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Equipment Specification

Page 1 of 10

Work Order #: 33436	WO Spec Rev. #: A	Customer PO:	Customer PO Date:
Proposal #:	Proposal Rev. #:	Proposal Date:	Proposed By:
Equipment Name: Flexible Wall 3 Glove Sterility Test Isoaltor			
Customer: Stock Unit	Contact:		
Address:			
Phone #:	Fax #:	Email:	
Equipment/Process Description: Isolator provides sealed environment with positive pressure to the room. Isolator sterilized by VHP from external sterilizer.			



Section 1A – Customer Facility and Product Information

1. Room Size (L x W x H):	36" x 81"
Limiting Doorway Opening (W x H):	Unit collapses to lower under 80" door

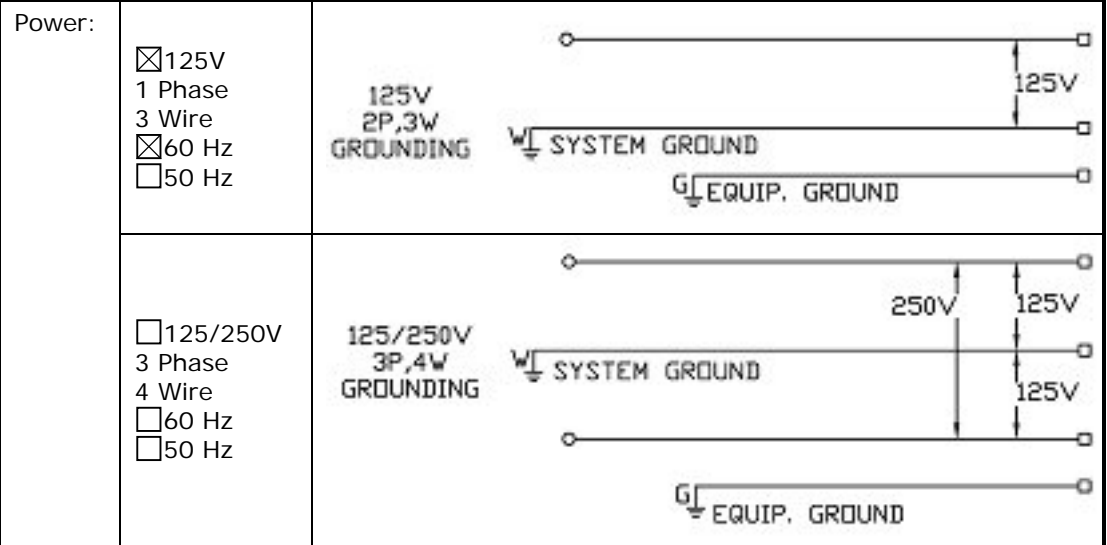
2. Room Conditions:	Temperature: Ambient	Relative Humidity: Ambient	Seismic: N/A
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3. Clean Room Classification:	N/A
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4. Room Electrical Classification:	<input checked="" type="checkbox"/> Non-Hazardous	<input type="checkbox"/> CENELEC	Rating:	Zone:
	<input type="checkbox"/> Class I	<input type="checkbox"/> Division 1	<input type="checkbox"/> Group A & B	<input type="checkbox"/> Group C & D
	<input type="checkbox"/> Class II	<input type="checkbox"/> Division 2	<input type="checkbox"/> Group E	<input type="checkbox"/> Group F <input type="checkbox"/> Group G

5. Chamber Electrical Classification:	<input checked="" type="checkbox"/> Non-Hazardous	<input type="checkbox"/> CENELEC	Rating:	Zone:
	<input type="checkbox"/> Class I	<input type="checkbox"/> Division 1	<input type="checkbox"/> Group A & B	<input type="checkbox"/> Group C & D
	<input type="checkbox"/> Class II	<input type="checkbox"/> Division 2	<input type="checkbox"/> Group E	<input type="checkbox"/> Group F <input type="checkbox"/> Group G

6. Room Utilities:	Water:	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:		Temp:		GPM:	
	Compressed Dry Air:	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:		CFM:			
	Nitrogen:	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:		CFM:			
	Blower Exhaust Connection:	2" TC							



