WEIGHING & DISPENSING CONTAINMENT ISOLATORS (WDCI)

ESCO
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How can I help you?

What am I?

What's my Market target?

Why am I Different?

How am I made?

What do I do?

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System Design – What am I used for?

Weighing & Dispensing of API's:-

- Open powder handling of API's can cause a serious health risk
- The use of PPE alone as protection is insufficient to counteract the health risks for long periods of exposure to certain potent API's
- The Operator Exposure Level (OEL) should be defined as the safe working limit for the operators and that the containment system is capable of achieving.
- Open powder handling is more prone to foreign materials entering the powder (Hair, skin particles, etc)

- Working in an isolator creates a protection barrier between the operator and equipment. This barrier is both physical and a pressure differential
- Isolators can achieve down to 1ng/m^3 containment over an 8 hour TWA

System Design – Isolator Design vs Containment Level

System Type (Process Chamber with Following Options)	Containment Level Achievable (Dependant on Process & SOP's)			
	1 to 10 µg/m³	0.5 to 1 µg/m³	0.1 to 0.5 µg/m³	1 to 100 ng/ m³
Process Chamber with RTP & Pass Chamber (dedicated process flow)	X	X	X	X
Process Chamber with RTP	X	X	X	
Process Chamber with bag-in / bag-out port or bulk drum transfer within an additional isolator chamber	X	X		
Process & Pass Chamber (product flow both directions)	X			
Process Chamber with Split Butterfly Valve or product / waste transfer through double tie and cut without secondary containment	X			

- This equipment is designed primarily for Operator Protection, therefore the containment levels and Esco's guarantee to meet them are the most critical in design consideration
- The above levels are provided as a general guide, however are process specific depending on material quantity handled and types of transfer containers in and out of the system.

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System Design – Standard Options / Configurations

Chamber Size	Pass Chamber	N2 Purge	Temp & Humidity Monitor	Drain	WIP	CIP Process Chamber	CIP Pass Chamber	4" Split Butterfly Valve	RTP Diam 105, 190, 270, 350, 460
									
2 Glove	X	X	X	X	X	X	X	X	X
3 Glove	X	X	X	X	X	X	X	X	X
4 Glove	X	X	X	X	X	X	X	X	X
5 Glove	X	X	X	X	X	X	X	X	X

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System Design – Manufacture - Chamber

- 316L Stainless Steel construction
- 4mm thick chamber material – Keeps shape and rigidity for excellent sealing and tighter tolerance
- 2mm thick service housing
- 1.5mm thick access panels
- All material traceable to the Mill with certification provided within the technical file for each isolator
- Fully welded and polished seamless chamber construction – cGMP
- 19mm chamber internal radius corners – cGMP
- 2.5” (63.5mm) round tube for support stand – easy to clean, reduces dust traps – cGMP
- 0.4µm Ra surface finish internally
- 0.6µm Ra surface finish externally
- Passivized Stainless steel with Citric Acid after fabrication

System Design – Internationally Recognized Sub-Suppliers

Advantage:-

- With the world market of Esco products and customer need for quick response in case of component failure it has been ensured that the selected components are of international quality and availability
- To compete against high quality European Isolators and target a mid-market position it is necessary to provide the highest quality components but utilize Asia manufacturing to supply a mid-range priced system at the highest quality and technology
- Key International Brands used are:-

camfil FARR

FESTO

SIEMENS

METTLER TOLEDO

PEPPERL+FUCHS

RITTAL

ABB

rotronic

Parker

Spraying Systems Co.
Experts in Spray Technology

System Design – Overall Size

- The system is shipped with high capacity Delrin, swivel castors for ease of mobility and anti-floor marking properties
- Adjustable leveling feet allow level final position
- The system is shipped in its lowest height position ready for install.
- The Systems lowered height 2080mm (6’8”) (when on wheels) and depth of 650mm (2’1”) is designed to fit through a standard doorway for ease of installation and movement around site.
- The isolator is supplied with coiled hoses fitted with quick connects. This connects to the isolator housing roof for utility supplies to allow quick installation and accommodates the isolator raise / lower:-
    - Compressed Air Supply – Blue
    - Compressed N2 Supply – Black (With Green band added)

- The exhaust air connection is supplied with a flexible bellows to accommodate the raise / lower function

System Design – Features - Chamber

Sloped Base to Tank Bottom Valve for Improved Drainage

2° Sloped ceiling to the rear to reduce water droplet retention after WIP/CIP

Sloped Pass Chamber floor to Process Chamber for common Drainage

St. St. Grain direction same as liquid flow to reduce liquid retention and promote drainage

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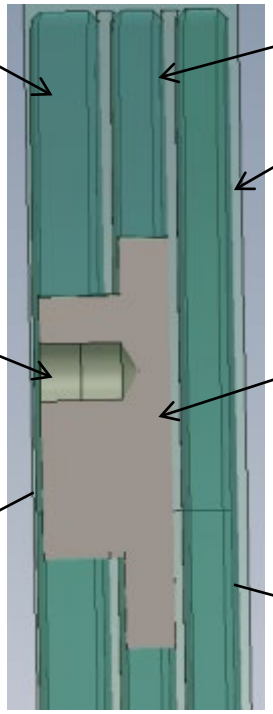
System Design – Features - Glass

