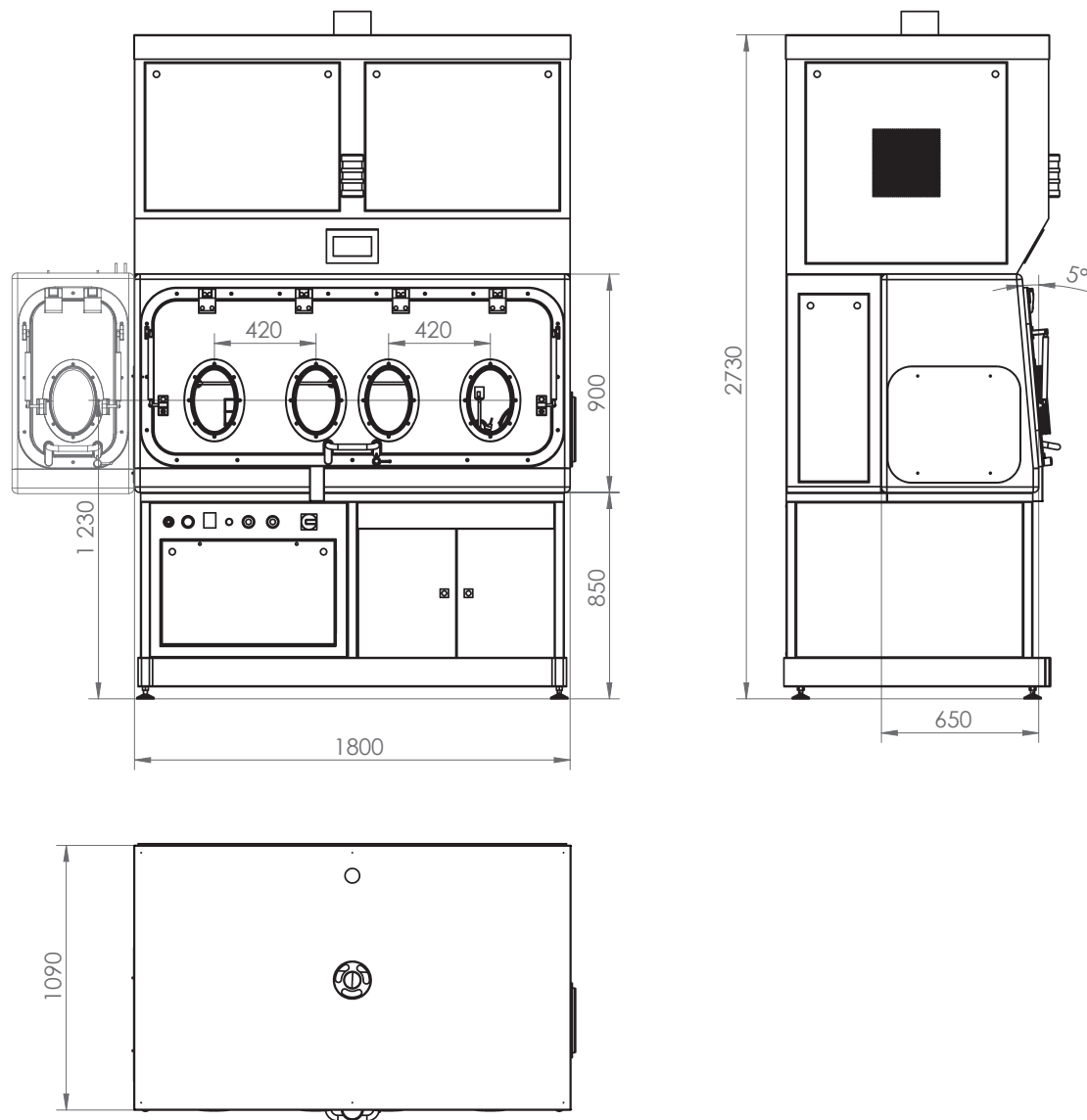


# Sterility Test Isolator

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

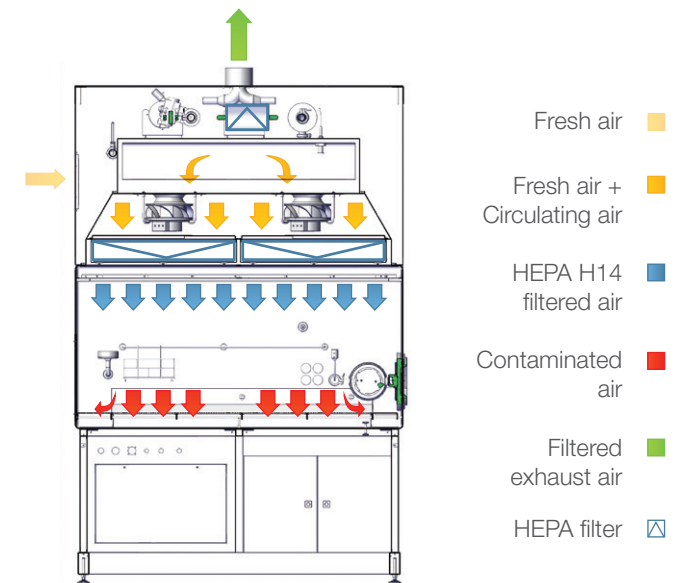
Width	1800
Depth	650
Height	900
Working chamber total volume	1,05 m <sup>3</sup>

### Dimensions in mm - Airlock

Width	550
Depth	650
Height	900
Airlock total volume	0,3 m <sup>3</sup>

## Laminar Flow

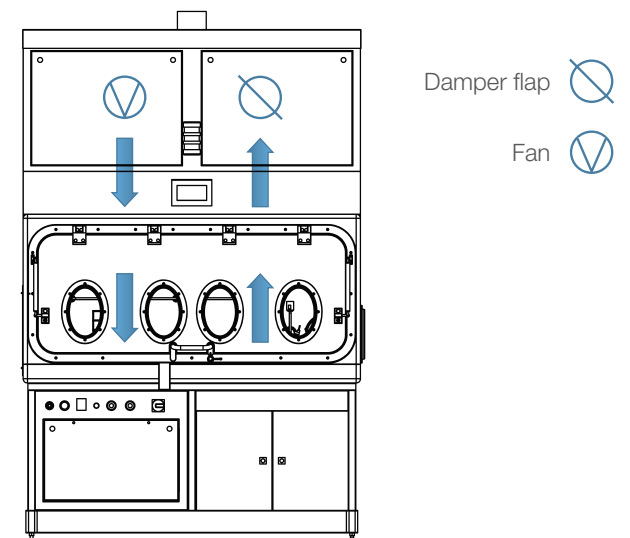
Laminar flow is used for "A" class cleanliness when unidirectional airflow must be ensured in a vertical orientation. A laminar frame is used to direct the flow – comprised of a special very finely perforated fabric. The velocity of laminar flow produced by the isolator technology amounts to 0,45 m/s ±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.



## 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.



## 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
- Possible to add airlock chamber and provide sterilization with  $H_2O_2$

## Features

- 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,  $Ra < 0.6 \mu m$
- Positive pressure mode
- Laminar flow  $0,45 \text{ m/s} \pm 20\%$
- Inlet filtration HEPA H14 - "A" Class cleanlines
- 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

## Standards



- 01 Visual and acoustic alarm
- 02 HMI panel
- 03 Working chamber
- 04 Main switch
- 05 F5 Pre-filter
- 06 Front window
- 07 Clamp for connection of a ball valve or waste piping
- 08 Equipped with a connection for a RTP (rapid transfer port)
- 09 Equipped with a connection for an airlock
- 10 Panel for a connection to an external  $H_2O_2$  generator (Puriter)
- 11 Service panel
- 12 Sensors for monitoring safe window closure

## HMI panel



## 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

## Description

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.

## 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.

### 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.

### Panel for connection of an external H<sub>2</sub>O<sub>2</sub> 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.

