



Equipment Specification

Work Order #:	WO Spec. Rev. #:	Customer PO #:	Customer PO Date:
32702	C		
Proposal #:	Proposal Rev. #:	Proposal Date:	Proposed By:
Equipment Name: 3 Glove Transfer Isolator			
Customer:		Contact:	
Address:			
Phone #:	Cell #:	Email:	
Equipment/Process Description:			
<p>The purpose of the Transfer Isolator(s) is to provide a highly aseptic environment for transfer of sterility test materials. The isolator has been designed with an emphasis on ergonomics and PLC control.</p> <p>The size of the isolator is approximately 60"W x 26"D, with an enclosure height of 30". The operator will access storage shelves via three glove ports. Isolator construction is of 316L stainless steel with laminated safety glass windows, in silicone channel gaskets. An inlet and outlet blower system will exhaust hydrogen peroxide vapors through 2" automatic ball valves, controlled by the PLC for fully automated decontamination cycle with a VHP-1000 generator by Steris Corporation. Under normal operations, the inlet blower will slightly pressurize the isolator through HEPA filters, providing a minimum Class 100 environment.</p> <p>Product and test materials are entered into the isolator via the large hatch back window and stored on shelves. After the window is sealed, the VHP decontamination cycle can be initiated. Upon completion of the decontamination cycle, the operator docks the 350mm RTP beta flange to the alpha flange found on the work center (testing) isolator. The door is opened from the work center isolator. After the door is opened, the operator enters the glove ports and passes the required materials into the work center isolator for testing. After testing, the operator passes media samples into the transfer isolator. The transfer isolator is taken to incubators, where sealed media containers are removed from the isolator and placed into Amgen's incubators. Other waste material can be removed from the isolator and any cleaning can take place. The isolator will need to be decontaminated again for the next sterility test.</p>			

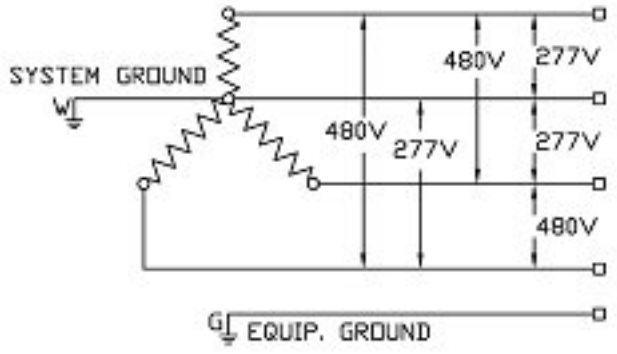
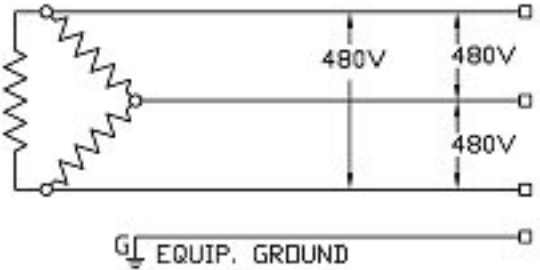


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Section 1A – Customer Facility and Product Information

1. Room Size (L x W x H):		Limiting Doorway Opening (W x H):						
2. Room Conditions:		Temperature:	Relative Humidity:		Seismic:			
3. Clean Room Classification:								
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:		
	Compressed Dry Air:	<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	Pressure:	90 psi	CFM:	10-15	
	Nitrogen:	<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	Pressure:		CFM:		
	Blower Exhaust Connection:							
	Power:	<input checked="" type="checkbox"/> 125V 1 Phase 3 Wire <input checked="" type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz						
		<input type="checkbox"/> 125/250V 3 Phase 4 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz						
	<input type="checkbox"/> 120/208V 3 Phase 5 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz							

Legend: TBDC = To Be Determined by Customer
 TBDE = To Be Determined by CLS Engineering
 N/A = Not applicable