Toughened Safety Glass

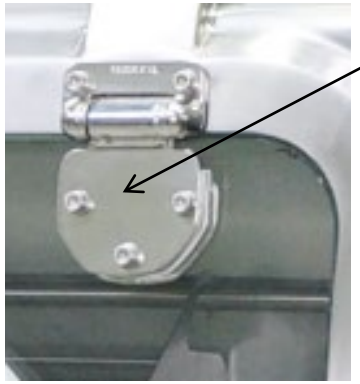
Laminate

Flush Interior Surface

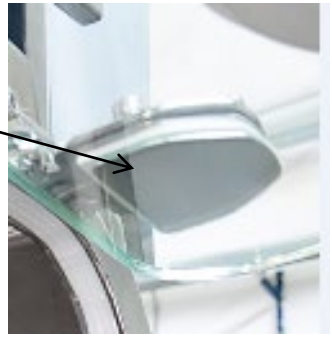


Threaded Blind Mounting Hole

Bonded in St. St. Mounts for Hinges, Handles & Gas Struts

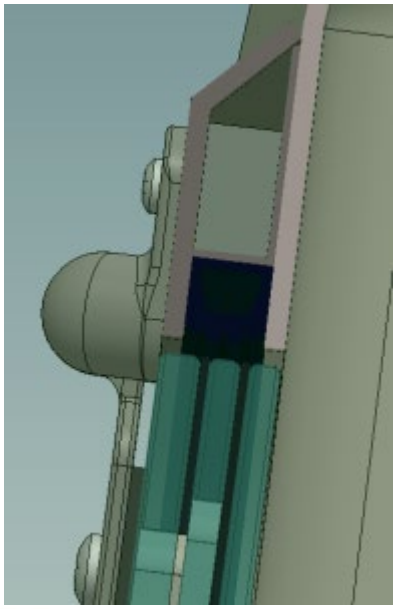


Outside View



Inside View

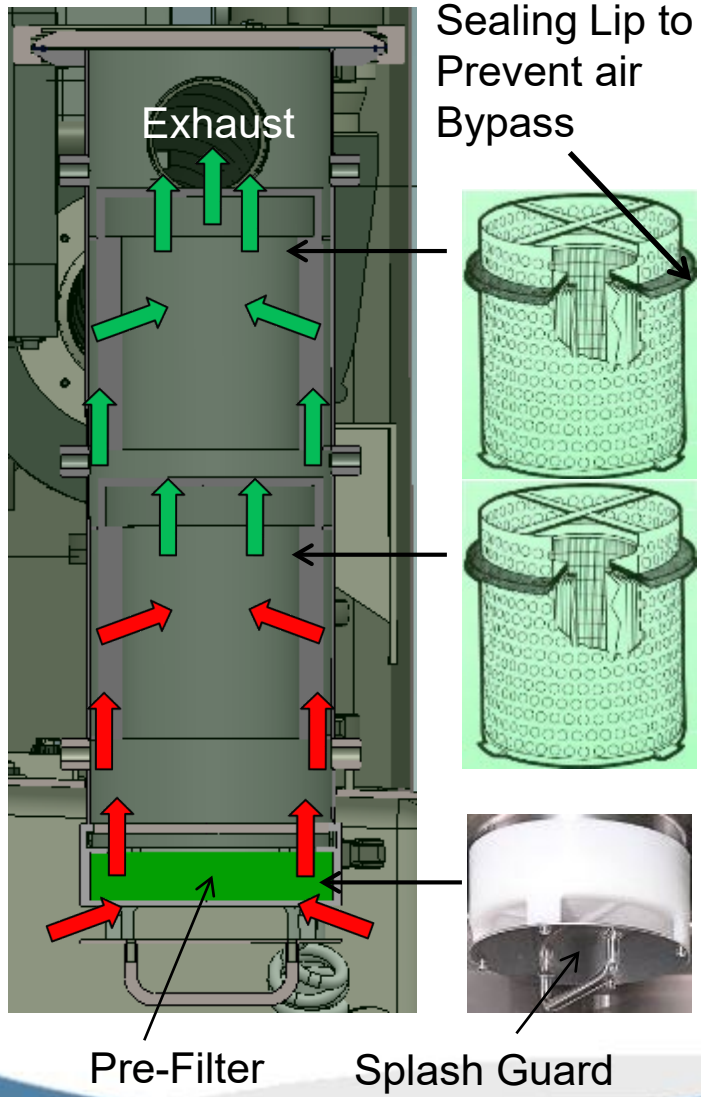
System Design – Features – Inflatable Seals



- Inflatable seals are more reliable and give a better seal than static seals. Static seals undergo compression each time the door closes and can be susceptible to reduced recovery to its original shape over time, especially if doors are left closed a long time.
- Static seals rely on tight tolerances to get the same compression and seal for each piece of equipment. Inflatable seals automatically take up any slight tolerance deviations to still seal.
- These ‘Bioquardian’ seals contain Silver particles within the raw material to make them AntiMicrobial
- The Seals are FDA Approved
- They are USP Class IV Compliant. This satisfies regulations that the elastomer or extract will not be harmful to human health
- Each seal is vulcanized during manufacture of the seal. This guarantees a permanent sealed closed length seal, unlike static seals which are often adhered by the vendor during production.
- Replacement seals are supplied at the correct closed length, ready for installation
- Seals are a press fit into the tolerance groove on the isolator, this includes the air valve connection

System Design – Features – Filters

Process Chamber:-



- H14 (99.995%) Push Push Filters allow safe change mid-process without the need to shutdown or clean down the chamber
- Clean filters are handled from outside the isolator while dirty filters are inside the contained chamber
- The splash guard prevents water damage to the filters during WIP/CIP. The integral Pre-Filter increases the life of the exhaust filter and is a protection for the Inlet filter
- Integrated Filter integrity test ports in the filter housing allow injection / scanning using PAO (Poly Alpha Olefin)
- Integrated ports for pressure differential monitoring over the filters. These provide filter condition status on the HMI based on pressure differential
- The Inlet Safe change housing has an additional port to connect an optional Nitrogen entry for purging of the chamber to achieve inert conditions.

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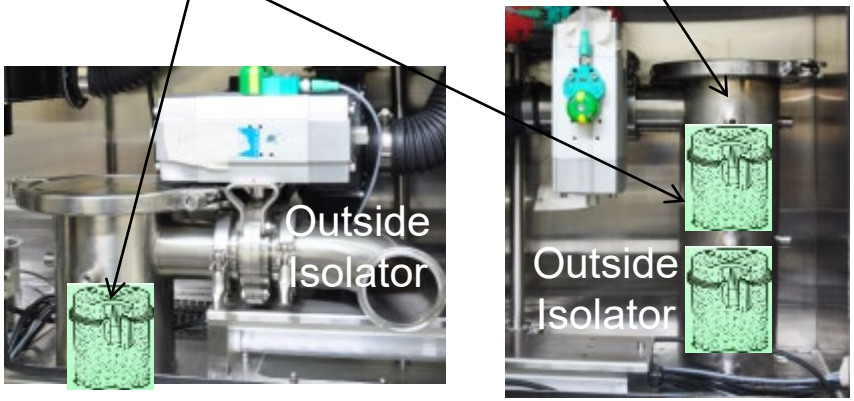
System Design - Operational– Filter Safe Change

