Maximum protection for your health and well-being
Safety Cabinet for Cytostatics BERNER FlowSafe® C-[MaxPro]³-130 and -190

What will be presented?
Safe drug production

- For the especially safe GMP production of potentially toxic, aseptic parenteral preparations.
- Safety cabinet for cytostatics in compliance with DIN 12980 (06.2005).
- Class II microbiological safety cabinets in compliance with DIN EN 12469 (09.2000).
- Highest degree of protection for personal, product and cross contamination.

😊 You should pay special attention to these points!
CMR drugs are hazardous substances with dangerous material properties.
- Dangerous characteristics, e.g.: carcinogenic, mutagenic, toxic to reproduction, poisonous, harmful to health, irritant, etc.
- Production in the laboratory protection level 4 in accordance with the dangerous chemical law.
- Protective measures, such as: Cytostatic safety cabinet.
- C-[MaxPro]$^3$ guarantees maximum safety at laboratory protection level 4.
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Fulfills latest safety requirements

- TÜV GS certificate for proven safety.
- Essential health and safety requirements of the relevant EC directive(s).
- CE marking and EC declaration of conformity.
- Designed in Germany: Safety equipment developed in BERNER research and test laboratory.
- Made in EU: Manufactured in the European Union.
Safety Cabinet for Cytostatics **BERNER FlowSafe® C-[MaxPro]³-130 and -190**  
**Worldwide the No. 1: Microbiological testing of safety functions**

😊 **BERNER International** is the **only manufacturer** in Europe with its own microbiological test laboratory.

😊 Testing the safety functions of safety cabinets in accordance with DIN 12980, DIN EN 12469 and NSF 49.

- Airflow is specifically exposed to bioaerosols.
- Dispersion from an apathogenic spore suspension of Bacillus subtilis.
- Different sampling methods are used to collect and evaluate data on contamination caused by leaking bioaerosols.
- Quality assurance, research and development.
The retaining capacity at the working aperture i.e. personal protection is the most important function of a cytostatic safety cabinet. The testing of our safety equipment is based on the following parameters:

- **Dispersal of $5-8 \times 10^8$ CFU**
  in 5 minutes. *Colony forming units.*

- **No more than 10 CFU in six liquid samplers and 5 CFU in two slit-type air samplers.**

- **5 or 15 test cycles.**

![Microbiological testing of personnel protection.](image)
Product protection is essential to ensure adequate manufacturing and experimental conditions. Our product protection equipment must pass the following tests:

- Dispersal of $5-8 \times 10^6$ CFU in 5 minutes.
- A maximum of 5 CFU on all sedimentation culture plates.
- 3 test cycles.

Microbiological testing of product protection.
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**Maximum cross contamination protection**

Your product or experiment should be protected from cross contamination from the work space. The strict compliance of these conditions are documented by the following tests:

- Dispersal of \(5-8 \times 10^4\) CFU in 5 minutes.
- No more than 2 CFU on all sedimentation culture plates.
- 6 test cycles.
The **ergonomic design** of „human-machine-system“ is a **preventive safety measure**.

Safeguards your **well-being**:

- Ergonomic sitting position
- User friendly design
- Relaxed working conditions
- Easy to clean
EAS (2): Ergonomic sitting position

- Leaning forward, upright or leaning backward sitting position.
- Dynamic sitting allows you to work comfortably and prevents postural problems.
- Window is inclined at 10° enabling the upper body more room to move.

😊 Sitting close to the procedure within easy reach of all utensils in the work area.

😊 Armrest and work areas at the same level – for an ergonomic and safe working position.

😊 Displays positioned in field of vision and thus easy to monitor.

- All control elements are within easy reach.

😊 No other comparable 3-filter system offers more legroom!
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**EAS (3): User friendly**

**BFC** – **BERNER FlowSafe® Control** panel:
High-quality, clear and convenient

- ☺ Numerical codes for switching on, off and changing settings.
  - Employee-specific numerical codes.
  - Normal, cleaning and night mode.
  - Comfortable: Electrically operated front window.
  - Power sockets in the work area.
  - Potential-free contact for controlling an external monitoring or air ventilation system.
- ☺ Illuminated display showing date, time, operating time, humidity as well as temperature in work area.
- ☺ Timer for monitoring important processes.
  - Control system circuit board with RS-232 interface.
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EAS (4): Relaxed working conditions

Optimal operating parameters and functional design safeguard a pleasant working environment:

😊 **Very quiet**, up to 57 dB(A)*. * C-[MaxPro]³-130

😊 **Bright anti-glare lighting** of up to 1.400 lx* in the work area. * C-[MaxPro]³-190

- Multi-layer glass with a PVB-multi-layer.

