

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

	IsoSphere™-AF	HemiSphere™-AF	IsoTransfer™-AF 2 or 3-glove
Applications	Pilot scale and Small to Medium Volume Aseptic Filling	Interface with process equipments	Decontamination Process and Aseptic transfer
External Dimensions	96" W x 32" D x 85" H Custom sizes available	70" W x 32" D x 67" H Custom sizes available	38" - 48" W x 32" D x 67" H
Materials of Construction	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 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	Unidirectional	Non-unidirectional
Air Classification	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
Process Connections	Peristaltic Pump Semi-Automatic Filler Monobloc Filler Lyophilizer Dry Heat Sterilizer Autoclave IsoTransfer™ Alpha-Beta Door VHP Generator	Lyophilizer Dry Heat Sterilizer Autoclave IsoTransfer™ Alpha/Beta Door VHP Generator	IsoSphere-AF™ HemiSphere-AF™ Alpha/Beta Door VHP Generator
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
Noise Level	< 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 : 20-24 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.



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Barrier Isolation Technology for Aseptic Filling



PROTECTING LIFE
PROTÉGER LA VIE
PROTEGIENDO LA VIDA



YOUR TURNKEY SOLUTION...

IsoSphere™-AF Filling Suite

- IsoClass 4 positive pressure unidirectional airflow isolator with monobloc filler integration.
- Decontamination with H₂O₂ Generator.
- PLC control panel for Isolator + Filler.



IsoSphere™-AF & IsoTransfer™

- IsoClass 4 positive pressure unidirectional airflow isolator.
- Monobloc filler integration.
- Decontamination with an H₂O₂ Generator.



Eliminate the Risk of High Start-up Costs, Extended Deadlines & 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 can greatly increase the risk of contamination, which could result in higher production costs and delays.

IsoTech Design's Isolators are the aseptic, most cost effective barrier isolators to meet the cGMP requirements (FDA + EC) for Aseptic Filling for better sterility assurance, contamination control and safety.

Isolator Advantages:

- Lower Contamination: Increased SAL.
- Aseptic: ISO class 4 (10) unidirectional flow isolator, exceeding the cGMP requirements of ISO class 5 (100).
- Reduced Costs vs. Cleanroom
- Complete Product / Operator Protection
- Operator physically separated from aseptic area.
- Smaller Critical Area.
- Minimal energy requirements.
- Turnkey solution: Design Qualification, Barrier Isolation Technology solution, Filling Equipment integration, Process equipment interface H₂O₂ sterilization, IQ/OQ/PQ documentation and execution.

2 or 3 Glove IsoTransfer™

- Positive Pressure IsoClass 4 Transfer Isolator.
- Non-Unidirectional Airflow.
- For material and product transfer.
- Fixed or mobile.



HemiSphere-AF™ Interface Isolator

- IsoClass 4, Unidirectional Airflow Isolator.
- Interface with Lyophilizers, Autoclaves and DHS.
- Decontamination with H₂O₂ Generator.

Stainless Steel Touch Screen



Interface Bellows



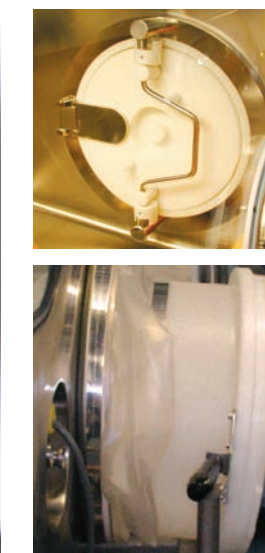
Accessories and Options:

- Casters
- Flush bottom ball valve drain
- Service plate for sanitary connections
- Recirculation fans
- FAT and SAT
- Integration of Aseptic Filling Equipments
- Interface with Lyophilizers, Autoclaves and DHS
- Installation, start-up and training
- Project Management
- IQ, OQ, PQ documentation and execution

Semi-automatic filler installed in IsoSphere™-AF



Alpha-Beta Door



Flexicon peristaltic pump and sanitary connections integrated in work surface of IsoSphere™-AF

