



**soloPLUS**

## The smart alternative to Hardshell Isolators

The versatile containment solution  
designed for easy operation.



## Developed to cater for easy process equipment integration soloPLUS has demonstrated its containment ability in many Pharmaceutical applications.

Operator protection at sub  $g/M^3$  levels and easy use is part of everyday performance for the soloPLUS range (when operated in accordance with Solo's potent compound handling procedures). soloPLUS is equally competent at aseptic and Bio-Hazard applications and can be interfaced with most  $H_2O_2$  gassing technologies and may generate ISO 1 CLEANROOM - conditions with turbulent HEPA filter airflow (at rest).

Whilst Solo offer a number of standard process package solutions, we are always prepared to develop custom solutions with the option of a full scale mock up to challenge and prove ergonomic suitability for specific tasks.

**Whatever design you select from the soloPLUS range you can be sure that all films and materials are fully certified for Regulatory Compliance.**

### Superior Performance Factors

To assure highest containment standards soloPLUS operation is based on a proven "one way street" operating strategy. Materials loading is typically through either an acrylic or flexible film loading airlock (load lock). Reach into the load lock is only permitted with contamination free gloves. For environment critical applications such as anaerobic or inert gas applications a range of BI/BO systems are available permitting drum or container entry with minimal loss of critical environment.

- All handling of API's or hazardous materials is confined to a central negatively pressurised product handling chamber (PHC) designed with ergonomic access to your process.

The PHC may feature a sanitary stainless steel base tray and wash/spray lances, powder transfer to contained valve technology and Nitrogen purge inlet filters. For applications where exposure of metal parts is unacceptable the PHC may feature a flexible film base panel with virgin PTFE powder transfer connections.

- Glove sleeves are welded into optically clear Seiden Crystal vision panels and are equipped with Solo's safe change glove cuff as standard.

Push Push change gloves are available for cytotoxic compound handling or applications requiring rapid glove change over. For applications requiring extreme reach or lifting that cannot be accommodated by glove sleeve access Solo offers a Half-Suit interface option.

- Product exit can be via contained valve technology or a conventional bag out system. At OEB 5 containment level our engineers will carry out a risk assessment and may recommend multi stage bag-out or weldable foil to ensure containment levels at exit locations.

- Where avoidance of batch to batch cross contamination is vital our engineering team can offer full film enclosures (stainless work deck underneath the film base) that may be vacuum collapsed at the end of each manufacture campaign.

Solo's engineers have taken special care to offer welded in HEPA filter technology for disposable envelope applications ensuring that the envelope and all filtration devices form an integrated particle entrapment during disposal.



**Above:** This 4 chamber API Transfer Isolator is designed to operate as a low humidity nitrogen inerted enclosure for Lyophiliser tray transfer and as negative pressure for API transfer to an Ezi-Dock system. See this system in operation in the video on our website.

## Right first time performance - guaranteed!

Innovative design and engineering lie at the core of every soloPLUS solution. The grid below demonstrates the different safety features available to incorporate within your soloPLUS solution to achieve the required containment level.

	Aseptic (Lab)	Anerobic (Lab)	OEB3 50-10 $\mu$ g/m <sup>3</sup>	OEB4 (10-1.0 $\mu$ g/m <sup>3</sup> )	OEB5 (1.0- 0.01 $\mu$ g/m <sup>3</sup> )
Solo Hardware Selection	Heavy Duty PVC Enclosure	✓	✓		
	FDA rated PU Film			✓	✓
	Single Chamber isolator Bi/Bo container entry			✓	
	Two Chamber isolator				✓
	Gas tight acrylic pass box: Compression Gasket Inflatable Gasket		✓		✓
	Multi-Chamber with pressure cascade				✓ + SOP
	3 step continuous liner operation			✓	✓ + SOP
	6 step continuous liner operation				✓
	Cuff mounted 3 groove safe change gloves	✓	✓	✓	✓
	Cuff mounted Push-Push safe change gloves				✓
	Contained Coupling Powder Transfer			✓	✓
	Contained Coupling Powder Transfer with secondary containment chamber				✓ + SOP
	RTP contained transfer bagged materials				✓
	Manual variable speed fan			✓	✓
	Automatic speed control fan				✓
	ATEX Fan option	✓	✓	✓	✓
	Filter condition / Leak test alarm				✓
	99.95% Effy P3 Breather filter		✓	✓	
	Screw Mount HEPA			✓	✓
	Push-Push safe change HEPA				✓
Nitrogen inertion via PALL filter		✓	✓	✓	
Grade A environment infill chamber	✓	✓			
Gamma Irradiated Enclosure	✓	✓		✓	
Solo Software Selection	Ergonomic Mock-Up	✓	✓	✓	✓
	FAT	✓			✓
	SOP development	✓	✓		✓
	Operator Training			✓	✓
	Surrogate API Challenge				✓

