

# BERNER FlowSafe® I-[MaxPro]³

GMP-compliant working in  
grade C and D cleanrooms



**BERNER**

safety systems  
made in Germany

## The isolator which gives you the advantages of a tested safety cabinet

**BERNER INTERNATIONAL is your guarantor for complete safety when producing drugs. We have been enhancing work and product safety for pharmaceutical and biotechnological applications since 1982.**

We keep you safe at all times thanks to innovative "Made in Germany" solutions. We have gone to great lengths when developing our work safety equipment to ensure your maximum protection when working with hazardous substances such as CMR drugs (e.g. cytostatics, virostatics.)

Due to increasing requirements on the laboratory environment by the new ordinance on the operation of pharmacies/pharmaceutical regulations, the redesign or new build of laboratory to create a class B cleanroom often cannot be avoided.

With the new cytostatic isolator I-[MaxPro]<sup>®</sup> you can work safely and economically in cleanrooms grade C and D. This way you can save on expensive modification measures and high maintenance costs.



Example: Isolator version with safety cabinet and airlock

# All good things generally come in threes

The patented 3-filter system of the **BERNER FlowSafe®** safety cabinet has treble the value for you.

## 1. Unique filter technology



**Unique cartridge filters: compact construction with twice the performance**

- The HEPA cartridge filters **Best-Filter-Protection** provide you with the smallest main filter elements.
- Only half as many filter elements as with conventional wedge filter systems: 50% smaller replacement and test outlay – Reduction in follow-up costs.
- Protective grid on the clean air side ensures safe installation and removal.
- Long lasting performance capacity due to large effective filter area.
- Perfect air conduction through circular construction: Optimum flow against the filter medium.
- Low noise level.
- Flexible and continuous PU sealing for better seal seat.
- HEPA filter H14 in accordance with DIN EN 1822-1.

## 2. Optimum waste management



**Cartridge filters can be disposed of in normal waste containers and autoclaves.**

- The manageable shape of the cartridge filter facilitates safe and fast filter replacement.
- Used filters can be transported in virtually every customary waste disposal container.
- Low contamination filter change in accordance with DIN 12980.

## 3. Perfect filter protection



**Main filter is protected against fluids and particles.**

- The utility model registered **Spill-Liquid-Guard** keeps blocked fluids away from the main filter.
- Protective grids prevent mechanical damage, e.g. when cleaning the work space.
- All filters have safety screens and safety guards.

## Filter Technology

The **BERNER Isolator FlowSafe® I-[MaxPro]³** is exactly like the **FlowSafe® safety cabinets**, equipped with an innovative, patented **3-filter system**.

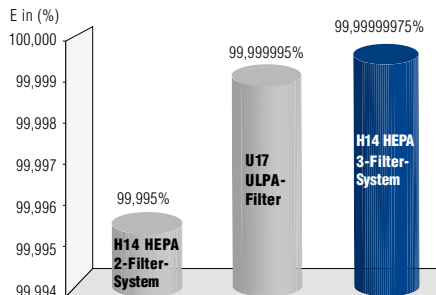
The advanced filter layout offers many advantages:

- Redundant HEPA filter system.
- Very high total filtration efficiency of 99.9999975% in MPPS (Most Penetrating Particle Size)
- Protects better than ULPA filters (Ultra Low Penetration Air) of the U17 class.
- Main filter level directly beneath the work surface filters out particulate contamination via an extremely short air channel.
- No unnecessary contamination in inaccessible areas.
- Essential air conducting components such as filters, ventilators and air channels remain free of contamination.
- Generally recirculation and exhaust filters do not need to be replaced.
- The low-contamination filter change is also possible in the isolator.

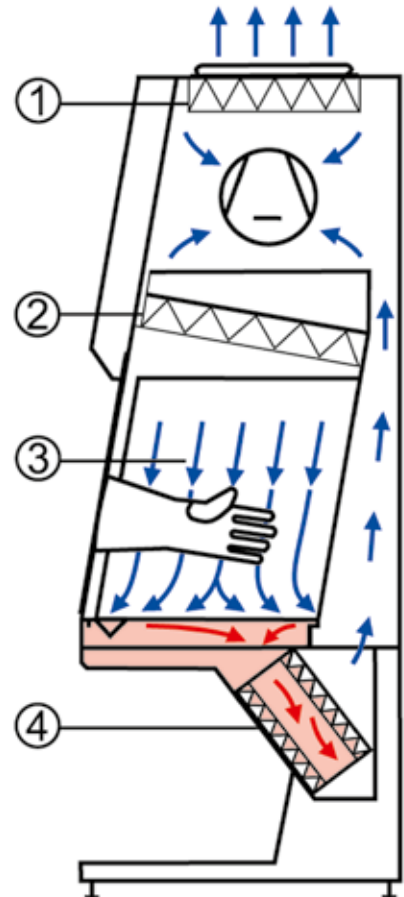


Low-contamination filter change

Total degree of filtration of 2-filter systems vs. 3-filter systems.



