

ISO TECH

D E S I G N



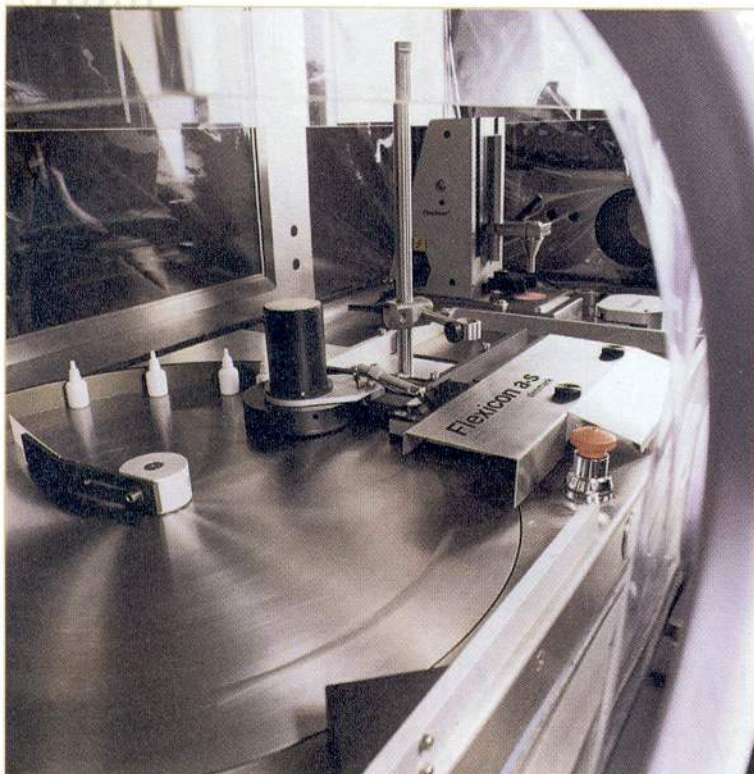
BARRIER ISOLATION TECHNOLOGY
FOR STERILITY TESTING, ASEPTIC FILLING
& CONTAINMENT PROCESSING

IsoTech Sterility Testing, Aseptic Filling & Containment Isolators

Provide barrier isolation technology for contamination control, sterility assurance and containment management.

STERILITY TESTING: Eliminate the risk of a false positive sterility test

Up until recently, most pharmaceutical, biotech & medical devices companies were using laminar airflow hoods in cleanrooms to perform sterility testing of their products. In such settings, the average false positive rate is typically higher than 0,25% per year. This results in high costs associated with investigating possible causes and could require that the batch be quarantined and/or sometimes rejected.