6. Continued:	Power:	<input type="checkbox"/> 120/208V 3 Phase 5 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz	<p>30Y 120/208V 4P,5W GROUNDING</p>		
		<input type="checkbox"/> 277/480V 3 Phase 5 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz	<p>30Y 277/480V 4P,5W GROUNDING</p>		
		<input type="checkbox"/> 480V 3 Phase 4 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz	<p>30 480V 3P,4W GROUNDING</p>		
7. Product Information:	<input type="checkbox"/> Liquid <input type="checkbox"/> Powder <input type="checkbox"/> Cytotoxic = OEL <input type="checkbox"/> Antibiotic <input type="checkbox"/> Suspension <input type="checkbox"/> Lyophilized <input type="checkbox"/> Multi-product <input type="checkbox"/> Chemical: <input type="checkbox"/> Radiological Isotope: _____ <input type="checkbox"/> Other: Product Bulk Density: _____				
8. Product Container Information:	Material:	<input type="checkbox"/> Glass <input type="checkbox"/> Plastic <input type="checkbox"/> Fiber <input type="checkbox"/> Stainless Steel			
	Type:	<input type="checkbox"/> Vial <input type="checkbox"/> Ampoule <input type="checkbox"/> Syringe <input type="checkbox"/> Drum			
	Size:	Largest:	Diameter:	Height:	Volume:
	Smallest:	Diameter:	Height:	Volume:	



Section 1B – General Equipment Construction Requirements

1. Chamber Exterior Size: Length x Width x Height: 60" x 26" x 30"

2. Overall Equipment Size: Length x Width x Height: 63-1/2" x 33-1/2" x 81"

3. Construction Information:

Item	Material	Finish / Color	Size / Gauge	Type / Comments
Shell	Polyurethane	Clear	16 mil	
Shell Pan:	316L	Interior: <25 Ra	12	
		Exterior : <35 Ra		
Stand:	304	<35 Ra	1" tube 11 ga.	With lower 14 ga. shelf
Flashing:	304	<35 Ra	14	
Flashing Cover:				
Flashing Gasket:				
Windows:				
Window Gaskets:				
Flat Gaskets:				
Door Gaskets:				
Other Gaskets:				
HVAC Piping:	316L	<35 Ra	2"	
CIP Piping:				
Hardware:				
Casters:	Polyolefin		5"	Four Swivel
Leveling Pads:				
Other:				



Section 2 – Equipment HVAC System Requirements

1. HVAC System: <input type="checkbox"/> None <input checked="" type="checkbox"/> On Equipment <input type="checkbox"/> Remote Location <input type="checkbox"/> House Exhaust									
2. Overpressure: <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Both / Zones Air Changes Per Hour:									
3. Unidirectional Airflow: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes Velocity at 6" below filter face (ft/min):									
4. Velocity Over An Open Glove Port: <input type="checkbox"/> 100 ft/min <input type="checkbox"/> Other:									
5. Decontamination System: <input type="checkbox"/> None <input checked="" type="checkbox"/> H ₂ O ₂ Type: TBDC <input type="checkbox"/> Wipe down Agent:									
6. Gas System: Supports Items 7, 8 and 9	<input checked="" type="checkbox"/> None <input type="checkbox"/> Once Through <input type="checkbox"/> Recirculated								
	Gas Type: <input type="checkbox"/> CDA <input type="checkbox"/> Nitrogen <input type="checkbox"/> Argon <input type="checkbox"/> Other:								
	<input type="checkbox"/> Regulator <input type="checkbox"/> Proportional Control Valve Size:								
	CLS Supplied Components: <input type="checkbox"/> Flow Meter w/valve <input type="checkbox"/> Flow Meter w/o valve Flow Meter Range (SCFH):								
7. Oxygen System:	<input checked="" type="checkbox"/> None <input type="checkbox"/> Monitor <input type="checkbox"/> Manual Control <input type="checkbox"/> Automatic Control Range: 0-20.9%								
	<input type="checkbox"/> Reduction only (no lower limit) <input type="checkbox"/> Reduction and addition (maintain setpoint)								
8. Humidity System:	<input checked="" type="checkbox"/> None <input type="checkbox"/> Monitor <input type="checkbox"/> Manual Control <input type="checkbox"/> Automatic Control Range:								
	Type: <input type="checkbox"/> Nitrogen <input type="checkbox"/> Super Dryer <input type="checkbox"/> Other:								
	<input type="checkbox"/> Nebulizer Valve info: (2) ¼" NPT Electrically actuated								
9. Ammonia Leak Test Pressure Control System: <input checked="" type="checkbox"/> None <input type="checkbox"/> Automatic									
10. Internal Equipment Heat Load: N/A									
11. Temperature System: <input type="checkbox"/> None <input type="checkbox"/> Monitor <input type="checkbox"/> Control Range (°F, °C):									
12. HVAC Filters:	Type		Inlet		Outlet		Unidirectional Flow		
			Qty	Size	Qty	Size	Qty	Size	
	6" dia. HEPA Push (Radial Flow)								
	Panel: <input checked="" type="checkbox"/> HEPA <input type="checkbox"/> ULPA		1	12"x12"x3"	1	12"x12"x3"			
	Pre-Filter / Diffusion Membrane								
Pressure Sensor Filter		2							

Section 2 – Equipment HVAC System Requirements (continued)

