

618 State Street  
New Lisbon, WI 53950  
www.walkerbarrier.com  
(608) 562-7700



## Equipment Specification

Page 1 of 11

<b>Work Order #:</b> <b>33745</b>	<b>WO Spec Rev. #:</b> <b>B</b>	<b>Customer PO:</b>	<b>Customer PO Date:</b>
<b>Proposal #:</b> <b>00366</b>	<b>Proposal Rev. #:</b> <b>0</b>	<b>Proposal Date:</b> <b>4/7/06</b>	<b>Proposed By:</b> <b>Jeff Johnson &amp; Ron Nuttall</b>
<b>Equipment Name:</b> <b>Sterility Test isolator</b>			
<b>Customer:</b>		<b>Contact:</b>	
<b>Address:</b>			
<b>Phone #:</b>		<b>Fax #:</b>	<b>Email:</b>
<b>Equipment/Process Description:</b>			

**Section 1A – Customer Facility and Product Information**

<b>1. Room Size (L x W x H):</b>		Limiting Doorway Opening (W x H):					
<b>2. Room Conditions:</b>		Temperature:	Relative Humidity:	Seismic:	None		
<b>3. Clean Room Classification:</b>							
<b>4. Room Electrical Classification:</b>	<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		
<b>5. Chamber Electrical Classification:</b>	<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		
<b>6. Room Utilities:</b>	Water:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:	Temp:	GPM:	
	Compressed Dry Air:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:	CFM:		
	Nitrogen:	<input type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:	CFM:		
	Blower Exhaust Connection:						
	Power:	<div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> 125V                      1 Phase                      3 Wire  <input type="checkbox"/> 60 Hz  <input type="checkbox"/> 50 Hz                 </div> <div style="width: 50%;"> </div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="checkbox"/> 125/250V                      3 Phase                      4 Wire  <input type="checkbox"/> 60 Hz  <input type="checkbox"/> 50 Hz                 </div> <div style="width: 50%;"> </div> </div>					

<b>6. Continued:</b>	Power:	<input type="checkbox"/> 120/208V 3 Phase 5 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz	
----------------------	--------	--	--

		<input type="checkbox"/> 277/480V 3 Phase 5 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz	<p>3Ø 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>3Ø 480V 3P,4W GROUNDING</p>
<p><b>7. Product Information:</b></p>	<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:		
<p><b>8. Product Container Information:</b></p>	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: 82" x 26" x 30"

**2. Overall Equipment Size:** Length x Width x Height:

**3. Construction Information:**

Item	Material	Finish / Color	Size / Gauge	Type / Comments
Shell:	316L SS	Interior: 18-22	7ga	
		Exterior: 18-22		
Stand:	316L SS		7ga	
Flashing:	304 SS		14ga	
Flashing Cover:	304 SS		14ga	
Flashing Gasket:				
Windows:	Laminated safety glass	Clear	3/8"	One 2 glove hatchback Window
	Laminated safety glass	Clear	3/8"	Two fixed Windows
Window Gaskets:	Silicone	FDA White	3/8" Channel	
Flat Gaskets:	Silicone	FDA White	1/8"	
Door Gaskets:				
Other Gaskets:				
HVAC Piping:	316L SS		3"	
CIP Piping:				
Hardware:				
Casters:			5"	
Leveling Pads:			1/2"	2" Adjustment
Other:				



Section 2 – Equipment HVAC System Requirements							
<b>1. HVAC System:</b> <input type="checkbox"/> None <input checked="" type="checkbox"/> On Equipment <input type="checkbox"/> Remote Location <input type="checkbox"/> House Exhaust							
<b>2. Overpressure:</b> <input checked="" type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Both / Zones    Air Changes Per Hour:							
<b>3. Unidirectional Airflow:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes    Velocity at 6" below filter face (ft/min):							
<b>4. Velocity Over An Open Glove Port:</b> <input checked="" type="checkbox"/> 100 ft/min <input type="checkbox"/> Other:							
<b>5. Decontamination System:</b> <input type="checkbox"/> None <input checked="" type="checkbox"/> H <sub>2</sub> O <sub>2</sub> Type: <input type="checkbox"/> Wipe down    Agent:							
<b>6. Gas System:</b> Supports Items 7, 8 and 9	<input type="checkbox"/> None <input checked="" type="checkbox"/> Once Through <input type="checkbox"/> Recirculated						
	Gas Type: <input type="checkbox"/> CDA <input checked="" type="checkbox"/> Nitrogen <input type="checkbox"/> Argon <input type="checkbox"/> Other:						
	<input type="checkbox"/> Regulator <input checked="" type="checkbox"/> Proportional Control Valve    Size:						
	CLS Supplied Components: <input checked="" type="checkbox"/> Flow Meter w/valve    Flow Meter Range (SCFH): <input type="checkbox"/> Flow Meter w/o valve						
<b>7. Oxygen System:</b>	<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)						
<b>8. Humidity System:</b>	<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						
<b>9. Ammonia Leak Test Pressure Control System:</b> <input type="checkbox"/> None <input checked="" type="checkbox"/> Automatic							
<b>10. Internal Equipment Heat Load:</b>							
<b>11. Temperature System:</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Monitor <input type="checkbox"/> Control    Range (°F, °C):							
Heating:				Cooling:			
<b>12. HVAC Filters:</b>	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"x 12" x 3"	1	12"x 12" x 3"		
	Pre-Filter / Diffusion Membrane						
	Pressure Sensor Filter	2	0.2 micron				
Other:							