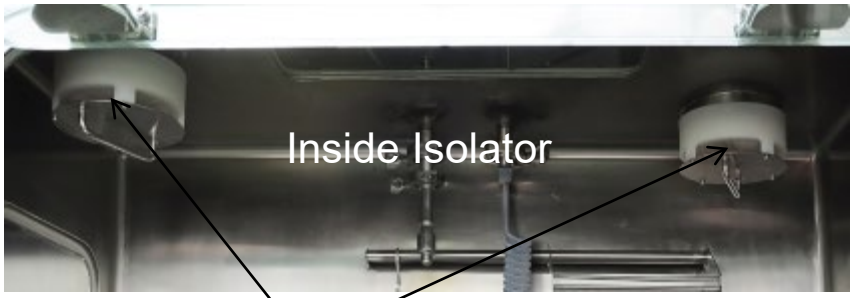
Process Chamber:-

STEP 1

Push Push Filters

Push Push Filter Housing

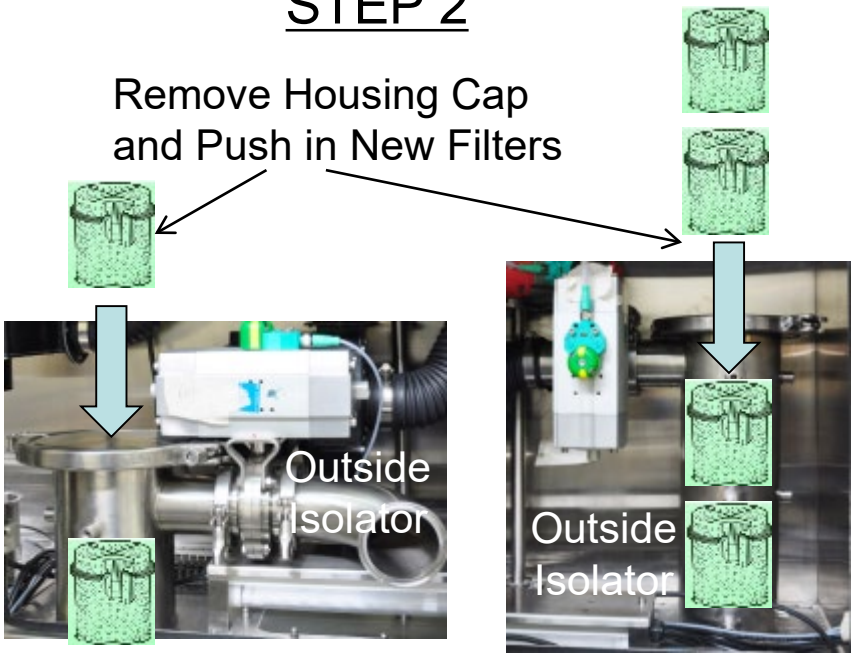


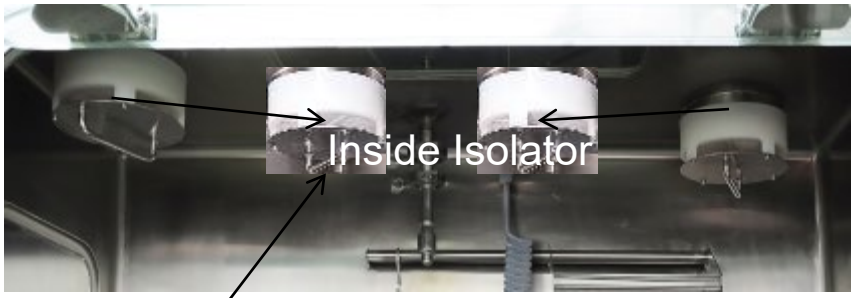


Filter Splash Guard with Pre-Filter

STEP 2

Remove Housing Cap and Push in New Filters





Remove Splash Guards

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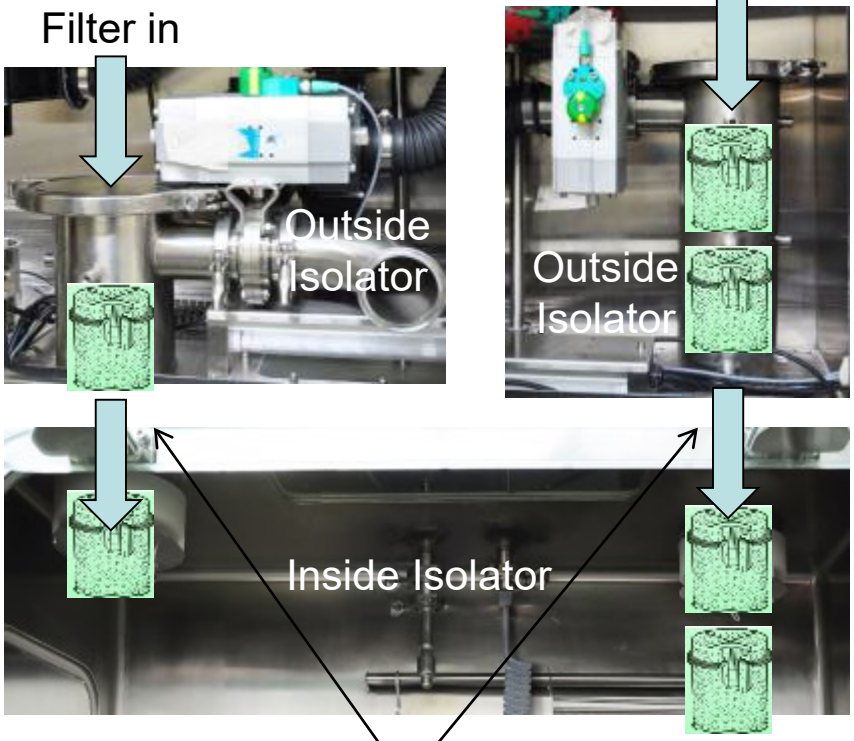
System Design - Operational– Filter Safe Change

Process Chamber:-

STEP 3

Push Clean Filter in

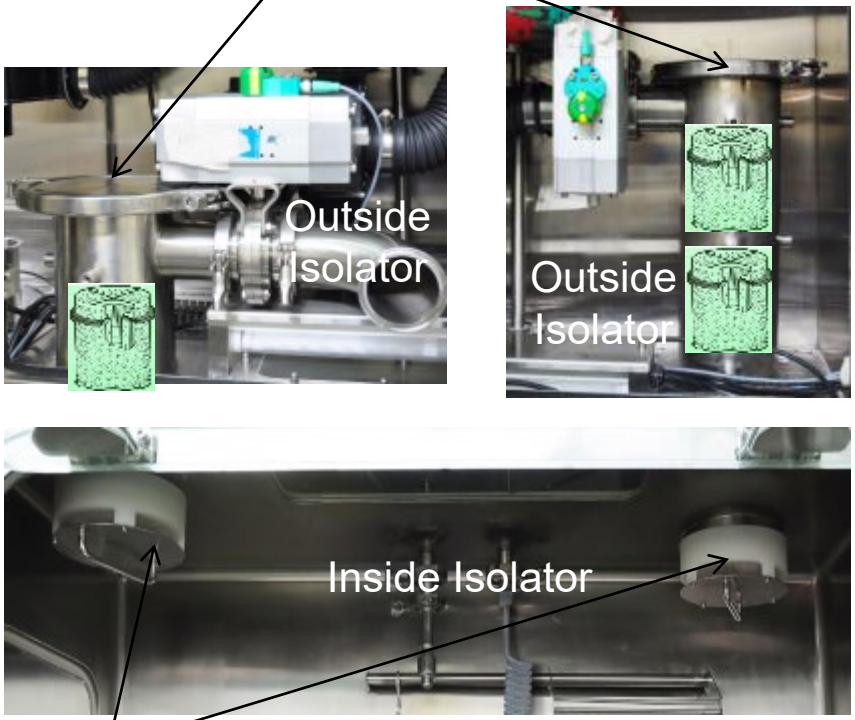
Push Clean Filters in



New Filters Push out the Old Filters Into the contained space for over-bag and removal via the RTP

STEP 4

Replace Housing Caps



Replace Splash Guards

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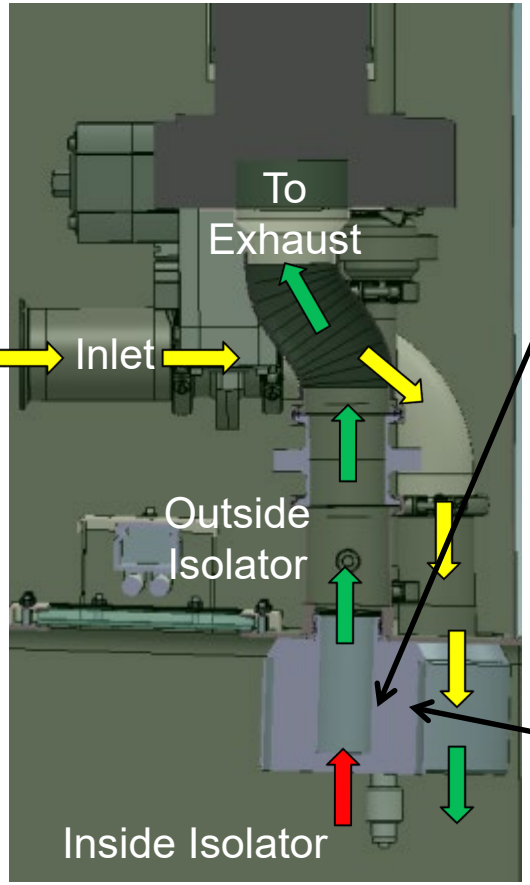
System Construction – Features – Filters

Pass Chamber:-



View of Filter

Inlet Exhaust

View Inside
Pass Chamber

- H14 (99.995%) Cartridge Filters allow safe change within the chamber
- As the Pass Chamber should be relatively clean, a new, clean filter can pass in for the change procedure
- Filter PVC casing protects the Filter media from damage
- The Filters screw in place from within the isolator and change takes place either with the pass chamber door open or through the glove port

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System Design – Operational – Filter Safe Change

