TIMOTEC



Timotec Reinraumtechnik a.s.

# Isolator for Cytotoxic Drug Preparation

Protection | Aseptic Safety | Custom Design



# Together We Create **Individual Solutions**

QUALITY | EXPERIENCE SINCE 2004 | FLEXIBILITY | PARTNERSHIP

# Laboratory Isolator for Cytotoxic Drug Preparation



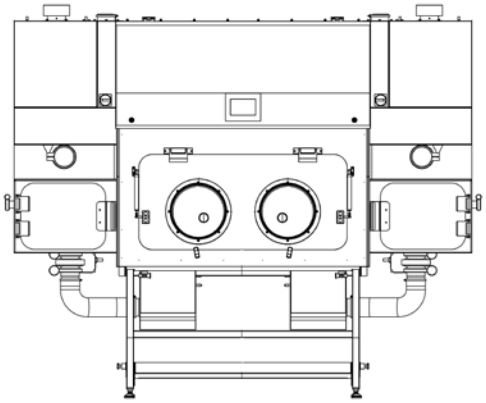
**The laboratory isolator is designed to ensure personnel protection when handling hazardous materials, particularly during the preparation, dilution and dosing of cytotoxic drugs in hospital pharmacies.**

Its Class A cleanliness and laminar airflow within the working chamber also ensure product protection and maintain the required conditions for safe preparation.

