618 State Street New Lisbon, WI 53950

Operations and Maintenance Manual

Emerson-Fiducia

Filling Isolator

Walker Barrier Systems

Work Order Number: 37642

Isolator Serial Number: 37642-1

Revision B

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A DIVISION OF WALKER STAINLESS EQUIPMENT COMPANY LLC

BARRIER SYSTEMS

Operations and Maintenance Manual

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Chapter 1 Introduction

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Walker Barrier Systems

Through the years, we have been designing and fabricating custom isolation and containment systems for the pharmaceutical and nuclear industries under various names. Our past names have included Carlisle Barrier Systems, Carlisle Life Sciences, CPS Barrier, and now we are under the name of Walker Barrier Systems. Although our name has changed several times, our dedication to customer satisfaction and our mission to "Meet Customer Expectations with Quality Products and a Sense of Urgency" has not.

We are confident that you will feel that we have accomplished our mission with this piece of equipment. If at any time, you have any questions or concerns about this equipment, please contact any one of the individuals listed on the upcoming 'Contact Names' page within this chapter.

Thank you for placing this order and for your confidence in us.

Equipment Safety Recommendations

The following is a chart of safety recommendations that Walker Barrier Systems feels are important to know for the operation of this Isolator. Most of these items will be discussed in detail in the corresponding chapters of this manual.

Things To Do	**Things Not To Do**
Refer to manufacturer's information for the proper use, care, and maintenance of all components.	Remove any placards, labels, or other identification markings.
Use care when handling sharp objects or tools within the Isolator.	Wear rings, jewelry, or other sharp objects when entering the gloves and sleeves.
Leave the Isolator running at all times at specified pressure.	Run the make-up blowers without pre-filters in place.
Frequently clean isolator surfaces (interior and exterior) and pre-filters.	Use abrasive cleaners on viewing windows or panels.
Frequently clean and lubricate RTP gaskets using a sterile low-particulate swab, or equivalent.	Open RTP door when the transport isolator is not connected. Do not forcibly close the RTP door.
Use proper safety precautions (as recommended by the manufacturer) when handling sanitization or cleaning agents.	Use chlorinated solvents on stainless steel surfaces.
Become trained and proficient at glove change procedure.	

Equipment Safety Recommendations:

- **NOTE:** All maintenance of the electrical equipment mounted on the isolator should be performed by a qualified electrician or by maintenance personnel who are familiar with electrical installations.

- **GFIC Warning:** Persons with heart problems, or other health problems which may make them susceptible to electric shock, can be injured by ground faults occurring in equipment connected to this circuit.

- **Confined Spaces:** Gloveboxes and/or Isolators are confined spaces. Consult your company confined space program. **Failure to use caution when entering the interior of a glovebox may result in injury or even death.**

- **Rotating Parts (ventilation system):** Do not stick body parts into the fan during maintenance procedures. Always use proper lock out and tag out procedures.

Warranty Information

Products manufactured by Walker Barrier Systems are warranted to be free of defects in material and workmanship for one (1) year from the date of installation or eighteen (18) months from shipment, whichever occurs first. In the case of products manufactured by others, Walker Barrier Systems will pass through the Original Equipment Manufacturer's warranty.

Qualified warranty remedy shall be repair or replacement of the part or equipment, or payment of the costs of repair or replacement, at the option of Walker Barrier Systems.

The warranty does not apply to any Walker Barrier Systems product that has been repaired or altered by someone other than Walker Barrier Systems without written authorization, or to equipment that has been subject to misuse. Also excluded are consumable items such as gloves, sleeves, filters, and gaskets.

Contact Names

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Chapter 2

Chapter 2 Isolator System Information

Isolator Description

Equipment Specification Form

Function Matrix

Software Design Specification (SDS)

Functional Specification (FS)

Design Specification (DS)

Isolator Description

Fill isolator is loaded using the airlock front hatchback window. Window is closed and latched, and sterilization cycle is started on VHP generator. Pre-condition, injection and aeration phases of isolator decontamination are completed using the VHP generator. After manual filling work is complete, Isolator is then opened to repeat the cycle.

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Equipment Specification Form

Function Matrix

Software Design Specification (SDS)

Functional Specification (FS)

Design Specification (DS)

Stainless Steel (S.S.)

Aluminum

Polyvinyl Chloride (PVC)

Silicone

Polypropylene

Laminated Safety Glass

Hypalon

Teflon – PTFE and FEP

Ultem

Neoprene

Viton

Nylon

Stainless Steel (S.S.)

The Isolator is constructed from 316L stainless steel of various gauges. Components are continuously welded, ground, and polished to the same finish, where required. The Shell is 7 gauge with 5/8" "coved" inside corners.

All machined components and hardware in the interior of the chamber or in the sterilized air stream are made of 316 stainless steel.

Components and hardware on the exterior are made of 304 or 18-8 stainless steel.

Material certifications for the various stainless steels used on this Isolator appear in Chapter 9.

Material Data Sheet: Stainless Steel 304 and 304L

Description

Type 304 (UNS S 30400) is an austenitic chromium-nickel stainless and heat resisting steel with excellent corrosion resistance when exposed to many types of chemical corrodents, as well as marine atmospheres. It also has superior creep strength at elevated temperatures. In the lower carbon 304L (S30403) material, carbide precipitation, as a result of welding, will be minimized, resulting in less susceptibility to intergranular corrosion.

Chemical Composition

Carbon	Manganese	Silicone	Chromium	Nickel
T304 0.08 max.	2.00	.75	18.00	8.00 – 10.50
T304L 0.03 max.	2.00	.75	18.00	8.00 – 12.00

Typical Mechanical Properties

Property	Yield Strength Psi	Tensile Strength Psi	Elongation In 2 in., %	Hardness Rockwell B
T304	30,000	75,000	40	92
T304L	25,000	70,000	40	92

Product Forms

- Ingots
- Slabs
- Hot bands
- Sheet
- Strip

Typical Applications

- Chemical screens, storage and transportation tanks, tubing
- Food processing equipment, steam-cooking kettles
- Oil refining equipment
- Paper digesters, evaporators, handling equipment
- Pharmaceutical processing equipment
- Scrubbers for environmental control
- Soap and photographic handling equipment
- Textile industry

Processing:

Annealing
Cool rapidly from 1120° C. The object of this treatment is to take the carbides into solution and keep them in solution by cooling rapidly (usually in water).

Hardening
These grades can be hardened only by cold working. See table of Typical Mechanical Properties.

Stress Relieving
The recommended temperature range for stress relieving is 450 - 600° C.

Hot Working
- Preheating temperature: 1150 - 1260° C for large sections
- Finishing temperature: 900 - 925° C

Forming
Types 304 and 304L can be formed into most shapes. However, as they will work harden, material should be in the annealed condition before each severe cold forming operation. It is also recommended that after severe cold forming operations, material be stress relieved as a final step.

Welding
Types 304 and 304L possess excellent welding characteristics. These grades can be welded by the electric arc, gas fusion or electric resistance processes. Welds in these alloys possess toughness, structural stability and high strength. Types 304 or 304L filler metal or electrodes may be used.

Corrosion
Type 304 stainless has good resistance to most organic acids, e.g., acetic, benzoic, lactic.

Oxidation
In ordinary atmosphere, Type 304 has good scaling resistance up to 1650° F in continuous service; 1500° F in intermittent service.

Material Data Sheet: Stainless Steel 316 and 316L

Description

Type 316 (UNS S 31600) is an austenitic chromium-nickel stainless and heat resisting steel with superior corrosion resistance to other chromium-nickel steels when exposed to many types of chemical corrodents, as well as marine atmospheres. It also has superior creep strength at elevated temperatures. In the lower carbon 316L material, carbide precipitation, as a result of welding, will be minimized, resulting in less susceptibility to intergranular corrosion.

Chemical Composition

Carbon	Manganese	Silicone	Chromium	Nickel	Moly.
T316 0.08 max.	2.00	1.00	16.00	10.00	2.00
T316L 0.03 max.	Max.	Max.	18.00	14.00	3.00

Typical Mechanical Properties

Finish/ Condition	Yield Strength Psi	Tensile Strength Psi	Elongation In 2 in., %	Hardness Rockwell B
No. 1/2D Finish, Annealed	40,000	84,000	52	79
No. 2/2B Finish, Skin passed	45,000	84,000	50	83

Product Forms

- Ingots
- Slabs
- Hot bands
- Sheet
- Strip

Typical Applications

- Chemical screens, storage and transportation tanks, tubing
- Food processing equipment, steam-cooking kettles
- Oil refining equipment
- Paper digesters, evaporators, handling equipment
- Pharmaceutical processing equipment
- Scrubbers for environmental control
- Soap and photographic handling equipment
- Textile industry

Processing:

Annealing
Cool rapidly from 1950 - 2050° F. The object of this treatment is to take the carbides into solution and keep them in solution by cooling rapidly (usually in water)

Hardening
These grades can be hardened only by cold working. See table of Typical Mechanical Properties.

Stress Relieving
The recommended temperature range for stress relieving is 400 - 750° F.

Hot Working
- Preheating temperature: 1500 - 1600° F for large sections.
- Forging and pressing temperature: 2100 - 2300° F.
- Finishing temperature: 1700° F (the reductions below 1800° F should be light).

Forming
Types 316 and 316L can be formed into most shapes. However, as they will work harden, material should be in the annealed condition before each severe cold forming operation. It is also recommended that after severe cold forming operations, material be stress relieved as a final step.

Physical Properties

Density Lb./cu. in.	Modulus of Elasticity In Tension X 10^6, psi	Specific Heat Btu/°F/lb	Thermal Conductivity Btu/hr/ft^2/ft		Mean Coefficient Of Thermal Expansion Per °F(x 10^{-6})				Melting Point Range	Electrical Resistivity Microhm-cm
		32-212° F	°F		°F				°F	@ 70° F
0.29	28.0	0.12	212	932	32-212	32-600	32-1000	32-1200	2500	74
			9.4	12.4	8.9	9.0	9.7	10.3	2550	

Elevated Temperature Strength

Creep Strength	Temperature			
Load for 1% elong.	1000° F	1100° F	1200° F	1300° F
10,000 hr, psi	25,000	18,200	12,700	7900

Welding

Types 316 and 316L possess excellent welding characteristics. These grades can be welded by the electric arc, gas fusion, or electric resistance processes. Welds in these alloys possess toughness, structural stability, and high strength. Types 316 or 316Cb filler metal or electrodes may be used.

Corrosion

Type 316 stainless has excellent resistance to most organic acids, e.g., acetic, benzoic, lactic. It is superior to the regular chromium- nickel stainless grades in seawater and is less susceptible to pitting attack.

Oxidation

In ordinary atmosphere, Type 316 has good scaling resistance up to 1650° F in continuous service, 1500° F in intermittent service.

Aluminum

The Isolator may contain various items made of Aluminum such as brackets, plates, tubes, and machined components. Aluminum is alloyed with small amounts of one or more elements such as copper, manganese, silicon, magnesium, or zinc to enhance desired characteristics such as increased strength, corrosion resistance, and weldability.

Aluminum alloys are worked by rolling, extruding, drawing, forging, etc., to produce semi-fabricated, product forms including sheet, plate, foil, wire, rod, bar, tubes, pipes, forgings, and extruded profiles. The processing of aluminum alloys into semi-fabricated, engineered products can be done in many ways with resulting variations in metallurgical characteristics.

The alloy-temper combinations of these semi-fabricated, engineered products have aluminum industry product standards with specific mechanical and physical properties.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

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Material Data Sheet: Aluminum

Aluminum Alloys, General

Material Notes: These properties are typical of commercial aluminum alloys. Some properties, such as strength and hardness, vary too much for a reasonable generalization.

Physical Properties	**Metric**	**English**	**Comments**
Density	2.7 g/cc	0.0975 lb/in^3	
Mechanical Properties			
Modulus of Elasticity	70 GPa	10200 ksi	
Poisson's Ratio	0.33	0.33	
Shear Modulus	26 GPa	3770 ksi	
Electrical Properties			
Electrical Resistivity	0.000005 ohm-cm	0.000005 ohm-cm	
Thermal Properties			
Heat of Fusion	390 J/g	168 BTU/lb	
CTE, linear 20ºC (32-212ºF)	24 µm/m-ºC	13.3 µin/in-ºF	from 0-100ºC
CTE, linear 250ºC	25 µm/m-ºC	13.9 µin/in-ºF	
Heat Capacity	0.88 J/g-ºC	0.21 BTU/lb-ºF	
Thermal Conductivity	190 W/m-K	1320 BTU-in/hr-ft^2-ºF	
Melting Point	620 ºC	1150 ºF	
Solidus	620 ºC	1150 ºF	
Liquidus	650 ºC	1200 ºF	

Polyvinyl Chloride (PVC)

The Isolator contains a limited amount of Polyvinyl Chloride (PVC) piping. This piping is used in the make-up air system. The components selected are generic Schedule 80 gray PVC pipe and fittings.

The components are bonded together with the vendors recommended cleaning agents and cements. The methods used are as specified by the cleaning agent and cement manufacturer's instructions.

