



**CLAIRE® ISO – HIGH-END ISOLATOR**  
Isolator technology at the highest level

**berner**

# FROM RESEARCH TO PRACTICE





## NEW STANDARDS & RESEARCH PRACTICALLY IMPLEMENTED

When the new DIN 12980 came into force in 2017, it had a strong impact on modern isolator technology. For the first time, a whole range of practical, binding requirements for cytostatic isolators were clearly defined as part of normal pharmacy operation. This new standard now determines the general state of the art for isolators and thus also affects isolators for applications, which are not just limited to the handling of CMR substances.

The comprehensive requirements of DIN 12980 have found its way into the new development of the isolator Claire® iso as well as the latest results from our own research. Part of the new design is therefore the most advanced airlock technology with a modular independent transfer airlock and the possibility of fast and effective fumigation for the disinfection of introduced material in less than 15 minutes. Altogether, our goal was the practical implementation of the research results and the new standards in technology. As a result, the high-end isolator Claire® iso is designed to meet the needs of our customers in the best possible way.

A handwritten signature in blue ink that reads "Thomas Hinrichs". The signature is fluid and cursive, with a horizontal line underneath the name.

Dipl.-Ing. Thomas Hinrichs  
Managing Partner



## **RESEARCH & DEVELOPMENT** **LATEST SOLUTIONS FOR THE FUTURE**

Berner International intensively conducts research in its own laboratory, because research is always the basis for innovation. In numerous research projects, including funding by the German Federal Ministry of Economics and Technology, our teams have been developing new solutions for working safely in the laboratory since 2002. The established test methods in accordance to EN 12469, the new DIN 12980 or the NSF 49 for testing the protective functions of new developments and customized designs are also used directly here.

Examples of our research projects:

- Movements as disruptive factors in the laboratory
- Extended test methods for safety cabinets
- Performance of safety cabinets depending on the air flows
- Safe aseptic parenteral preparation in isolators
- Optimization of air flows in high-performance particle filters
- Energy-efficient safety cabinets
- Airlock systems with automated disinfection

For isolator applications of prime importance: The investigations on aseptic production, which show and verify how parenterals can be safely prepared in an isolator in cleanroom environments C or D. Another interesting recent research project was the design of an automatic disinfecting isolator airlock for fast and effective fumigation. This has found its way into the construction of our latest product for practice-oriented implementation in technology as our research goal. Thus, the newly developed isolator Claire® iso has state-of-the-art airlock technology with the ability to disinfect introduced material in less than 15 minutes.

Supported by:



on the basis of a decision  
by the German Bundestag



# QUALITY FROM GERMANY

## MADE IN GERMANY – QUALITY, RELIABILITY AND INNOVATIVE TECHNOLOGY FOR THREE DECADES

The prime goal of the new isolator concept was to make working simple and comfortable, to enable intuitive and practical operation and, at the same time, to further increase protection. Our engineers and designers have incorporated the ideas gained during the development of the new generation of Claire® safety cabinets in various development projects – and again form and function enter into a perfect symbiosis with the "Shield Design". Additionally, the latest isolator-specific results from our research were implemented. The combination of proven and new technology as well as the production and quality "Made in Germany" make this isolator something special- a premium product with high-end technology.



# CLAIRE® NEW

## CYTOSTATIC ISOLATOR DESIGN IN ACCORDANCE TO DIN 12980

Claire® iso is the most modern compact isolator with high-end design and convincing technology at the highest level. The solid negative pressure isolator has been designed to handle substances with toxic or CMR properties in line with the requirements of the new DIN 12980: 2017-05. Thus, it offers the highest level of personal and product protection according to the latest technology.

- Laminar air flow in the working room with GMP-compliant flow velocity between 0.36 and 0.45 m/s
- Workspace with a cleanroom class A according to EU GMP guideline or ISO class 5 according to EN ISO 14644-1.
- In a class C or D cleanroom environment, to maintain the necessary cleanroom cascade, it is possible to combine with pass-through airlocks and Claire® safety cabinets
- High quality glove-oversleeve combination with glove changing system, recommended every 30min when handling substances with CMR-properties
- Suitable for leakage test with glove testing devices, has to be carried out daily according to DIN 12980
- Setting for use as a overpressure isolator (sterile isolator) is possible



### Unique Filter Technology

*Compact HEPA cartridge filters for low noise and energy consumption and for particularly low-contamination filter change in airlocks and isolator*

# ISO – SETTING STANDARDS



## Touch Display

Intuitive operation and user-friendly menu navigation with screensaver mode for displaying all important parameters



## Modular Design

Base frame and airlocks modularly designed as stand-alone units. For easy transport and installation with a wide variety of possible combinations



## Independent airlock system

With its own fans and filter technology, completely independent of the isolator, electric window opening for airlock and isolator access



## Fast airlock fumigation

Optionally with fast, active fumigation to disinfect materials with peracetic acid (PES) or hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>)



## Protection Shield

The isolator takes over the award-winning "Shield Design" of the Claire® pro, which perfectly combines innovation in form and function.