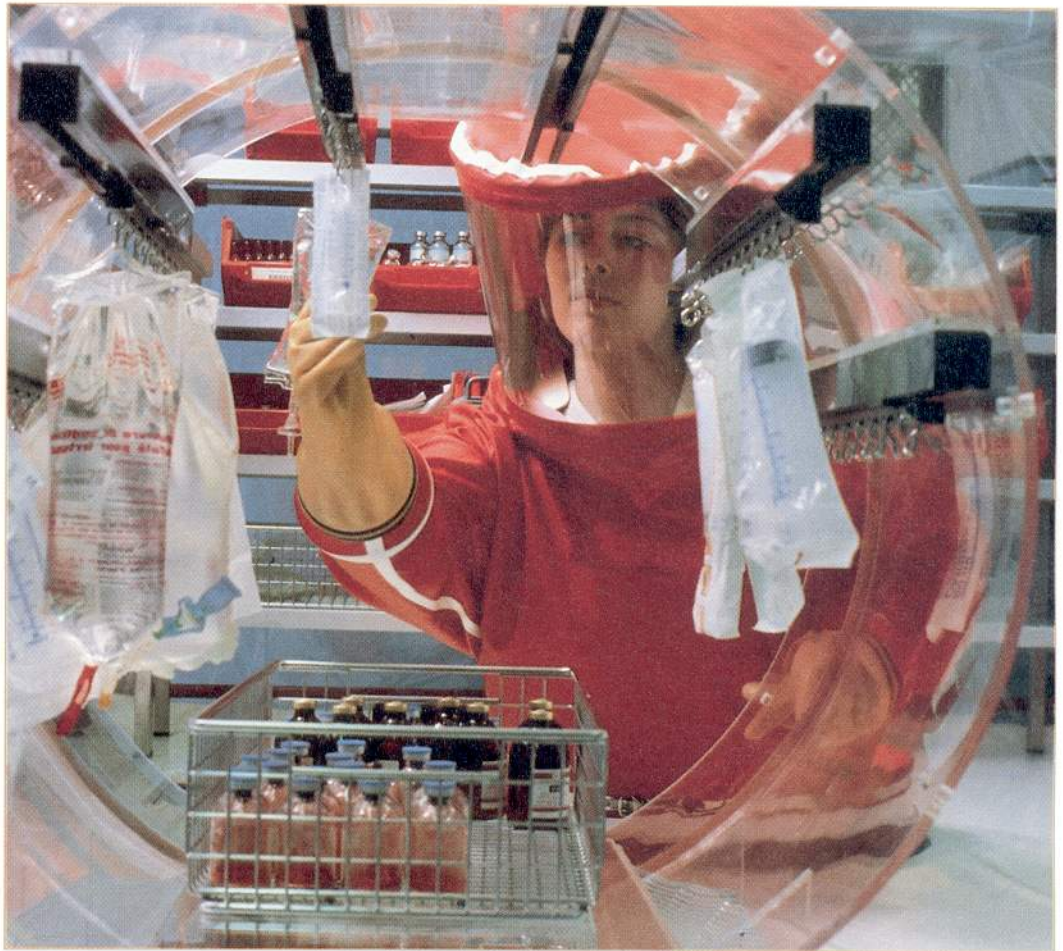
Pilot scale aseptic filling with a semi-automatic filler
in IsoTech Isolator IsoSphere-AF

ASEPTIC FILLING: Eliminate the risk of high start-up costs, extended deadlines and possible contamination in small volume and pilot scale aseptic fillings

Costs associated with constructing, validating and operating a cleanroom can be a considerable investment. In a cleanroom setting using laminar airflows, there are human and environmental contacts which greatly increase the risk of contamination, which could result in higher production costs and delays.

CONTAINMENT: Eliminate the risk of the operator's safety when handling toxic powder and compounds

In most pharmaceutical and biotech companies, handling powder and toxic compounds represents a hazardous environment for the operator. Process operations such as weighing, transferring and handling such compounds must be contained to provide a safe environment for the operator while maintaining an aseptic environment.



Large volume sterility testing in IsoTech Isolator HemiSphere-ST

Barrier isolation technology offers cost savings over traditional cleanroom technology, better sterility assurance, contamination control & safety

Barrier isolation technology can offer up to 50% cost savings when compared to constructing, validating and operating a cleanroom. IsoTech isolators do not require a controlled background environment and are compact. Consequently, only low cost laboratory space for sterility testing is required for siting the isolators. Gowning is reduced, which can save up to 70% of the operational, maintenance, energy and labor costs, and greatly increases employee comfort. The successful performance history of the isolators enables ease in validation while being widely accepted by the FDA and EC GMP.

In recent years, barrier isolation technology has been introduced for sterility testing, aseptic filling and containment processing, and by the end of 1998, over 100 systems have been installed and approved by the FDA and EC GMP. Because barrier isolation technology eliminates human and environmental contact with the product, the risk of contamination is greatly reduced. The success with barrier isolation technology systems can be substantiated by the fact that many sterility testing systems have been in use for over 5 years without a single false positive test. In aseptic filling process, isolators on both continents have been in operation and validated with high level of sterility assurance. As for containment, operator safety is assured within an aseptic environment.