Interface with these components will mainly be done at installation or during routine maintenance by specified personnel.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

Material Data Sheet: PVC

FINISHED PROFILE, BAR STOCK, DUCT, ANGLE, JOINING STRIP, And PIPE MADE FROM RIGID PVC and CPVC THERMOPLASTIC

SECTION I

Manufacturer's Name	**Telephone Number**	**Address**
Harvel Plastics, Inc.	(215) 252-7355 FAX: (215) 253-4436	P.O. Box 757, Easton, PA 18044-0757
Chemical Family	**Formula**	**Trade Designation**
Ethene, chloro- (homopolymer and chlorinated)	Mixture of PVC or CPVC polymer with functional additives.	
Chemical Name/Synonyms	**NFPA 704[1]**	**HMIS[2]**
Polyvinyl chloride, PVC and chlorinated Polyvinyl chloride, CPVC.	Health: 2 Flammability: 1 Reactivity: 0 Special: None	Health: 0 Flammability: 1 Reactivity: 0

Hazard Code Key: 0 = Insignificant; 2 = Moderate 3 = High; 4 = Extreme
[1]National Fire Protection Ass'n [2]National Paint and Coatings Ass'n

SECTION II---HAZARDOUS INGREDIENTS

All ingredients are bound-up in the manufacturing process and are not expected to create any hazard in handling or use. Finished goods (e.g., rigid pipe, bar stock, duct, angle, joining strip, or profile) are inert.

SECTION III---PHYSICAL DATA (Typical data, not specifications)

Boiling Point	**Melting Point**	**Specific Gravity** (H_2O = 1)
Not applicable (NA)	NA	1.35-1.55
Solubility in Water	**% Volatile by Weight**	**Vapor Density** (Air = 1)
Insoluble	NA	NA
Vapor Pressure (mm Hg)	**PH**	**Particle Size**
NA	NA	NA

Appearance and Odor
Rigid pipe, bar stock, duct, angle, joining strip, or profile. No odor.

SECTION IV---FIRE AND EXPLOSION HAZARD DATA

Flashpoint	**Ignition Temperature**	**Flammable Limits in Air**
Not applicable to solid products	PVC: >730°F (>388°C) CPVC: >830°F (>433°C)	(% by volume) Lower: NA Upper: NA

Extinguishing Media
Water. ABC dry chemical. AFFF. Protein type air foams. Carbon Dioxide may be ineffective on larger fires due to a lack of cooling capacity which may result in re-ignition.

Special Firefighting Procedure
Wear positive pressure self-contained breathing apparatus (SCBA). Personnel not having suitable respiratory protection must leave the area to prevent significant exposure to toxic combustion gases from any source. In enclosed or poorly ventilated areas, wear SCBA during cleanup immediately after a fire as well as during the attack phase of firefighting operations.

Unusual Fire and Explosion Hazards
None known.

SECTION V---HEALTH HAZARD DATA

Threshold Limit Value
None established.

Effects of Overexposure
There are no significant health hazards from vinyl compound at ambient temperature.
Inhalation of decomposition or combustion products, especially hydrogen chloride, will cause irritation of the respiratory tract, eyes and skin. Depending on the severity of exposure, physiological response will be coughing, pain and inflammation. Individuals with bronchial asthma and other types of chronic obstructive respiratory diseases may develop bronchial spasm if exposure is prolonged.

Emergency and First Aid Procedure
If irritation persists from exposure to decomposition products, remove the affected individual from the area. Provide protection before reentry.

SECTION VI---REACTIVITY DATA

Stability
Stable

Hazardous Polymerization
Will not occur.

Hazardous Decomposition Products
CO, CO_2 hydrogen chloride and small amounts of benzene and aromatic and aliphatic hydrocarbons. CPVC may also contribute small amounts of chloroform and carbon tetrachloride.

Incompatibility (materials to avoid)
Contact the manufacturer for chemical resistance information.

SECTION VII---SPILL OR LEAK PROCEDURE

Steps to be taken in case material is released or spilled: If material is inert, then place it into a container for reuse or disposal.

Waste Disposal Method
Dispose of waste in accordance with federal, state, and local regulations. For waste disposal purposes, these products are not defined or designated as hazardous by current provisions of the Federal Resources Conservation and Recovery Act (RCRA) 40CFR261.

SECTION VIII---SPECIAL PROTECTION INFORMATION

Ventilation
Provide efficient exhaust at all operations capable of creating fumes or vapors. Cutting or sawing, machining, heat welding, thermo folding and other operations involving heat sufficient to result in degradation should be examined to ensure adequate ventilation.

Respiratory Protection
Not normally required.
If overheating results in decomposition resulting in smoke or fumes, then a NIOSH/MSHA-approved, combination high efficiency particulate filter with organic vapor cartridge can be used. Gross decomposition may require the use of a positive pressure self-contained breathing apparatus.

Protective Equipment
Wear safety glasses.

SECTION IX---SPECIAL PRECAUTIONS

Solvent Cements

Certain operations, such as the installation of piping systems, may require the use of solvent cements. The user must obtain and comply with all safety precautions recommended by solvent cement manufacturers. Avoid continued or prolonged breathing of vapors produced by overheating.

SECTION X---TRANSPORTATION

For domestic transportation purposes, these products are not defined or designated as a hazardous material by the U.S. Department of Transportation under Title 49 of the Code of Federal Regulations, 1983 Edition.

- DOT Proper Shipping Name: Not applicable
- DOT Hazard Class: Not hazardous
- DOT Label: None required
- UN/NA Hazard No: Not applicable

USER'S RESPONSIBILITY

A bulletin such as this cannot be expected to cover all possible individual situations. As the user has the responsibility to provide a safe workplace, all aspects of an individual operation should be examined in order to determine if, or where, precautions, in addition to those described herein, are required. Any health hazard and safety information contained herein should be passed on to your customers or employees, as the case may be. Harvel Plastics must rely on the user to utilize the information that we have supplied in order to develop work practice guidelines and employee instructional programs for the individual operation.

DISCLAIMER OF LIABILITY

As the conditions or methods of use are beyond our control, we do not assume any responsibility and expressly disclaim any liability for any use of this material. Information contained herein is believed to be true and accurate, but all statements or suggestions are made without warranty, expressed or implied, regarding accuracy of the information, the hazards connected with the use of the material, or the results to be obtained from the use thereof. Compliance with all applicable federal, state, and local laws and regulations remains the responsibility of the user.

Silicone

The gaskets on the Isolator are made of white silicone of 30 - 40 durometer. It has been determined that silicone is one of the best-suited gasket materials for Isolators designed for these applications.

The windows on this Isolator incorporate a custom designed and fabricated extruded gasket. This is also made of white silicone of 30 - 40 durometer. Since these are specifically manufactured for the windows provided, the customer may require these as spare parts.

The gaskets used on the alpha and beta containers are also made from silicone. Silicone gaskets have been selected due to there ability to withstand the high temperatures associated with autoclaving or steam in place processes. These gaskets have a durometer between 45 - 50, elongation between 325 - 375%, and tensile strength between 776 - 898 psi. The gaskets are self lubricating, using low-viscosity silicone oil.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

Material Data Sheet: Silicone

Common Name	Silicone
Trade Names	Thermo flex – Compound No. 2850R
ASTM D-2000 Classification	FC, FE, GE
Military (MIL STD 417)	TA
Chemical Definition	Polysiloxane

GENERAL CHARACTERISTICS

Durometer Range (Shore A)	30 – 90
Tensile Range (P.S.I.)	200 – 1500
Elongation (Max. %)	700
Compression Set	Good
Resilience – Rebound	Good
Abrasion Resistance	Fair to Poor
Tear Resistance	Poor
Solvent Resistance	Poor
Oil Resistance	Fair to Poor
Low Temperature Usage (F°)	-60° to -150°
High Temperature Usage (F°)	to 450°
Aging Weather – Sunlight	Excellent
Adhesion to Metals	Good

COMMENT

Silicone Rubber has a great many variations and can be compounded to meet any number of applications. Silicone can be compounded to have tensile in the area of 1500 PSI and tear up to 200 lbs.; low compression set and good resilience; moderate solvent resistance; excellent heat resistance; good release characteristics; extreme low temperature properties; and can be highly resistant to oxidation and ozone attack.

Silicone is generally attacked by most concentrated solvents; oils, concentrated acids, and dilute sodium hydroxide.

Polypropylene

Polypropylene is a thermoplastic resin that is a polymer of propylene. Hard and tough, polypropylene has a high melting point and resists moisture, oils, and solvents. Polypropylene can be molded and machined. The alpha flange door, beta flange door, and beta cell flange are machined from polypropylene. Containers can be made from rotationally molded polypropylene.

Technical data sheets describing the properties of polypropylene appear following this page.

Material Data Sheet: Polypropylene

Polypropylene thermoplastic resins are produced from propylene gas, a by-product of petroleum refining. The natural resin is semi-translucent and milky white in color and has excellent color ability.

Most polypropylene parts are produced by injection molding, blow molding, or extrusion of either unmodified or reinforced compounds. Other applicable processes for polypropylenes are structural – foam molding and solid-phase and hot-flow stamping of glass-reinforced sheet stock (Azdel, a product of PPG Industries Inc.). Molding and extruding resins can be pigmented by any of the conventional methods.

Properties

Polypropylene is a low-density resin that offers a good balance of thermal, chemical, and electrical properties, along with moderate strength. Strength properties are increased significantly with glass fiber reinforcement. Increased toughness is provided in special, high molecular weight, rubber-modified grades.

Electrical properties of polypropylenes are affected to varying degrees by service temperature. Dielectric constant is essentially unchanged, but dielectric strength increases and volume resistivity decreases with increased temperature.

Polypropylene has limited heat resistance, but heat-stabilized grades are available for applications requiring prolonged use at elevated temperatures. Useful life of parts molded from such grades may be as long as five years at 250°F, ten years at 230°F, or 20 years at 210°F. Specially stabilized grades are UL-rated at 120°C (248°F) for continuous service.

Polypropylene resins are inherently unstable in the presence of oxidative conditions and UV radiation. While all grades are stabilized to some extent, specific stabilization systems are often used to suit a formulation for a particular environment.

Polypropylenes resist chemical attack and staining and are unaffected by aqueous solutions of inorganic salts or mineral acids and bases, even at high temperatures. Most organic chemicals do not attack them, and there is no solvent for the resin at room temperature. The resins are attacked, however, by halogens, fuming nitric acid and other active oxidizing agents, and by aromatic and chlorinated hydrocarbons at high temperatures.

Applications

Un-reinforced polypropylene is used for packaging applications such as blow-molded pharmaceutical, medical, cosmetic, and food containers. Structural-foam grades are used for furniture and for automotive seatbacks.

Both reinforced and un-reinforced grades are used in automotive, appliance, and electrical applications. Examples are automotive battery cases, lamp housings, blower wheels, fan shrouds, fender liners, and glove boxes; appliance pumps, blower housings, fan blades, and vegetable bins; and as sole support for current-carrying electrical parts, coil bobbins, cable covers, TV yokes, fuse housings, and insulators.

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Typical Properties of Polypropylene

ASTM or UL test	Property	Unmodified Resin	Glass Reinforced	Impact grade
	PHYSICAL			
D792	Specific Gravity	0.905	1.05 - 1.24	0.89 - 0.91
D792	Specific Volume ($in.^3/lb$)	30.8 - 30.4	24.5	30.8 - 30.5
D570	Water absorption, 24h. 1/8-in. thk (%)	0.01 - 0.03	0.01 - 0.05	0.01 - 0.03
	MECHANICAL			
D638	Tensile Strength (psi)	5,000	6,000 - 14,500	2,800 - 4,400
D638	Elongation (%)	10 - 20	2.0 - 3.6	350 - 500
D638	Tensile modulus (10^5 psi)	1.6	4.5 - 9.0	1.0 - 1.7
D790	Flexural modulus (10^5 psi)	1.7 - 2.5	3.8 - 8.5	1.2 - 1.8
D256	Impact strength, Izod (ft-lb/in. of notch)	0.5 - 2.2	1.0 - 5.0	1.0 - 15
D785	Hardness, Rockwell R	80 - 110	110	50 - 85
	THERMAL			
C177	Thermal conductivity (10^4 cal-cm/sec-cm^2-°C)	2.8	---	3.0 - 4.0
D696	Coef of thermal expansion (10^{-5} in./in. - °F)	3.2 - 5.7	1.6 - 2.9	3.3 - 4.7
D648	Deflection temperature (°F)			
	At 264 psi	125 - 140	230 - 300	120 - 135
	At 66 psi	200 - 250	310	160 - 210
UL94	Flammability rating*	HB	HB	HB
	ELECTRICAL			
D149	Dielectric strength (V/mil)			
	Short time, 1/8-in. thk	500 - 660	475	500 - 650
D150	Dielectric constant			
	At 1 kHz	2.2 - 2.6	2.36	2.3
D150	Dissipation factor			
	At 1 kHz	0.0005 - 0.0018	0.0017	0.0003
D257	Volume resistivity (ohm-cm)			
	At 73°F, 50% RH	10^{17}	2×10^{16}	10^{15}
D495	Arc resistance(s)	160	100	---

* V-2, V-1, and V-0 grades are also available.

Laminated Safety Glass

Some of the Isolator windows or viewing panels are constructed of 3/8" thick, Laminated Safety Glass. This type of glass offers excellent resistance to scratches, abrasion, and chemicals, and has no absorptive qualities.

Laminated Safety Glass is made of two sheets of glass sandwiched around a reinforcing sheet of clear plastic. This plastic sheet adds strength and if broken will help contain loose glass particles. As with any glass objects, caution should be taken when handling. Glass windows should never be flexed.