- Front window without a border a clear view of the work area.

- Large side windows creates a pleasant working atmosphere.

- Low vibration of less than 5 µm on the solid work surface.

Powerful anti-glare lighting and clear view of the work area.
Work area designed to be easy to clean and made of stainless steel and safety glass:

- Daily cleaning and disinfection take very little time.
- Interior has few joints and easy to clean.

😊 Segmented worktops:
  - Easy to lift and set aside in the work space
  - Can be decontaminated safely in the work space
  - Improved safety at work as compared to large one-piece, very heavy worktops.
  - Can be sterilised in autoclaves.

- Front window can be opened by up to 550 mm:
  For easy cleaning of all areas.
Innovative and intelligent air technology for your safety:

😊 High personal, product and cross contamination protection:
- Stable air inflow & laminar displacement flow
  UDF – Uniform-DownFlow.

- BPP – Best-Pressure-Plenum for an even distribution of air and rapid particle transport.
- IDR – Inflow-Downflow-Regulator for ideal flow conditions.
- BGP – Block-Guard-Plus for maximum personal protection.
- Safe low pressure and gas-tight casing: All contamination is safely contained within the casing.
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Powerful airflow at all times (2)

- Safety control panel BFC – BERNER FlowSafe® Control controls and monitors permanent flow conditions.
- Sensor-controlled, electronic regulation of the fans safeguards compensation of filter contamination.
- High air exchange rate in the work space of at least 1668/h:
  - Rapid elimination of contamination
  - Perfect aseptic as well as particle-free production and experimental conditions.
- Unfiltered air intake guard made of stainless steel to protect filters from tiny parts.

Smoke test:
Reliable and rapid extraction of contamination.

Particles are removed from the work area quickly. t = 2,2 seconds
Safe operating conditions at all times

😊 Maximum safety **at any point of the work opening** due to low air intake ports:
- Partial blocking of forearms is prevented for more personal protection.
- Prevents cross contamination from the work area.
- Prevents work utensils from falling out of the workspace.

😊 **Large display & control lights:**
- Precise error signalling.
- Clear information.
- Detailed fault diagnosis.

- 24 hour battery powered backup power failure alarm.

😊 **Safety control panel BFC – B E R N E R FlowSafe® Control**
monitors the power supply, position of window, air flow and filter.
3-Filter systems offer further additional important advantages:

- Double protection and immediate filtration.
- Unique filter technology BFP – Best-Filter-Protection.
- Optimal waste management.
- Perfect filter protection.
- In sensitive laboratories especially safety level 4*, the use of 3-filter systems is recommended! * In accordance with GefStoffV
3-Filter system (2): Double protection and immediate filtration

- Redundant HEPA* filter system.
  * High Efficiency Particulate Air

😊 Very high degree of filtration of 99,999 999 75% in MPPS*. * Most Penetrating Particle Size

😊 Main filter level directly below the work surface filters out particulate contamination immediately.

- In general, recirculated and exhaust filter do not have to be changed.

- No unnecessary contamination of inaccessible areas.

😊 Laborious and cost-intensive filter changes or crushings, as required with 2-filter systems, is not usually necessary.
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3-Filter System (3): Unique filter technology

Patented main filter system with BFP - Best-Filter-Protection cartridge filters provides significantly more safety and performance than conventional wedge filter systems:

- HEPA-Filter H14 in accordance with DIN EN 1822-1.
- Improved seal seat due to flexible & continuous PU seals.
- Lower sound level.
- Round design channels air perfectly.
- Optimal filter medium flow.
- Large effective filter area.

😊 Guard on clean air side for safe installation and removal.

😊 Half as many filter components as conventional wedge filter systems.