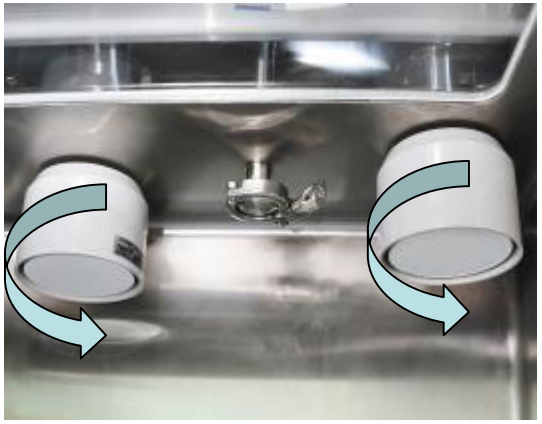
Pass Chamber:-

STEP 1

Open the Outer Pass Chamber Door

Pass In the New Clean Filters & Close the Outer Pass Chamber Door

STEP 2

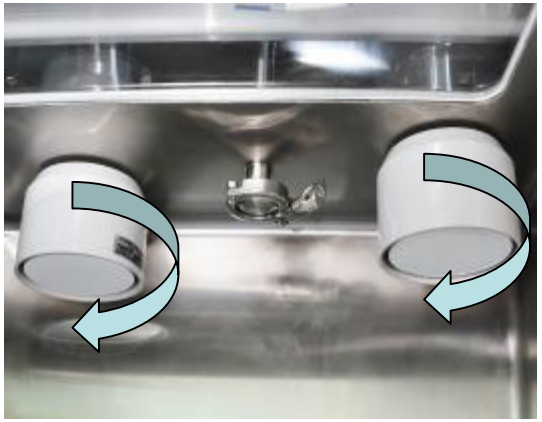


Working Through the Gloves, Unscrew the Old Filters, Rotating Anti-Clockwise

System Design – Operational – Filter Safe Change

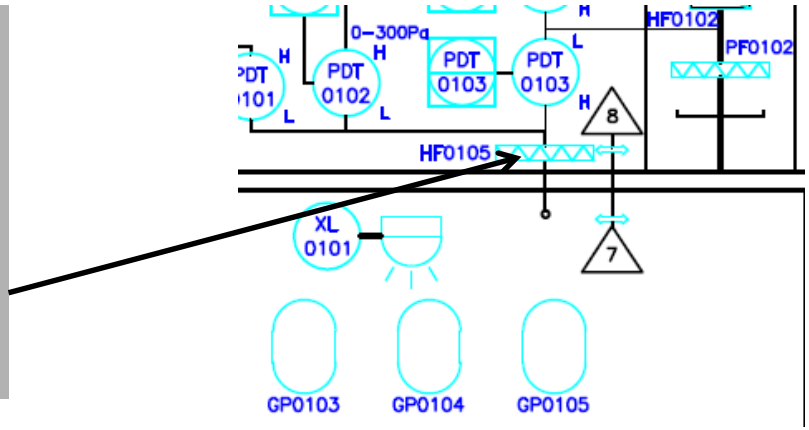
Pass Chamber:-

STEP 3



Screw in the New Filters, Rotating Clockwise until hand tight

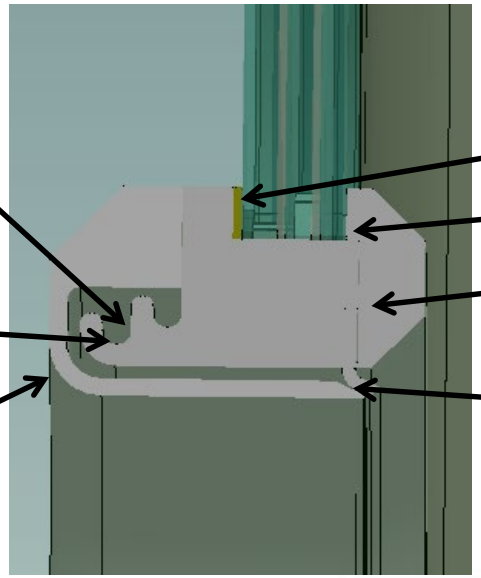
System Design – Instrument Protection



- Instrument Filter, installed at the boundary of the chamber & protects the monitoring device from contaminants. As this is a pressure sensor, there is very little contaminant that enters this line as no draw of air to the sensor, only a small line for monitoring pressure.
- These lines are always installed in vertical orientation to the chamber so are self draining should any liquid enter the line during clean down.

System Design – Features – Glove-Ports – Safe Change

- Manufactured from FDA compliant POM (Acetal Copolymer)
- 200mm x 300mm elliptical design (Suits 10” diameter Glove sleeve) to allow increased vertical motion
- Safe change design system allows glove change mid-process
- Gloves in CSM (Hypalon), Neoprene, Butyl or Polyurethane
- Cover ring to leave minimal external cervices
- Inner gasket is Anti-Microbial, FDA approved and USP Class IV compliant
- Outer Gasket from FDA approved Silicone



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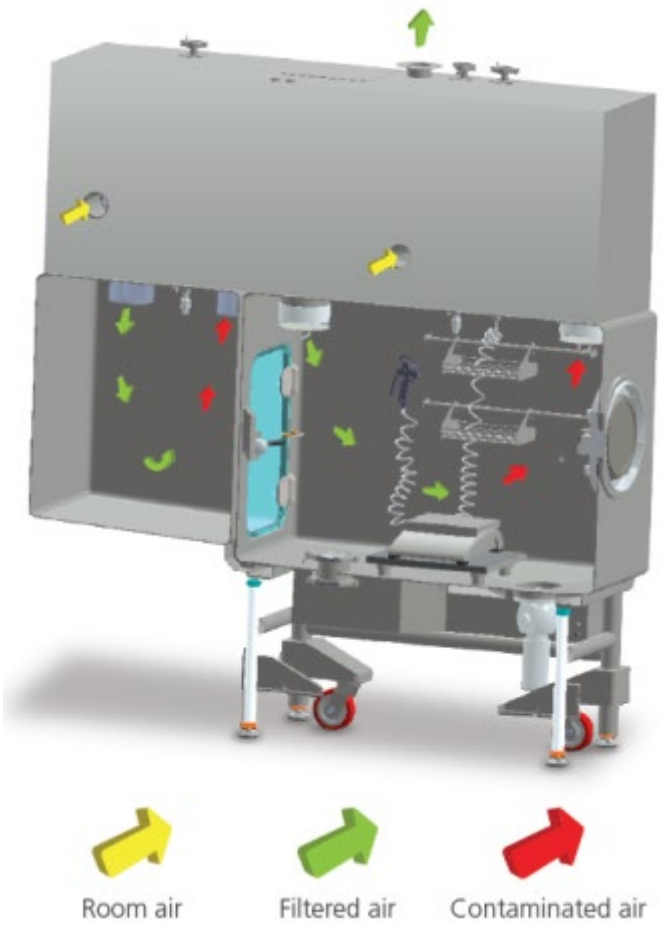
System Design – Lighting

- T5 lighting for maximum output.
- Externally mounted lighting for clean finish.
- Safe change of lighting via technical space outside of the chamber.
- Internal sealing gasket is Anti-Microbial, FDA and USP Class IV compliant.
- External gasket FDA compliant Silicone
- Toughened Safety Glass.