Section 2 – Equipment HVAC System Requirements (continued)						
<b>13. HVAC Blowers:</b>	Type:	Pos. Press.	Neg. Press.	Unidirectional Flow	Recirculation	Distribution Fan
	Qty:	1				2
	Size:	AF-9				
	Motor HP:	3/4				
<b>14. HVAC Valves:</b>	Type	Qty	Size	Actuation		
	Butterfly	2	3"	Pneumatic		
	Other					

**Section 3 – Equipment Cleaning and Utility Component Requirements**

**1. Cleaning System:**     Water     Dry Air     Solvents:    Type:

Item	Qty	Material	Size / Type	Location / Comments
Chamber Drain Fitting	1	316L	2" to ½"	
Chamber Drain Valve	1	316L	½"	Diaphragm pneumatic actuation
Cleaning System Valves				
Spray Wand				
Spray Wand Hook				
Spray Wand Port				
Spray Balls				
Vacuum Wand				
Vacuum Wand Hook				
Vacuum Wand Port				



**Section 3 – Equipment Cleaning and Utility Component Requirements**

**2. Utility Connections:**

Item	Qty	Material	Size / Type	Location / Comments
Utility Panel Tri-Clamp Fittings	2	316L	1 ½" spooled TC's	
Utility Panel Compression Fittings	2	Teflon	3/8"	
Compression Fitting				
Product Entry & Exit Fitting				
Other Fittings				
Utility Hooks				
Other:				



Section 4 – Equipment Material Handling Component Requirements				
Item	Qty	Material	Size / Type	Location / Comments
1. Gloves	4	Hypalon	9A	
2. Glove Sleeves	4	Hypalon		
3. Glove Ports	4	Ultem	10" oval	
4. Glove Extenders	4			
5. Half Suit				
6. Access Door				
7. Air Lock				
8. Bag Out Ring				
9. Transfer Tray				
10. RTP Alpha	?			
11. RTP Beta				
12. Transport Container	?			
13. Liquid Transfer Container				
14. Autoclavable Container				
15. Autoclavable Cont. Cart				
16. Container Lift				
17. Swing Out Table				
18. Shelving	2			
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	1			Steritest



**Section 5A – Equipment Control System Requirements**

<b>1. Control System Type:</b>		<input type="checkbox"/> None	<input type="checkbox"/> AMP1000	<input checked="" type="checkbox"/> AMP2000	<input type="checkbox"/> AMP3000
Special Notes:					
<b>2. Supply Voltage:</b>		Volts:	Phase:	Freq. (Hz):	Amps:
<b>3. Control Panel:</b>	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 type="checkbox"/> None	<input type="checkbox"/> X	<input type="checkbox"/> Y	<input type="checkbox"/> Z
<b>4. Display Panel Location:</b>		<input type="checkbox"/> Flashing	<input checked="" type="checkbox"/> Swing Arm	<input type="checkbox"/> Other:	
<b>5. Battery Backup:</b>	<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:
<b>6. Grounding Provision for Internal Equipment:</b>				<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes
<b>7. GFCI Power Receptacle:</b>		<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	Internal Qty:	External Qty: 1
<b>8. Equipment Lighting:</b>	<input type="checkbox"/> None		<input type="checkbox"/> Fluorescent	<input type="checkbox"/> Halogen	<input type="checkbox"/> Other:
	Qty: 2	Location: (1) under the stand (1) roof or Back wall			

**Section 5B – Equipment Control System Phases of Operation**

Phase	Description



<b>Section 6 – Factory &amp; Site Acceptance Test (FAT &amp; SAT) Requirements</b>			
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 <sup>-4</sup> 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



**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	
2	
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	
3	

**Section 8 – Equipment Specification Revision History**

Rev. #	Revised By	Rev. Date	Revision Description	Released
A	SJW	9/28/06	Initial Release from proposal	9/28/06 SJW
B	CSS	3/14/07	Changed due to business name change	3/14/7 css