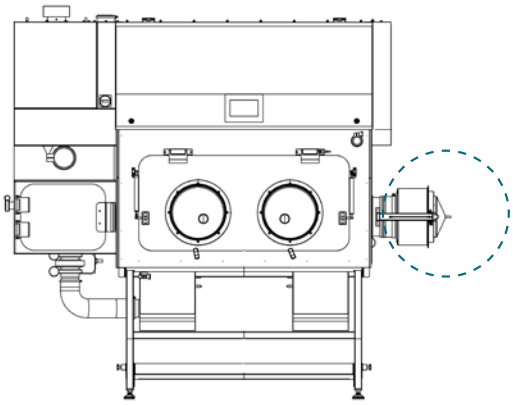
**Preparation of Cytotoxic Drugs**

**Handling of Hazardous Materials**

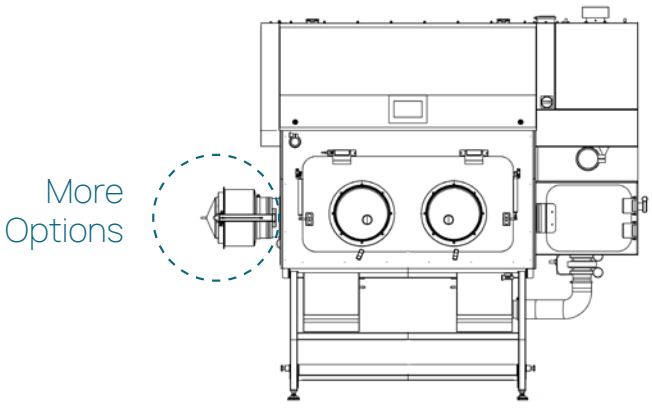
# Isolator Configuration Options



Isolator with **2 sleeves** and **2 airlocks**




Isolator with **1 left airlock** and **2 sleeves**




Isolator with **1 right airlock** and **2 sleeves**

# Isolator Configuration Options

**Airlock | Incubator | RTP port | Continuous liner | Passive airlock | Cover**





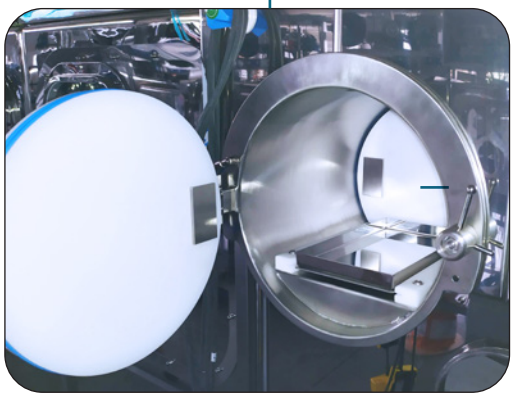
Airlock



RTP port



Continuous liner



Passive airlock

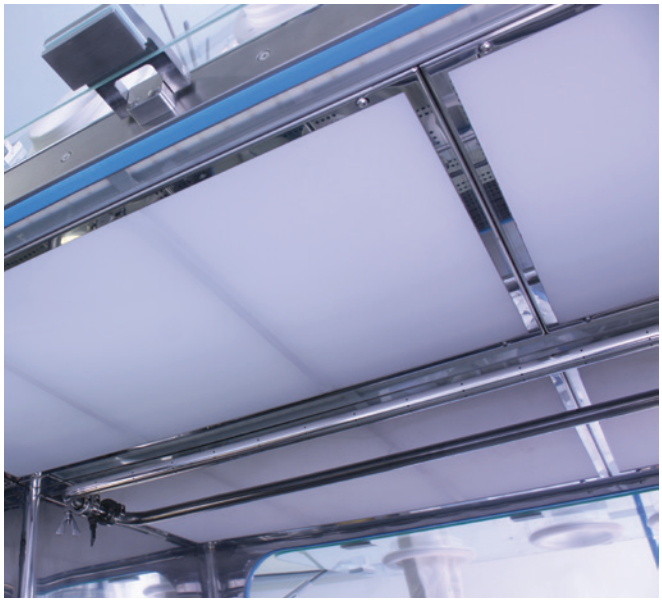


Cover

# Chamber Design & Construction

- **Chamber housing made of AISI 304 stainless steel, 3 mm thick.**
- Internal and external chamber surfaces with a vibrated finish, Ra max. 0.8 µm.
- Powder-coated structural steel upper housing.
- AISI 304 stainless steel support frame.
- Main chamber equipped with two glove ports
- Circular glove flanges, 300 mm in diameter, made of POM-C.
- **One sliding shelf in the transfer chamber**. Sliding shelf made of AISI 316L stainless steel with POM-C sliding plate.
- Integrated LED lighting.
- Adjustable support feet.





# Safety, Containment & Air Handling

- Electronic regulation of pressure differentials and air exchange rates.
- **Hydrogen peroxide ($H_2O_2$) distribution system for decontamination.**
- Dedicated exhaust air connection with pressure relief protection.
- Integrated pressure, temperature, humidity and airflow sensors.
- Red LED warning indication for fault conditions.

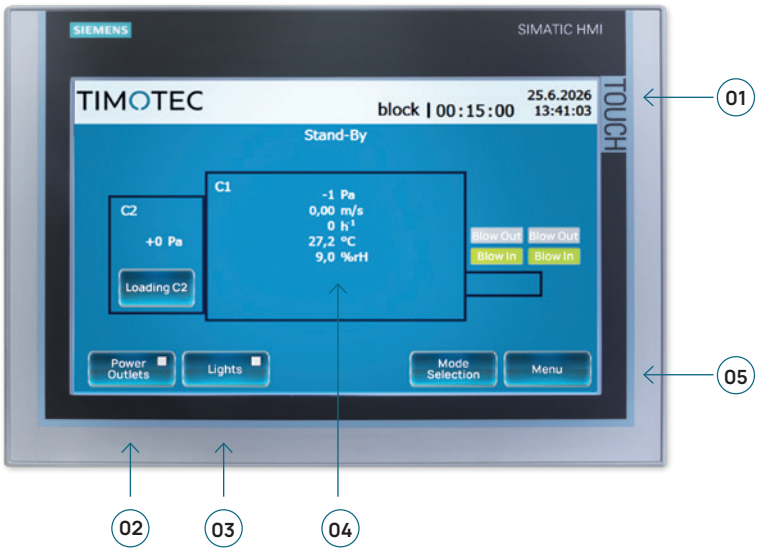
# Control System & Operation

The isolator is equipped with an integrated Siemens SIMATIC PLC-based electronic control system, designed to control, manage and regulate all operating modes and emergency conditions of the entire isolator workstation. The system is operated via a colour HMI touchscreen panel, located in the upper structure above the chambers. The intuitive interface provides access to operating functions, process data, system status and fault messages.