HemiSphere-ST™



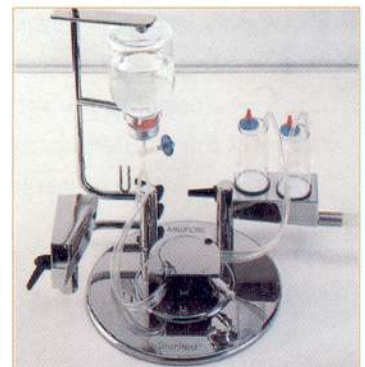
Large volume sterility testing isolator system

HemiSphere™

- Standard design for interfacing with Kuhlman GMP Sterilizers
- Softwall or hardwall half-suit workstation with gloveport product handling for operator comfort
- Cabinet-enclosed piping and control systems
- Rigid wall *IsoTransfer™* isolator for material surface decontamination and rapid product transfer
- Standard half-suit position design allows for greater mobility
- Custom integrations and connections for specific applications
- Applications with laminar airflow hood for aseptic filling with or without environmental control
- Class 10 (M2.5) at rest

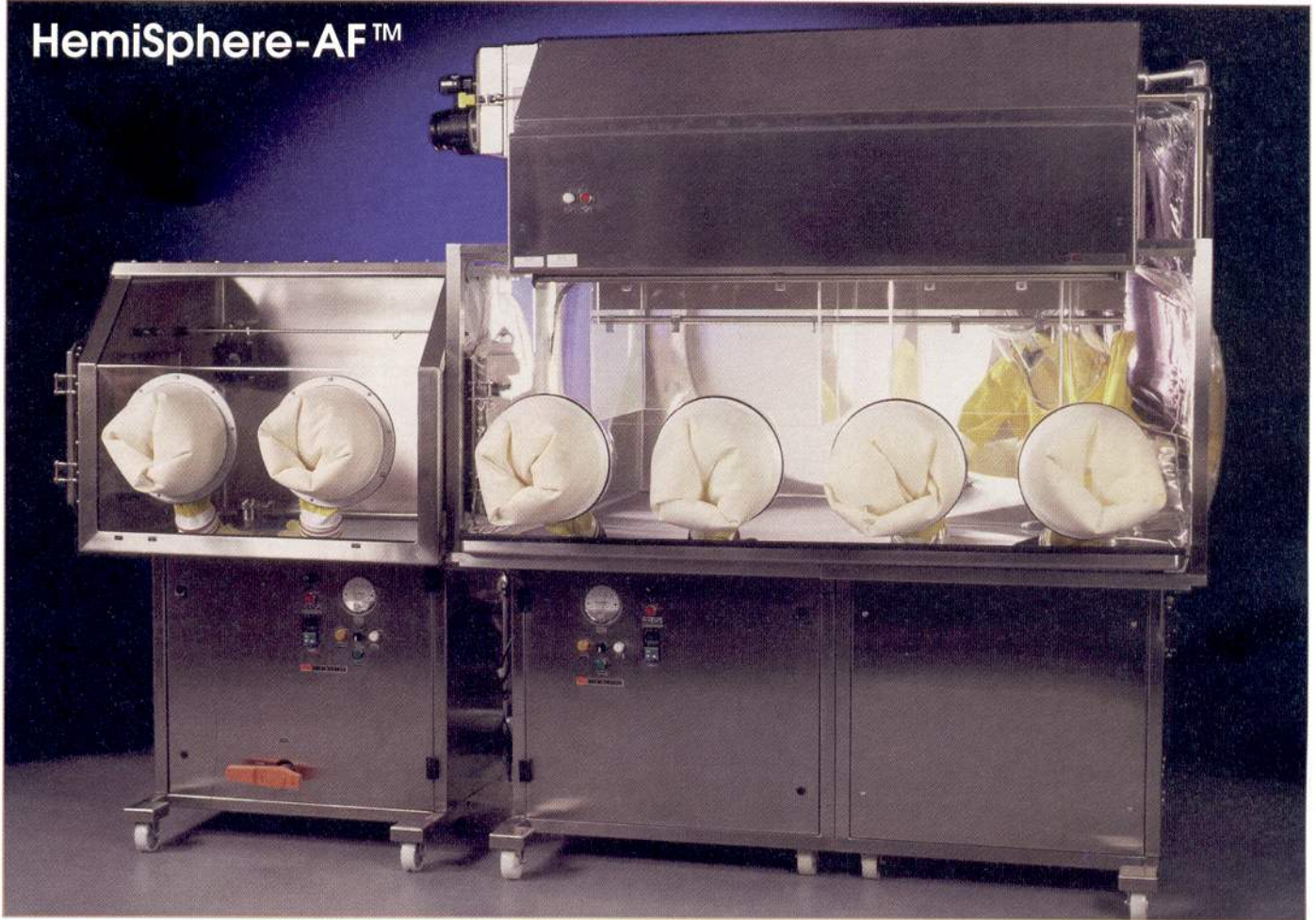


Kuhlman Pharma Pro Vertical Sliding Door Autoclaves are engineered and designed to fully interface with the IsoTech HemiSphere isolator



The *Millipore Steritest™* Integral 316 II for sterility testing is easily integrated into the work surface of the isolator. Only the components for conducting sterility tests are exposed to the clean environment

HemiSphere-AF™



Small volume aseptic filling isolator system