## Test Data

At Solo we are continuously striving to improve the performance of our flexible containment systems. We regularly undertake independent tests on our Isolators to prove the levels of containment we can achieve, both for us and our clients.

A test was recently undertaken on an API **soloPLUS** subdivision Isolator. The Isolator, a bespoke design for both subdivision and extrusion, comprised a flexible film enclosure, mobile support tables and negative pressure fan/filter exhaust system.

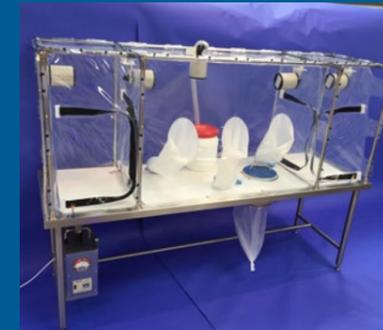
As with any containment trial, a statistical evaluation over several runs is essential to prove the reliability of the data, so 4 runs were undertaken. Runs 1, 2 & 3 were challenged with an API 8x the production powder volume and run 4 (the drop test) was conducted with 20x the production powder volume.

The client's performance target was OEB 5 level, with a target exposure limit of  $<0.1\mu\text{g}/\text{m}^3$ , and the Isolator was tested to  $\leq 25\%$  of this value i.e.  $\leq 0.025\mu\text{g}/\text{m}^3$  in order to be confident that all future results will meet the target level.

### **soloPLUS** API Sub-Division Isolator test data:

	Airborne concentration of lactose over task ( $\mu\text{g}/\text{m}^3$ )			
	RUN 1	RUN 2	RUN 3	RUN 4
Pre-Trial Background	< 0.042	< 0.042	< 0.042	< 0.042
Quantity API Transfer	50gr x 8	50gr x 8	50gr x 8	1000gr drop test
PERSONAL	0.021	< 0.029	< 0.032	< 0.046
POSITION 1	< 0.017	< 0.029	< 0.032	< 0.046
POSITION 2	< 0.017	< 0.029	< 0.032	< 0.046
POSITION 3	< 0.017	< 0.029	< 0.032	< 0.046
POSITION 4	< 0.017	0.12	< 0.032	< 0.046
POSITION 5	< 0.017	< 0.029	< 0.032	< 0.046
POSITION 6	< 0.017	< 0.029	< 0.032	< 0.046
Run Time (Mins)	73	43	39	27
	8h TWA Exposure ( $\mu\text{g}/\text{m}^3$ )			
	RUN 1	RUN 2	RUN 3	RUN 4
PERSONAL	0.0032	< 0.0026	< 0.0026	< 0.0026

## Typical soloPLUS applications



Sub-Division



Charge Bag - Loading



Granulation



Milling



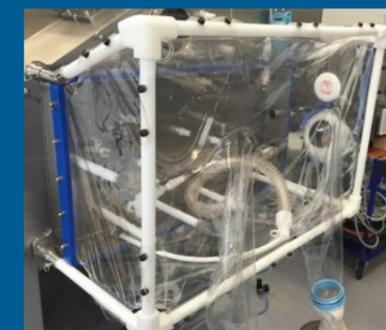
Tray Dryer



Tablet Press



Process Isolation



Roller Compactor



Clinical Trials Packing

**soloPLUS** provides a cost effective, and easy to use alternative to a Hard Shell System.

With **soloPLUS** you can specify a stainless steel work tray that creates a durable work platform for the PHC whilst the containment enclosure is created from flexible film. The **soloPLUS** provides for easy changeover of the flexible canopy when manufacturing campaigns change over and minimise cleaning validation issues.