### Ready-equipped for an Airlock

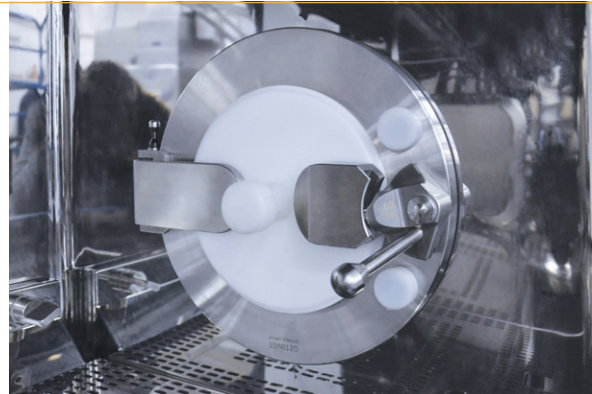


### Sensors for monitoring safe window closure



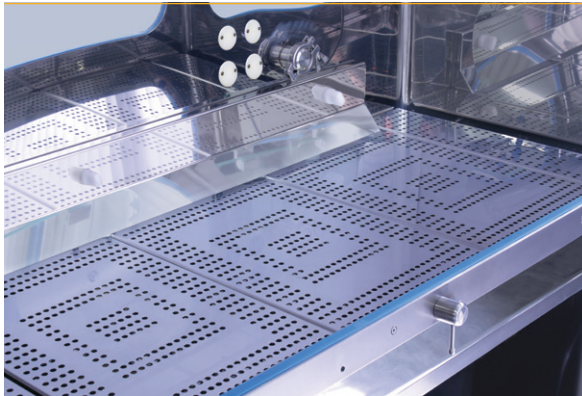
## Standards

### Equipped for an RTP (rapid transfer port)



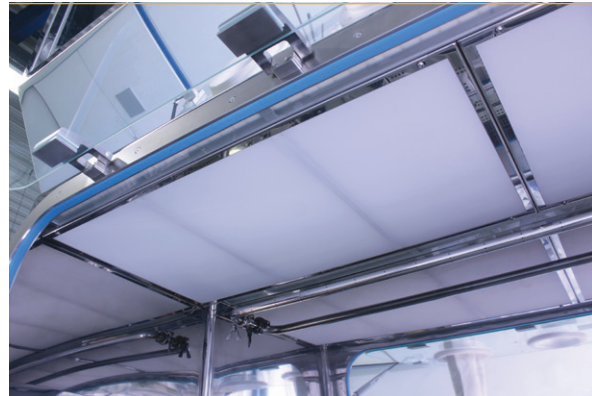
Option to integrate an RTP alpha port and beta container for sterile transfer of materials. Chamber's right wall is prepared for integration of the equipment.

### Perforated grates



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

### Laminar frame



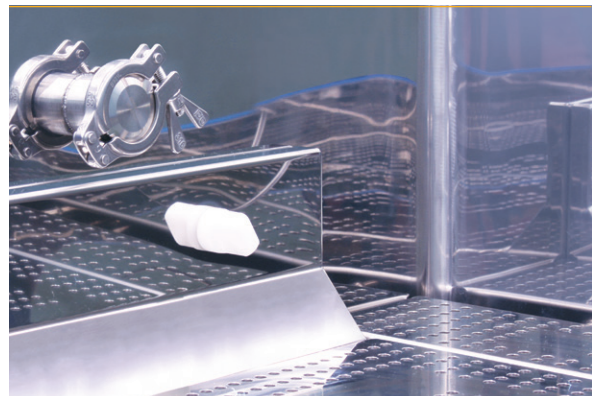
The chamber ceiling is fitted with a laminar frame for producing laminar flow, and includes built-in LED lights. Inlet HEPA filters are situated above the laminar frame.

### Distribution pipe for H<sub>2</sub>O<sub>2</sub>



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.

## Standards

- **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.
- **Velocity sensor for laminar flow - Schmidt**
- **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**

## Safety Features

- **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.

## Options

- **Steritest Symbio ISL**
  - Located on the right portion of the chamber's worktop.



- **H<sub>2</sub>O<sub>2</sub> 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 stainless steel.
- **Glove Holder**
  - For positive pressure isolators not in operation so that the gloves do not extrude into the space in front of the isolator.
  - For isolators where sterilization with a hydrogen peroxide vapour generator is used.
- **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.
- **RTP (rapid transfer port)**
  - Option to integrate an RTP alpha port and beta container for sterile transfer of materials. Chamber's right wall is prepared for integration of the equipment.
- **Airlock**
  - Sliding tray
  - Connecting clamp for Puriter and H<sub>2</sub>O<sub>2</sub> 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