



The Optimum Aseptic Containment Solution for Pharmaceutical Industry

## **ASEPTIC ISOLATION TECHNOLOGY**



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## Aseptic Isolation Technology

This technology is a fast-growing trend among first-class pharmaceutical and biotechnology companies around the world. Today, the use of isolators has become standard practice for sterility testing.

Aseptic isolator system is a set of integrated system which providing a controlled clean environment to ensure product safety or operator safety. Its performance characteristics are mainly reflected in the integrity of the sealing system, the effectiveness of the surface sterilization procedure, the ability to maintain the aseptic state and so on.

## Application

- Sterility Testing Isolator
- Production Isolator

## Application case

### Microbial laboratory-Medicine QC research department

△Sterility test for sterile preparation and sterile raw material. It is recommended product by ChP, USP, EP and JP, avoiding appearing false positive result in the test.

### Aseptic production workshop-pharmaceutical industry

△Aseptic subpackage, aseptic sampling, aseptic dosing, aseptic weight and other aseptic production process. Isolated operator from the product, effective protect the product when producing.

△Toxicity and highly allergenic workshop-Pharmaceutical Industry

△Special product have the risk of dangerous for operator during the production, such as Hormone products, penethamate.



Production Isolator



QC Inner sterility test pump



RTP Transfer system

## Sterility test Isolator

Sterility test Isolator is a type of integrated containment system designed for large volume sterility testing. It can be customized for suitable working area to accommodate various batch sizes and process flows. It is normally composed of stainless steel and toughened glass matched with suitable glove port for person operation. And it can reach Class A inside when operation.

Integrated system is full automatic control by PLC system

Complies with GMP, EP, USP, CP

According to GMP, the sterility test is allowed to be made in the sterility test isolator which is installed in the Class D background.

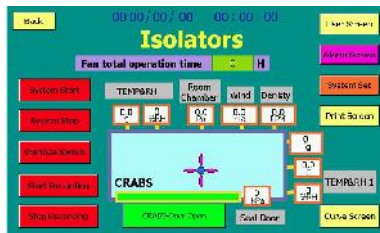
## Feature



### Smooth interior

Smooth flushed interior of isolator glazing means less crevices to improve clean ability / decontamination.

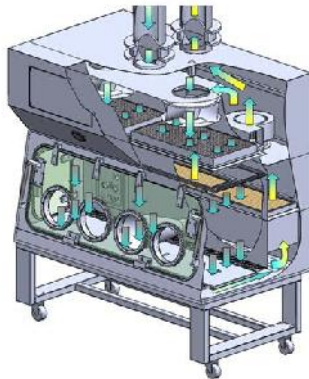
Main material: Polypropylene/SS304 and Tempered glass



### Integrated Siemens PLC control system

The operation information of each parameter will be displayed on the display screen by data or curve, such as: airtightness, temperature, humidity, H2O2 concentration, wind speed, etc., for easy observation.

Access control by password at 4 levels.



### Air flow and HEPA

Adopts vertical unidirectional flow, air will pass through the primary effect filter to pre filter large particles of dust particle. After air being pre-treatment, it goes through the HIEPA H14 (filtration efficiency: 99.995%) via the centrifugal fan which provided with pressure so that it can meet the requirements of clean. Clean air is sent to the air supply unit, through the wind distributing plate, forming a vertical uniform



### Integrated Hydrogen Peroxide Fogging Technology

It is controlled by PLC system.

Adopts 30-35% food grade Hydrogen Peroxide solution.

Sterilization: the ability to kill stearothermophilus spores reaches 6-log.

## Main Technical Parameter

Technical Parameter	Description
Cleanliness of working area	Class A
Wind speed	0.36-0.54m/s, adjustable
Pressure difference during sterility test step	20-50Pa
Sterilization method	H2O2 fogging technology
H2O2 sensor	Integrated with temperature and humidity
H2O2 concentration measuring range	0-2000ppm, display as curve graph
Residual allowable limit	Less than 1ppm
Air flow direction	Uniflow
Air in and Air out	HEPA H14 (filtration efficiency: 99.995%)
Touch screen	Siemens 9 inches
Control system	Siemens PLC
Input & output	Siemens
Noise	≤65dB(A)
Steritest pump	≤270rpm
Air source	Clean compressed air
Glove holder	Available
Sample rack	Available
Illuminance	Available
Real time printer	Available
Alarm	Available
Emergency switch	Available
Reservation port for air sampler	Available
Reservation port for particle counter	Available
Data integrity and safety	21CFR Part 11 compliance

## Options

Air Sampler, Particle Counter  
 Portable concentration sensor for operator safe  
 Integrated glove integrity tester  
 Chemical indicator

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## Wearing parts

Glove  
 Sealing strip for glove  
 HEPA  
 Chemical indicator

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