The *HemiSphere* isolator systems are designed to meet the stringent demands of the Pharmaceutical and Biotech industries for large volume size lot sterility testing applications (*HemiSphere-ST™*) and small volume aseptic filling applications (*HemiSphere-AF™*). The workstation is a turbulent airflow system for sterility testing or laminar airflow system for aseptic filling with a side-mounted half-suit and four glove ports. The ventilated half-suit allows for easy management of material transfer. The glove ports are used for actual product manipulation. IsoTech's unique ergonomic design allows the operators to accomplish the majority of the work in the human friendly environment of the laboratory rather than in the half-suit.



Monoblock filler is ergonomically & aseptically integrated in the IsoTech aseptic filling isolator

All piping and controls are located in the lower portion of each isolator to provide a clear pathway for ceiling lights and to eliminate dust-collecting areas. The flexibility of our systems allows an interfacing with other possible equipment such as autoclaves, lyophilizers or dry heat ovens. Optional items such as sterility testing pumps or aseptic filling equipment can be flush mounted into the work surface of the isolator.



Peristaltic pump is easily integrated into the work surface of IsoTech aseptic filling isolator



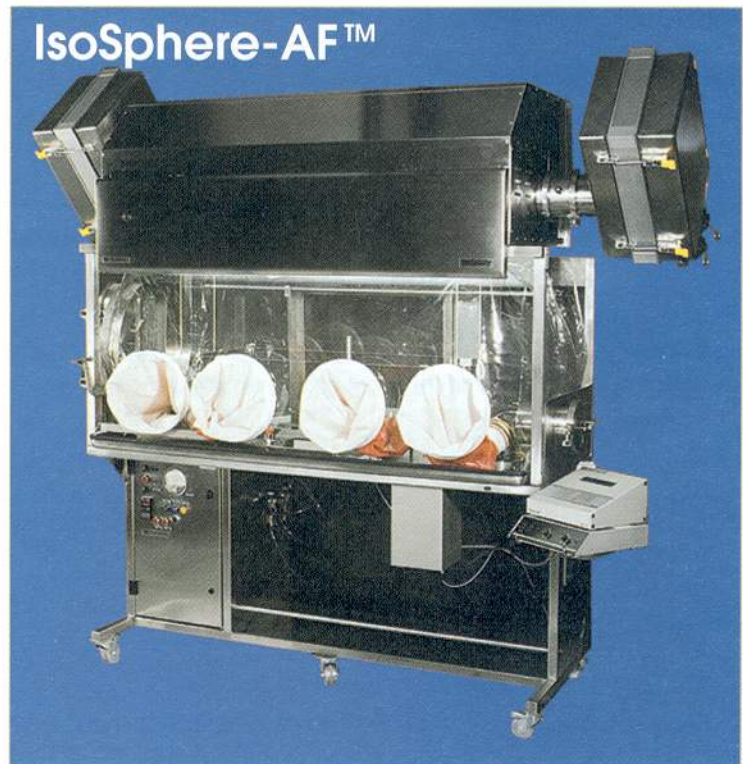
Medium volume sterility testing isolator system