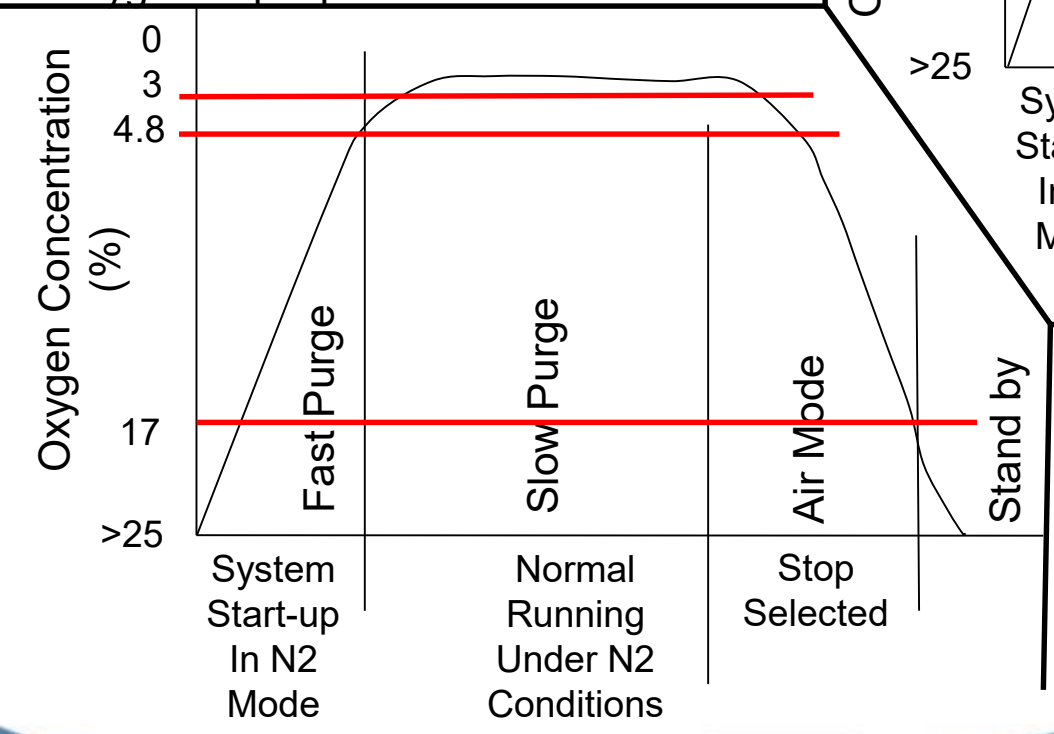
System Design – Operational – Turbulent Airflow



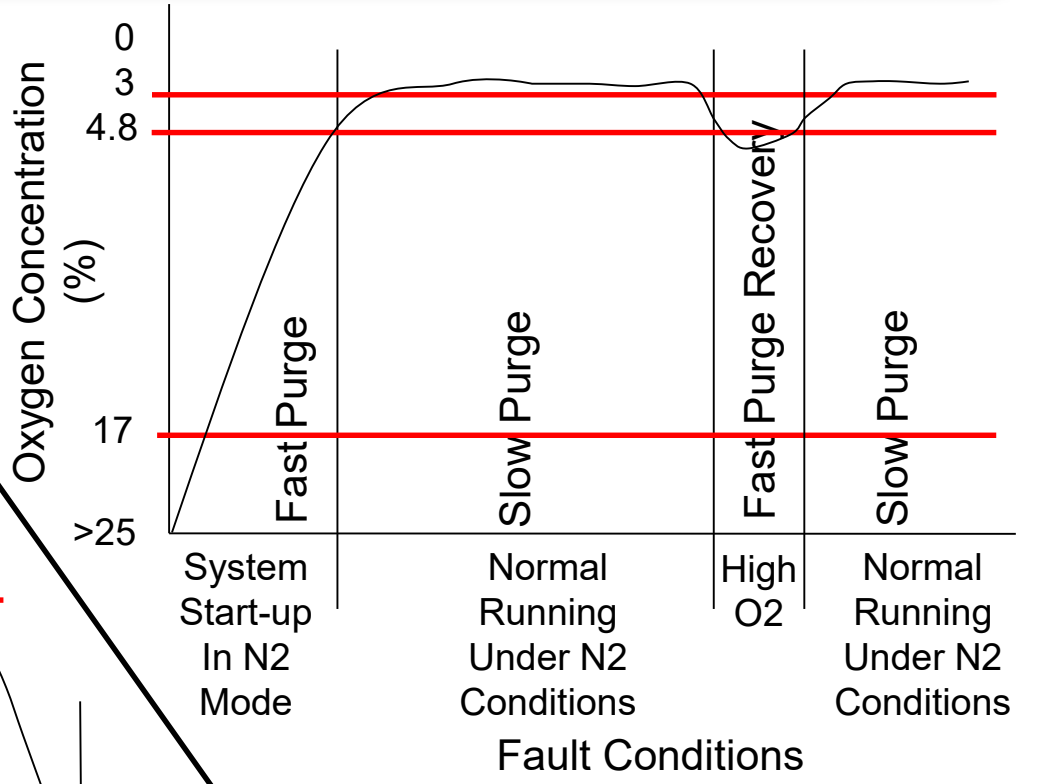
- The word ‘turbulent’ is sometimes taken as a negative feature over ‘Laminar’ or ‘Unidirectional’ Airflow. Whilst this is true for Aseptic applications, for API processing turbulent flow is a benefit.
- Key Benefits are:-
  - Reduced airflow
    - 21m^3/hr under Air
    - As low as 2m^3/hr under N2
  - Less effect of air on weigh balance creating reading fluctuation
  - Smaller Filters – Easier to change
  - More cleanable design – As no large filter face and fixings

System Design – Features – Nitrogen Purge

- System Designed to maintain Oxygen Concentration of ≤3% Oxygen. Below 5% is considered Inert conditions.
- Inert conditions are used for potentially explosive environments especially labs where standard lab equipment used in Isolators may not be explosion rated
- Inert conditions are also used for Hygroscopic products



Normal Operating Conditions



Fault Conditions

Oxygen Transmitter

Duct Mounted Probe

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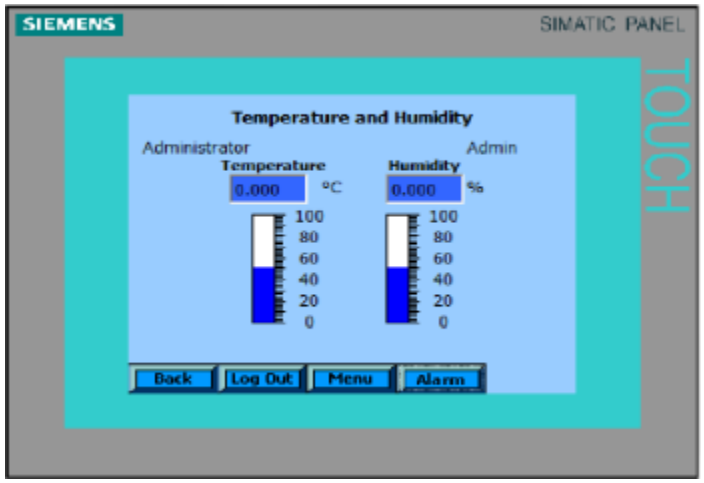
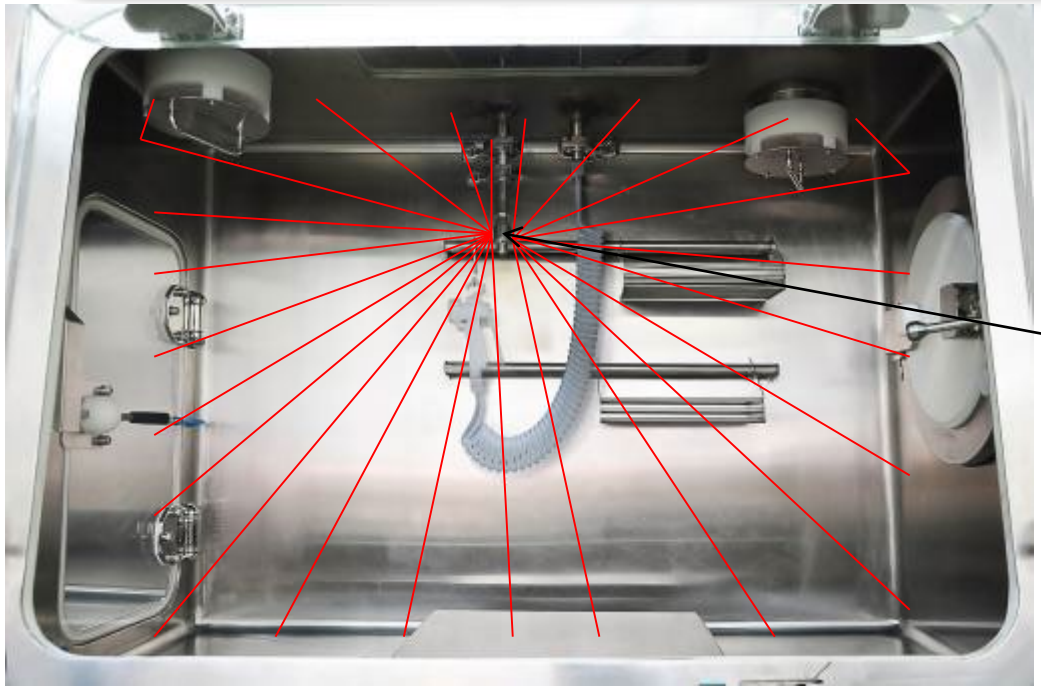
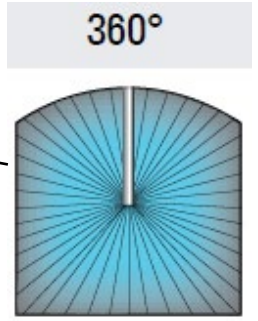
System Design – Features – Temp & Humidity Monitoring