**The control system provides the following functions:**

- Electronic control of operating modes and chamber pressure differentials
- Real-time monitoring of chamber pressure
- Monitoring of air exchange rates
- Temperature and humidity monitoring
- Monitoring of laminar airflow velocity
- Historical trend visualisation of operating parameters
- Alarm notifications and alarm history
- Configurable operating parameters for individual chambers
- Automatic lighting control according to the selected operating mode
- Dedicated operating modes, including Working, Standby, Transfer, Ventilation and Decontamination
- Integrated leak-tightness testing function
- Foot switch operation for convenient material transfer
- User access management with different permission levels

## HMI Panel




### Overview of Functions

01 User login and automatic log-off countdown timer

02 Socket control icons

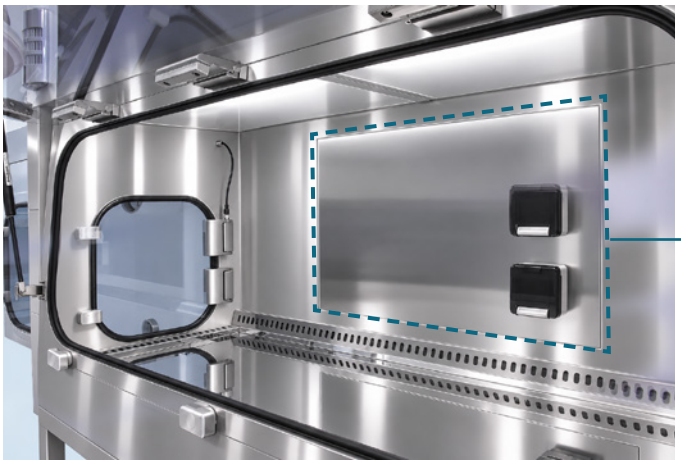
03 Illumination control icons

04 Chamber interior physical values measurement display

05 Device operation modes menu, Alarms and Settings menu

# Wide Range of Options for the Rear Integrated Panel

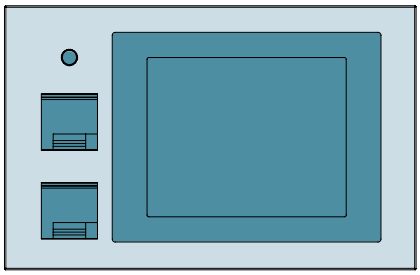
The interchangeable rear panel allows accessories to be integrated according to customer requirements. Customers can choose between a standardised panel design and a fully customised, tailor-made solution.



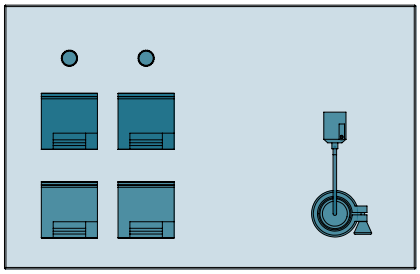
## The rear integrated panel can be equipped with

- Shelf
- More energy and environment
- UV-C lamps
- Microbiological monitoring
- Weighing terminal with display
- Electric sockets
- Inert gas
- Isokinetic probe
- Ethernet

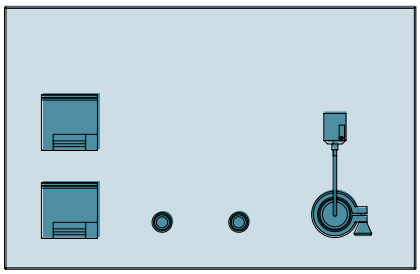
## Rear Panel Configuration Examples



Two electric sockets, Ethernet, Display



Four electric sockets, Isokinetic probe



Two electric sockets, Inert gas, Isokinetic probe

# Optional Equipment

### Weighing scale
Optional integration of any type of weighing scale and terminal.

### Bar-code reader
Integration of a bar-code reader.

### LCD screen
The rear wall of the working chamber can be equipped with an LCD screen, while applications for the dilution of cytostatic can be accessed on a built-in PC.

### $H_2O_2$ decontamination
Sterilization can be performed using vaporised hydrogen peroxide. These vapours are generated by an additional external device – Puriter (our hydrogen peroxide vapour generator).