To provide an airtight seal, two types of gaskets are used when mounting windows.

Laminated Safety Glass windows can be cleaned with liquid detergents and water. Some commercial cleaners such as Glass Plus ® are suitable for use to clean the surfaces of these windows.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

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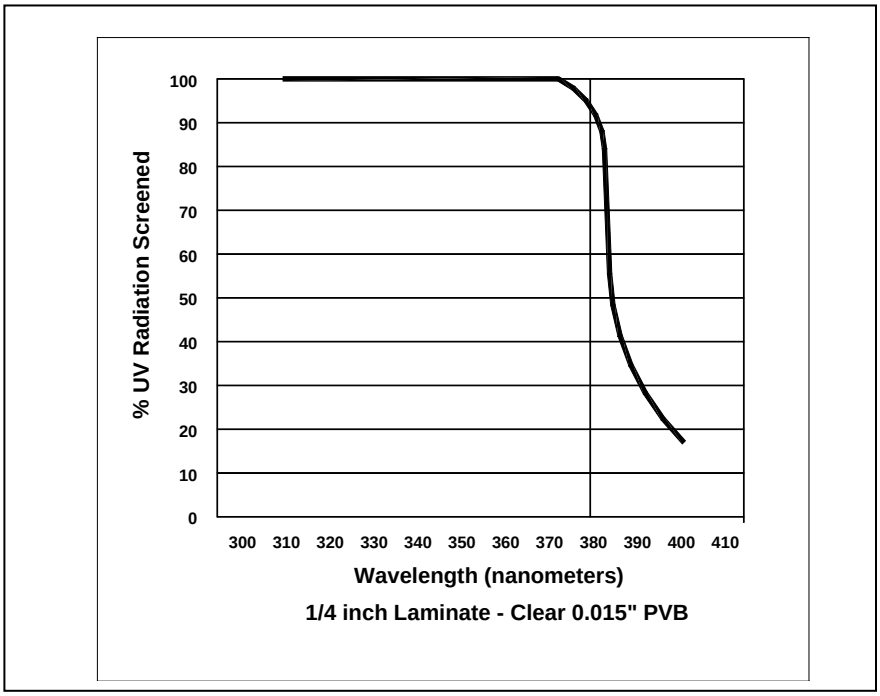
Material Data Sheet: Laminated Safety Glass

PRODUCT:	3/8” LAMINATED GLASS
MAKE UP:	3/16” Clear Annealed Glass .030” Interlayer 3/16” Clear Annealed Glass
SIZE:	84” X 120”
WEIGHT:	5.25 lbs/sq.ft.
APPLICABLE STANDARDS:	Consumer Product Safety Standard 16 CFR 1201, Category II ANSI Z97.1, Safety Glazing Materials Used in Buildings ASTM C1036, Flat Glass ASTM C1172, Laminated Architectural Flat Glass

NOTE: Design/manufacturing considerations may limit glass size.



ULTRAVIOLET CONTROL

Laminated glass outperforms ordinary glass in screening ultraviolet radiation (radiation below 380 nanometers). Glass made with either a clear or tinted interlayer screens out more than 99% of UV, thus, providing protection against fading and deterioration of fabrics and finishes.

UV screening does negatively effect plant growth since the photoreceptors in plants absorb in regions around 450 nm, 660 nm, and 730 nm. Additionally, laminated glass can help protect plants from fading and brittleness.

Hypalon®

The gloves and/or sleeves of the Isolator are made of Hypalon. This provides the best flexibility and chemical resistance to VHP (sterilizing agent) and rigorous cleaning agents.

The gloves are available in various hand sizes and also left hand, right hand, and ambidextrous versions.

The care and maintenance of the gloves are discussed in Chapter 7, Preventative Care and Maintenance. Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

HYPALON GLOVES

These products are manufactured from a Chlorosulphonated Polyethylene Elastomer, which gives mechanical and chemical resistance results as shown below. The white surface gives good visibility (i.e. contamination will be easily seen). This makes it good for the food industry. They are designed for work requiring good sensitivity and dexterity.

Physical and Chemical Properties of Hypalon Gloves

Mechanical Properties to BSEN 388:1994.

For thicknesses between 0.36 and 0.76mm, the following results apply:

Abrasion Resistance	Level 1	Result 100 cycles
Blade Cut Resistance	Level 1	Result index of 1.3
Tear resistance	Level 1	Result 12.8 Newtons
Puncture Resistance	Level 1	Result 32.4 Newtons

For thicknesses above 0.76mm, the following results apply:

Abrasion Resistance	Level 4	Result 8000 cycles
Blade Cut Resistance	Level 1	Result index of 1.7
Tear resistance	Level 1	Result 19.6 Newtons
Puncture Resistance	Level 2	Result 76.5 Newtons

Chemical Properties to BSEN 374:1994 Parts 1 and 2

For thicknesses between 0.36 and 0.76mm, the following results apply:

Chemical	Standard	Level	Breakthrough
Hexane	EN374-3	Level 5	408 mins
Acetone	EN374-3	Level 2	31 mins
Sulphuric Acid 98%	EN374-3	Level 6	>480 mins
Chloroform	EN374-3	Level 1	13 mins

For thicknesses above 0.76mm, the following results apply:

Chemical	Standard	Level	Breakthrough
Hexane	EN374-3	Level 6	>480 mins
Acetone	EN374-3	Level 3	119 mins
Sulphuric Acid 98%	EN374-3	Level 6	>480 mins
Chloroform	EN374-3	Level 2	43 mins

The gloves have also been subjected to testing to BSEN 374:1994 Part 2 Resistance to Penetration to Level 3 (0.65 Acceptable Quality Level) as all gloves are electrically tested at control point number 13 to insure glove integrity.

Hazardous substances should be checked for chemical resistance and chemical adsorbsion to the specific glove material.

BARRIER SYSTEMS

Material Data Sheet: Hypalon

Common Name	Hypalon
Trade Names	Chlorosol – Compound No. 19040
ASTM D-2000 Classification	CE
Military (MIL STD 417)	SC
Chemical Definition	Chlorosulfonated/polyethylene

GENERAL CHARACTERISTICS

Durometer Range (Shore A)	45 – 100
Tensile Range (P.S.I.)	1000 – 3000
Elongation (Max. %)	500
Compression Set	Fair
Resilience – Rebound	Fair
Abrasion Resistance	Excellent
Tear Resistance	Good
Solvent Resistance	Fair to Good
Oil Resistance	Fair to Good
Low Temperature Usage (F°)	-30° to -60°
High Temperature Usage (F°)	to 225°
Aging Weather – Sunlight	Excellent
Adhesion to Metals	Excellent

COMMENT

Hypalon has very good resistance to oxidation and ozone, as well as good flame resistance; it is similar to neoprene, except with improved acid resistance; abrasion resistance is excellent, about the equivalent of nitrile, low friction surface; and oil and solvent resistance about intermediate between neoprene and nitrile.

Hypalon is not recommended for immersion in water or exposure to concentrated oxidizing acids, esters, ketones, and chlorinated, aromatic and nitro hydrocarbons.

Teflon® - PTFE and FEP

The Isolator may contain various items made of Teflon ®. Teflon ® is the commercial name for various types of Fluorocarbon plastics. Specifically PTFE (polytetrafluoroethylene) and FEP (fluorinated ethylene propylene). The advantages of these materials include good thermal and chemical resistance, nonadhesiveness, low dissipation factor, and low dielectric constant. They are available in a variety of forms such as molded components, extruded shapes, film, or tape.

PTFE is characterized by its extreme inertness to chemicals, very high thermal stability, and low frictional properties. Some of its applications include compression fitting plugs, bearings, hoses, gaskets, and tapes and coatings for metal and fabric.

FEP possesses most of the properties of PTFE and has a melt viscosity low enough to permit thermoplastic processing. It is used for molded components and extruded shapes and as dispersions for spray or dip coating processes.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

Material Data Sheet: Teflon

PTFE, FEP, and PFA

PTFE resins, because of their high melt viscosity, cannot be processed by conventional extrusion and molding techniques. Instead, molding resins are processed by press-and-sinter methods (similar to powder-metallurgy processing) or by lubricated extrusion and sintering.

PTFE resins are opaque, crystalline, and malleable. When heated above 648°F, they are transparent, amorphous, relatively intractable, and they fracture if severely deformed. They return to their original state when cooled.

Unlike PTFE, FEP resins can be molded by conventional melt processing. FEP offers nearly all of the desirable properties of PTFE resins, but maximum recommended service temperature is lower by about 100°F.

PFA fluorocarbon resins are also melt-extrudable, but are easier to process than FEP and have higher mechanical properties at elevated temperatures. Service temperature capabilities are the same as those of PTFE.

PTFE resins are supplied as granular molding powders for compression molding or ram extrusion, as powders for lubricated extrusion, and as aqueous dispersions for dip coating and impregnating. FEP and PFA resins are supplied in pellet form for melt extrusion and molding. FEP resin is also available as an aqueous dispersion.

Properties

Outstanding characteristics of the fluoroplastics are chemical inertness, high and low-temperature stability, excellent electrical properties, and low friction.

The resins are fairly soft. Their resistance to wear and creep is low, but these characteristics are improved by compounding the resins with inorganic fibers or particulate materials. For example, the relatively poor wear resistance of PTFE as a bearing material is overcome by adding materials such as glass fiber, carbon, bronze, or metallic oxide. Wear resistance is improved by as much as 1,000 times, and the friction coefficient increases only slightly. As a result, the wear resistance of filled PTFE is superior, in its operating range, to that of any other plastic bearing material and is equaled only by some forms of carbon.

The static coefficient of friction for PTFE resins decreases with increasing load. Thus, PTFE bearing surfaces do not seize, even under extremely high loads. Sliding speed has a marked effect on friction characteristics of unreinforced PTFE resins; temperature has very little effect.

PTFE resins have an unusual thermal expansion characteristic. A transition at 65°F produces a volume increase of over 1% in the 60 to 70°F range. Thus, a machined part, produced within tolerances at a temperature on either side of this transition zone, will change dimensionally if heated or cooled through the zone.

Electrical properties of the fluorocarbons are excellent, and they remain stable over a wide range of frequency and environmental conditions. Dielectric constant, for example, is 2.1 from 60 to 10^9 Hz. Heat-aging tests at 572°F for 6 months show no change in this value. Dissipation factor of PTFE remains below 0.0003 up to 10^8 Hz. The factor for FEP and PFA resins is below 0.001 over the same range. Dielectric strength and surface arc resistance of fluorocarbon resins are high and do not vary with temperature or thermal aging.

Applications

PTFE resins are used in applications utilizing the unusual electrical, chemical, and mechanical properties of the material. These can be classified in five categories:

1. Fluid conveying systems – gaskets, molded packings and seals, piston rings, and bellows.
2. Static and dynamic load supports – bearings, ball and roller-bearing components, and sliding bearing pads.
3. Release surfaces – sheet for preventing adhesion, pressure-sensitive tapes, and heat-shrinkable roll covers.
4. Electrical and electronic – insulation for coaxial cable, fixture and motor lead wire, hookup and panel wiring, industrial signal and control cable, and for stand-off and feed-through components.
5. Thermal system components – ablative shields.

WALKER
BARRIER SYSTEMS

Typical Properties of PTFE		
ASTM or UL test	**Property**	**PTFE**
	PHYSICAL	
D792	Specific gravity	2.13 - 2.24
D792	Specific volume ($in.^3/lb$)	13 - 12.3
D570	Water absorption, 24 h, 1/8 –in. thk (%)	<0.01
	MECHANICAL	
D638	Tensile strength (psi)	3,350
D638	Elongation (%)	300
D638	Tensile modulus (10^5 psi)	0.5
D790	Flexural strength (psi)	No break
D790	Flexural modulus (10^5 psi)	0.5 - 0.9
D256	Impact strength, Izod (ft-lb/in. of notch)	3.5
D785	Hardness, Rockwell Shore D	--- 50 - 65
	THERMAL	
C177	Thermal conductivity (Btu-in./hr-ft^2-°F)	1.7
D696	Coef of thermal expansion (10-5 in./in.-°F)	5.5 - 8.4
D648	Deflection temperature (°F)	
	At 264 psi	132
	At 66 psi	250
UL94	Flammability rating	V-0
	ELECTRICAL	
D149	Dielectric strength (V/mil) Short time, 1/8-in. thk	500 - 600
D150	Dielectric constant At 1 kHz	2.1
D150	Dissipation factor At 1kHz	0.00005
D257	Volume resistivity (ohm-cm) At 73°F, 50% RH	$>10^{18}$
D495	Arc resistance (s)	>300
	OPTICAL	
D542	Refractive index	1.350
D1003	Transmittance, 1-mil film	---
	FRICTIONAL	
---	Coefficient of friction	
	Against steel	
	(100 psi, 10 fpm)	0.050

Material Data Sheet: Ultem

The following table lists a generally accepted summary of properties that we believe to be reliable. Please note that many of these resins are produced in several varieties and property characteristics may vary. Therefore, determination of resin is dependent on the application and this table is only meant to serve as a general guideline.

