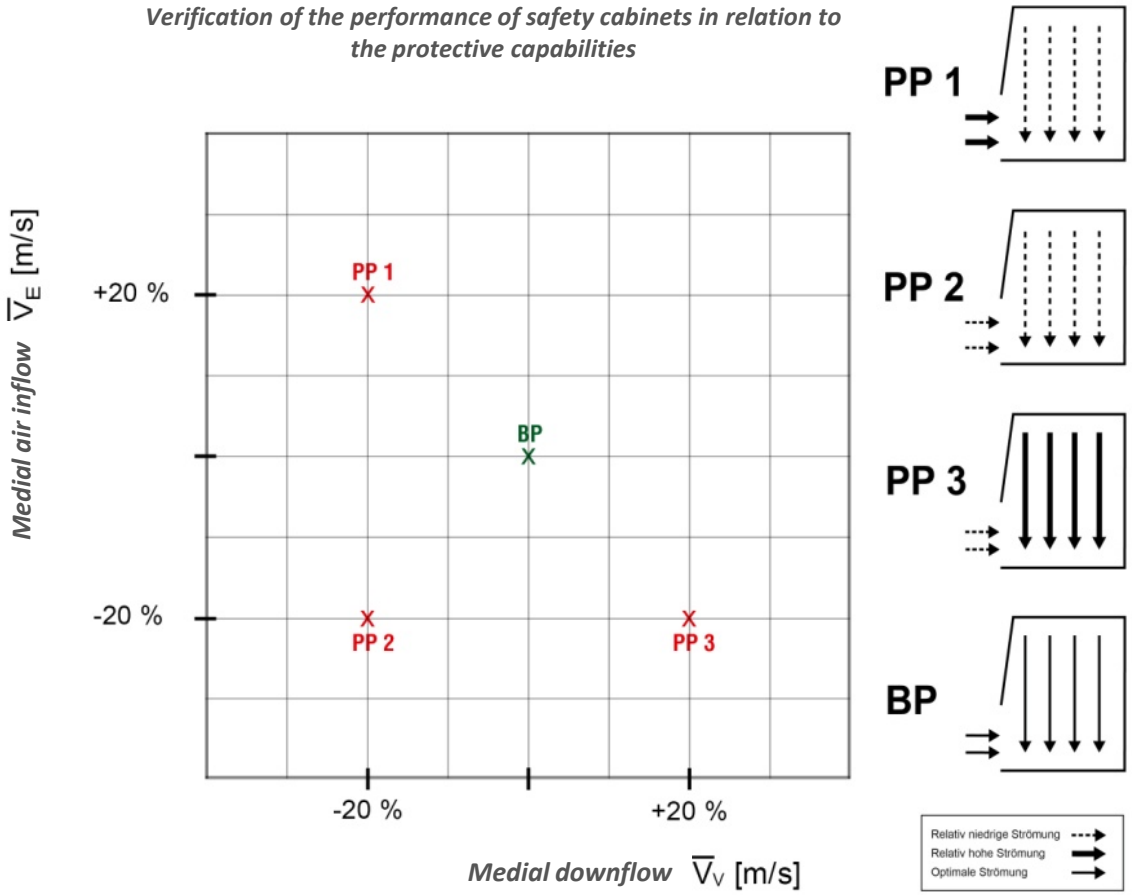
Performance Envelope Test (PET) – Performance capability