Minimising the flexible film canopy reduces running costs - whilst the robust stainless steel work table and canopy support frame create the ideal structure for attachment of Rapid Transfer Port's service connections such as WFI or drain lines or alternative powder transfer valve systems. Where drum lifting or tilting is needed Solo's engineers have a number of proven solutions.

**soloGRIP** is an engineered film to table interface that leaves nothing to chance.

Unlike our competitors our **soloGRIP** system creates a snap into place canopy base detail that is clamps the film enclosure onto the stainless base tray using **soloGRIP** sections creating a gas tight GMP joining detail.

With **soloGRIP** the film mounting is right this time, next time every time.



Sanitary stainless work tray



Clean contamination free PHC



Engineered flexible film attachment **soloGrip**



**soloGRIP** fast fit every time  
No envelope gluing - No u-grip

**Air Filtration Options**

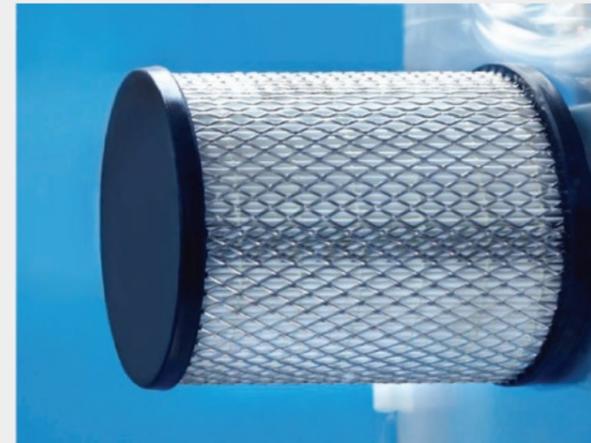
As you would expect from the Solo Containment team, the negative pressure airflow cascade in **soloPLUS** isolators leaves nothing to chance.

Solo offer certified H14 HEPA filters on innovative single use mount brackets enabling both the contaminated flexible envelope and the used HEPA filters to be disposed as a contained unit.

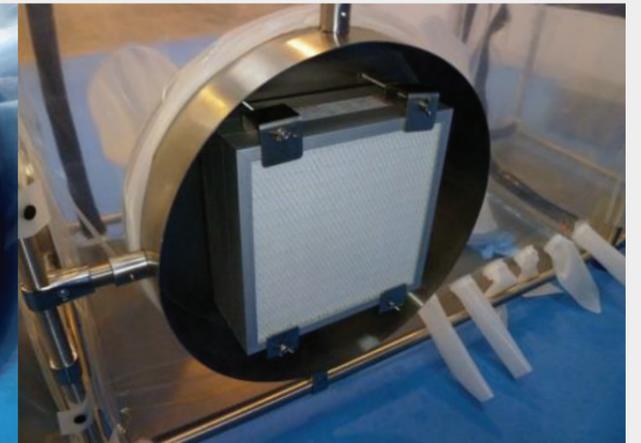
Where HEPA filter change out is required we offer Push-Push safe change HEPA filters in tandem providing two stage exhaust filtration.

Instrumentation showing static pressure and filter pressure drop can be incorporated into the LOP (local operator panel) along with the option of manual fan speed control or automatic closed loop control to agreed set points.

For applications including high airflow exhaust such as house vacuum interface Solo are able to offer H14 inlet HEPA filters to accommodate most airflow requirements.