BARRIER SYSTEMS

Properties	ASTM or Unit	ULTEM®
MECHANICAL PROPERTIES		
Specific Gravity	D792	1.27~1.51
Elongation %	D638	60
Tensile Strength (psi)	D638	16,500
Flexural Strength (psi)	D790	20,000
Compressive Strength	D695	22,000
Tensile Elastic Modulus (Young's Modulus) (psi)	D638	475,000
Flexural Modulus (psi)	D790	500,000 103MPa (103kgf/m2)
Flex Life (MIT cycles)	D2176	n.a
Hardness Durometer Shore M		M109
Coefficient of Friction on steel	D1984	n.a
Abrasion Resistance 1000 revs.	Taber	10
Impact Strength IZOD 73°F/23°C, notched ft/lbs/in	D256	1.0
THERMAL PROPERTIES		
Melting Point	°C (°F)	349 (660)
Upper Service Temperature(20,000h)	°C (°F)	200 (392)
Flame Rating**	UL 94	V-0
Thermal Conductivity	BTU/hr/ft^2/deg F in	n.a
	cal/sec/cm^2,°C/cm	0.22
Linear Coefficient of Thermal Expansion	D696	3.1 10^{-5}°F-1
Heat of Fusion	BTU/LB	n.a
Heat of Combustion	BTU/LB	n.a
Low Temperature Embrittlement	°C (°F)	n.a n.a
ELECTRICAL PROPERTIES		
Dielectric Constant	50Hz-10kHz	3.15
	D150/10^6Hz	n.a.
Dielectric Strength 10 mil film	D149	n.a.
Volume Resistivity ohm-cm	D257	6.7 x 10^{16}
Surface Resistivity ohm/sq.	D257	n.a
GENERAL PROPERTIES		
Chemical/Solvent Resistance	D543	Good
Water Absorption, 24h,%	D570	0.25
Refractive Index		1.63-1.68
Limiting Oxygen Index %	D2863	47

Neoprene

Some components in this application are made from neoprene. Except for polybutadiene and polyisoprene, neoprene is perhaps the most rubberlike of all, particularly with regard to dynamic response. Neoprenes are a large family of rubbers that have a property profile approaching that of natural rubber (NR) and with better resistance to oils, ozone, oxidation, and flame. They age better and do not soften on heat exposure, although high-temperature tensile strength may be lower than that of NR.

These materials, like NR, can be used to make soft, high-strength compounds. A significant difference is that, in addition to neoprene being more costly than NR by the pound, the density of neoprene is about 25% greater than that of natural rubber. Neoprenes do not have the low-temperature flexibility of natural rubber, which detracts from their use in shock or impact applications.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

BARRIER SYSTEMS

Material Data Sheet: Neoprene®

Common Name:	Neoprene®
Trade Names:	Matchless – Compound No. AX-1060 Mirprene – Compound No. 1050
ASTM D-2000 Classification:	BC, BE
Military (MIL STD 417):	SC
Chemical Definition:	Polychloroprene

GENERAL CHARACTERISTICS

Durometer Range (Shore A)	20 – 95
Tensile Range (P.S.I.)	500 – 3000
Elongation (Max. %)	600
Compression Set	Good
Resilience – Rebound	Excellent
Abrasion Resistance	Excellent
Tear Resistance	Good
Solvent Resistance	Fair
Oil Resistance	Fair
Low Temperature Usage (F°)	+10° to –50°
High Temperature Usage (F°)	to 250°
Aging Weather – Sunlight	Good
Adhesion to Metals	Good to Excellent

COMMENT

Neoprene is an all-purpose polymer with many desirable characteristics. It has additional plus-features: high resilience with low compression set; flame resistant; compounds free of sulphur are easily made; animal and vegetable oil resistant; generally not affected by moderate chemicals, fats, greases, and many oils and solvents.

Neoprene is generally attacked by strong oxidizing acids, esters, ketones, and chlorinated aromatic and nitro hydrocarbons.

Nylon

The Isolator may contain a limited amount of Nylon. It is the material component of some compression fittings and nuts. Compression fittings provide strain relief and liquid-tight entry for cable, wire, and tubing. Nylon withstands temperatures ranging from -40 F to +212 F.

Nylon is a generic designation for a family of synthetic polymers. Nylon is one of the most common polymers used as a fiber. Solid nylon is used for mechanical parts such as gears and other low- to medium-stress components previously cast in metal. Engineering grade nylon is processed by extrusion, casting, and injection molding. Type 6/6 Nylon 101 is the most common commercial grade of nylon. Nylon 6 is the most common commercial grade of cast nylon. Nylon is available in glass-filled and molybdenum-filled variants which increase structural and impact strength and rigidity.

Interface with this material will mainly be done at installation or during routine maintenance by specified personnel.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear following this page.

Material Data Sheet: Nylon

Nylon is available in a variety of special formulations. Molybdenum disulphide-filled and oil-filled nylons have enhanced wear properties, while heat stabilized nylon will withstand higher operating temperatures. For enhanced strength and stiffness, nylon is also available in glass-filled grades.

Nylon Typical Properties

Formulation	ASTM test	Property	Units	
Extruded Nylon 6/6	D-638	Tensile Strength	psi	12,400
	D-790	Flexural Modulus	psi	410,000
	D-256	Izod Impact (notched)	Ft-lbs/in of notch	1.2
	D-648	Heat Deflection Temperature@264 psi	ºF	194
	N/A	Maximum Continuous Service Temperature in Air	ºF	210
	D-570	Water Absorption (immersion 24 hours)	%	1.20
	D-696	Coefficient of Linear Thermal Expansion	in/in/ºFx10^{-5}	4.5
	N/A	Coefficient of Friction (Dynamic)	N/A	0.28
Cast Nylon 6	D-638	Tensile Strength	psi	10,000-13,500
	D-790	Flexural Modulus	psi	420,000-500,000
	D-256	Izod Impact (notched)	Ft-lbs/in of notch	0.7-0.9
	D-648	Heat Deflection Temperature@264 psi	ºF	200-400

Formulation	ASTM test	Property	Units	
	N/A	Maximum Continuous Service Temperature in Air	ºF	230
	D-570	Water Absorption (immersion 24 hours)	%	0.60-1.20
	D-696	Coefficient of Linear Thermal Expansion	in/in/ºFx10^{-5}	5.0
	N/A	Coefficient of Friction (Dynamic)	N/A	0.22
MD-Filled Cast Nylon 6	D-638	Tensile Strength	psi	10,000-14,000
	D-790	Flexural Modulus	psi	400,000-500,000
	D-256	Izod Impact (notched)	Ft-lbs/in of notch	N/A
	D-648	Heat Deflection Temperature@264 psi	ºF	200-470
	N/A	Maximum Continuous Service Temperature in Air	ºF	N/A
	D-570	Water Absorption (immersion 24 hours)	%	0.05-1.40
	D-696	Coefficient of Linear Thermal Expansion	in/in/ºFx10^{-5}	N/A
	N/A	Coefficient of Friction (Dynamic)	N/A	0.30
Oil-Filled Cast Nylon 6	D-638	Tensile Strength	psi	9,500-11,000
	D-790	Flexural Modulus	psi	375,000-475,000
	D-256	Izod Impact (notched)	Ft-lbs/in of notch	1.4-1.8
	D-648	Heat Deflection Temperature@264 psi	ºF	200-400

Formulation	ASTM test	Property	Units	
	N/A	Maximum Continuous Service Temperature in Air	ºF	230
	D-570	Water Absorption (immersion 24 hours)	%	0.50-0.60
	D-696	Coefficient of Linear Thermal Expansion	in/in/ºFx10^{-5}	5.0
	N/A	Coefficient of Friction (Dynamic)	N/A	0.12
Heat Stabilized Cast Nylon 6	D-638	Tensile Strength	psi	12,000-13,500
	D-790	Flexural Modulus	psi	420,000-500,000
	D-256	Izod Impact (notched)	Ft-lbs/in of notch	0.7-0.9
	D-648	Heat Deflection Temperature@264 psi	ºF	200-430
	N/A	Maximum Continuous Service Temperature in Air	ºF	250
	D-570	Water Absorption (immersion 24 hours)	%	0.50-0.60
	D-696	Coefficient of Linear Thermal Expansion	in/in/ºFx10^{-5}	5.0
	N/A	Coefficient of Friction (Dynamic)	N/A	N/A

Viton® (Fluoroelastomer)

General description:
This fluoroelastomer compound, which is commonly called Viton®, is Dupont's registered trade name for the original fluoroelastomer rubber. This is a step above our silicone rings in extreme temperature resistance plus it has resistance to a wide array of chemicals. It has a range in temperature of -20 degrees F to +400 degrees F, with intermittent exposure up to +600 degrees F. This material is excellent against abrasion and oils and it does well against ozone, weather, and flame.

BARRIER SYSTEMS

Material Data Sheet: Viton

Common name: **Fluoroelastomer**
Trade name: **Viton**
Military: **MIL-R-83248C Type 1, Class 1**

Characteristics	Mil-R-83248C / 1	Actual Test Data
Physical Properties		
Tensile, PSI, Minimum	1400	1744
Elongation % Minimum	125	229
Hardness, Shore A	75+/-5	77
Specific Gravity	-	1.85
Temperature Retraction. 10 % Maximum	+5	+1
Air Age - 70 Hrs @ 270º C		
Tensile Strength Decrease, % Maximum	35	+5
Elongation Decrease, % Maximum	15	-8%
Hardness Change	+10/-5	+2
Weight Loss, % Maximum	10	3.9%
Air Age - 22 Hrs @ 200º C		
Compression Set - % Original Deflection		
.066 to .110 inch, Maximum	20	
Over .110 inch, Maximum	15	8.5
Air Age - 336 Hrs @ 200º C		
Compression Set - % Original Deflection		
.066 to .110 inch, Maximum	45	
Over .110 inch, Maximum	40	11.4
0 Oil Age - 70 Hrs @ 200º C		
Tensile Strength Decrease, % Maximum	30	-16
Elongation Decrease, % Maximum	20	-5
Hardness Change	0/-15	-11
Volume Change, % Maximum	+1/+25	+17
Compression Set - % Original Deflection		
.066 to .110 inch, Maximum	30	
Over .110 inch maximum	10	3.0
Fuel Age - 70 Hrs @ 240º C (Fuel B)		
Tensile Strength Decrease, % Maximum	20	-10%
Elongation Decrease, % Maximum	20	-8%
Hardness Change	+5/-5	-1
Volume Change, % Maximum	0/+5	+1.0

Chapter 4

Chapter 4 Components of Ventilation/Filtration & Control Systems

INLINE FILTERS, MILLIPORE

BLOWER – POSITIVE PRESSURE

AIRFLOW-UNIDIRECTIONAL

HEPA FILTERS – POSITIVE PRESSURE

HEPA FILTER INTEGRITY PORTS

PRE-FILTERS

STERILIZATION CONNECTIONS

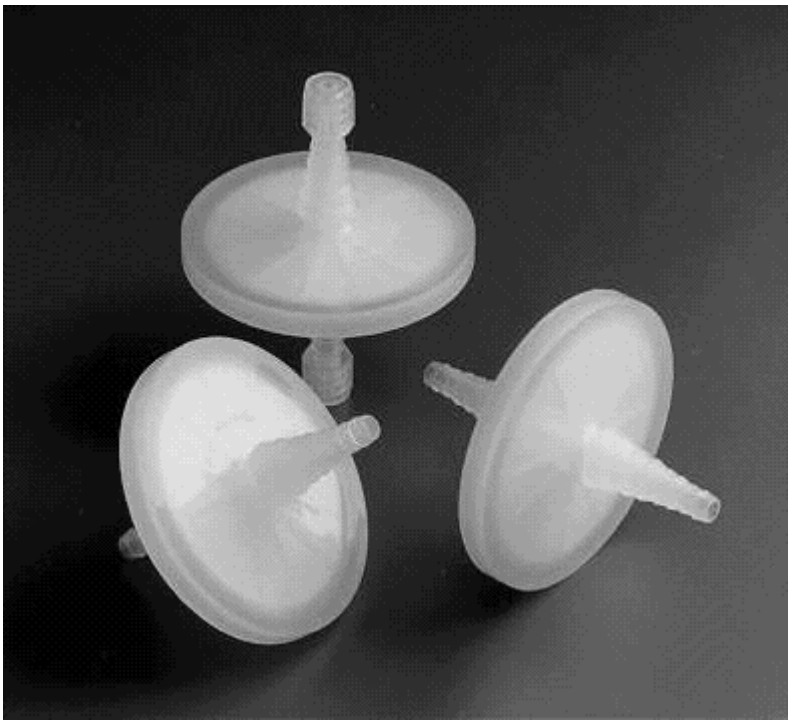
VHP DISTRIBUTION FANS

PLC CONTROLS

DIFFERENTIAL PRESSURE CONTROL SYSTEM

Inline Filters, Millipore

For small-flow sterile gas filtration



Cost effective sterile gas filtration is assured by maximizing the useful service life of a hydrophobic filter device while minimizing associated risk of service related filter integrity failures.

Description

Aervent-50 filters are sterilizing-grade devices manufactured with hydrophobic PTFE membrane and polypropylene hardware. These filters are 100% integrity tested during manufacturing to guarantee filter integrity and sterility assurance. The Aervent-50 filter production process has been validated and the manufacturing plant meets ISO 9002 Quality Systems Standards.