### Additional equipment and media connection
Interchangeable rear wall and options to integrate additional equipment (incubators, an LED screen, balance and weighing terminal, etc.) or include a media connection.

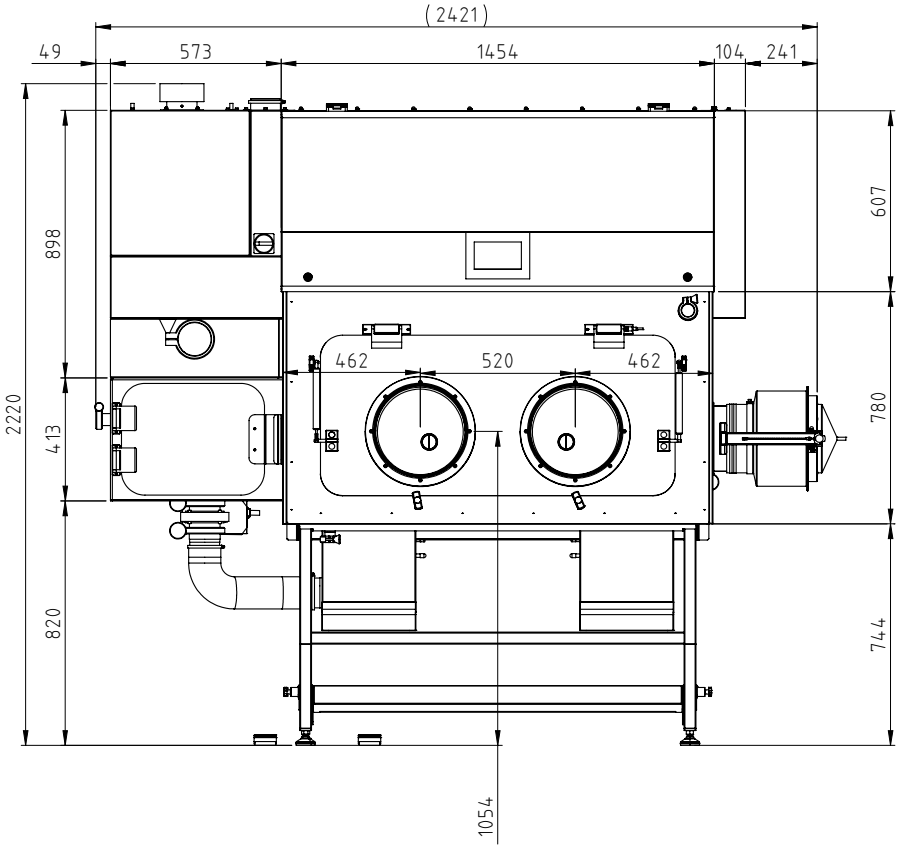
### Accessories
The rear panel can be fitted with wire trays, hangers and other accessories made of AISI 304 stainless steel.

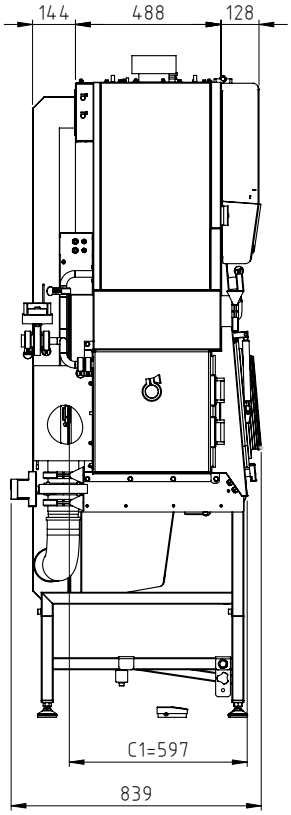
### Independent UPS power supply
An independent UPS (Uninterruptible Power Supply) can be installed inside the isolator. In the event of an interruption in the supply of electricity, short-term operation is maintained through a power supply in the isolator so that the process and the environment may be secured.

### Glove holder
Holders for gloves are utilised in isolators where sterilisation with vaporised hydrogen peroxide is used.



