TIMOTEC

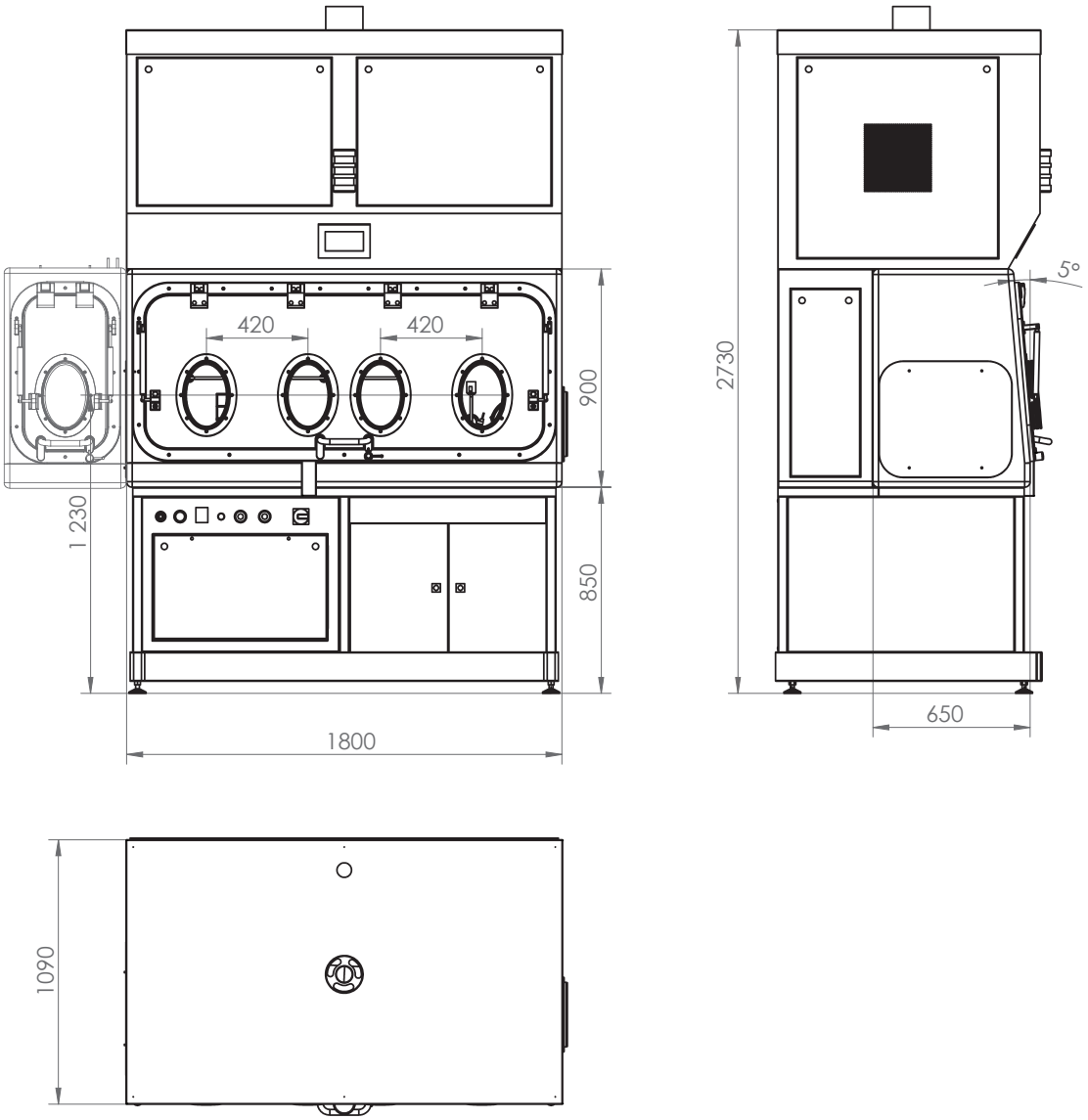


Timotec Reinraumtechnik a.s.