BIOLOGICAL SAFETY CABINETS

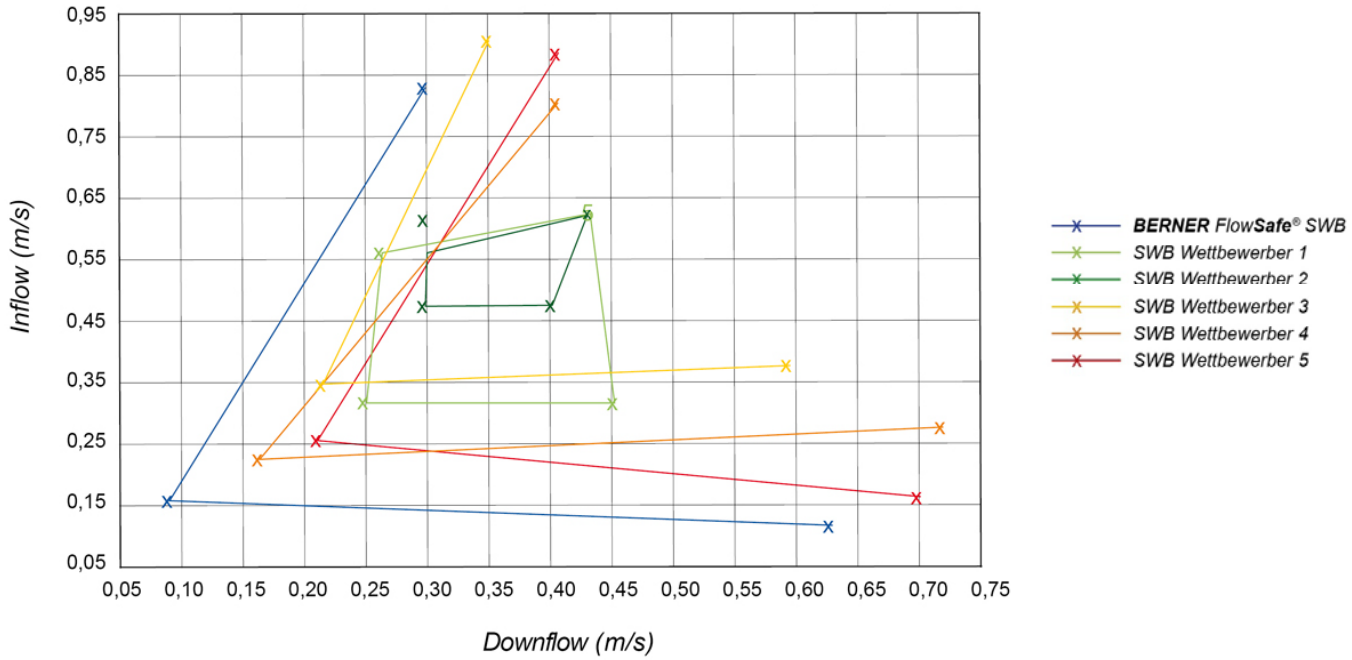
Performance Test Methods

Verification of the performance of safety cabinets in relation to the protective capabilities



BIOLOGICAL SAFETY CABINETS

Performance Limits of different safety cabinets



BIOLOGICAL SAFETY CABINETS

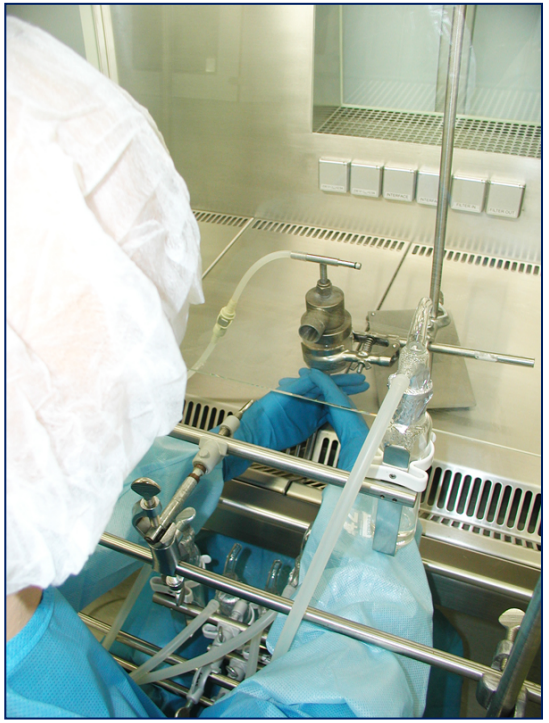
State of the art technology: Testing the protection functions without a person

Chemical testing („KI-diskus-test“) of personal protection.

Microbiological testing of personal protection.