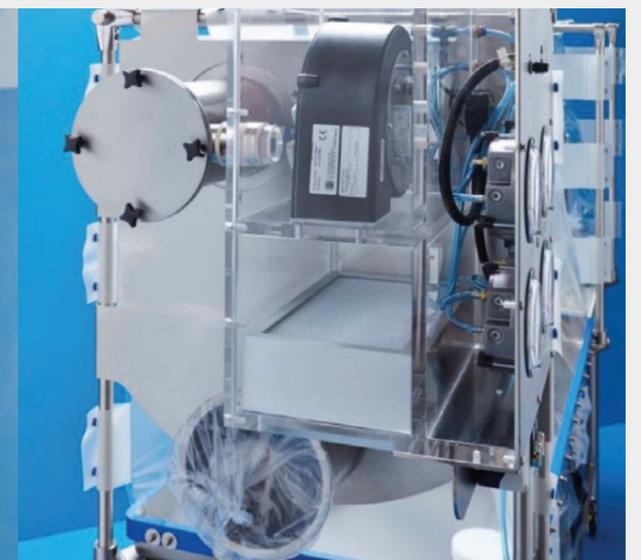
Standard H14 HEPA filter



HEPA filter high volume air inlet



H14 "Push-Push" HEPA filter exhaust housing



Safe change housing for tandem push - change HEPA filter - with variable speed exhaust fan

## Typical soloPLUS Options and Accessories



Nitrogen Purge Filters



Container coupling interface



Raise/Lower Platforms



Drum Raise/Lower & Tipping



Instruments and Alarms



Wash Lance/Drains



Rigid Airlock System



Push Change Gloves



Rapid Transfer Port for material transfer

## Process Interface Isolator System

The perfect partner for Spray dryer, filter dryer or reactor vessel containment. Rugged support frame capable of supporting up to 500Kg. Fully welded services connections through sanitary stainless steel base tray.

- Nitrogen inlet
- Wash lance supply pipe
- Drainage



## Tell us what you need.

### 1 Containment Target for soloPLUS applicaton

Occupational exposure limit for material to be handled

µg/M3

Define mass of powder to be handled within the soloPLUS isolator during normal operation

gr/Kg

Please list any solvents to be used in the enclosure



### 2 Operation to be contained

Please detail operational steps involving hazardous materials, transfers into and exit from isolator are critical

### 3 Equipment to be housed within isolator

Balance, Make/Model

Number of electrical power supplies needed

Equipment dimensions

<input type="text"/>	<input type="text"/>	<input type="text"/>
W (mm)	H (mm)	L (mm)

### 4 Material drums/containers

Please list largest drum/container size to enter isolator

Height (mm)

Diameter (mm)

### 5 Inert Environment

Is inert environment needed?

Yes / No

Typical purge time

**6 Preferred soloPLUS layout**

2 Glove PHC

3 Glove PHC

4 Glove PHC

My preferred layout

**7 Exhaust Fan and HEPA filtration system**

Does exhaust system need to run isolator at negative pressure for added safety? (Venturi is vibration free)

Yes / No

**8 Please choose your preferred options to be itemised on quotation**

Stainless steel frame

Additional utility sleeves

Granite base tray

PVC base tray

Wash lance

Safe change glove cuffs

Set-up zip in front panel

Additional airlock

Additional glove ports

FAT

Site set-up and commissioning

Validation: IQ/OQ

**9 Your contact details**

Name

Company

Telephone Number

Email Address

**Notes**

Upon completion of this form please save it to your desktop then email it to [sales@solocontainment.com](mailto:sales@solocontainment.com) and one of our team will be in touch shortly.

## What are the benefits of soloPLUS?

- ✓ **Fast delivery timings**
- ✓ **Rapid set up**
- ✓ **Proven performance**
- ✓ **Wide range of options and accessories**
- ✓ **Cost effective**

**soloPLUS** can be shipped flat pack to your facility and may be set up by in house technicians. Alternatively we offer a full service option that includes:

- **Site assembly and set up**
- **Operator training for potent compound handling**
- **HEPA filter and air flow validation**
- **IQ / OQ**
- **Material certification for regulatory compliance**



**solocontainment**

[www.solocontainment.com](http://www.solocontainment.com)

+44(0)1625 344014 | [sales@solocontainment.com](mailto:sales@solocontainment.com)

Solo Containment Limited, Unit 6 Rupert Park, Poynton, Cheshire, SK121PQ



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#### DISCLAIMER:

Whilst every effort has been made to ensure the technical details are correct Solo Containment reserve the right to change designs and dimensions from time to time. All dimensions will be confirmed at time of ordering. Containment performance will be dependent on the containment device being used with the correct work procedures. Contact your own EHS specialist for advice.