Sterility Test Isolator

Suitable for sterility testing and product protection

Dimensions Sterility Test Isolator



Sterility Test Isolator

Dimensions in mm - Sterility test isolator	
Width	1800
Height	2730
Front height	1750
Depth	1090
Working plate height	940
Gloves position*	1230*
Usable space depth	650

*Adaptable on request

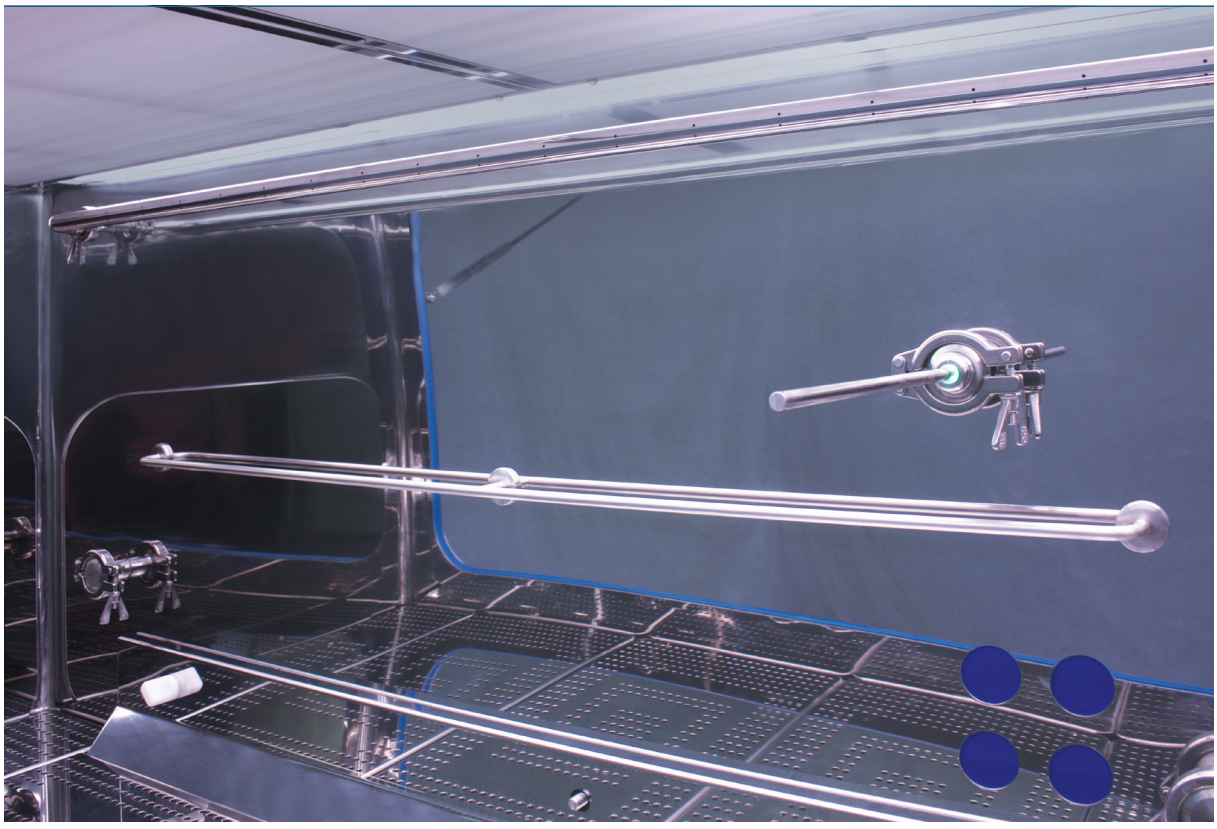
Dimensions in mm - Working chamber	
Width	1800
Depth	650
Height	900
Working chamber total volume	1,05 m^3

Dimensions in mm - Airlock	
Width	550
Depth	650
Height	900
Airlock total volume	0,3 m^3

Description

This isolator provides a high degree of product protection being handled in aseptic conditions. The main task is performed in the working chamber where sterility testing of final products occurs.