BIOLOGICAL SAFETY CABINETS

Interference of a person in front of the SC



berner

BIOLOGICAL SAFETY CABINETS

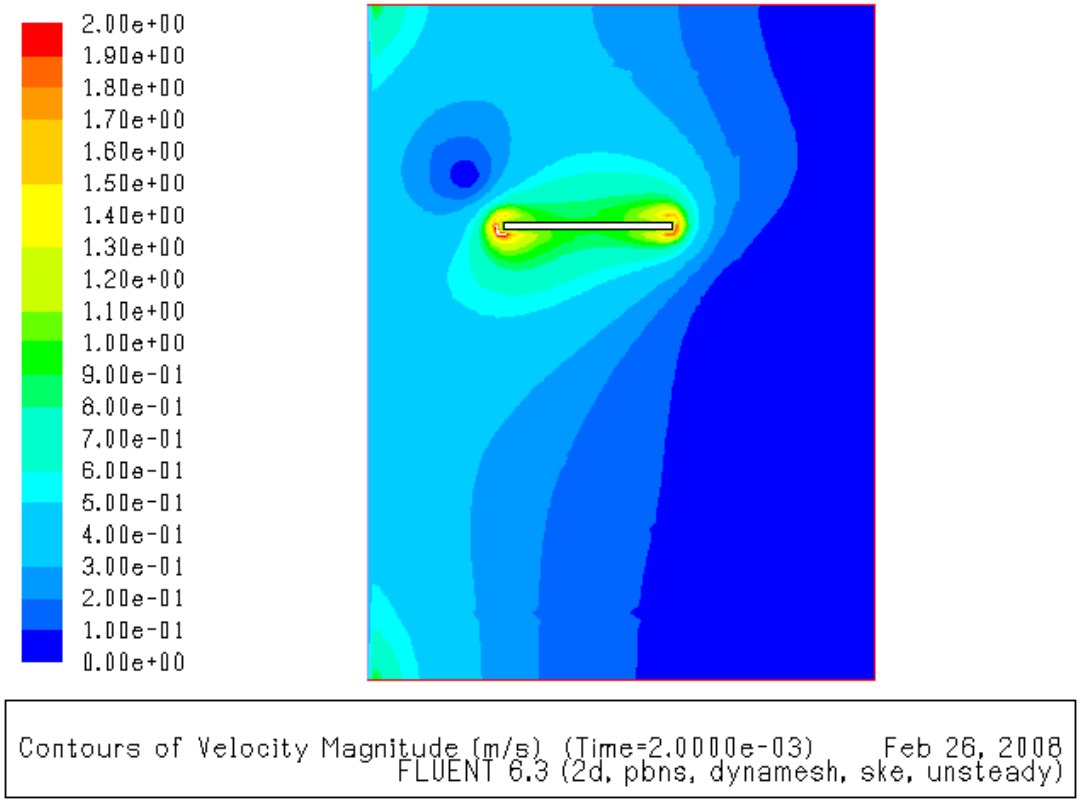
Performance limits with perturbation: Moving arm

BIOLOGICAL SAFETY CABINETS

Performance limits with perturbation: Moving person

BIOLOGICAL SAFETY CABINETS

Visualisation of perturbation by a moving person



BIOLOGICAL SAFETY CABINETS

Airflow Reduction Potential

Table 2. Airflow Reduction Potential as a Function of Airflow Disturbing Factors.[a]

	Airflow Reduction Potential, %					
	Undisturbed	Dummy Worker	Body Plate	Moving Arm: R	Moving Arm: L	Walking Man
Downflow						
BSC 1	69	64	54	54	43	25
BSC 2	58	63	58	53	35	29
Mean	63.5	63.5	56	53.5	39	27
Inflow						
BSC 1	57	57	43	43	34	9
BSC 2	70	67	58	53	35	33
Mean	63.5	62	50.5	48	34.5	21

Abbreviation: BSC, biological safety cabinet; L, left side; R, right side.

[a]Airflow reduction potential: maximum acceptable negative deviation from the set point. Airflow-disturbing factors: airflow velocities at the nominal set points = 100%.

berner

BIOLOGICAL SAFETY CABINETS

Solution: Detection system for motion recognition

Performance limits

Without perturbation:

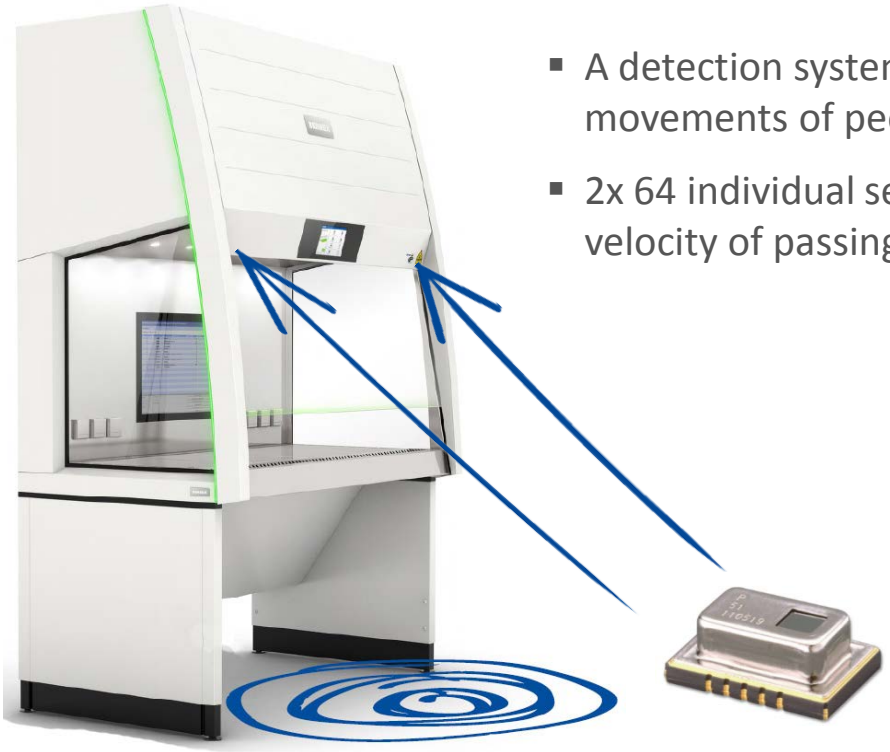
- 0.19 m/s air inflow
- 0.09 m/s downflow