# Dimensions & Technical Specifications

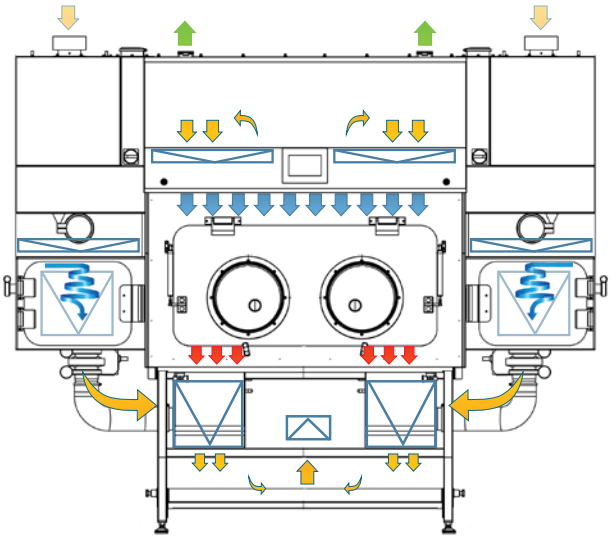



| Parameter | Specification |
|---|---|
| Width | 2421 mm |
| Height | 2220 mm |
| Depth | 839 mm |
| Gloves position | 1054 mm |
| Number of main chamber | 1 |
| Number of transfer chamber | 1-2 |
| Number of sleeves | 2-4 |
| Leakage tightness class | Class 3 according to EN ISO 10648-2 |
| Main chamber cleanliness | EU GMP Class A |
| Transfer chamber cleanliness | EU GMP Class B |
| Main chamber airflow | Laminar |
| Transfer chamber airflow | Turbulent |
| Filtration | HEPA H14 |
| Main chamber pressure | −200 ± 45 Pa |
| Transfer chamber pressure | −15 Pa |
| Electrical supply | 230 V / 50 Hz |
| Total connected power (model with 1 transfer chamber) | 3.79 kW |

# Laminar Flow in Main Chamber, Turbulent Flow in Transfer Chamber

Laminar flow is used for "A" class cleanliness when **unidirectional airflow must be ensured in a vertical orientation**. A laminar frame is used to direct the flow— it is comprised of a special very finely perforated fabric. The velocity of laminar flow produced by the isolator technology amounts to 0,45 m/s ±20%. **HEPA filters** (H14), with an efficiency of 99.995% are used to filter incoming and outgoing air. This system is often coupled with air re-circulation inside the chamber.



Fresh air

Hepa H14 filtered air

Filtered exhaust air

Fresh air + Circulating air

Contaminated air

Hepa H14 filter

# Negative Pressure

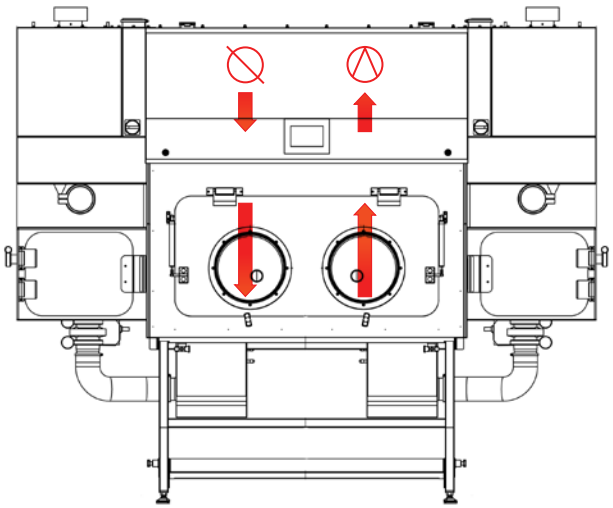
An HVAC system allows for the formation of negative pressure inside the isolator. This function is mostly used in case of isolation failure - compromised leak-proofness - and **assists in protecting personnel.**

Another level of protection for critical points in the process is the creation of a **pressure cascade**, so that the vicinity where the dangerous substance is handled is in the location with the highest negative pressure. This minimizes the risk for contamination of other chambers or the surroundings.

In order to prevent damage to the equipment caused by insufficient pressure a **pneumatic valve** is used for device protection. This protective function prevents the pressure from dropping even further thus saving the technology from damage.

Damper flap

Fan



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