Typical Applications

The Aervent-50 hydrophobic filter will remove particles and microorganisms greater than 0.2 µm from gases and liquids. Aervent-50 filters will sterilize air or gas streams in:

Venting

- Bioreactor inlet and outlet filtration
- Filling vessels
- Carboys
- Autoclaves
- Transfer vessels

Gas Filtration

Filling Machines
Utilities
Fermentation
Moisture-free gas supply lines
Particulate removal

Efficacy

Using fully qualified manufacturing processes and controls, every Aervent-50 filter is integrity tested prior to packaging. The bubble point integrity testing value is fully correlated to bacterial retention using the HIMA challenge methodology.
A Certificate of Quality, included in each box, certifies that Aervent-50 filters meet quality assurance lot release criteria. Each Aervent-50 unit is hot-stamped with its catalogue number and lot number.

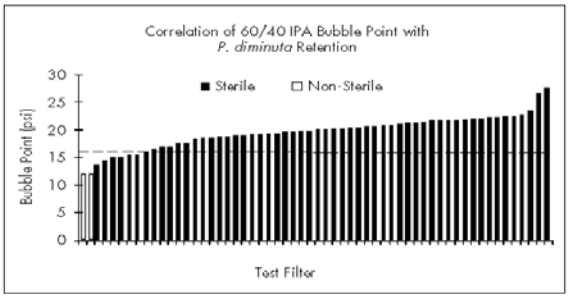
Cost Effective

Aervent-50 filters are a reliable and economical solution to your filtration needs. Every unit is qualified for 10 autoclave cycles at 30 °C for 30 minutes.

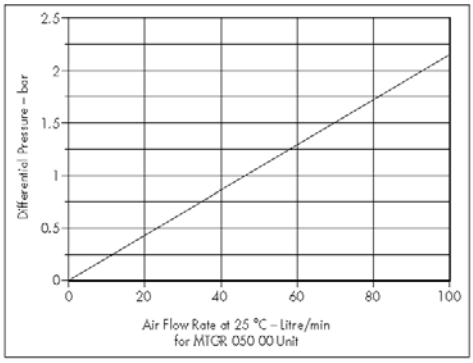
Ease of Use

The hydrophobic membrane is bi-directionally supported in a lightweight housing. Aervent-50 filters are easily integrity testable

Correlation Curve



Typical Air Flow Rates



Specifications

Materials

Polypropylene housing; hydrophobic PTFE membrane

Pore Size

Liquid: 0.22 µm
Gas: 0.0 1 µm

Filtration Area

19.6 cm2

Operating Conditions

Maximum Inlet Pressure

4. bar (60 psi) at 25 °C

Maximum Differential Pressure

2 bar (30 psi) at 25 °C

Sterilizability

Qualified for 10 times at 130 °C for 30 minutes

Integrity

100% integrity tested during production
Bubble Point: >1100 mbar (16 psi) in 60% isopropanol 40% water at 25 °C

Bacterial Endotoxin

An extract from the device contains less than 0.5 EU/mL as determined using the Limulus Amebocyte Lysate (LAL) test.

Bacterial Retention

The unit produces sterile effluent when challenged with a solution of *Pseudomonas diminuta* of a minimum concentration of $10^7/cm^2$ following HIMA methodology.

Gravimetric Extractables

< 1 mg per 10 unit after a 24 hour soak in 70/30 Isopropanol at ambient temperature.

Toxicity

Component materials meet the requirements of the USP Class VI Biological Test for Plastics. Aervent-50 filters also meet the requirements of the current UPS Mouse Safety Test.

Blower – Positive Pressure

There is a separate air flow system to provide the Isolator with a Positive Differential Pressure (relative to ambient).

As part of this system, the chosen blower is designed with the motor and blower completely integrated together to assure long-term, efficient, maintenance and trouble free operation.

Construction of the blower is aluminum with aluminum mounting brackets and stainless steel hardware.

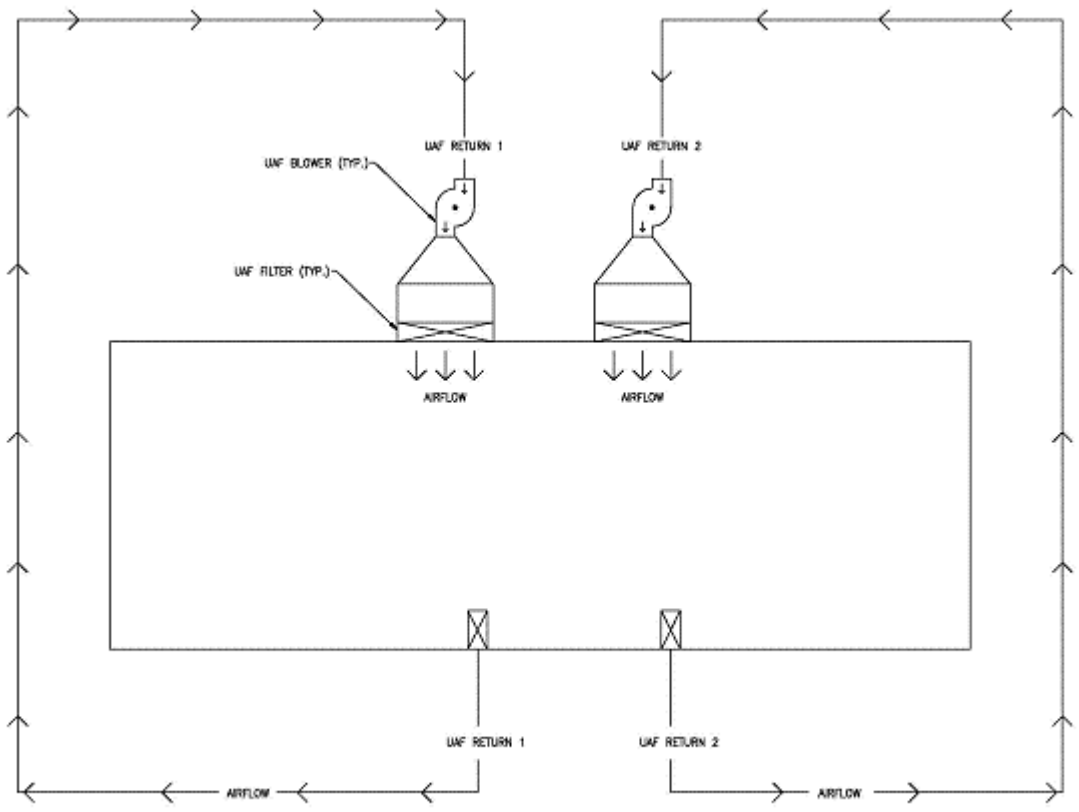
Blower and motor data sheets that provide more information on the specific performance characteristics and other technical information appear in Chapter 8, Drawings/Schematics & Technical Information.

Air Flow – Unidirectional

The unidirectional air flow (also: laminar flow) is a controlled airflow in a specified direction through the entire cross section with a continuous velocity and in approximately parallel streamlines.

Below is a diagram of a typical unidirectional airflow within an isolator. Filtered air enters the isolator, exits through the UAF return filters and is re-circulated to the blower(s) to repeat the process again.

The arrows represent the direction of the airflow.



UNIDIRECTIONAL AIRFLOW

HEPA Filters – Positive Pressure

The Make-up air flow system's air being forced through a HEPA filter on the inlet and a HEPA filter on exhaust provides the positive pressure condition within the Isolator. The HEPA filters are rated for a minimum efficiency of 99.97% on 0.3 µm particles.
HEPA filter media is constructed from glass fibers and the frame material is aluminum. For this application, the frame is designed for mounting in custom designed filter housing. This housing is designed to have the filters mounted so that operators or maintenance personnel can access the filters easily. The construction of the filter housing is 316L stainless steel with stainless steel mounting hardware.

Interface with these components by specified personnel will mainly be done at installation or during routine maintenance. Care should be taken when handling these filters, as the filter media is delicate.

Filter data sheets that provide more information on the specific performance characteristics and other technical information appear following this page.

Product Data Sheet: AAF AstroCel® II LPD Series

HEPA and ULPA Filters For State-of-the-Art Class 1 Cleanroom Requirements

- **Lightweight And Compact**
- **Easy Installation—No Corrugated Separators**
- **Mini-pleat Design Features Maximum Media Cleaning Potential**
- **Lowest Possible Pressure Drop Reduces Operating Costs**
- **Available In A Range Of Cleaning Efficiencies**

The AAF International, AstroCel II® LPD Series is a unique family of mini-pleat HEPA and ULPA filters designed to meet the demanding airflow and efficiency requirements of the semiconductor, pharmaceutical, biotech, food processing, and other industries in which airborne contaminants must be carefully controlled. AstroCel II combines the right features to give you optimum efficiency while keeping operating costs to a minimum.

MINI-PLEAT MEDIA PACK

Space Saving Media Pack

Designed to combine maximum efficiency with low pressure drop, our AstroCel II pleated media pack is available in sizes from 2" to 4" deep.

Our compact size results from a mini-pleat filter design which reduces resistance and provides the lowest possible pressure drop. Ribbons of media spaced every 1¼" maintain separation of pleats within the pack, while allowing a more compact filter depth than corrugated separators. The separation and precision straightness of the pleats allow air to move throughout the entire depth of the filter utilizing the full cleaning potential of the media.

- **Highest Efficiency And Lowest Possible Pressure Drop**
- **Pack Depths From 2" to 4"**
- **7½" – 8 Pleats Per Inch Allows The Greatest Amount Of Media In The Shallowest Depth**
- **Pleat Straightness to ±¼" – Unmatched By Competitors**
- **Requires No Foreign Or Organic Separators Such As Adhesive Or Strings**
- **Meets UL 900 Class 1, UL 586, and Factory Mutual**

ONGOING QUALITY CONTROL

Process control starts with sample flats of each roll of media tested for efficiency, using either a Q-127 penetrometer (HEPA media) or a Condensation Nucleus Counter (ULPA and above). The media is also tested for thickness, basis weight, tensile strength, binder content, water repellency, and pressure drop.

Once a roll meets our specification, it is carefully pleated and assembled in the cell side designed for the specific application. The filter is then tested and certified to meet the designated efficiency requirement. If required by the customer specification, the filter is also tested for pinhole leaks. A final visual inspection ensures that dimensional tolerances have been met.

Every filter is identified by serial and order number and is labeled with performance criteria, media lot number, operator number, and part number.

Meticulous scrutiny during every phase of the production process enables AAF to trace a filter back to the roll of media from which it was manufactured, should a defect be identified.

This elaborate testing ensures that you receive only the highest quality cleanroom filtration products; cost-effective products that meet your toughest requirements.

STURDY CONSTRUCTION

Manufactured from boron-silicate microfibers, AstroCel II glass media is water-resistant and fire-retardant.

The media pack is permanently attached to an anodized extruded aluminum frame with a UL classified, white urethane adhesive.

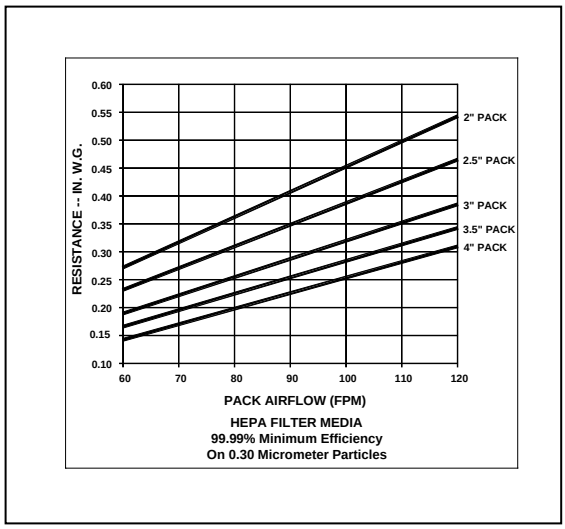
Frames are available with gasket seal, gel seal, or knife edge seal for fluid seal grid applications.

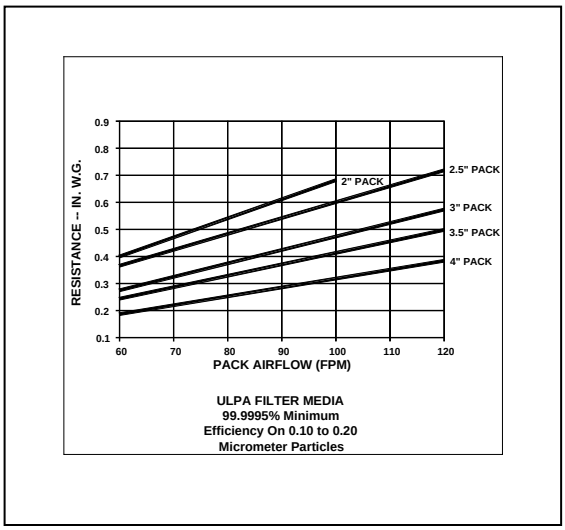
The AstroCel II LPD Series with knife edge cell sides was designed specifically for our AstroGel™ gel seal grid system. The grid consists of a network of E-channel extrusions in which a gel sealant is poured to assure an airtight seal around the edges.

STATE-OF-THE-ART TESTING

AAF has established an air filtration testing methodology that is among the most comprehensive and accurate in the industry. Testing is essential in documenting filter efficiency and assisting in research and development of filtration products. AAF's testing facilities meet the highest standards for quality control.

Every HEPA and ULPA filter is tested and certified, using procedures tailored to your specifications, to meet your performance requirements prior to shipping. AAF testing procedures for overall efficiency include laser particle counters with liquid or solid aerosol challenge. Pin hole leaks can be detected using either AAF's proprietary static scan test or automatic scan testing.