With perturbation:

- 0.38m/s air inflow
- 0.25m/s downflow

BIOLOGICAL SAFETY CABINETS

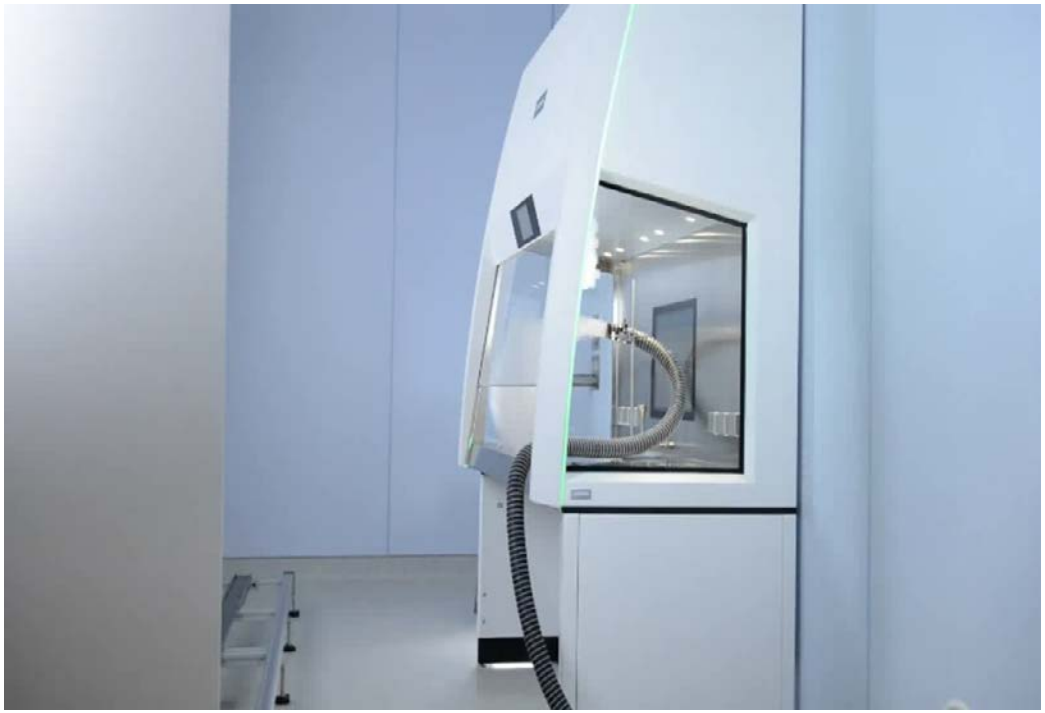
Solution: Detection system for motion recognition



- A detection system for air perturbation recognizes movements of people and generates a warning signal.
- 2x 64 individual sensors detect temperature and velocity of passing persons.

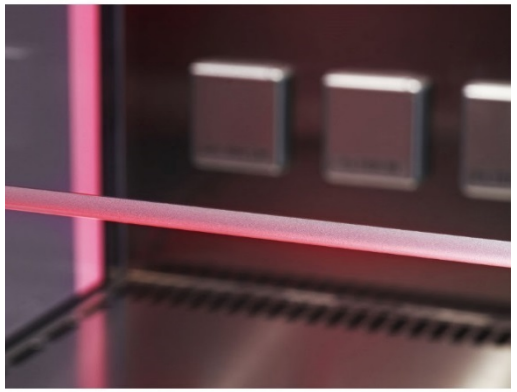
Quelle: www.reifen.de

Demo-Video: Simulation of air perturbation at lowered inflow & downflow:



BIOLOGICAL SAFETY CABINETS

Solution: Clear visual warning signals



Display

- Pictogram „Personal movements“
- Red header
- Icon „Info“ for additional information
- In the visual field of the user

LED-Light bands

- Easily recognisable at a distance
- Operating state indicated with colour coding
- Left & right

Illuminated lower edge

- Clear & conspicuous
- Edge of the work opening
- Important for personnel & product protection
- In the field of view of the user

