

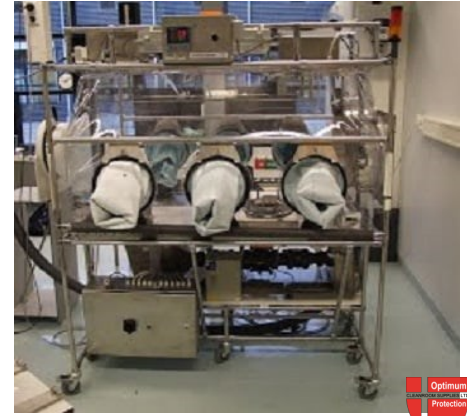
TECHNICAL DATA SHEET

Aseptic Isolator



DESCRIPTION

The PES range of Aseptic isolators are designed and developed to comply with all aspects of the document 'Pharmaceutical Isolators' - a guide to their application, design and control. The standards / regulations laid down in this document relate to equipment of this type, this document provides the technical reference to any proposal that is made to our customers. The isolators was designed and developed to provide a cost effective, well engineered solution to the majority of Aseptic processing requirements.



TECHNICAL SPECIFICATION

Material	Antistatic flexible uPVC, polyethylene and polyurethane
Options	2 Glove or 4 Glove
Recommended Use	High accuracy balances (various versions including granite base), compounding, sterility testing, weighing operations, mixing operations, filling operations.

FEATURES

- Well engineered
- Cost effective
- Disposable
- Flexible film technology
- Dual pressure system
- Turbulent airflow system

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We also have a unique small scale demonstration model. If you have a current requirement and would like to see the unit in operation, please contact us. We can also provide you with references for satisfied customers who are currently operating these isolators across many facilities within the ~UK and Europe.

Standard Aseptic Positive Pressure Isolators

We offer a range of two or four glove standard isolators that compromise of the following features:

A one piece RF welded canopy in a variety of materials including optical quality antistatic flexible upvc, polyethylene and polyurethane. Canopies are supplied c/w quick release button loops, glove ports (two versions are available: with or without shoulder rings), supply and exhaust HEPA filters, pressure sensor coupling gas tight access zip.

Work tray, 2mm thick in grade 304 or 316 stainless steel with a 0.8 Ra (240 grit) surface finish.

Canopy / work tray support frame in 32mm diameter tubular stainless steel with a mirror finish.

Supply / exhaust pipework systems in either flexible upvc, rigid upvc or stainless steel tube.

Interface with FlexiVent airflow control system (FV) including exhaust HEPA filter pressure drop sensor coupling, canopy pressure sensor coupling, inlet / outlet HEPA filter adaptors, etc.

FlexiVent Airflow Control System.

Derivatives of the Standard Range of Aseptic Positive Pressure Isolators

The flexibility of our standard design enables it to be modified to interface with a range of pharma process equipment. Typical examples of standard isolators supplied for use with other equipment includes:

High Accuracy Balances (various versions including granite base)

Compounding

Sterility Tesing

Weighing Operations

Mixing Operations

Filing Operations

Please contact us if you have a specific piece of equipment that you may wish to interface with an isolator, we shall be happy to advise on your application.

Service

We service all our isolators as required by the various authorities and guidelines that apply to them. This is on a timed schedule, we would be happy to provide details on request. We can also provide containment testing, particle counting etc.

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Application Specific Aseptic Positive Pressure Isolators

For certain applications we would suggest an isolator is designed specifically for the function intended. For this purpose we can provide a comprehensive design facility that undertakes the more specialised project work involved. We can assist in the compilation of the User Requirement Specification (URS) that is the recognised industry method of providing the information necessary for suppliers to carry out the design process. In response to the URS we shall provide a Functional Design Specification (FDS) that outlines the design specification required for the design staff to undertake the project. This is followed by a Design Qualification, installation Qualification, Operational Qualification, Process Qualification and final test and commissioning before handover to the client. We also are responsible for the project engineering to ensure all milestones and deadlines are met.

Please find below a range of application specific isolators we have provided in the past, please contact us for advice on this type of equipment, we would be happy to assist you.

Performance

PES isolators are designed to provide specific performance levels, the main containment process requirements being:

Internal Pressure: + 25 to + 60 PA (adjustable by the FLExiVent display HMI membrane panel) Total Volume Flow rate (minimum 50 total volume changes per hour, pre-set on commissioning of machine)

Breach Velocity (minimum 0.8 metres per second taken at a glove cuff with diameter of 100mm, please note that we also provide a similar breach velocity where a transfer port of a given diameter is installed.

Alarms (high and low pressure) For more information on the performance of these isolators please refer to the section on the FlexiVent Airflow control unit.

Standard Components

The standard range of PES isolators in both positive and negative pressure versions use standard component parts, this enables us to offer a cost effective product. This relates particularly to the fact that both types of isolator use identical enclosures, work trays, filters and support frames. Both versions are also equipped for connection to the FlexiVent airflow control unit.

Dual Pressure Systems

A major advantage of using the PES range of isolators relates to the dual pressure system we can apply, this basically means we can switch between positive and negative pressure using a simple card change that is installed in the FlexiVent airflow control system. The facility means the client can use the isolator in both an aseptic and containment role.

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Turbulent Flow / Unidirectional Airflow

All PES isolators are supplied with the turbulent airflow systems, this applies to our standard and application specific isolators. If a specific application requires unidirectional airflow we can provide a unidirectional airflow unit that is sealed into the enclosure. The design of this unit enables us to offer it in a range of sizes linked directly to the physical size of HEPA filter required. The unit is supplied as a complete package of parts that can be installed with the minimum amount of production time, it has its own fan and control system that can be set to provide the velocity required to achieve the unidirectional zone required. Please note that the unidirectional airflow unit can be fitted to new and existing isolators.

Cascade Principle

For applications where a multiple number of isolators chambers are required a pressure cascade system may be required. The FlexiVent airflow control unit has the facility to control multiple numbers of chambers from one PLC control unit. Each chamber would have its own dedicated fan unit.

Transfer Devices

The standard PES aseptic positive pressure isolator is supplied with a gas tight zipped access panel externally and a standard polyester zipped panel fitted internally. If an interlocking arrangement is required we replace this system with a rigid pass box unit that has interlocking doors. The isolator guidelines indicates that various types of transfer devices that are used on this type of isolator, please contact us if you require assistance in specifying the correct type for your application.

FlexiVent Concept

We use the FlexiVent airflow control system on all our range of isolators, this system was developed to provide the following features:

Capable of being used in both a positive or negative pressure options. A simple card change transforms the unit from one mode to another

The FlexiVent is issued as a mobile unit, it can be used as a dedicated isolator airflow system or as a mobile unit that can be used around the site to provide an airflow control arrangement on any other isolator or enclosure onsite that is equipped with filters and a pressure sensor connection.

The FlexiVent can provide breach conditions in either positive or negative pressure conditions. The FlexiVent can control the internal pressure to plus or minus 1 PA, the operator can pre-set the internal pressure from the HMI display screen. The FlexiVent can cope with a range of isolator volumes using that standard fan(s) / filter arrangement, for increased size enclosures the fan(s) / filters are increased in capacity, though the PLC control remains the same. The FlexiVent can interface with other equipment that have their own dedicated control systems, typical examples include H2O2 gas generators, automatic valve systems etc.