## Innovative LED-Technology

In addition to the LED lighting of the workspace, lateral light bands visualize the current operating status and potential alarm, thus guaranteeing the highest level of safety in the laboratory.



## Ergonomics

Particularly quiet and bright operating conditions, individually adjustable work surface height and optimum legroom as required by DIN 12980.



## Integrated constant pressure test

leakage test for airlocks and isolator acc. to DIN 12980

## MODULAR DESIGN INDEPENDENT AIRLOCK SYSTEM

Special features of the new isolator concept Claire® iso are modular design and the independent airlock system. The base frame and the individual airlocks are designed as stand-alone units. Thus, not only transport, assembly and installation on-site is straightforward. The individual modules also fit together directly to a harmonious self-contained overall device with GMP-compliant joints without gaps. At the same time, there are so many possible combinations of several isolator units, with various airlocks and with Claire® safety cabinets.

The modular design goes so far that each airlock represents an independent containment. The self-contained airlock system is equipped with its own ventilation and H14-HEPA filter technology, which operates independently of the isolator. In addition, the system has two electrically operated window systems for access to the airlock and for transfer to the isolator

- 1 Modern Filtertechnology**  
H14 HEPA supply air filter and two H14 HEPA filter cartridges as the main filter
- 2 Ergonomic Access**  
Access to the airlock with electrical, vertical window opening for convenient loading and unloading, height x width: 320 mm x 540 mm, operation from outside of the airlock
- 3 Easy Transfer to Isolator**  
Transfer windows to the workspace open and close vertically, control via foot switch, clearance height 279 mm, width 376 mm
- 4 Transfer system**  
Practical push system for material transfer
- 5 Fast Disinfection**  
Fast fumigation for disinfecting materials and products. Process with peracetic acid (PAA) or hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>) possible
- 6 PAA-Method**  
PAA process with very fast cycle time less than 15 minutes, additional use of active carbon filter



Connection of airlock  
left or right side



## ISOLATOR TECHNOLOGY KEY FEATURES IN OVERVIEW

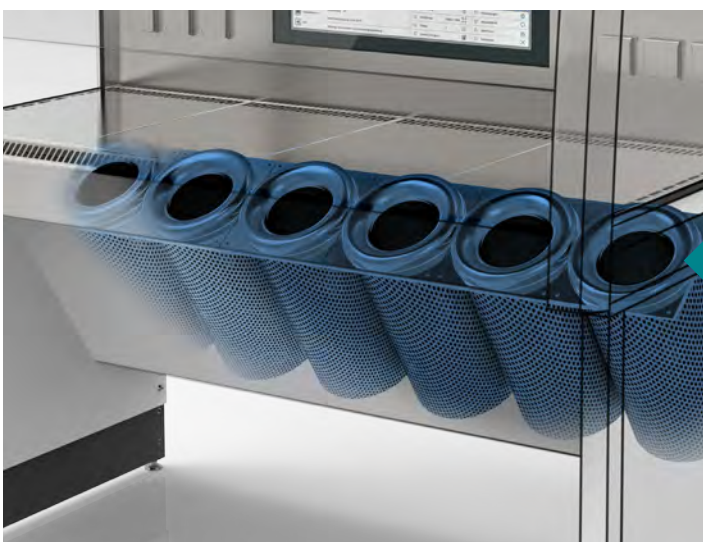
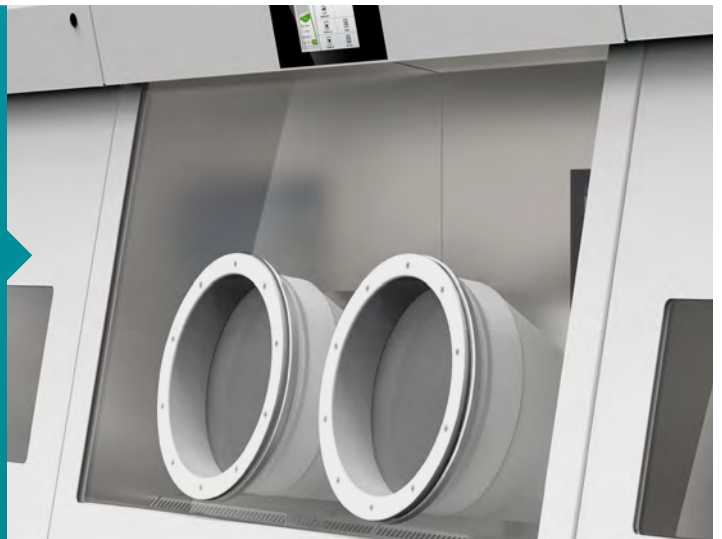