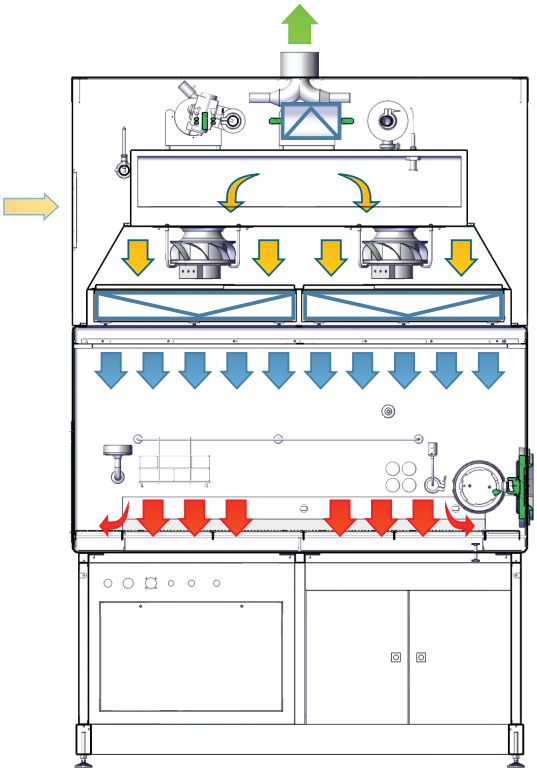
- Single-chamber isolator for sterility testing
- Chamber with 4 sleeves for work with sterile materials
- Airlock for material loading with an option for sterilizing with H_2O_2
- Leak tightness class 3 according to ISO 10648-2
- "A" class cleanliness according to EU GMP "Audit Trail" Compliant
- Option to decontaminate with H_2O_2
- Electronic control system for automatic adjustment of basic operating modes managed by Siemens PLC
- Colour touchscreen control
- Jacket material: stainless steel AISI 304
- Chamber material – AISI 316L with a thickness of 3.00 mm
- Polished surface finish, Ra < 0.6 µm
- Positive pressure mode
- Laminar flow 0,45 m/s ±20%
- Inlet filtration HEPA H14 - "A" Class cleanlinnes
- Easy-to-clean inner and outer surfaces
- Sliding trays in Airlock for easy material transfer (applicable with airlock)
- Oval holes with gloves for improved material handling



Laminar Flow

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 – 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
- Fresh air + Circulating air
- Hepa H14 filtered air
- Contaminated air
- Filtered exhaust air
- Hepa filter

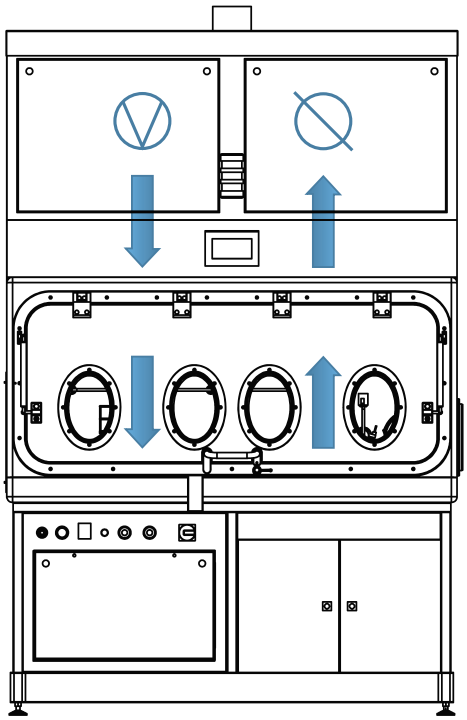


Positive Pressure

The HVAC system allows for the formation of positive pressure in the interior of the isolator. This function is mostly used in case of a failure - compromised leak-proofness - and helps protect products.

In order to prevent damage to the equipment caused by insufficient pressure a pneumatic valve is used. This protective function prevents the pressure from dropping further, protecting the technology from damage.

- Damper flap
- Fan



Standards



Working chamber 03

HMI panel 06

Service panel 08

F5 Pre-filter 12

Temperature and humidity sensor - Rotronic
Used for monitoring critical parameters and/or to control a decontamination process. Rotronic is an accurate and high-quality product resistant to hydrogen peroxide vapors.

Pressure sensor with analogue output

Cable glands
Cable glands are mounted in the rear isolator wall.

Equipped for microbiological monitoring – DN 1" clamp

Equipped for an ISO kinetic sensing unit – DN 10 clamp

Built-in LED lights
Built-in LED lights ensure illumination levels of at least of 500 lux in the workspace.

Cross-bar for hanging rack

Pressure fuse
The pressure fuse serves as a safety element indicating increased pressure in the chamber. In the event that the assigned pressure in the chamber is exceeded a pneumatic flap valve is opened and the pressure value is decreased without deterioration of internal atmosphere.

Safety glass
We use tempered safety glass for the front windows and ports of our equipment. This glass has improved mechanical properties and is durable. When damaged it forms small chunks which reduce the risk of injury from cuts.

Safe replacement of sleeves
Our glove / sleeve flanges have two grooves. The first for sealing the glove and the second for an o-ring. This design conforms to standard procedure for the safe replacement of gloves.

Standards

Visual and acoustic alarm



A beacon light and an acoustic alarm providing a quick audible and visual assessment of operation and failure states for the user.

Front window



Inflatable sealing safety glass fitted with sleeved flanges and sensors for monitoring safe window closure. A gas spring is used for easy opening.