😊 Reduction in subsequent costs due to durability, and less time spent on replacement and testing.
Innovative filter technology for safe waste management:

- Cartridge filter: Compact and well-thought out format.
- Significantly smaller and more compact design the comparable wedge filter systems.
- Low-contamination filter change in accordance with DIN 12980.
- Filter cartridges fit into many laboratory autoclaves, and disinfection and waste disposal containers for thermal and or chemical decontamination.
SLG – Spill-Liquid-Guard protects main filter from spilt liquids.

Only undamaged filters can protect you and your environment reliably:

😊 The patented **SLG – Spill-Liquid-Guard** keeps spilt liquids away from the main filter.

- Protective guards prevent mechanical damage to the main, pre- and exhaust filter, e.g. during cleaning of the workspace.
- All filters have eye protection and a finger guard.
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**Ergonomic EDP workstation (1)**

- Mass- and volume- oriented manufacturing of drugs with software programmes such as Cypro, cato®, Zenzy, MoZ, SteriBase etc.

😊 Information always in view with the 20“ display window ErgoView – this way you avoid postural problems.

😊 Integrated into the back panel is the RS-232 interface DataLink – allows you to send data from the workspace directly into the laboratory.

- Marginal vibration of less than 5 µm on the stable worksurface.

😊 High quality standard:
  - display window ErgoView
  - RS-232 interface DataLink
  - stable and low vibration worksurface
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Ergonomic EDP workstation (2)

Flat screen holder ScreenBase.

- Optional flat screen holder ScreenBase and ScreenBase plus for attaching the flat screens* outside the safety cabinet: * Not supplied as standard.
- No contamination of the flat screen.
- No disruption of air flow.
- Slides off sideways for cleaning and repair – this eliminates the need of moving your safety cabinet.
Fast and safe service

- All servicing work can be carried out from the front: For increased safety and lower costs.
  - Efficient setting of all operating parameters.
- Very exact adjustment of flow conditions.
- Rapid filter change.
- Connections for filter testing in the clean area.
- All components behind the main filter are in the clean area.
  - TÜV NORD CERT trained and individually certified service technicians.
  - Comprehensive inspection protocols with reproducible results.
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Tests for your safety (1)

Only safety cabinets which are regularly tested can provide maximum protection:

- Development » Type testing
- Production » Routine test
- Installation » Commission test
- Operation » Routine test
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Tests for your safety (2)

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Optional flexibility (1): Seated or standing workstation

- Ergonomic sitting or standing workstation.*
  * Standing aid recommended.
- C-shaped base frame.
- Firm and stable.
- Unlimited legroom especially at the sides.
- Standard for 3-filter system.
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Optional flexibility (2): Safe discharge of exhaust air

- **GMP-Cover** for connection to an exhaust system without any adverse effects.
- Simultaneous ventilation of laboratories.
- GMP-compliant lining.
- Surfaces to be cleaned are minimised.

Connection to an exhaust systems with a GMP-Cover.
Optional flexibility (3): Activation of monitoring and ventilation systems

Floating contacts for controlling an external monitoring air conditioning system:

- Operation mode normal-, night- or summary alarm.

😊 Summary alarm for unsafe operating conditions:
  - Front window position
  - Displacement flow
  - Air inflow.

- Optimal co-ordination and safe operating positions at all times.

😊 High quality standard:
  - Potential floating contact normal mode
  - Potential floating contact night mode
Optional flexibility (4): Permanent Cleanroom monitoring

Permanent monitoring, control and documentation with PCM - Permanent-Cleanroom-Monitoring:

- Fully integrated particle measurement technology for continuous monitoring of particles in the work area in accordance with EC GMP guidelines appendix 1.

- Connection to the ICM–System* via a CAN or RS 485 interface.

Integral cleanroom monitoring is a product of the company Briem®

😊 Monitoring and documentation of the particle numbers in the work space and comprehensive operational data of the SC.

😊 Connection to the isokinetic probe in the work area.
Optional flexibility (5): Special installation

- Modular construction.
- Installation and assembly on site also possible for laboratories where access is difficult.
- Perfect solution for:
  - Narrow stairways
  - Narrow doors
  - Premises with many corners
  - Laboratories on floors without a goods lift.
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Maximum protection and well-being for your health

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