IsoSphere™

- Softwall or harwall workstation
- Stainless steel rigid wall *IsoTransfer™*
- Rigid airtight transfer doors
- Independent ULPA filtration systems
- Compact space-saving design
- Low capital, operating and maintenance costs
- Standard design for sterility testing applications
- Applications with laminar airflow hood for aseptic filling with or without environmental control
- Custom integration for specific applications
- Class 10 at rest

IsoSphere™

The *IsoSphere-ST™* is designed to meet the demands of small to medium size lot sterility tests. The *IsoSphere-AF™* with laminar airflow hood is designed for small or pilot scale aseptic filling applications. The true isolation design eliminates the need for a controlled room or a very highly classified room by providing two totally enclosed, self-contained environments with a semi-permanent connection. This makes it possible to lower investment costs and reduce the amount of floor space needed. The IsoSphere workstation isolator is equipped with four or more glove ports and is ergonomically designed for operator comfort. Independent ULPA or HEPA filtered, single pass or recirculated turbulent or laminar air is maintained throughout the system to ensure air quality and an aseptic working environment. The flexibility of our system allows for integration of optional items such as sterility testing pumps, aseptic filling equipment and other equipment.

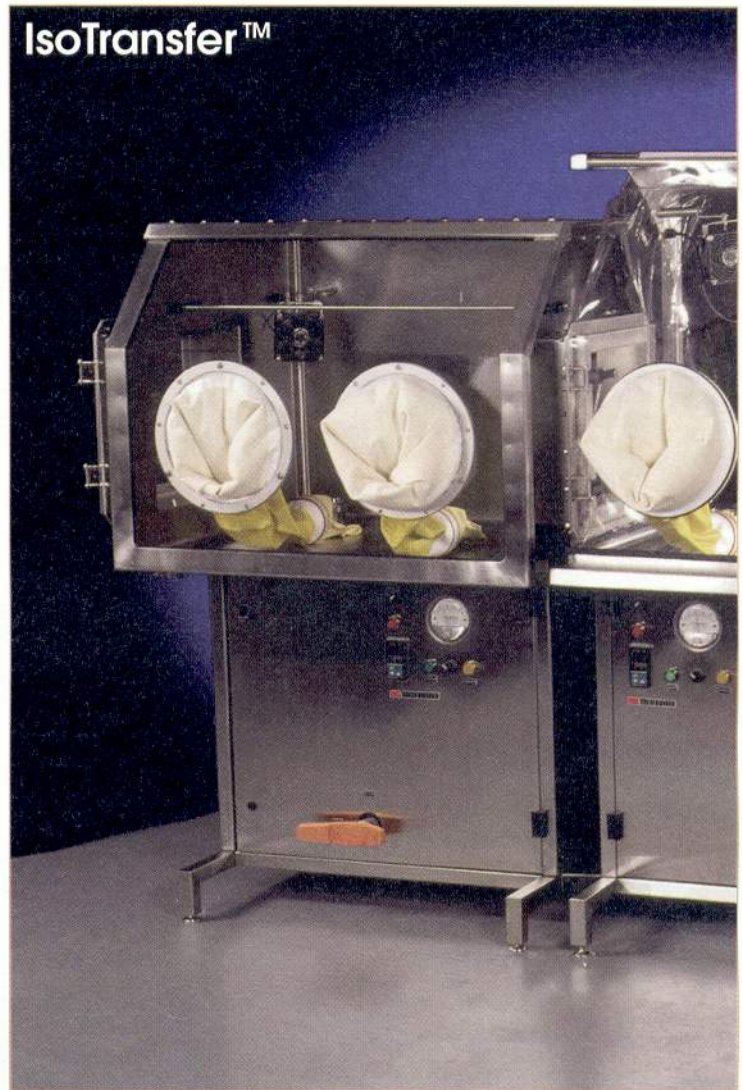


Small volume aseptic filling isolator system

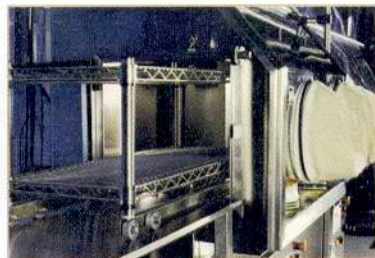
IsoTransfer™

- Stainless steel hard wall isolator
- Equipped with large standard airtight rectangular transfer doors to enable easy loading & unloading of large container
- Connected to a hydrogen peroxide generator for surface decontamination of materials
- Independant ULPA filtration systems
- Standard design to connect with any of the IsoTech working isolators
- Transfer mechanism, trolley, mobile storage to improve ergonomics, reduce direct operator handling and facilitate procedural steps
- Custom design racking systems for specific sample sizes to improve process
- Inclined front panel and clear PVC top panel for better visibility
- Class 10 (M2.5) at rest

The all-stainless-steel construction of the *IsoTransfer™* allows rigorous surface decontamination with aggressive sterilants and enables faster decontamination cycles with the hydrogen peroxide vapor generator because of quicker aeration phases. The *IsoTransfer™* can be equipped with Alpha/Beta ports for moving and transferring materials with a high level of sterility assurance. A loading cart and transfer trolley make it possible to load and unload materials quickly and efficiently.