BIOLOGICAL SAFETY CABINETS

Disruptive factors: Moving person

Conclusion

- Movements of people near a safety cabinet can have a considerable effect on the protective functions.
- Existing test requirements are not covering the real conditions.
- State of the art – EN 12469 - has to be changed, especially for
  - Performance Envelope Testing (PET)
  - Moving plate
- Detection system & clear warning signals

berner

Article

ABSA INTERNATIONAL

Applied Biosafety:
Journal of ABSA International
1-7

DOI: 10.1177/1535676016635369
apb.sagepub.com
SAGE

Biological Safety Cabinets: Simulation and Quantifying of Airflow Perturbation Caused by Personnel Activities

Thomas Hinrichs[1], Sven Gragert[1], and Michael Klein[1]

Abstract

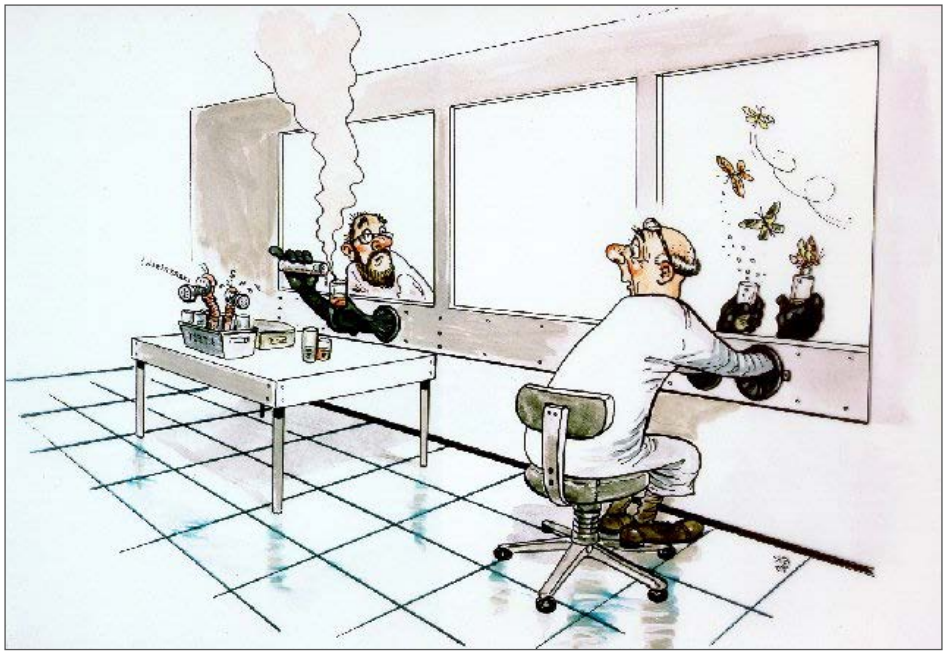
It is a well-known fact that personnel activities can have an adverse effect on the protective functions of biological safety cabinets. Increased air turbulence within the work area or within the surrounding room can disrupt the essential directional airflows of the cabinet, which generate the protective barrier between the environment and the products handled inside. This may result in an enhanced escape and/or invasion of airborne particles or microorganisms. Nevertheless, manufacturers tend to reduce downflow and inflow velocities up to the limits of the allowed values to improve energy efficiency or to reduce noise and vibration. Reliable data based on standardized test procedures to estimate the consequences arising from these measures are rare. In this study, the influence of different static and dynamic disturbing factors on the personnel protection performance of 2 class II biological safety cabinets was quantified. A microbiological test procedure given by the relevant European and US standards (EN 12649, NSF/ANSI 49) was used, but in contrast to the low requirements defined there, 4 more complex and realistic test scenarios were chosen to simulate working activities: static covering of the front sash opening caused by a sitting or standing person was simulated by a "dummy worker" and a "body plate," respectively. Dynamic airflow perturbations were generated by an artificial "moving arm" swinging regularly inside the cabinet and by a flat plate running outside the cabinet parallel to its front opening to simulate a "walking man". It could be demonstrated that dynamic airflow disturbances caused by rapid body movements have a major impact on the cabinet's protecting performance. Compared with an undisturbed working situation, personnel-protecting capabilities of both safety cabinets tested declined substantially when the worker's movement next to the front opening was simulated. Therefore, downflow and inflow velocities should not be reduced to minimum values, to allow a sufficient margin of safety for actual in-use laboratory conditions ("disturbed").

berner

BIOLOGICAL SAFETY CABINETS

The end & thank you!

Safe working on qualified safety cabinets …



For further information: **www.berner-safety.eu**

berner