PACK AIRFLOW (FPM)

LOWEST POSSIBLE PRESSURE DROP

Because of the relatively large volumes of air handled in a typical cleanroom application, operating cost is a prime consideration in the design of the air filtration system. One of the most important areas to be evaluated is the resistance or pressure drop across the HEPA filters, because fan horsepower is the single biggest energy consumer in the cleanroom.

Pressure drop is measured by manometer as the test filter is subjected to a metered air volume. Testing on a volumetric basis is specified in the Institute of Environmental Sciences IES-RP-CC007 standard on ULPA filters.

AAF calculates the total square footage of usable media pack area (outside dimensions of filter minus the frame thickness and adhesive) and multiplies this number by 100 fpm to determine an accurate volumetric test flow. (This value is approximately 720 cfm for a nominal 24" x 48" filter.) This method simulates actual cleanroom airflow conditions ensuring a true measurement of pressure drop.

Some manufacturers determine the test flow by measuring the velocity (100fpm) at 1 or 2 points on the downstream side of the filter using an anemometer. This procedure assumes the airflow is uniform 2" from the downstream side of the filter and in the majority of cases the assumed test flow will be less than 550 cfm for a nominal 24" x 48" filter.

Since reduced operating pressure drop is so important, volumetric testing as performed by AAF is essential to determining true pressure drop and its impact on your cleanroom costs.

HEPA Filter Integrity Ports

Ports have been provided on the isolators for testing of each filter. This test is to confirm the integrity of each HEPA filter. The ports allow for the introduction of a test aerosol upstream of each filter and the measurement (scanning) of the filter face. There is also a second port upstream of each filter to measure the test aerosol concentration.

Testing of each filter should take place on a scheduled periodic basis, be conducted by qualified personnel, and follow industry regulatory documentation such as the Institute of Environmental Sciences, IES-RP-CC001.3, HEPA and ULPA Filters, or equivalent.

Pre-Filters

The Isolator may contain Pre-Filters at various locations. Some of the most typical Pre-Filter locations include the following: 1. At the inlet of the make-up air blower on positive pressure systems, 2. On the upstream side of the inlet HEPA filter on negative pressure systems, and 3. Upstream of ULPA filters.

The Pre-Filter media is 1" thick and is cut into specific shapes for specific pre-filtering applications. Such Pre-Filters are made of a filter media called POLYKLEAN™. The media is made of tough, durable, resilient, 100% Polyester fibers. This material is lightweight, fully incinerable, not affected by moisture, non-toxic, and non-allergenic.

A product data sheet that provides more information on the specific physical properties and airflow resistance appears following this page.

BARRIER SYSTEMS

Product Data Sheet: PolyKlean

Synthetic Air Filter Media

Product Information

Performance Data:

Media	[1] Rated Initial Resistance (In. W.G.)			[1] Rated Average Arrestance (%)		Recommended Final Resistance (In. W.G.)
	300 FPM	500 FPM	625 FPM	300 FPM	500 FPM	
PolyKlean White (Dry)						
1/2”	0.16	0.30	N/R	80-85	65-70	0.5
1”	0.20	0.32	0.43	90-95	75-80	1.0
2”	0.24	0.45	0.60	90-95	80-85	1.0

(1) All performance data is based on the ASHRAE 52.1-1992 test method. Performance tolerances conform to Section 7.4 of ARI Standard 850-93.

Temperature Limits:

Storage Temperature
-40°F to 220°F
-40°C to 104°C

Continuous Operating Temperature
PolyKlean 175°F (79°C)

Sterilization Connections

Vaporized Hydrogen Peroxide (VHP) is often specified as a sterilizing agent. Typically, this is accomplished using a stand-alone VHP Generator which is connected to dedicated, VHP Inlet and Outlet connections [Banjo or tri-clover (TC)] on the isolator. Also, an interface cable is used to tie the isolator control system to the VHP Generator. Additionally, a chamber pressure sense port is connected to the VHP Generator. During the VHP (sterilization) cycle, the VHP Generator will control certain functions of the isolator operation.

Depending on the type of VHP Generator used, VHP exits the isolator during the VHP cycle through one of the following two methods: 1. VHP returns to the generator through an exhaust system connection just outside the exhaust HEPA filter, or 2. VHP returns to the generator through a dedicated, VHP Outlet connection.

During the Aeration Phase (after the end of the VHP cycle), remaining VHP is removed from the isolator by being pushed through the exhaust HEPA filter and out the exhaust system. This is achieved by the blower cycling room air through the isolator.

Care needs to be taken to ensure that the connections between the isolator and the VHP Generator are not removed during a VHP cycle. Likewise, care needs to be taken to ensure that the caps of the dedicated VHP connections are kept in place during regular operation of the isolator (non-sterilization). Refer to the user manual, which came with the VHP Generator, for further information on its use and safety precautions.

VHP Distribution Fans

Isolators may require additional air distribution to assure complete coverage of Vaporized Hydrogen Peroxide (VHP) throughout the isolator. The isolator configuration, process, and volume often determine the coverage limitations of the VHP process. One way of decreasing the time required by the VHP process is by circulating and mixing the air within the isolator. Pushing the air around inside the isolator will ensure that the VHP has uniform concentration throughout it and that "dead" areas are eliminated by forcing air exchanges in those areas.

To accomplish the mixing of air and air exchanges in dead spaces, distribution fans are installed inside the isolator. The fans only operate during the VHP sterilize and aeration modes to assist in the VHP coverage and aeration process. AC fans are used for this application.

PLC Controls

Programmable Logic Controllers (PLCs) are solid-state members of the industrial computer family that use integrated circuits and software-based command sets (programming parameters / settings stored in memory), instead of electromechanical devices, to implement control functions. This programming provides the needed control sequencing for operation of the isolator and its various modes of operation. Operator / machine interfacing is accomplished via a touch screen control panel. The PLC also allows for remote supervisory control of the isolator and is capable of passing measured data values from connected sensors to a central data system.

This isolator has been equipped with an Allen-Bradley MicroLogix 1500. Its user manual and support information can be found in Chapter 8.

Differential Pressure Control System

Pressure Control System: The system consists of a differential pressure transducer which senses the chamber pressure, relative to ambient room pressure, and converts this sensed pressure into a 4 - 20 mA signal. This signal is sent to a digital controller where it is conditioned by a PID control algorithm to a preset desired isolator chamber pressure set point which is displayed in inches of water column ("W.C.). This signal is also displayed as a pressure value on the controller's faceplate display in inches of water column ("W.C.).

After conditioning, the signal is sent as a 4 - 20 mA control output to a variable frequency AC drive. The drive provides a variable frequency, 230 VAC control voltage to a fractional horsepower, permanent split capacitor motor. The motor, in turn, powers a single inlet centrifugal blower that, ultimately, was based on this 4 - 20 mA control signal.

Specific details regarding the differential pressure transducer can be found in Chapter 8 of this manual. Also, the AC drive parameter settings can be found in Chapter 2 (or the Controls Schematics in Chapter 8) and the AC drive manual is in Chapter 8.

Pressure Control System Alarms: The digital controller provides a high and low pressure alarm output based on preset alarm set point parameters, which in turn produce a relay output when an alarm condition exists. This output supplies 120 VAC to a piezoelectric audio alarm and a fixed frequency flasher unit, which powers a red pilot light indicator for high and low alarm conditions. A momentary contact push button switch powers a start/stop seal circuit in order to provide an auto-resetting, silence alarm function should the operator desire to silence the audio alarm during an alarm condition. An auxiliary interface connector may also be connected to these alarm outputs in order to provide a means of interfacing another piece of equipment to the pressure control system. This provides secondary pressure alarms to that equipment in the event that the equipment's primary pressure-sensing system should fail.

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Chapter 5 Operator Interface Systems

GLOVES (STERILE)

ERGOCLEAN GLOVEPORT ASSEMBLY AND INSTALLATION

GLOVE OPERATING PROCEDURES

GLOVE CHANGE PROCEDURE

Gloves (Sterile)

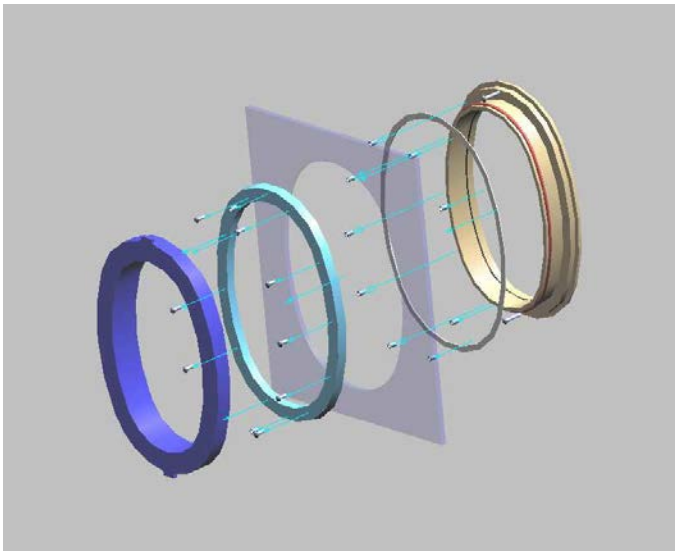
For Isolators operating in Sterile conditions, the operator gains access to the Isolator interior by means of glove and sleeve assemblies. With these assemblies, the operator can have their hands and arms physically within but biologically separated from the isolated environment.

As part of these assemblies, the gloves are attached to a wrist collar with o-rings. The wrist collar and o-rings allow the glove to be changed without breaking the barrier. To do this, pre-sterilized gloves must be stored in the Isolator at all times. Gloves can then be changed on a routine basis or as required by puncture or when an operator needing a different size glove begins to work within the Isolator.

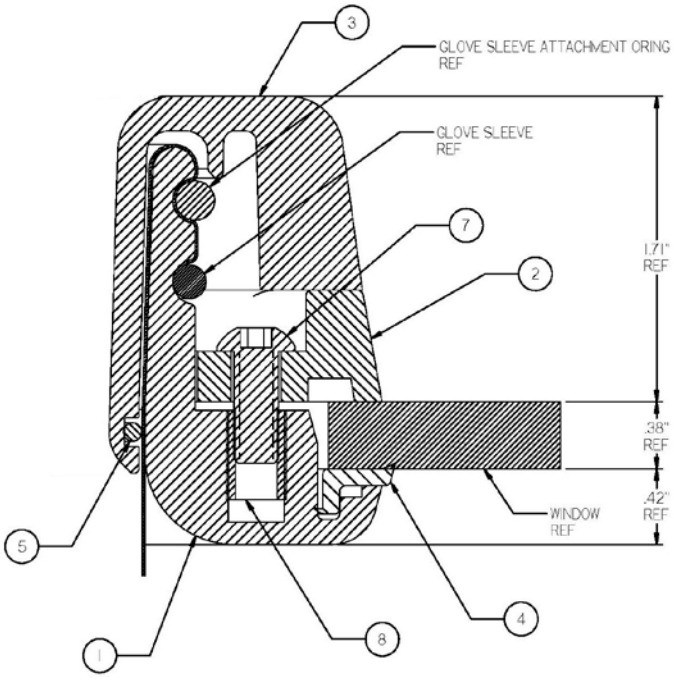
While these gloves are durable, it is important to avoid cutting or puncturing them. Operators should be aware that sharp fingernails, jewelry, and watches may cut the glove material. Also sharp instruments and tools used within the Isolator should be used with caution.

Material data sheets that provide more information on the specific physical properties and chemical resistance appear in Chapter 3, Materials of Construction. If hazardous chemicals are used, absorption properties of the chemical and the glove material should be checked.

Ergoclean Gloveport Assembly And Installation



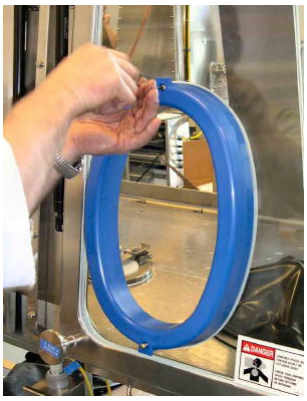
Exploded view of ErgoClean Gloveport



ErgoClean Gloveport Assembly Detail

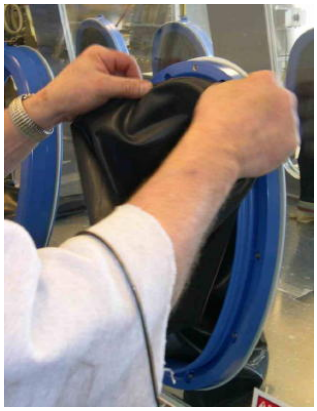
Parts ErgoClean Gloveport	
1	ErgoClean Gloveport
2	ErgoClean Clamping Ring
3	ErgoClean Glove Retainer
4	ErgoClean Gloveport Molded Seal
5	Retainer O-Ring
6	M6 x 35mm Long Retainer Screw (Not shown on detail)
7	M6 x 16mm Long Mounting Screw Torque specification – 12 inch. lbs
8	Ultrasonic Threaded Insert

Procedure for Glove Installation on the ErgoClean Gloveport Assembly



Remove the 2 screws from the retainer.

Remove the retainer from the gloveport assembly.



Align the hand of the glove in the proper rotation and start the glove bead on the innermost groove of the port.

Continue the installation by stretching the glove bead to fit the port – Note: be certain that you are installing the correct glove (i.e. 10” glove for a 10” port).

Check to see that the sleeve bead is firmly seated in the inner groove and there are no twists or folds in the sleeve as it forms to the edge of the port.

