

Protecting Life Protéger La Vie Protegiendo La Vida

# BARRIER ISOLATION TECHNOLOGY For **Sterility testing**



Applications	<b>Microsphere<sup>M</sup> - ST</b> Small Volume	<b>IsoSphere™ - ST</b> Medium Volume	lsoTransfer ™- ST 2 or 3-glove
Applications	Small Volume	Madium Valuma	
		Medium volume	Decontamination Process and Aseptic transfer Large Volume
External Dimensions	96"Wx32"Dx85"H	78" W x 33" D x 85" H	38"-48"Wx32"Dx67"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
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 on the inlet and outlet
Airflow	Unidirectional 650 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)
Internal Pressure	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa	+ 0.15 WC + 37 Pa
Process Connections	Sterility Testing Pump	Sterility Testing Pump Alpha/Beta Door H2O2Generator	lsoSphere™- ST Alpha/Beta Door H <sub>2</sub> O <sub>2</sub> 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:

16-20 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.



#### ISOTECH DESIGN CANADA: 1320 Graham Blvd, #120 Montreal (Quebec) Canada H3P 3C8 Tel. : 514. 956.1602 Direct: 800. ISO.2010 Fax : 877. 476.1032

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YOUR

TURNKEY

SOLUTION ...

# ISOLATOR ADVANTAGES :

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

# FOR SMALL VOLUME



### MICROSPHERE™ - ST

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

# FOR LARGE VOLUME



# ISOSPHERE<sup>™</sup> - ST WITH ANTECHAMBER

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

# FOR MEDIUM VOLUME



## ISOSPHERE™ - ST

IsoClass 4 Hardwall non-unidirectional airflow Isolator with open lid window. Decontamination with a 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





ALPHA-BETA

DOOR

INTERFACE





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

HMI Touch screen