### Contemporary technology

- + Multifunctional touch display for easy, intuitive operation with user-specific access codes, individual user profiles and in many different languages
- + Main display with new screensaver function, in which the operating state of the airlocks, pressure cascade and airflows are clearly visible at all times
- + Energy efficient EC fans and LED lighting on the outside as a light band, without affecting the laminar airflow

### High quality access device

- + Isolator with two arm inlets, edging in front window made of highly resistant HD-polyethylene, diameter 300 mm
- + Innovative glove changing system that can be used during operation with guaranteed personal protection in case of glove loss
- + Option for using tested & certified protective cytostatic gloves by BERNER\*
- + Designed for leak testing with glove testing device (once a day according to DIN 12980)
- + Front window made of laminated safety glass, mounted on gas springs, opens easily and fully, securely lockable



### Unique filter technology

- + Isolator with six compact H14-HEPA main filter cartridges for safe and optimal low-contamination filter change
- + Filter elements fit into all standard 60L containers for easy disposal
- + Best ergonomics, maximum foot and leg room depth through 45° arrangement of the filter box
- + Maximum serviceability and cost-effectiveness during maintenance, individual filter cartridges can be checked quickly
- + Filter test connections (filter in/out) accessible from the outside.

\* "Double-gloving" is recommended to reduce the residual risk by perforation, preferably with different coloured gloves

## CONSTRUCTION AND INSTALLATION OF CLAIRE® ISO

### → Options

Many options are available for Claire® iso with a broad variety and for different applications e.g. the flush-mounted monitor integration into the rear wall. In principle, this is the same range of equipment as our Claire® pro series of safety cabinets.

Information on other options available on request. You are welcome to contact our partners' sales staff for advice, a site visit may also be possible.

### → Premium quality

The interior work space has a first-class and solid finish, is made entirely of stainless steel and safety glass, durable, resistant, virtually joint-free and easy to clean. All components, options or modifications of the isolator are implemented by our qualified employees in the design and production department with the highest quality standards.

### → Low and flexible overall height

During planning and installation, weight and size should be kept in mind. The empty weight of an isolator combined with two airlocks is approximately 775 kg, the width 2700 mm and the height is 2,210 mm. If required, our partners' service engineers will gladly assist you in assessing the installation options.

### → Transport & installation

Transport and installation is carried out by our trained logistics partners or our partners' own service engineers. Again, an on-site examination of the access routes may be useful. The modular design of Claire® iso makes it simple and offers so many possibilities. The safety cabinet or airlocks and base frame can be transported separately from the base. Further partial disassembly, up to complete on-site construction are also an option.

**Airlock left**      **Claire® iso**      **Airlock right**  
Article-No. 204005    Article-No. 204000    Article-No. 204006



Safety cabinets from Berner International meet the highest quality requirements and undergo a comprehensive test program before being delivered to the customer. We also offer intensive commissioning, maintenance and other services by our certified staff or our sales partners. From product development through production to commissioning in your laboratory and beyond- quality "Made in Germany".

**Berner Safety Hotline: +49 4121 4356-0**  
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# TECHNICAL INFORMATION FOR CLAIRE® ISO

## General data

Device	Laboratory device
Device type	Isolator for cytostatics (negative pressure) or Sterilisolator (pressure)
Standards	DIN EN ISO 14644-7; VDI 2083 page 16; DIN EN 12469; DIN 12980
Standards	CE
Quality management	DIN EN ISO 9001:2008

## General technical data

Nominal illuminance	0–1.200 lux
Vibration (RMS) on the worktops	≤ 5µm

Mechanical data (in mm)	Claire® iso I-3-130	Air lock
Sizes, outside (WxHxD)	1.332x2200x925	677x2200x925
Work room (WxHxD)	1.260x640–700x600	ca.540 x400x600
Usable work surface (WxD) [1]	1.217x445	ca.460 x 445
Work surface height	773	773
Weight	ca. 395 kg	ca. 190 kg