13. HVAC Blowers:	Type:	Pos. Press.	Neg. Press.	Unidirectional Flow	Recirculation	Distribution Fan
	Qty:	1				2
	Size:	EBM160				
	Motor HP:	1/3				
14. HVAC Valves:	Type	Qty	Size	Actuation		
	Butterfly	2	2"	Manual		



Section 3 – Equipment Cleaning and Utility Component Requirements

2. Utility Connections:

Item	Qty	Material	Size / Type	Location / Comments
Utility Panel Tri-Clamp Fittings				
Utility Panel Compression Fittings				
Compression Fitting				
Product Entry & Exit Fitting				
Other Fittings	2	Polypropylene	1-1/2" Banjo	VHP entry & exit, through HEPA filters
Utility Hooks				
Other:				



Section 4 – Equipment Material Handling Component Requirements				
Item	Qty	Material	Size / Type	Location / Comments
1. Gloves	3	Hypalon	10"	
2. Glove Sleeves				
3. Glove Ports	3	Ultem	10" oval with inserts	
4. Glove Extenders	3	SST / Poly	Attached to lower rail	Option price
5. Half Suit				
6. Access Door	1	Polyurethane	565mm	With stainless ring, band clamp, silicone pad
7. Air Lock				
8. Bag Out Ring				
9. Transfer Tray				
10. RTP Alpha				
11. RTP Beta	1	Polypropylene	350mm	With extender, with 565mm stainless ring, band clamp, silicone pad, polyurethane sleeve
12. Transport Container				
13. Liquid Transfer Container				
14. Autoclavable Container				
15. Autoclavable Cont. Cart				
16. Container Lift				
17. Swing Out Table				
18. Shelving	3	Stainless steel	14" x 30"	Optional
19. Scale <input type="checkbox"/> CLS Providing <input type="checkbox"/> Customer Providing		Max. Capacity:		Display: <input type="checkbox"/> Inside <input type="checkbox"/> Outside
		Accuracy (±):		Foot Pedal: <input type="checkbox"/> No <input type="checkbox"/> Yes
		Brand:		Printer: <input type="checkbox"/> No <input type="checkbox"/> Yes
		Model:		Other:
20. Other				



Section 5A – Equipment Control System Requirements

1. Control System Type:		<input type="checkbox"/> None	<input checked="" type="checkbox"/> AMP1000	<input type="checkbox"/> AMP2000	<input type="checkbox"/> AMP3000
Special Notes:					
2. Supply Voltage:		Volts: 120	Phase: 1	Freq. (Hz): 60	Amps: 20
3. Control Panel:	Listing Required:	<input type="checkbox"/> None	<input checked="" type="checkbox"/> UL	<input type="checkbox"/> CE	<input type="checkbox"/> Other:
	Mounting Location:	<input checked="" type="checkbox"/> Attached to Equipment		<input type="checkbox"/> Remotely Located	
	NEMA Rating:	<input checked="" type="checkbox"/> 4X	<input type="checkbox"/> 4	<input type="checkbox"/> Other:	
	Purge Classification:	<input checked="" type="checkbox"/> None	<input type="checkbox"/> X	<input type="checkbox"/> Y	<input type="checkbox"/> Z
4. Display Panel Location:		<input type="checkbox"/> Flashing	<input type="checkbox"/> Swing Arm	<input checked="" type="checkbox"/> Other: Main control panel	
5. Battery Backup:	<input checked="" type="checkbox"/> None		<input type="checkbox"/> Controls Only	<input type="checkbox"/> Complete System	
	Duration:	<input type="checkbox"/> 5 Minutes	<input type="checkbox"/> 10 Minutes	<input type="checkbox"/> 15 Minutes	<input type="checkbox"/> Other:
6. Grounding Provision for Internal Equipment:			<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	Type:
7. GFCI Power Receptacle:		<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	Internal Qty:	External Qty:
8. Equipment Lighting:	<input type="checkbox"/> None		<input checked="" type="checkbox"/> Fluorescent	<input type="checkbox"/> Halogen	<input type="checkbox"/> Other:
	Qty:	1	Location: Ceiling		

Section 5B – Equipment Control System Phases of Operation

Phase	Description
Off	Fan and lights off, valves closed.
Sterilize	VHP generator has pressure control of isolator. inlet and outlet valves closed manually..
Aerate	Blower 100%, operator opens inlet valve, operator opens air outlet valve. Overpressure blower controls isolator pressure
Run room air Positive	Blower controls isolator pressure, inlet valve manually operated, air outlet manually operated.



Section 6 – Factory & Site Acceptance Test (FAT & SAT) Requirements

Notes: Test #'s 1-7 are included at no cost as applicable to the equipment design.
 Test #'s 8-14 are included at no cost as applicable to the equipment options selected.
 Test #'s 15-20 are Optional and involve additional charges.
 SAT tests are only applicable if installation is performed by CPS Barrier.

