

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

	Microsphere™-ST	Softwall IsoSphere™-ST	Hardwall IsoSphere™-ST	IsoTransfer™-ST 2 or 3-glove	HemiSphere™-ST
Applications	Small Volume	Small to Medium Volume	Medium to Large Volume	Decontamination Process and Aseptic transfer	Large Volume
External Dimensions	96" W x 32" D x 85" H	70" W x 32" D x 67" H	78" W x 33" D x 85" H	38"-48" W x 32" D x 67" H	76" W x 76" D x 85" H
Materials of Construction	Anodized Aluminum / 316L stainless steel	316L stainless steel, No. 4 finish base with coved corner	316L stainless steel, No. 4 finish base with coved corner	316L stainless steel, No. 4 finish base with coved corner	316L stainless steel, No. 4 finish base with coved corner
Air Filtration	HEPA filters (99.99% DOP at .3 u) on the inlet	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet	HEPA filters (99.99% DOP at .3 u) on the inlet and outlet
Airflow	Unidirectional 650 CFM	Non-unidirectional 20 CFM	Non-unidirectional 20 CFM	Non-unidirectional 20 CFM	Non-unidirectional 20 CFM
Air Classification	ISO class 4 (Class 10)	ISO class 4 (Class 10)	ISO class 4 (Class 10)	ISO class 4 (Class 10)	ISO class 4 (Class 10)
Internal Pressure	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa
Process Connections	Sterility Testing Pump	Sterility Testing Pump IsoTransfer™-ST Alpha/Beta Door H ₂ O ₂ Generator	Sterility Testing Pump Alpha/Beta Door H ₂ O ₂ Generator	IsoSphere™-ST HemiSphere™-ST Alpha/Beta Door H ₂ O ₂ Generator	Sterility Testing Pump IsoTransfer™-ST Alpha/Beta Door H ₂ O ₂ Generator Autoclave
Electrical Supply	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A	115-120V, 60 Hz, 6A 210-230V, 50 Hz, 3A
Noise Level	< 65 dB	< 65 dB	< 65 dB	< 65 dB	< 65 dB

Installation, Start-up and Training :

Full factory testing is your assurance of reliability once the equipment reaches your facility. Each IsoTech Design 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 qualifications. All electrical components meet international standards.

Delivery Delays : 12-16 weeks from drawing approval.

Warranty :

We believe our customers deserve the best equipment available in terms of performance, safety and service. We offer our customers a solid 18-month warranty. We want you to know that your confidence in the IsoTech product is justified.



Barrier Isolation Technology for Sterility Testing



PROTECTING LIFE
 PROTÉGER LA VIE
 PROTEGIENDO LA VIDA



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YOUR TURNKEY SOLUTION...

Eliminate the Risk of a False Positive

In cleanroom and laminar airflow hood 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.

Why Build a Cleanroom?

IsoTech Design's Isolators are the aseptic, most cost effective barrier Isolators to meet the USP requirements (*Chapter 1211*) for sterility testing and to eliminate the risk of a false positive test.

Isolator Advantages:

- No False Positives
- Lower Contamination: Increased SAL
- Aseptic: Exceeding the cGMP requirements of ISO class 5 (100)
- Reduced Costs vs. Cleanroom
- Complete Product / Operator Protection
- Smaller Critical Area: Increase Test Efficiency
- Minimal energy requirements
- Turnkey solution: Load analysis, Barrier Isolation Technology solution, Pump integration, H₂O₂ sterilization, IQ/OQ/PQ documentation and execution

SMALL VOLUME (up to 5 batches/day)

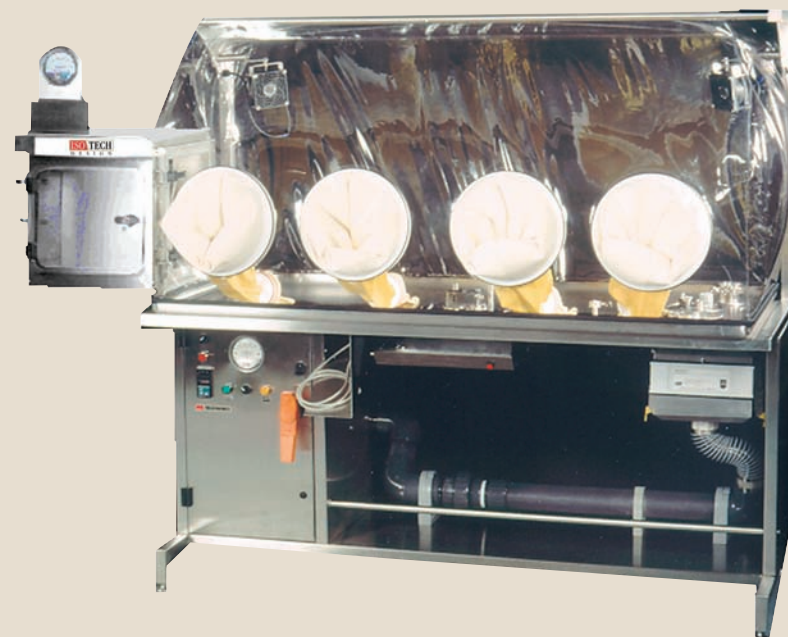
MicroSphere™-ST

IsoClass 4, unidirectional microenvironment with a unidirectional antechamber. Manual decontamination with a cold sterilant.



Softwall IsoSphere™-ST with Antechamber

IsoClass 4 non-unidirectional airflow Softwall isolator with an antechamber. Decontamination with an H₂O₂ Generator.



MEDIUM VOLUME (5 - 10 batches/day)

Hardwall IsoSphere™-ST

IsoClass 4 Hardwall non-unidirectional airflow Isolator with open lid window. Decontamination with an H₂O₂ Generator.



Softwall IsoSphere™-ST with IsoTransfer™

IsoClass 4, Softwall non-unidirectional airflow isolator with 2 or 3 glove IsoClass 4 Transfer Isolator. Transfer Isolator can be fixed or mobile. Decontamination with an H₂O₂ Generator.



LARGE VOLUME (over 10 batches/day)

HemiSphere™-ST

IsoClass 4 non-unidirectional airflow Halfsuit Softwall Isolator with 2 or 3 glove IsoClass 4 Transfer Isolator. Transfer Isolator can be fixed or mobile. Decontamination with an H₂O₂ Generator.



Accessories and Options:

- Casters
- Flush bottom ball valve drain
- Lifting system
- Service plate for sanitary connections
- Recirculation fans
- Ergonomic chair
- FAT and SAT
- Installation, start-up and training
- IQ, OQ, PQ documentation and execution

The Millipore™ or Sartorius® Pumps can easily be integrated into the work surface



Alpha-Beta Door



Touch Screen HMI