Panel for connection of an external H_2O_2 generator (Puriter)



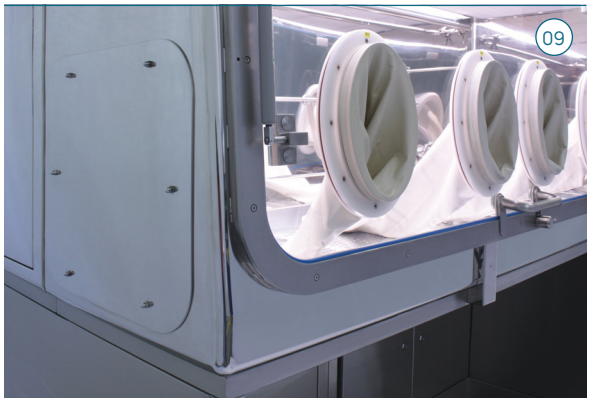
This isolator can be sterilised with hydrogen peroxide vapours. These vapours are generated by an additional external device – Puriter (hydrogen peroxide vapour generator). Coupling clamps are located on the rear and bottom sides of the isolator.

Clamp pro connection of a ball valve or waste piping



For outlet of liquid waste originating from sterility testing. Connection to a collecting tank or central waste.

Ready-equipped for an Airlock



Sensors for monitoring safe window closure



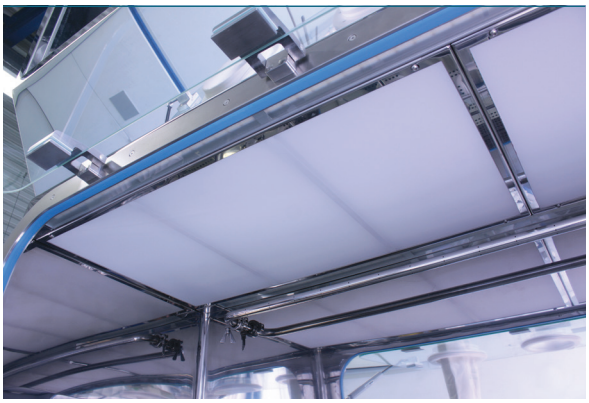
Standards

Equipped for an RTP (rapid transfer port)



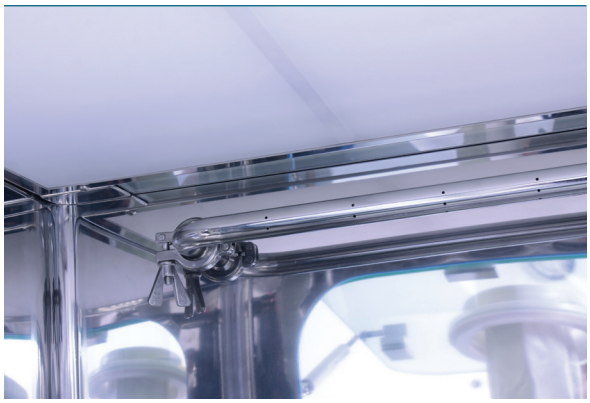
The site for the RTP is placed on the chambers right wall. Option to integrate an RTP alpha port and beta container for sterile transfer of materials.

Laminar frame



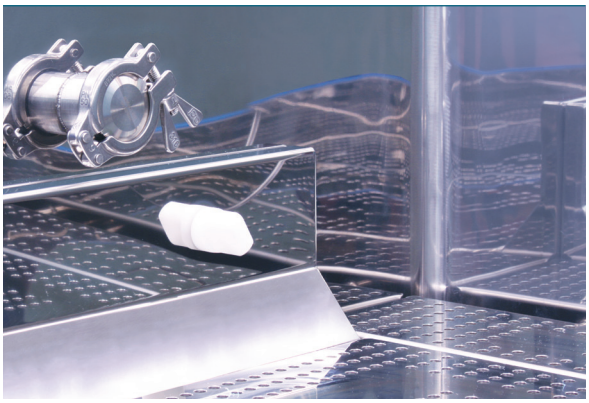
The chamber ceiling is fitted with a laminar frame for producing laminar flow, and includes built-in LED lights. Inlet HEPA filters are situated above the laminar frame.