## Material-specific data (housing)

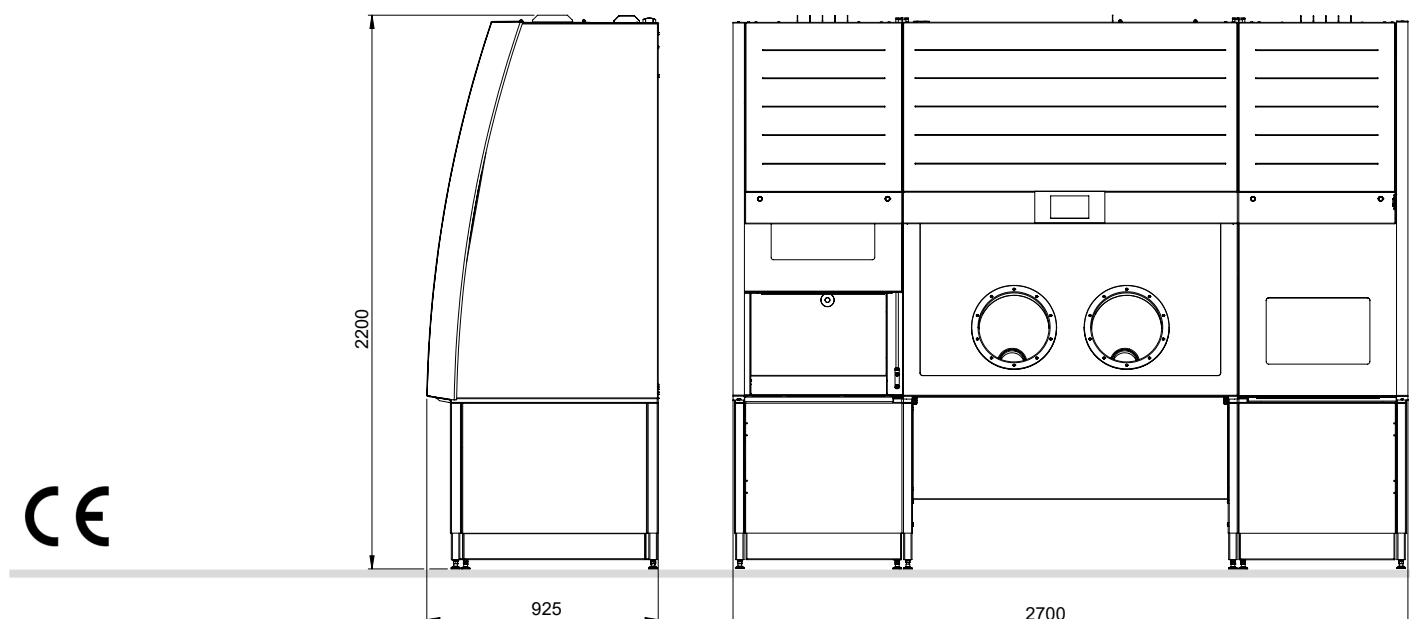
Material of work area	1.5 mm thick stainless steel “V2A”, material no.: 1.4301
Surface quality of work area	320 grind, medium roughness $R_a \approx 1,6 \mu\text{m}$
Housing material	Powder-coated 1.5 mm thick Zincor steel plate, material no.: 1.0330
Front-, side and rear panels	Multi-layer safety glass with intermediate film to absorb UV radiation
Powder coating colour	White RAL 9003 matt; black RAL 9005 matt

## Electrical data

Nominal voltage/ nominal frequency	230 V AC / 50 Hz
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## Technical air data (“3-Filter-System”)

Exhaust and supply air volume flow	ca. 375 m³/h total
Displacement flow velocity	ca. 450 m³/h
Filterclass(s) with recirculation and exhaust air filter	Min. H 14 (separation efficiency [2]: $E \geq 99,995\%$ ), in accordance with EN 1822-1 [3]
Cleanroom class in the work area	EC-GMP-guide: class A; DIN EN ISO 14644-1: ISO-class 5
Low turbulence displacement flow	0,36–0,45 m/s



[1] without the air inlet openings in front, back or sideways

[2] Integral retention level at the minimum or with maximum penetration at the so-called Most Penetrating Particle Size (MPPS)

[3] Values determined acc. to ISO 14644-3



\* Awards were given to a model version of Claire® pro

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