6. Continued:	Power:	<input type="checkbox"/> 277/480V 3 Phase 5 Wire <input type="checkbox"/> 60 Hz <input type="checkbox"/> 50 Hz	<p>3ØY 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> 	
7. Product Information:	<input type="checkbox"/> Liquid <input type="checkbox"/> Powder <input type="checkbox"/> Suspension <input type="checkbox"/> Antibiotic <input type="checkbox"/> Cytotoxic <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:
	Smallest:	Diameter:	Height:	Volume:



Section 1B – General Equipment Construction Requirements

1. Chamber Exterior Size: Length x Width x Height: Approx. 60”L X 26” W X 30” H

2. Overall Equipment Size: Length x Width x Height: Approx. 65”L X 33” W X 86” H

3. Construction Information:

Item	Material	Finish / Color	Size / Gauge	Type / Comments
Shell:	316L S.S.	Interior: ≤ 22 Ra	7 Ga.	
		Exterior: ≤ 35 Ra		
Stand:	304 S.S.	≤ 35 Ra	1-1/2” Sq. Tube	
Flashing:	304 S.S.	≤ 35 Ra	14 Ga.	
Flashing Cover:				
Flashing Gasket:				
Windows:	Safety Glass		3/8” SG	Front hatchback window
	Safety Glass		3/8” SG	Back wall light window
Window Gaskets:	Silicone	White	3/8” Channel	
Flat Gaskets:	Silicone	White	1/8” Thick	
Door Gaskets:				
Other Gaskets:				
HVAC Piping:	316L S.S.	≤ 22 Ra I.D.	2” diameter	
CIP Piping:				
Hardware:	S.S.			
Casters:	S.S./Polyolefin		5”	4 swiveling casters, with brakes
Leveling Pads:				
Lift:	Movotech (Electric) ^B			2000 lb Capacity ^B

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

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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				
Chamber Drain Valve				
Cleaning System Valves				
Spray Wand				
Spray Wand Hook				
Spray Wand Port				
Spray Balls				
Vacuum Wand				
Vacuum Wand Hook				
Vacuum Wand Port				

2. Utility Connections:

Item	Qty	Material	Size / Type	Location / Comments
Utility Panel Tri-Clamp Fittings	2	316L S.S.	1 1/2" T.C.	
Utility Panel Compression Fittings	2	Teflon	3/8" Compression	
Compression Fitting				
Product Entry & Exit Fitting				
Other Fittings				
Utility Hooks				
Other:				

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Section 4 – Equipment Material Handling Component Requirements				
Item	Qty	Material	Size / Type	Location / Comments
1. Gloves	3	Hypalon	14" / Size 8A	2 Piece, p/n: GLV-HY-8A ^B
2. Glove Sleeves	3	Hypalon	10"	
3. Glove Ports	3	Aluminum	10" Oval, Sterile	
4. Glove Extenders				
5. Half Suit				
6. Access Door				
7. Air Lock				
8. Bag Out Ring				
9. Transfer Tray				
10. RTP Alpha				
11. RTP Beta	1	Polyprop.	350 mm	Beta Transfer Sleeve – right side of isolator Needs to be able to dock to a CRL Alpha ^B
12. Transport Container				
13. Liquid Transfer Container				
14. Autoclavable Container				
15. Autoclavable Cont. Cart				
16. Container Lift				
17. Swing Out Table				
18. Shelving	1	S.S.	14" x 30"	3 shelves
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				