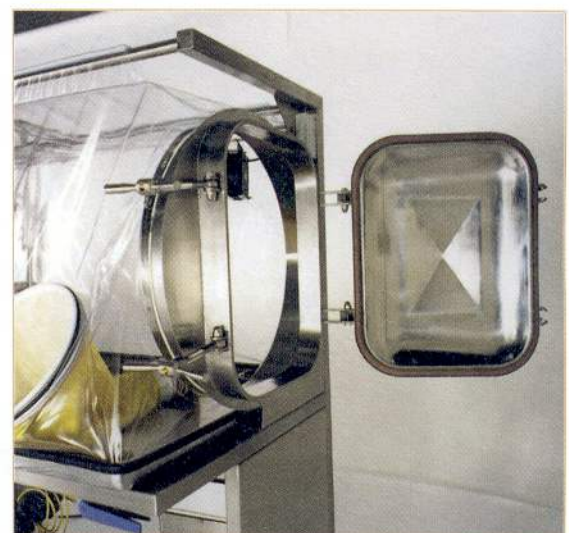


Aseptic transfer & decontamination isolator system

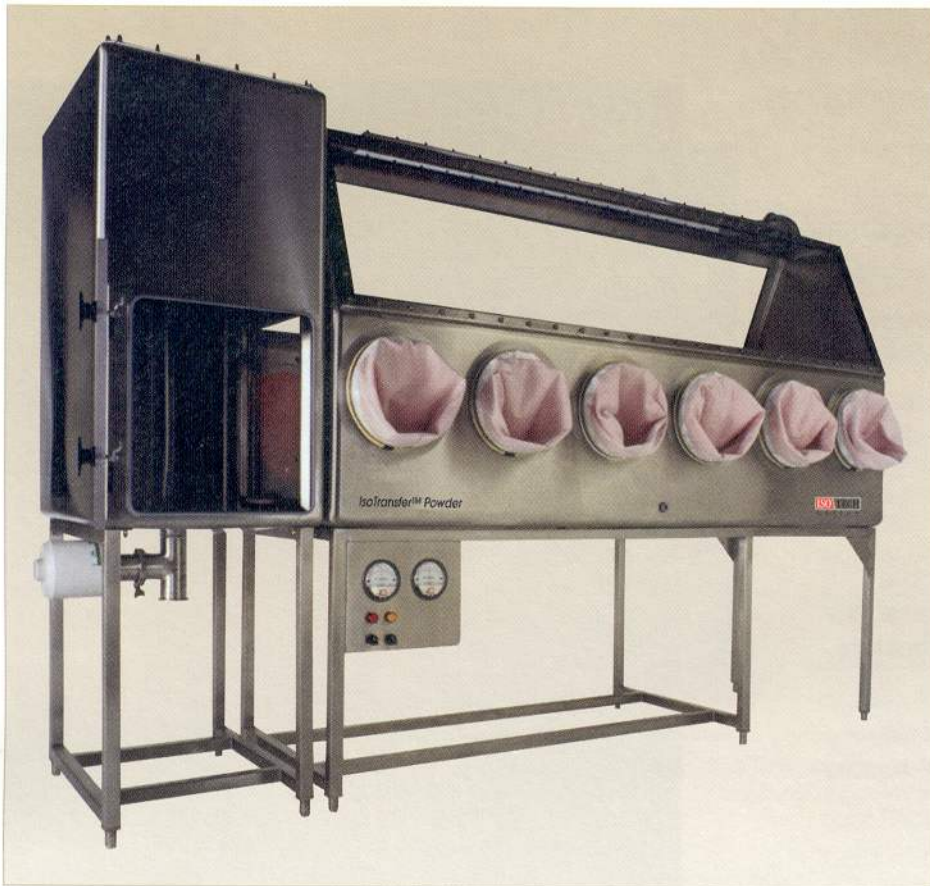


Transfer mechanism

Alpha/Beta Ports can be installed to provide transfer of product into a halfsuit workstation from a mobile *IsoTransfer™* without loss of integrity to either environment



The *IsoTransfer™* is equipped with superior heavy-duty stainless steel doors for lifetime durability, airtight, safe and rapid product transfer



IsoTransfer™ Powder

Two, four glove or custom design isolator, class 10 (M2.5), turbulent flow in negative pressure for handling, weighing and transferring powder.



IsoProtect™

Two, four glove or custom design, class 10 (M2.5) isolator, turbulent or laminar flow, negative pressure with or without environmental control for all types of toxic compound manipulations: Biological, chemical, nuclear and radiopharmaceutical.

HemiSphere™ Powder Transfer



HemiSphere™ Powder Transfer

Half-suit isolator, class 10 (M2.5), turbulent flow in negative pressure for large volume powder handling, transferring and/or weighing.

T E C H N I C A L D A T A

	HemiSphere-ST™	HemiSphere-AF™	IsoSphere-ST™	IsoSphere-AF™
Applications	Large Volume Sterility Testing Process	Small Volume & Pilot Scale Aseptic Filling Process	Small to Medium Volume Sterility Testing Process	Small Volume & Pilot Scale Aseptic Filling Process