- An optional system is to monitor temperature and Humidity of the process chamber environment, indicating and alarming the high and low conditions.
- **Note: This is monitoring only, not control**
- It is sometimes requested for temperature, humidity, or both to be controlled within a process chamber. This is not usually required as most clean rooms have controlled temp and humidity and the isolator draws in that air, and is single pass airflow.
- Temp / Humidity control is typically more present for recirculating systems to counteract heat gain and it is more efficient to condition recirculating air, than single pass airflow.
- The probe can be easily removed as fitted through a special gland entry port.

System Design – Clean In Place (CIP)

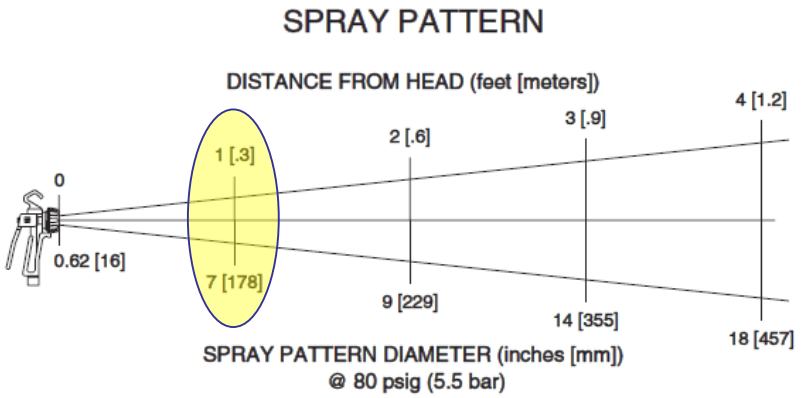




Spray Pattern

- CIP provides an automated valve sequence cleaning process to 99% clean the chamber with no manual intervention.**100% should not be guaranteed.**
- The special nozzle has 360˚ coverage and high powered jets which creates not only strong direct cleaning but allows the water to bounce off the contact surface and clean in shadow areas. Customer supply pressure is therefore important for optimized cleaning (6 Barg)
- Effective cleaning is verified using Riboflavin (Vitamin B2) dissolved in water (0.2gm/l). This is sprayed on the chamber and illuminates with a Black Light (UV-A).
- Visual coverage is observed and verified.

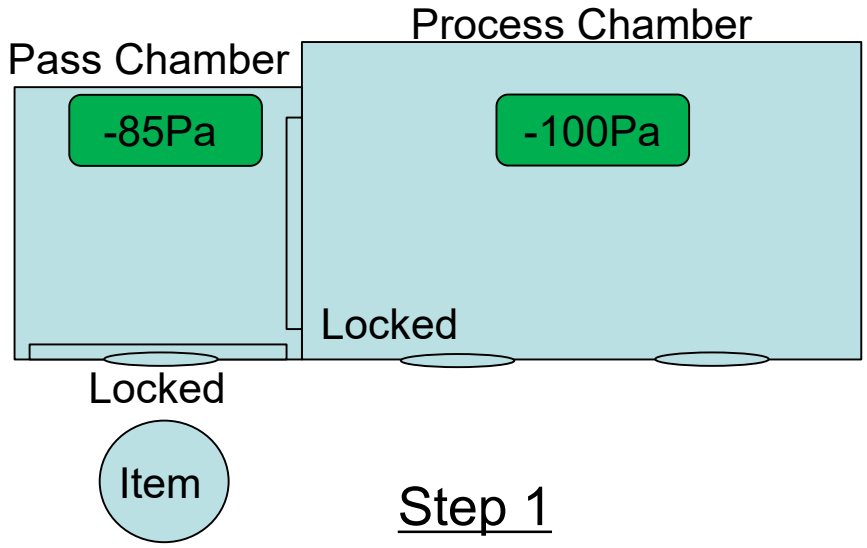
System Design – Wash In Place (WIP)



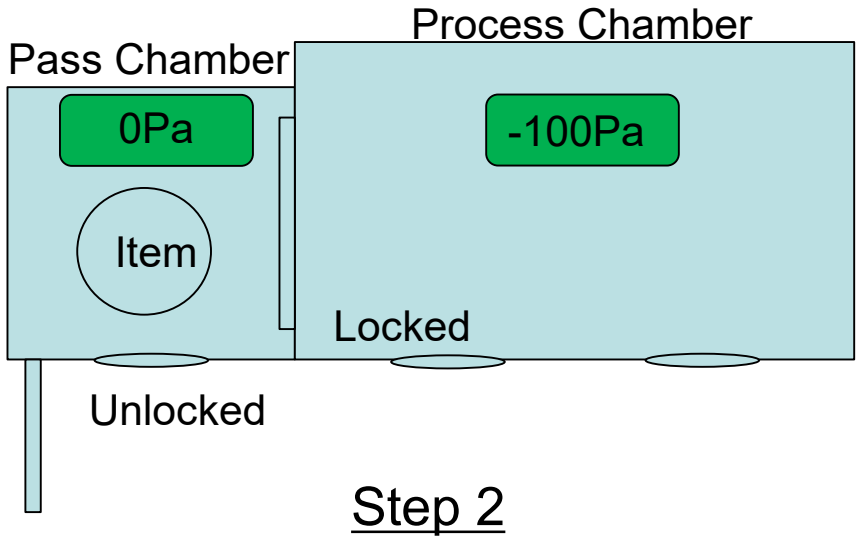
- WIP provides a manual method to clean inside the chambers via a ‘spray gun’
- This has an actuated valve to control the cleaning media supply and manual trigger on the gun to start and stop the flow
- Once the cleaning is completed and acknowledged on the HMI, the system will automatically purge the line with air for ‘x’ seconds (requires the operator to press and hold the trigger) and then close the drain valve.
- Note: The purge time not only ensures the lines are flushed to prevent bacterial growth, the compressed air can also be used to direct and surface water towards the drain.
- The was gun is made from PTFE/PFA, as is the coiled hose, suitable for most environments and cleaning solutions.