Start the glove sleeve attachment o-ring in the outer groove over the sleeve.

Stretch the o-ring to fit and insure it is seated in the outer groove of the port

Check the retainer to verify the retainer o-ring is installed in the retainer groove

Align the retainer with the gloveport and start the retainer with a gentle rocking top and bottom motion.

Seat the retainer by pulling the retainer and port together with a clamping motion of your hands as shown above.

Verify that the retainer and port assembly are seated all the way around and reinstall the 2 retainer screws that were removed in step one.

Glove Operating Procedures

Glove and Glove Sleeve Use:

Gloves and glove sleeves permit the introduction of the operator's hands and forearms into the isolator while the operator is stationed outside. Several glove types and sizes are available to fit various needs.

1. Place one pair of gloves in a Steri-Peel Pouch, Tower® Pouch, or equivalent, and autoclave per your validated procedure. If gloves are not steam-sterilizable, then decontaminate using hydrogen peroxide gas or other decontaminating agent.

2. It is recommended that an extra pair of sterile gloves be stored in the isolator to avoid downtime or other inconvenience in the event that a glove needs to be changed due to damage.

Using the Gloves and Glove Sleeves:

1. Before using the gloves and glove sleeves, make sure that all rings with sharp edges or gemstones and watches are removed from hands and wrists. In addition, it may be necessary to groom sharp fingernails before using the gloves.

2. Wash hands thoroughly with an antiseptic soap and warm water. Dry hands thoroughly.

3. Put on a pair of latex gloves, or equivalent, to reduce bioburden within the isolator gloves and help prevent cross-contamination between operators. An operator may wish to put on a pair of cotton gloves prior to putting on the latex gloves.

4. Inspect isolator gloves for damage by stretching various areas of the glove while closely observing the surface of the glove. Pay particular close attention to the underside of the cuff area and the finger tips. Inspect glove sleeves for damage.

5. Decontaminate the outside of the glove and glove sleeve portions, before testing is to be initiated and whenever gloves are replaced, using hydrogen peroxide gas and/or an approved bactericidal agent. Additionally, it is recommended that the outside of the gloves and glove sleeves be wiped with a sterile low-particulate wipe, which is saturated in an approved bactericidal agent, throughout the day that testing is performed. Dispose of wipes when testing is completed for the day.

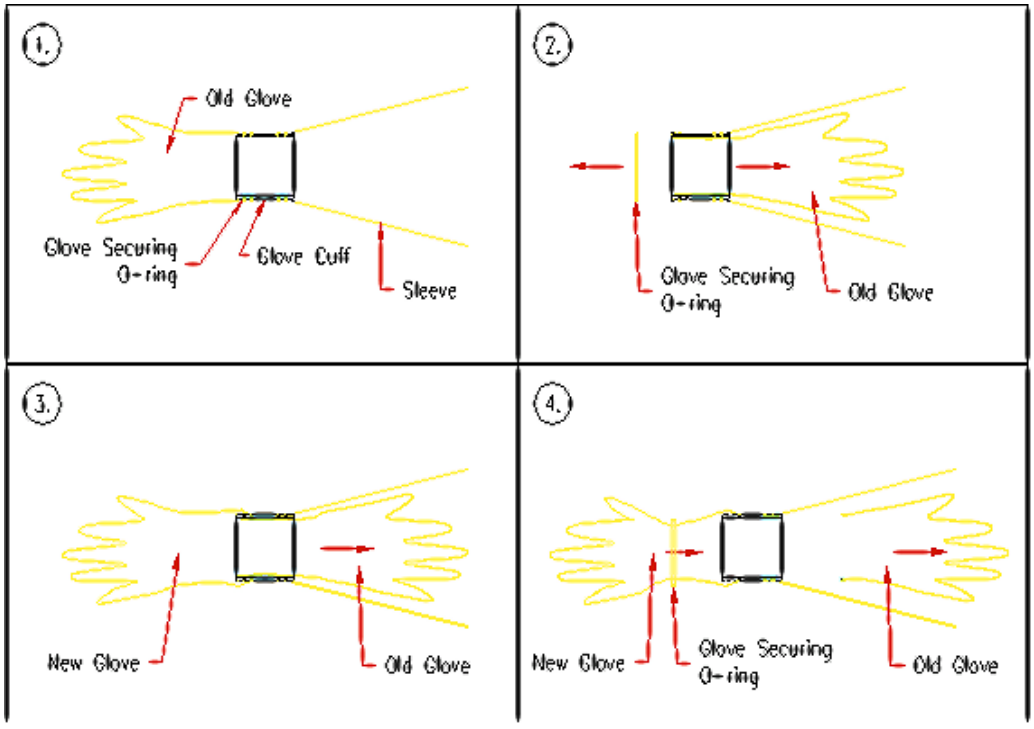
6. When exiting from glove sleeves, slowly and gradually withdraw hands and arms. If this is not done slowly and gradually, you may damage the glove sleeves and/or create a negative pressure within the isolator.

BARRIER SYSTEMS

Glove Change Procedure

For Isolators operating in sterile conditions, the gloves are designed to be changed while maintaining sterile conditions. As part of the training of this equipment, all pertinent personnel will be shown how to complete this procedure. The following is a pictorial description of the procedure:

1. Initial Glove/Sleeve orientation.
2. Retaining o-ring removal.
3. Placement of the new “sterile” glove.
4. Retaining o-ring replacement and removal of old glove.



Chapter 6

Chapter 6 Pass Through Systems

GAS-SHOCK-ASSIST (HATCHBACK) WINDOW

WINDOW CHANGE PROCEDURES

ELECTRICAL COMPRESSION FITTINGS

SANITARY FITTINGS

Gas-Shock-Assist (Hatchback) Window

A gas-shock-assist (hatchback) window is used where the operator needs quicker access to the interior process and the window needs to remain open until it is physically closed.

Gas-Shock-Assist Window Operation

To operate the gas shock window, loosen retaining knobs (4 - 6 depending on window size). Open window by lifting it up and out of the way. The gas shocks will help it to open and remain open.

Caution: Open the window by lifting evenly on the handles. Undo pressure on the corner of a glass window may cause glass breakage. To close the window, reverse the above procedure.

Gas-Shock-Assist Window Maintenance

After every week of operation (opening and closing of window), inspect the "D" shaped gasket. There should be no cuts, abrasions, or other discontinuities. Gasket memory should also be checked. The gasket should spring back to its original shape. If the gasket does not meet any of these requirements, then replace it. To replace the "D" gasket, scrape off the old gasket with a putty knife and replace it with a new gasket. The gasket comes with a self-adhesive backing. Use caution not to kink the gasket (since this will cause leaks). The gasket must have a full radius in the corners.

To remove gas shock, loosen the spring clip (about 1/8") on each end.

Caution: Do not completely remove the spring clip, they are very difficult to get back on. Pull shock mount off of the ball. To reinstall, reverse the procedure. Note: Gas shock must be compressed by hand and this is a brute-force job.

Gas Shock “D” Gasket Replacement

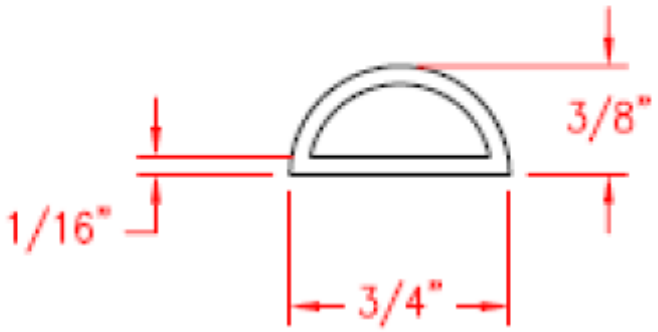
Store spare gasket material at 70°F +/- 6°F. Apply seals between 60°F and 85°F.

Parts needed to install gasket:	“D” Gasket	WGKT-SI-D-HB
	Caulk	CALK-SI-HT-WHT

Use a non-residual cleaner (Isopropyl Alcohol) for thoroughly cleaning the area where the seal is to be applied. The area will be dry before applying the seal.

Take the seal in hand and begin peeling the paper at about two feet at a time. Press the adhesive side of the seal down to ensure good adhesion. **DO NOT STRETCH SEAL WHEN APPLYING!**

When working around corners, the gasket should be pushed down to ensure that stretching will not occur. The glue joint can be determined when one foot of the gasket is left to be installed. Cut the butt joint 1/16” longer and finish applying the gasket. Use CALK-SI-HT-WHT to glue the butt joint together. It is very important to ensure that the butt joint is glued 100% without excess buildup on the internal side of the gasket. The butt joint may require a second coat to ensure flatness. Cure time for the butt joint is 24 hrs.



Window Change Procedures

For isolators with windows that are referred to as permanent mount, the following is a procedure for removing and replacing this type of window. The word permanent does not necessarily mean that the window cannot be removed it refers that the window is not designed to be removed easily or daily. It is designed to be removed during major cleaning or maintenance. To remove this type of window refer to the diagram and follow the step by step procedure outlined below:

Removing the Window

1. Locate and identify which window is to be removed.
2. Familiarize yourself with the components of the window assembly.
    - Window
    - Channel Gasket
    - Window Frame (stainless steel)
    - Cap Screws
    - Female Weld Studs
    - Isolator Shell
3. Depending on the size of the window, one or two people may be required to perform this operation.
4. Personnel are to have proper size Allen Wrench

    ¼" Socket head cap screws require a 5/32" Allen wrench

    5/16" Socket head cap screws require a 3/16" Allen wrench

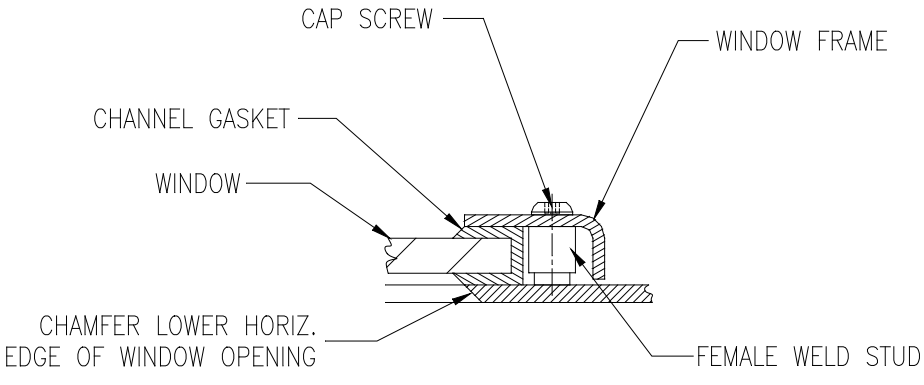
    Note: Do not use power tools for window installation

5. Loosen all Cap Screws so that equal pressure is applied to the Window. (Some windows are made of Laminated Safety Glass and some are made of Polycarbonate)

6. After Cap Screws are loose, remove all of them while holding the window in place. Depending on the size, one or more people may be required to hold the window. Note, store all Cap Screws in a safe location to avoid misplacing them. Spare Cap Screws should be kept in inventory.

7. Once Cap Screws are removed the Window and Frame can be lifted off the Female Weld Studs. When handling a Laminated Safety Glass Window, extreme care should be taken so as not to scratch, crack or chip the Window. When handling a Polycarbonate Window, care should be taken so as not to scratch the Window.

8. Store the Window and Frame in a secure location where accidental damage can be avoided.



WINDOW DETAIL
SCALE: NONE

Reinstalling the Window

1. Locate the Window, Frame and Cap Screws that are to be replaced.

2. Prior to reinstalling the Window, inspect the window for cracks and chips. Also inspect the Channel Gasket for damage, fit and cleanliness. Each Channel Gasket is specifically designed for each Window and should fit properly.

3. Depending on the size of the Window one or two people may be required to reinstall the Window.

4. Personnel are to have proper size Allen Wrench:

   1/4" Socket head cap screws require 5/32" Allen wrench

   5/16" Socket head cap screws require a 3/16" Allen wrench

Note: Do not use power tools for window installation

5. Lift Window, Gasket and Frame assembly into position over the Female Weld Studs. Check for proper fit of the Window Gasket in the Isolator Window opening.

6. Loosely install all Cap Screws so that equal pressure is applied to the Window.

7. Once all Cap Screws are in place and the Window and Gasket is properly positioned, start to tighten each of the Cap Screws. This is done by applying light but firm pressure to the Cap Screw (one turn maximum). Start with putting one screw in each corner of the window. After tightening the corner screws finger tight, put the remaining screws in along one side. Tighten these screws finger tight and continue along each side (clockwise or counter clockwise) until all the screws are installed. Continue tightening screws clockwise or counter clockwise until all screws are tight. Stop when the screw turns hard. **Note do not over tighten! Laminated Safety Glass can break if uneven pressure is applied during this procedure.**

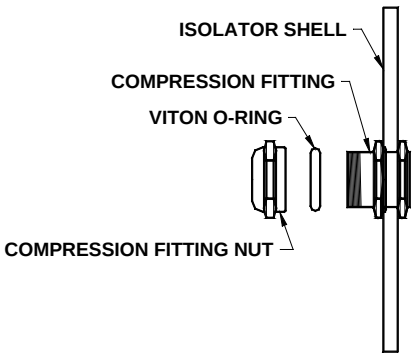
8. Once all Windows are reinstalled it is recommended that the isolator be Leak Tested prior to putting the unit back into operation.