Distribution pipe for H_2O_2



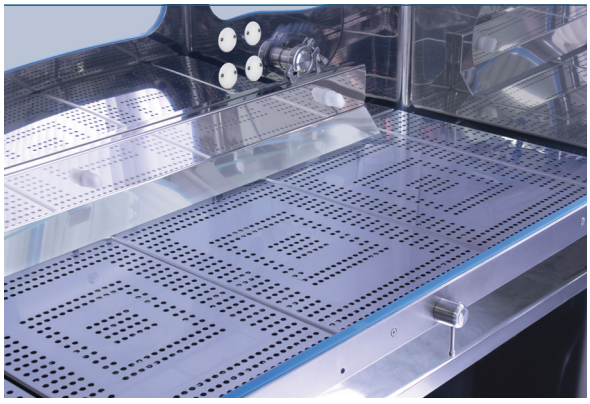
This isolator can be sterilised using hydrogen peroxide vapours. A uniform distribution of vapour is achieved using a perforated pipe installed through the whole length of the chamber.

Rounded edges/corners inside the chambers



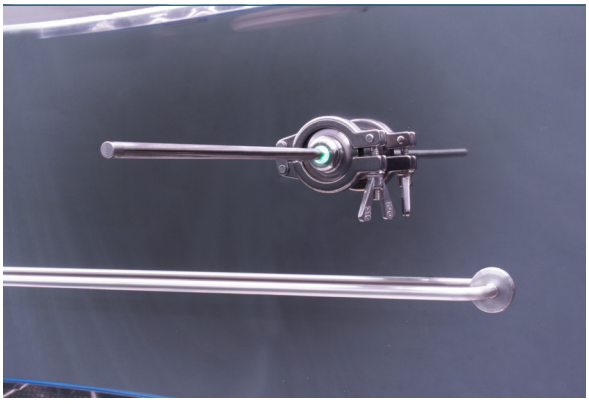
Rounded corners and highly polished surfaces allow for easy cleaning of the chamber. The chambers are seal-welded which guarantees their leak tightness.

Perforated grates



The worktop is equipped with 6 perforated grates. The grates can be fitted with a device for sterility testing.

Velocity sensor for laminar flow - SCHMIDT®



HMI panel

This isolator control system is operated with a Siemens colour touch screen. The Simatic control system from Siemens together with a foot operated switch creates an intuitive and user-friendly experience. The screen displays the actual parameters of the environment and monitors emergency statuses. The system includes remote access for customer service support. As required, it is possible to implement connection to an additional device for production data storage and export.



Overview of Functions

- 01 User login and automatic log-off countdown timer
- 02 Illumination control icons
- 03 Chamber interior physical values measurement display
- 04 Device Operation modes menu, Alarms and Settings menu

Options

H_2O_2 decontamination
This isolator can be sterilised with vaporized hydrogen peroxide. Vapours are generated by an additional external device – Puriter (hydrogen peroxide vapour generator).

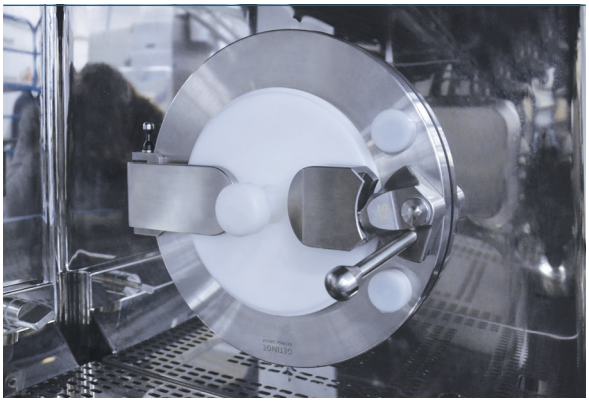
Wire trays & accessories
The rear panel can be fitted with wire trays and hangers made from AISI 316L.

Power supply sockets for additional equipment
Sockets are placed on the rear wall of the isolator. Sockets are operable from the control display. Sockets available in all country variants.

Steritest Symbio ISL
Located on the right portion of the chambers worktop.



RTP (rapid transfer port)
The site for the RTP is placed on the chambers right wall. Option to integrate an RTP alpha port and beta container for sterile transfer of materials.



Glove Holder

Airlock
- Sliding tray
- Connecting clamp for Puriter and H_2O_2 distribution nozzle
- Humidity and temperature measuring sensor – Rotronic
- Schmidt speed sensor for laminar flow
- Equipped for microbiological monitoring – DN 1"clamp
- Equipped for ISO kinetic sensing unit – DN 10 clamp

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TIMOTEC processes with TÜV SÜD certification:

ISO 9001:2015

ISO 14001:2015

ISO 45001:2018 (OHS)

06-2021