System Design – Operational – Pass Chamber - Interlocked

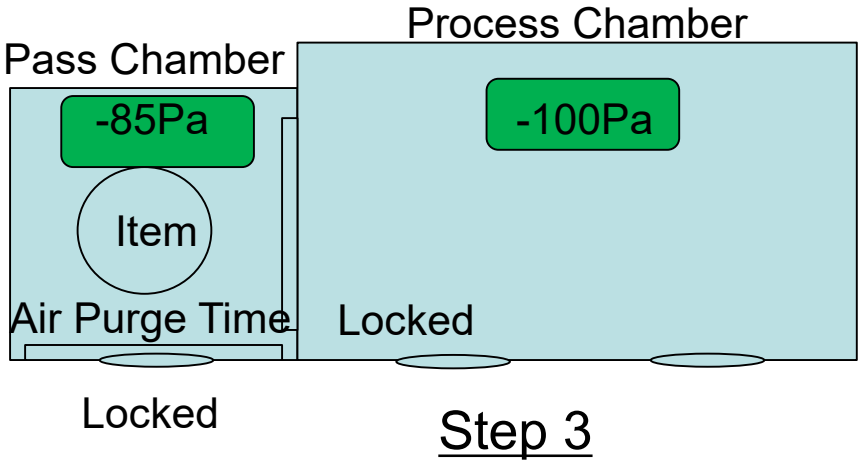
Operating in Air Mode – Pass In:-



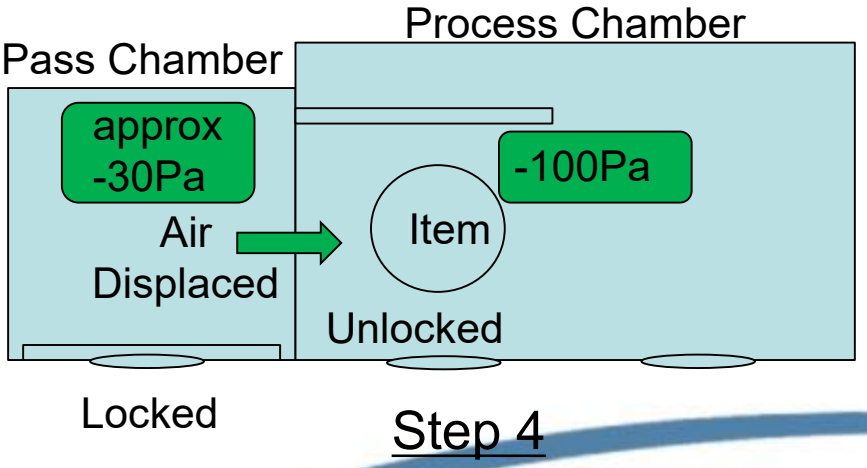
Step 1



Step 2



Step 3



Step 4

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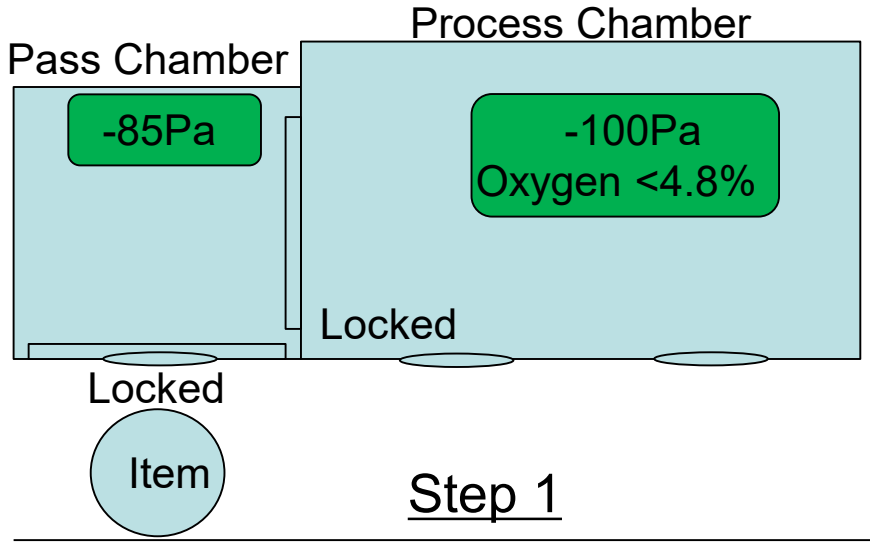
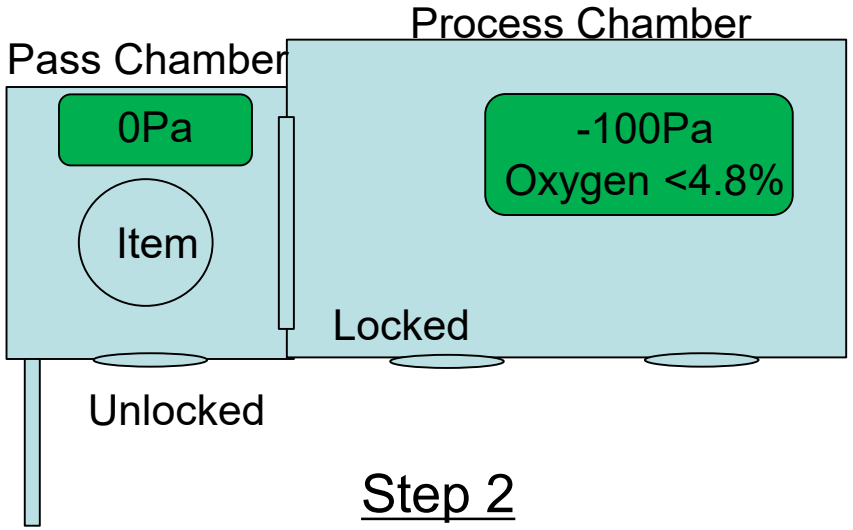
System Design – Operational – Pass Chamber - Interlocked

Operating in Nitrogen Mode – Pass In:-



Step 1



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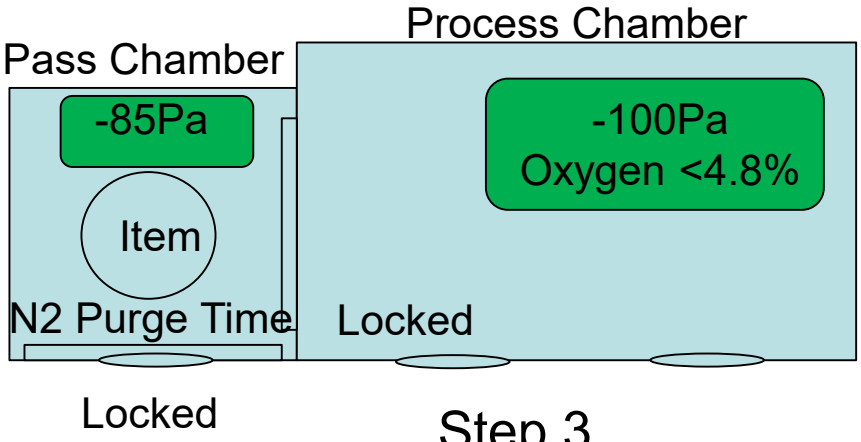