E: Integral total degree of filtration in MPPS.



- ① Exhaust air
- ② Recirculation filter
- ③ Downflow
- ④ Main filter
- Contaminated air
- Clean air
- Contaminated area

### Innovative glove and sleeve cover system with tested and certified PPE

#### Changing gloves - safe and easy!



Pull glove to the inside.



Position new glove ring onto the "old" one.



Push out the "old" glove ring using the "new" one.



Remove the "old" glove ring "rotating to the left" through the sleeve cover.

## The best reason: Your safety

### Personal protection

The innovative glove changing system „**Easy-Change**“ with tested and certified cytostatic protective gloves and sleeve covers, means keeping to the changing intervals recommended by the German BGW and QUAPOS is easily achievable.

### Safety

The BERNER I-**[MaxPro]**<sup>3</sup> is based on a tested and certificated BERNER Flow**Safe**<sup>®</sup> safety cabinet with a certificated 3-fold HEPA-H14 filter systems.

### Product protection

An actively ventilated material airlock with HEPA filters and a high air exchange rate ensure the fast removal of contaminated air.

### Air quality

The air quality in the inner work space meets the requirements of a cleanroom grade A in accordance with the EU GMP guidelines. Due to the separation of the workspace and the surroundings the GMP compliant production of cytostatic applications is also possible in a “D” room.

### Ergonomics

The cytotoxic glovebox, despite the 3-filter system, has maximum legroom and in connection with the optional height-adjustable base unit ErgoMove (not possible for all versions) can be adjusted with a push of a button to fit the individual's height.

### Modular Design

Every laboratory has a different design. For this reason we offer the I-**[MaxPro]**<sup>3</sup> as different models with numerous options. Whether sampling probe, monitor workstation, extra interfaces, GMP cover, ... – many of the options available for safety cabinets are also available for the cytotoxic isolator.

### Cleaning

The device has been designed with few joins and is therefore easy to clean and disinfect.

### Laminar Downflow

Just as the safety cabinets by Berner International, the I-**[MaxPro]**<sup>3</sup> also has a laminar downflow. Any particles which may be released during working are thus quickly and safely transported to the filters.



Laminar downflow



Example: Glove box version with 2 airlocks

## Technical Data

Technal Data BERNER FlowSafe® I-[MaxPro]³		
Width (inside workspace)	1254 mm	
Wattage	600 Watt	
Lighting	1200 Lux	
Glove arm holes & size	2 / 300 mm	
Glove change system Easy-Change	2 part system	
Glove type	Cytostatic glove Latex or Neoprene	
<b>Downflow</b>	<b>for 0,36 m/s</b>	<b>for 0,45 m/s</b>
Air exchange rate usable space	1500/h	2365/h
Air exchange rate material air lock	2010/h	2300/h
Air exchange rate exhaust air	250/h	310/h
Exhaust air	140 m³/h	175 m³/h
Sound level (ISO 11201)	50,5 db(A)	52,5 db(A)
Negative pressure	-45 Pa	-65 Pa
Display of airlock status	yes	
Air velocity inside workspace	1 m/s	1,8 m/s
<b>Material</b>		
Isolator casing	steel sheet, powder coated	
Material airlock	Stainless steel 1.4301	
Work surface	Stainless steel 1.4301	
Stainless steel finish	Optional	
Elevated base frame	Optional	
Folding front screen	yes	
Low-contamination filter change	yes	
ISO 14644-1	ISO 5	
EU GMP Annex 1	Grade A	
TUV-testing	registered	

### Item Numbers:

Version:	Item No.
I-[MaxPro]³ with SC & airlock	0101600130
I-[MaxPro]³ with SC & 2 airlocks	0101600135
I-[MaxPro]³ with 1 airlock	0101611130
I-[MaxPro]³ with 2 airlocks	0101612130
Expansion kit I-[MaxPro]³	0101623130
GMP- Documentation Isolator	0101670001

### Investment security

An already existing BERNER FlowSafe safety cabinets of the type C-[MaxPro]³ can be modified onsite to an isolator or built onto an isolator.

### Comprehensive accessories available (e.g.):

- Integrated particle monitoring
- integrierter Flachbildschirm
- Keyboard and printer shelf
- Various interfaces (USB, CAT 5, RS 232, PS/2, Roxtec, MURR)
- Weighing worktop
- GMP cover
- Media connections
- etc.

### Your advantages at a glance

- Cytostatic isolator with all the advantages of a fully developed safety cabinet
- Innovative glove and sleeve cover changing system with tested & certificated PPE
- Low contamination filter change in accordance to DIN 12980
- Exceptional ergonomics
- Available in different versions with material locks and attached safety cabinet

Für your  
Smartphone!



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