External Dimensions	76" W x 76" D x 85" H 1930 mm W x 1930 mm D x 2159 mm H	76" W x 76" D x 94" H 1930 mm W x 1930 mm D x 2388 mm H	74" W x 32" D x 66" H 1880 mm W x 813 mm D x 1676 mm D	74" W x 32" D x 94" H 1880 mm W x 813 mm D x 2388 mm D
Internal Dimensions	72" W x 72" D x 48" H 1829 mm W x 1829 mm D x 1219 mm H	72" W x 72" D x 48" H 1829 mm W x 1829 mm D x 1219 mm H	72" W x 31.5" D x 31.5" H 1829 mm W x 800 mm D x 800 mm H	72" W x 31.5" D x 31.5" H 1829 mm W x 800 mm D x 800 mm H
Materials of Construction	Stainless 316L / PVC	Stainless 316L / Polycarbonate	Stainless 316L / PVC	Stainless 316L / Polycarbonate
Inlet Air Filtration	ULPA	ULPA	ULPA	ULPA
Airflow	Turbulent	Laminar	Turbulent	Laminar
Air Classification	Class 10 (M2.5) at rest	Class 10 (M2.5) at rest	Class 10 (M2.5) at rest	Class 10 (M2.5) at rest
Internal Pressure	± 0.15" WC ± 37 Pa	± 0.15" WC ± 37 Pa	± 0.15" WC ± 37 Pa	± 0.15" WC to ± 0.40" WC ± 37 Pa to ± 100 Pa
Pressure Controller	Y	Y	Y	Y
Process Connections	IsoTransfer™ Alpha/Beta Door VHP Generator Autoclave Sterility Testing Pump	IsoTransfer™ Alpha/Beta Door VHP Generator Autoclave Lyophilizer Dry Heat Oven Aseptic Filling Equipment Environmental Control	IsoTransfer™ Alpha/Beta Door VHP Generator Sterility Testing Pump	IsoTransfer™ Alpha/Beta Door VHP Generator Aseptic Filling Equipment Environmental Control
Electrical Supply	115-120V, 60 Hz, 6A 210-220V, 50 Hz, 3A	115-120V, 60 Hz, 10A 210-220V, 50 Hz, 10A	115-120V, 60 Hz, 3A 210-220V, 50 Hz, 3A	115-120V, 60 Hz, 6A 210-220V, 50 Hz, 3A