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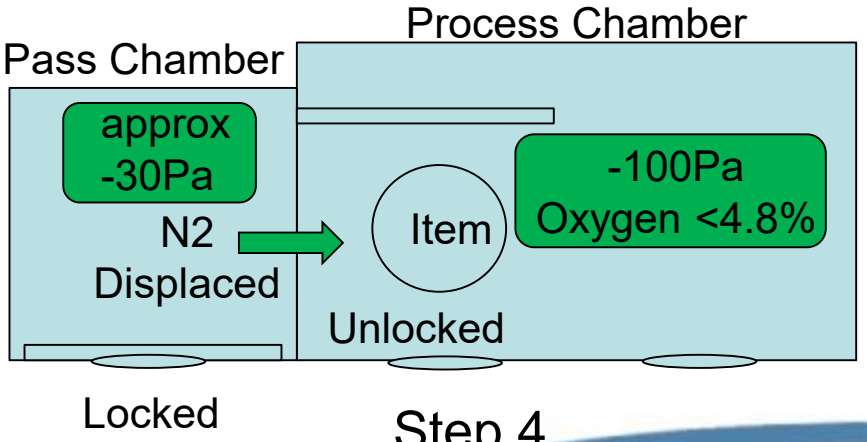

Step 4

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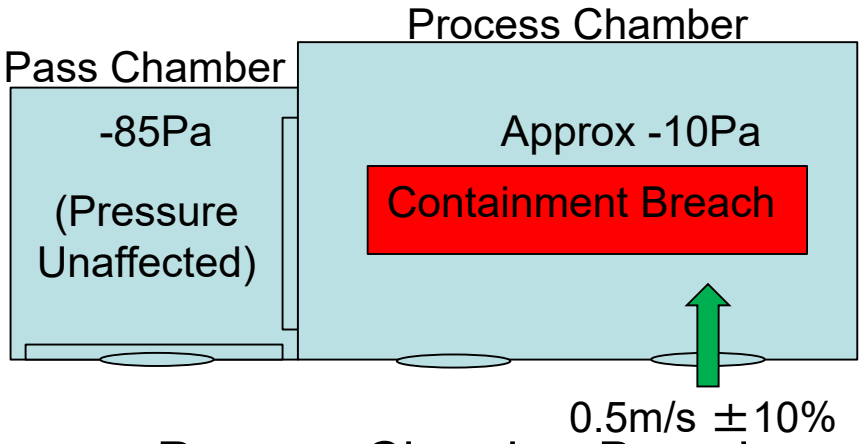
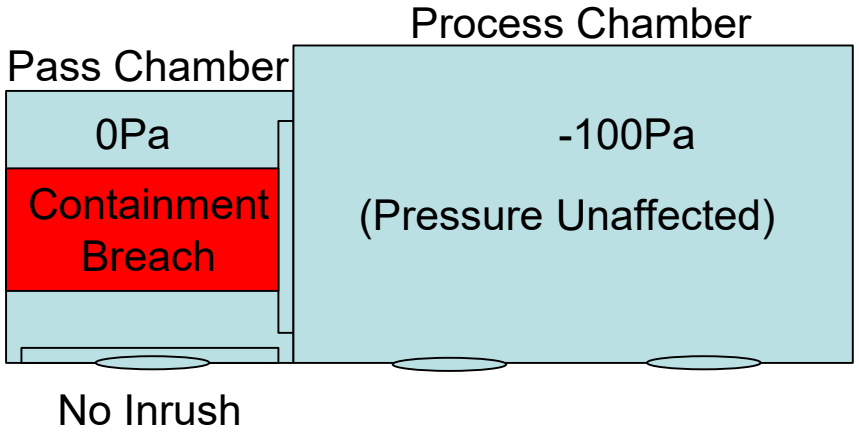
System Design – Operation – Containment Breach

Containment Breach:-



Process Chamber Breach

- The chamber pressure sensor is used to detect a containment breach. On sensing the breach the fan speed increases to provide an inrush of 0.5m/s ±10%. The system will automatically recover to normal operating mode once the breach is fixed.
- Higher inrush flow rates have proven to have the reverse effect and can cause contaminants to be pushed back out of the port due to turbulence.
- Lower inrush flow rates my not contain.



Pass Chamber Breach

- Although the Pass chamber transmitter detects a breach situation, the fan speed is not increased, only an alarm is sounded.
- The Pass Chamber should always be in a relatively clean state and therefore prevents little risk from a breach situation.
- Inner & Outer Doors are locked during a breach condition to prevent pass-in / out of the Process Chamber until the condition has been rectified.

System Design – Hazardous Area Levels

European and IEC Standards	
Equipment Group	
I	For mines - Category M1 and M2
II	For all other locations - Categories 1, 2 and 3.
Category	
1	Equipment that is intended for use in areas where an explosive atmosphere is present continuously for long periods or frequently.
2	Equipment that is intended for use in areas where an explosive atmosphere is likely to occur in normal operation and must ensure a high level of protection.
3	Equipment that is intended for use in areas where an explosive atmosphere is unlikely to occur in normal operation and must ensure a normal level of protection.
Gas	
G	For Gasses
D	For Dusts
Type of Protection	
D	Flameproof
Ia	Intrinsically Safe
E	Increased safety
Gas Group	
I	Mines
II	Surface above ground industries
Gas Sub Group	
A	Less easily ignited gases eg propane.
B	Easily ignited gases eg ethevlene.
C	Most easily ignited gases eg hydrogen or acetylene.
Temperature Classification	
T1	450°C
T2	300°C
T3	200°C
T4	135°C
T5	100°C
T6	85°C

ExII 2G Eexd IIB T4

Ex - Explosion proof in accordance with ATEX.
II - Equipment group: II surface industries.
2 - Category 2 equipment (suitable for us in Zone 1)
G - Gas: Suitable for atmospheres containing gas.
E - European certificate in accordance with harmonised standards.
Ex - Explosion-proof electrical equipment.
d - Type of protection is 'Flameproof enclosure'-.
II - Gas Group II - surface industries
B - Gas sub group B
T4 - Temperature class T4 (135 degrees centigrade surface temperature).

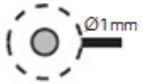
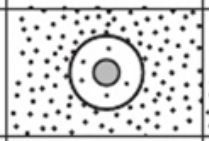
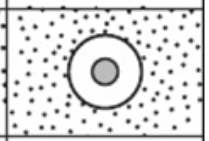
Example of European and IEC Marking

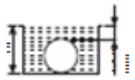
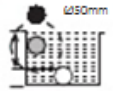
- Equipment / room hazardous area levels are important to establish prior to quotation as they can have a large bearing on cost and are extremely important to safety:-
  - Internal area rating (Inside Chamber)
  - External area rating (Room)
- External ratings have the biggest implication to cost as it affects every electrical and pneumatic part on the system.

System Design – IP Ratings

INDEX OF PROTECTION (IP XX)

IP** degree of protection of enclosures of electrical equipment in accordance with standards IEC 529, EN 60529 and NFC 20-010

1st figure: Protection against solid bodies							
IP	0	1	2	3	4	5	6
							
	No Protection	Protected against solid bodies of 50 mm and greater (e.g. accidental contact with the hand)	Protected against solid bodies of 12.5 mm and greater (e.g. finger)	Protected against solid bodies of 2.5mm and greater (e.g. tools, wires)	Protected against solid bodies larger than 1 mm (e.g. thin tools and fine wires)	Protected against dust (no harmful deposit)	Completely protected against dust

2nd figure: Protection against liquids									
IP	0	1	2	3	4	5	6	7	8
									
	No Protection	Protected against vertically falling drops of water (condensation)	Protected against drops of water falling up to 15° from the vertical	Protected against drops of water falling up to 60° from the vertical	Protected against splashing water from all directions	Protected against jets of water from all directions	Protected against powerful jets of water from all directions	Protected against the effects of temporary immersion in water	Protected against the continuous effects of immersion in water having regard to specific conditions

- IP ratings need to be established for key electrical components:-
  - Anything electrical inside the isolator
  - MCP

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Questions?

Thank you

Questions?