

# TECHNICAL DATA

	IsoSphere™-AF	HemiSphere™-AF	IsoTransfer™-AF 2 or 3-glove
<b>Applications</b>	Pilot scale and Small to Medium Volume Aseptic Filling	Interface with process equipments	Decontamination Process and Aseptic transfer
<b>External Dimensions</b>	96" W x 32" D x 85" H Custom sizes	70" W x 32" D x 67" H Custom sizes	38" - 48" W x 32" D x 67" H
<b>Materials of Construction</b>	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
<b>Air Filtration</b>	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
<b>Airflow</b>	Unidirectional	Unidirectional	Non-unidirectional
<b>Air Classification</b>	ISO class 4 (Class 10)	ISO class 4 (Class 10)	ISO class 4 (Class 10)
<b>Internal Pressure</b>	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa
<b>Process Connections</b>	Peristaltic Pump Semi-Automatic Filler Monobloc Filler Lyophilizer Dry Heat Sterilizer Autoclave IsoTransfer™ Alpha-Beta Door H <sub>2</sub> O <sub>2</sub> Generator	Lyophilizer Dry Heat Sterilizer Autoclave IsoTransfer™ Alpha/Beta Door H <sub>2</sub> O <sub>2</sub> Generator	IsoSphere-AF™ HemiSphere-AF™ Alpha/Beta Door H <sub>2</sub> O <sub>2</sub> Generator
<b>Electrical Supply</b>	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
<b>Noise Level</b>	< 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.

**ISO TECH**  
DESIGN

## Barrier Isolation Technology for Aseptic Filling



PROTECTING LIFE  
PROTÉGER LA VIE  
PROTEGIENDO LA VIDA

**ISO TECH**  
DESIGN

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# ISO TECH DESIGN

## YOUR TURNKEY SOLUTION...

### IsoSphere™-AF Filling Suite

- IsoClass 4 positive pressure unidirectional airflow isolator with monobloc filler integration.
- Decontamination with H<sub>2</sub>O<sub>2</sub> Generator.
- PLC control panel for Isolator + Filler.



### IsoSphere™-AF & IsoTransfer™

- IsoClass 4 positive pressure unidirectional airflow isolator.
- Monobloc filler integration.
- Decontamination with an H<sub>2</sub>O<sub>2</sub> 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 and 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: 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 H<sub>2</sub>O<sub>2</sub> 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 H<sub>2</sub>O<sub>2</sub> Generator.



Stainless Steel Touch Screen

Interface Bellows

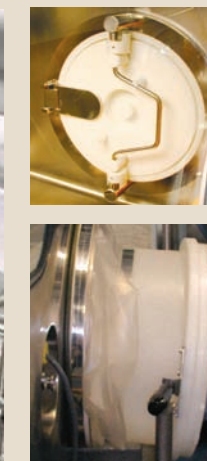
### Accessories and Options:

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

### FPC50 filler installed in IsoSphere™-AF



### Alpha-Beta Door



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