Testing, Start-up and Training

Full factory testing is your assurance of reliability once the equipment reaches your facility. Each IsoTech product is thoroughly inspected in our factory prior to shipment.

Our qualified service engineers will do the start-up of the IsoTech equipment along with the training and installation qualification. All electrical components meet international standards.

Warranty

We believe our customers deserve the best equipment available in terms of performance, safety and service.

We offer our customers a solid, effective one-year warranty. We want you to know that your confidence in the IsoTech product is justified.

T E C H N I C A L D A T A

	IsoTransfer™	IsoTransfer™ Powder	IsoProtect™	HemiSphere™ Powder Transfer
Applications	Aseptic Transfer and Decontamination Process	Contained Aseptic Powder Weighing & Transfer Processing	Contained Manipulation of Toxic Compounds: Biological, Chemical Nuclear and Radiopharmaceutical	Contained Transfer, Weighing and Manipulation of Large Volume Powder
External Dimensions	48" W x 32" D x 67" H 1219 mm W x 813 mm D x 1702 mm H	48" W x 32" D x 67" H 1219 mm W x 813 mm D x 1702 mm H	87.2" W x 33" D x 99" H 2215 mm W x 838 mm D x 2514,6 mm H	76" W x 54" D x 85" H 1930,5 mm W x 1371 mm x 2159 mm H
Internal Dimensions	43" W x 31.5" D x 31.5" H 1092 mm W x 800 mm D x 800 mm H	37.5" W x 31.5" D x 31.5" H 952,5 mm W x 800 mm D x 800 mm H	47.2" W x 19.7" D x 27.5" H 1199 mm W x 500 mm D x 699 mm H	72" W x 53,5" D x 48" H 1829 mm W x 1359 mm D x 1219 mm H
Materials of Construction	Stainless 316L / Polycarbonate	Stainless 316L / Polycarbonate	Stainless 316L / Polycarbonate	Stainless 316L / Polycarbonate
Inlet Air Filtration	ULPA	ULPA	ULPA	ULPA
Airflow	Turbulent	Turbulent	Turbulent or Laminar	Turbulent
Air Classification	Class 10 (M2.5) at rest	Class 10 (M2.5) at rest	Class 10 (M2.5) at rest	Class 10 (M2.5) at rest
Internal Pressure	± 0.15" WC ± 37 Pa	-0.15" WC to -0.40" WC -37 Pa to -100 Pa	-0.50" WC -125 Pa	-0.15" WC to -0.40" WC -37 Pa to -100 Pa
Pressure Controller	Y	Y	Y	Y
Process Connections	IsoSphere-ST™ IsoSphere-AF™ HemiSphere-ST™ HemiSphere-AF™ Alpha/Beta door VHP Generator	Alpha/Beta door Funnell Powder Process Equipment Scale	IsoTransfer™ Alpha/Beta Door Transfer Chamber VHP Generator Process Equipment	Alpha/Beta Door Funnel Dry Heat Oven Lyophilizer Powder Process Equipment Scale
Electrical Supply	115-120V, 60 Hz, 3A 210-220V, 50 Hz, 3A	115-120V, 60 Hz, 5A 210-220V, 50 Hz, 3A	115-120V, 60 Hz, 10A 210-220V, 50 Hz, 6A	115-120V, 60 Hz, 5A 210-220V, 50 Hz, 3A

Customer Service

Our customers stand by our products. We develop strong relationships with our customers.

We fully support and service our equipment.

ISO TECH
DESIGN

**Protecting life with barrier
isolation technology
and clean air environments
for contamination control,
sterility assurance and
containment management.**

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