Electrical Compression Fittings

The Isolator is equipped with a number of electrical compression fittings. These fittings are used for providing an airtight method for running electrical cords or sensing lines in and out of the chamber. They are made of either stainless steel or Teflon ®.

Cords or lines are passed through the fitting. As the nut is tightened around the fitting, the gasket collapses around and seals against the cords or lines.

An illustration of an electrical compression fitting follows.



COMPRESSION FITTING

Sanitary Fittings

This isolator is equipped with one or more, 316L sanitary fitting ports. This is a double sanitary fitting that allows for the connection (with sanitary fittings) on both the inside and outside of the chamber. This port comes with one gasket, cap and clamp.

Chapter 7

Chapter 7 Preventative Care and Maintenance

PREVENTATIVE MAINTENANCE CHART

ROUTINE MAINTENANCE PROCEDURES

CLEANING PROCEDURES

AMMONIA LEAK TEST PROCEDURES

Preventative Maintenance Chart

The following is a recommended schedule for preventative maintenance for this Isolator. For items not listed, refer to the manufacturer's data sheets found in their corresponding chapter.

Item	Schedule of Service	Service to be Performed
RTP Gaskets	Weekly	Lubricate with silicone oil.
Pre-filters	As Required	Clean out or wash.
Gloves	As required	Change*
HEPA/ULPA Filters	Annually	DOP certification
RTP Gaskets	Annually	Replace
Pre-filters	Annually	Replace
Glove Sleeves	Annually	Replace
HEPA/ULPA Filters	As Required	Replace
Half-Suits	Annually	Evaluate/Replace*
Leak Test	Periodic	Test**

* Inspect for holes, cuts, leaks before each use.

** Containment Boxes need to be thoroughly cleaned before a positive pressure leak test.

The Isolator has a One Year Limited Warranty for defective parts and workmanship (excluding wear items such as gloves, sleeves, filters, and gaskets).

Routine Maintenance Procedures

Frequency:

Daily:

- Inspect gloves, glove sleeves, and half-suit(s) for any signs of damage or leakage. Repair or replace as necessary.
- Document in Maintenance Log Sheet for Isolators.
- Note any specific repairs or replacements in the "Comments" section of the Maintenance Log Sheet for Isolators.

Weekly:

- Inspect and lubricate RTP gaskets and with sterile silicone oil.
- Wipe silicone oil on RTP gaskets using a sterile swab, or equivalent.
- Document in Maintenance Log Sheet for Isolators.
- Note any specific repairs or replacements in the "Comments" section of the Maintenance Log Sheet for Isolators.

As Required and/or Prior to Initiating a Gas Bio-decontamination Cycle:

- Replace gloves.
- Document in Maintenance Log Sheet for Isolators.
- Leak test isolator using the selected leak test method.
- See Leak Testing Procedures found later in this chapter.
- Document in Leak-Testing Log Sheet for Isolators.

Semi-Annually:

- Inspect HEPA filters.
- Perform appropriate integrity test of HEPA filters as per appropriate procedure. Document in Maintenance Log Sheet for Isolators.
- Note any specific repairs or replacements in the "Comments" section of the Maintenance Log Sheet for Isolators.

Annually:

- Replace RTP gaskets, pre-filters, rubber bands, PVC docking collar, glove sleeves, HEPA filters, and half-suit(s) based upon their usage.
- Document in Maintenance Log Sheet for Isolators.
- Note any specific repairs or replacements in the "Comments" section of the Maintenance Log Sheet for Isolators.

Glove and Glove Sleeve Care and Maintenance:

- Inspect gloves for damage by stretching various areas of the glove while closely observing the surface of the glove.
- Pay particular close attention to the cuff area. Inspect glove sleeves for damage.

Half-Suit Care and Maintenance:

- During daily inspection of the half-suit, pay particularly close attention to the area of the half-suit where the materials are bonded together. This area is the most likely place for bond separation and damage.

BARRIER SYSTEMS

MAINTENANCE LOG SHEET

Isolator Type:_____

Serial Number:_____

Performed By:	Date:	Time:	Daily	Weekly		Monthly
			Inspect gloves/ sleeves/half-suits for damage	Clean Pre-Filters	Inspect & lubricate RTP gaskets	Leak Test Isolator*

***perform prior to a sterilization cycle and/or monthly**

Integrity Test HEPA Filter(s) (Due Date)_____

Reviewed by: _____ **Date:** _____

BARRIER SYSTEMS

MAINTENANCE LOG SHEET (cont.)

Isolator Type:_____

Serial Number:_____

Comments:
Performed by: **Date:**

Performed by: **Date:**

Performed by: **Date:**

Reviewed by: _____ **Date:** _____

Cleaning Procedures

Isolator Surface Cleaning:

Wipe the outside of the isolator with sterile distilled water using sterile low-particulate wipes. Dry with sterile lint-free wipes. A ladder may be necessary to reach and clean the top of the isolator. Exercise extreme caution while on the ladder and have a colleague hold the ladder firm. Dispose of wipes when finished cleaning/drying.

Wipe the inside of the isolator with sterile distilled water using sterile low-particulate wipes. Dry with sterile lint-free wipes. Dispose of wipes when finished cleaning/drying.

Place several packages of sterile low-particulate wipes within the isolator. If media and/or product spillage occurs, promptly clean using the sterile low-particulate wipes and sterile distilled water, or an approved bactericidal agent. Dispose of wipes when completed.

Half-Suit Cleaning:

Wipe the inside of the face shield with a sterile low-particulate wipe saturated in a suitable bactericidal agent prior to entry and upon exit from the half-suit to reduce the possibility of contamination between operators that may use the same half-suit.
DO NOT use alcohol or alcohol based products to perform this disinfection. Alcohol may damage the polycarbonate face shield in an effect known as "crazing".

Pre-Filter Cleaning:

Cleaning of the pre-filters is accomplished by running the filter over hot water, followed by washing with a mild detergent, followed by several distilled water rinses. Allow to fully dry before replacing.

It is recommended that when a pre-filter is removed for cleaning, another pre-cleaned, dry, a pre-filter is immediately substituted.

BARRIER SYSTEMS

CLEANING LOG SHEET

Isolator Type:_____

Serial Number:_____

Performed By:	Date:	Time:	Daily	Weekly		Monthly
			Inspect Isolator for Cleanliness	Clean Pre-Filters	Clean RTP	Clean Isolator*

***perform isolator cleaning prior to a sterilization cycle and/or monthly**

Integrity Test HEPA Filter(s) (Due Date)_____

Reviewed by: _____ **Date:** _____

BARRIER SYSTEMS

CLEANING LOG SHEET (cont.)

Isolator Type:_____

Serial Number:_____

Comments:	
Performed by:	**Date:**

Performed by:	**Date:**

Performed by:	**Date:**

Reviewed by: _____ **Date:** _____

Ammonia Leak Test Procedures

Safety
Industrial strength Ammonia Hydroxide is a strong irritant. Do not get on skin or in eyes. Do not ingest or inhale. Wash thoroughly after handling. Wash clothing before re-use. Discard contaminated shoes. Use with adequate ventilation (be careful as to where the glovebox is vent to). Keep container closed. **Important! Do not proceed unless material safety data sheet has been read and understood.**

1. Test Objective

   To verify that the Isolator is leak tight and meets the customers Requirements as specified.

2. Test Conditions

   The Isolator to be completely assembled with all components and systems installed. Isolator is to be ready for all functional tests.

3. Documentation Required

   - Inspection Form # WBS-QC-06

4. Personnel Required

   - A qualified Test Technician

5. Equipment Required

   - Industrial Liquid Ammonia Hydroxide (concentrated >25%)
   - Yellow Ammonia Sensitive Cloth (Walker Stainless Equipment part # AM-CLOTH)
   - Plastic, glass, or stainless steel funnel
   - Low profile dish (low sides, large area).
   - Container for waste ammonia.

6. Test Procedure

Calibration

- Test the cloth/Ammonia Hydroxide combination by holding the cloth over the mouth of the opened Ammonia Hydroxide bottle. The cloth should instantaneously turn blue in color.

Leak Checking

- Insert the Ammonia Hydroxide container inside the Isolator. (For large Isolators, more containers can be used.)
- Completely seal the Isolator by closing all doors, windows, or by using blank-off plates, etc.
- Open the Ammonia Hydroxide container using the gloves on the Isolator.
- For larger isolators pour Ammonia Hydroxide solution into a low profile dish to increase the evaporation rate by increasing the exposed surface area of the Ammonia Hydroxide
- Pressurize the Isolator using the Ventilation system or with air pressure for static Isolator to 2.0" water column.
- Wait 15 - 30 minutes for Ammonia Hydroxide distribution
- Create artificial leak by opening a connection port and test to see if the cloth turns blue.
- Test all sealing surfaces, gasketed connections, penetrations, windows and doors, by holding the cloth over segments of the Isolator for 3 - 5 second intervals.
- Upon completion of leak testing reseal Ammonia Hydroxide container. Funnel is used for returning Ammonia Hydroxide to waste container as the ammonia should not be reused. Vent Isolator to house exhaust.

WARNING, do not vent to the room. Ammonia vapors cause much irritation to eyes and breathing passages.

7. Reporting Results

Mark each location where the cloth turns blue. Repair and repeat tests until the cloth no longer turns blue.

Record the results of the inspection on Inspection Form # WBS-QC-06 with all appropriate information completed on the form.

Specified System	Requirement	Pass/Fail	Walker Barrier Systems Initial/Date
Isolator Pressure	2.0” water column		
Comments:			
Isolator Ammonia Concentration	Blue color shows on test cloth.		
Comments:			
Windows	No color change.		
Comments:			
Boyer Doors	No color change.		
Comments:			
Gasketed Pipe Flanges	No color change.		
Comments:			
HEPA Filter Housings	No color change.		
Comments:			
Other Gasketed Connections	No color change.		
Comments:			
Gloveports	No color change.		
Comments:			

	Name	Signature	Date
Test Technician			
Customer			

Chapter 8

Chapter 8 Drawings/Schematics & Technical Information

AS-BUILT DRAWINGS, MECHANICAL

AS-BUILT DRAWINGS, CONTROLS SCHEMATICS

ADDITIONAL TECHNICAL INFORMATION

- A-B MICROLOGIX 1500 USER MANUAL
- A-B PANELVIEW PLUS USER MANUAL
- A-B POWERFLEX 4 DRIVE USER MANUAL
- A-B MISCELLANEOUS CUT SHEETS
- ASHCROFT PRESSURE TRANSDUCER
- FAN AND BLOWER INFORMATION
- OUTLETS
- MISCELLANEOUS CUT SHEETS
- VAISALA INFORMATION
- VALVE INFORMATION

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BARRIER SYSTEMS

As-Built Drawings, Mechanical

Drawing Number	Revision	Sheet Number
37642-1A-D	B	Sheet 1 of 2
37642-1A-D	B	Sheet 2 of 2
Drawings Approved / Released By: Matt Wickert	Date	
(Signed) Matt Wickert	8/14/14	

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BARRIER SYSTEMS

As-Built Drawings, Controls Schematics

Drawing Number	Revision	Sheet Number
37642-6A-D1	C X D	1 of 1
37642-6B-D1	B	1 of 20
37642-6B-D2	B	2 of 20
37642-6B-D3	B	3 of 20
37642-6B-D4	B	4 of 20
37642-6B-D5	B	5 of 20
37642-6B-D6	B	6 of 20
37642-6B-D7	B X E	7 of 20
37642-6B-D8	B	8 of 20
37642-6B-D9	B	9 of 20
37642-6B-D10	B	10 of 20
37642-6B-D11	B	11 of 20
37642-6B-D12	B X E	12 of 20
37642-6C-D1	B X E	13 of 20
37642-6C-D2	B	14 of 20
37642-6C-D3	B	15 of 20
37642-6C-D4	B	16 of 20
37642-6E-D1	B X E	17 of 20
37642-6E-D2	B	18 of 20
37642-6F-D1	B	19 of 20
37642-6F-D2	B	20 of 20
Drawings Approved / Released By: Terry Bardell		Date
(Signed) Terry Bardell		8/27/14

Additional Technical Information

The following sections contain user manuals, maintenance information, and cut sheets for specific units or assemblies of the Isolator.

A-B MicroLogix 1500 User Manual

A-B PanelView Plus User Manual

A-B PowerFlex 4 Drive User Manual

A-B Miscellaneous Cut Sheets

Ashcroft Pressure Transducer

Fan and Blower Information

Outlets

BARRIER SYSTEMS

Miscellaneous Cut Sheets

Vaisala Information

Valve Information

Chapter 9

Chapter 9 Certifications and Inspection

PART CERTIFICATIONS

S.S. CERTIFICATIONS

ISOLATOR INSPECTION

FACTORY ACCEPTANCE TEST (FAT)

COMMISSIONING DOCUMENTATION

Part Certifications

S.S. Certifications

Isolator Inspection

All Walker Barrier Systems Isolators are inspected in the factory prior to shipment. There are standard tests required of each Isolator and optional tests can also be performed per customer purchase specifications. In addition, there are tests that can be performed onsite at the customer location per purchase specifications.

The completed inspection test results appear following this page.

BARRIER SYSTEMS

Factory Acceptance Test (FAT)

BARRIER SYSTEMS

Commissioning Documentation

Chapter

10

Appendix

MANUAL REVISION LOG

SPARE PARTS LIST

Manual Revision Log

Spare Parts List