FAT	SAT	Inspection / Test	Inspection / Test Description
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Supplied Equipment Review (WC-ATP-01)	Verify that all items specified on the customer's PO, approved assembly drawing and the Equipment Specification are present
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2. Workmanship, Appearance and Identification Inspection (WC-ATP-02)	Verify workmanship and appearance of the complete Equipment, including welding, polishing and labeling
<input checked="" type="checkbox"/>	N/A	3. Dimensional Inspection (WC-ATP-03)	Verify the general dimensions of the Equipment and the locations of critical components with the approved Equipment assembly drawing
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4. Product Manipulation Systems Functional Inspection (WC-ATP-04)	Verify that the Equipment product manipulation systems (such as doors, RTP's, gloves & containers) operate properly
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. HVAC System Test (WC-ATP-05)	Verify that the HVAC System of the Equipment operates properly and meets specified requirements
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Electrical Control System Test (WC-ATP-15)	Verify that all electrical controls (controllers, monitors, alarms, lights, switches and indicators) operate as specified
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Ammonia Leak Test (WC-ATP-06)	Verify that no leaks are detectable around seal joints with Ammonia inside the Equipment chamber
<input type="checkbox"/>	<input type="checkbox"/>	8. Unidirectional Airflow Test (WC-ATP-08)	Determine the air velocity and uniformity at specified locations in the Unidirectional Airflow Equipment
<input type="checkbox"/>	<input type="checkbox"/>	9. CIP Sequence of Operations (WC-ATP-14A)	Verify the performance of the CIP equipment in regard to the sequence of operations
<input type="checkbox"/>	<input type="checkbox"/>	10. Oxygen Concentration Control System Test (WC-ATP-19)	Verify that the Equipment controls the oxygen level as specified
<input type="checkbox"/>	<input type="checkbox"/>	11. Humidity Control System Test (WC-ATP-18)	Verify that the Equipment controls the humidity level as specified
<input type="checkbox"/>	<input type="checkbox"/>	12. Temp Control System Test (WC-ATP-11A)	Verify that the Equipment controls the chamber temperature as specified
<input type="checkbox"/>	N/A	13. Atmospheric Oven Temp Control System Test (WC-ATP-11B)	Verify the temperature performance of the dryer oven
<input type="checkbox"/>	N/A	14. Vacuum Oven Temp Control System Test (WC-ATP-11C)	Verify the temperature performance of the dryer oven
<input type="checkbox"/>	N/A	15. Helium Leak Test (WC-ATP-07)	Verify that no leaks exceed the specified leak rate at known standard conditions around seal joints with Helium inside Equipment chamber Leak Rate: 1 x 10 ⁻⁴ cc/sec Test Pressure: 2" Water Column
<input checked="" type="checkbox"/>	N/A	16. VHP (H2O2) Chemical Indicator Test (WC-ATP-12)	Verify that all surface areas inside the Equipment chamber are reached through the H2O2 decontamination process
<input type="checkbox"/>	<input type="checkbox"/>	17. Measure Air Changes Per Hour Test (WC-ATP-09)	Determine the rate of air changes per hour within the Equipment
<input type="checkbox"/>	N/A	18. Air Flow Smoke Test (WC-ATP-22)	Determine airflow patterns in the Equipment and ensure that air flows without dead zones and eddies
<input type="checkbox"/>	N/A	19. CIP Coverage Test (Riboflavin) (WC-ATP-27)	Verify the coverage of liquid delivered by CIP spray balls and/or spray wand inside the Equipment chamber using Riboflavin
<input type="checkbox"/>	<input type="checkbox"/>	20. HEPA/ULPA Filter Integrity Test (CLS-1017-M1)	Verify the Equipment's HEPA / ULPA filters for integrity using an aerosol (option)



Section 7A – Additional Items

Note: Items identified as optional are priced separately and not included in the system price, please contact your Technical Sales Representative for further information and recommendations.

Item	Item Description
1	Options: 240 VAC 1 phase power for EU. CE Stamp Exhaust hose option 2" Enhanced airflow option with 3" line size Electric actuated valves for "lights out" sterilization cycle control. HEPA filter integrity test Shelving Top flashing cover Glove extenders Steritest with drain
2	Spare Parts to quote Bag Gloves HEPA filters Sense Line filters
3	
4	
5	
6	
7	
8	
9	
10	

Section 7B – Equipment Design Exceptions

Note: The following items have been identified as special exceptions that are not included in the equipment design and price, please contact your Technical Sales Representative for further information and recommendations.

1	
2	

Section 8 – Equipment Specification Revision History

Rev. #	Revised By	Rev. Date	Revision Description	Released
A	C. Johnson	12/19/05	Initial Release	12/21/05 SJW