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Section 6 – Factory & Site Acceptance Test (FAT & SAT) Requirements			
Notes: 1. Test #'s 1-7 are included at no cost as applicable to the equipment design. 2. Test #'s 8-15 are included at no cost as applicable to the equipment options selected. 3. Test #'s 16-23 are Optional and involve additional charges. 4. SAT tests are only applicable if installation is performed by Carlisle Life Sciences.			
FAT	SAT	Inspection / Test	Inspection / Test Description
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1. Supplied Equipment Review (CLS-1017-M1)	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 (CLS-1017-M2)	Verify workmanship and appearance of the complete Equipment, including welding, polishing and labeling
<input checked="" type="checkbox"/>	N/A	3. Dimensional Inspection (CLS-1017-M3)	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 (CLS-1017-M4)	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 (CLS-1017-M5)	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 (CLS-1017-M6)	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 (CLS-1017-M7)	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 (CLS-1017-M8)	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 (CLS-1017-M9)	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 (CLS-1017-M10)	Verify that the Equipment controls the oxygen level as specified
<input type="checkbox"/>	<input type="checkbox"/>	11. Humidity Control System Test (CLS-1017-M11)	Verify that the Equipment controls the humidity level as specified
<input type="checkbox"/>	<input type="checkbox"/>	12. Leak Test Control System Test (CLS-1017-M12)	Verify that the Equipment senses leakage as specified
<input type="checkbox"/>	<input type="checkbox"/>	13. Temperature Control System Test (CLS-1017-M13)	Verify that the Equipment controls the chamber temperature as specified
<input type="checkbox"/>	N/A	14. Atmospheric Oven Temperature Control System Test (CLS-1017-M14)	Verify the temperature performance of the dryer oven
<input type="checkbox"/>	N/A	15. Vacuum Oven Temperature Control System Test (CLS-1017-M15)	Verify the temperature performance of the dryer oven
<input type="checkbox"/>	N/A	16. Helium Leak Test (CLS-1017-M16)	Verify that no leaks exceed the specified leak rate at known standard conditions around seal joints with Helium inside Equipment chamber Leak Rate: 1×10^{-5} cc/sec Test Pressure: 2" Water Column
<input checked="" type="checkbox"/>	N/A	17. Hydrogen Peroxide (H ₂ O ₂) Chemical Indicator Test (CLS-1017-M17)	Verify that all surface areas inside the Equipment chamber are reached through the H ₂ O ₂ decontamination process
<input type="checkbox"/>	<input type="checkbox"/>	18. Measurement of Air Changes Per Hour Test (CLS-1017-M18)	Determine the rate of air changes per hour within the Equipment



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FAT	SAT	Inspection / Test	Inspection / Test Description
<input type="checkbox"/>	N/A	19. Air Flow Smoke Test (CLS-1017-M19)	Determine airflow patterns in the Equipment and ensure that air flows without dead zones and eddies
<input type="checkbox"/>	N/A	20. CIP Coverage Test (Riboflavin) (CLS-1017-M20)	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"/>	21. HEPA/ULPA Filter Integrity Test (CLS-1017-M21)	Verify the Equipment's HEPA / ULPA filters for integrity using an aerosol
<input type="checkbox"/>	N/A	22. Particle Count Measurement Test (CLS-1017-M22)	Verify that the Equipment chamber meets specified particle count requirements
<input type="checkbox"/>	<input type="checkbox"/>	23. Other Tests: (CLS-1017-M23)	Special tests not covered above as specified in Section 7A – Additional Items.

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	Fold-down handles (left end)
2	Inlet filter heater for rapid aeration ^C
3	All VHP connections are Banjo type, mounted on rear flashing.
4	All power cords are to have twist-lock plugs.
5	Reference Amgen 32261 & 32262: (Please note for P&ID / GA info, that the there is only qty1 Alpha 350mm, & there is Temperature control & Automatic Ammonia Leak Test on both 32701 & 32702.
6	
7	
8	

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	Bardell	7/21/04	Initial Release (reviewed & updated by Riepe)	7/22/04 SJW
B	Riepe	7/26/04	Design & Controls Update	7/27/04 SJW
C	Riepe	8/02/04	Removed Inlet Filter Heater information (Can requote after order if needed)	8/3/04 SJW