

Pharmaceutical Aseptic Isolators and Barriers



Aseptic Processing

For more than 150 years, the Howorth name has represented technical creativity and expertise in air engineering and its application to protect people and products from contamination

Threat of contamination

Human operators pose the greatest risk to product contamination during “conventional cleanroom” aseptic processing and manufacturing.

Even under optimal conditions, a gowned, motionless human may generate 100,000 particles per ft³/min within a cleanroom, while a walking operator may generate 10,000,000 per ft³/min

Using isolation systems minimizes the extent of personnel involvement and separates the external cleanroom environment from the aseptic processing line.

A positive pressure isolator or Restricted Access Barrier system (RABs), supported by adequate procedures for its maintenance, monitoring, and control, offers tangible advantages over classical aseptic cleanrooms, including fewer opportunities for microbial contamination during processing.

History of Clean Air Technology

Over 150 years ago, Howorth & leading orthopaedic surgeon, Sir John Charnley, worked together to develop the world renowned Exflow Ultra Clean Ventilation System, now used in operating rooms worldwide to reduce the entrainment of air borne contaminants during surgery.

This expertise has proven fundamental to Howorth’s success in providing world-class containment solutions from Glovebox Isolators to Downflow Containment Booths, ensuring that Howorth remains at the forefront of air technology and contamination control.





Restricted Access Barrier Systems

Restricted Access Barrier Systems (RABS) are an effective alternative to isolators and cleanrooms where protection from contaminants is of paramount importance.



Whether you are developing brand new facilities or modifying existing ones, a full site survey from Howorth will ensure that you receive the optimum barrier solution for your facility.

Benefits of choosing a RAB system

- Improved contamination control and consequently improved product quality.
- Modular design facilitates speedy delivery, thereby ensuring minimum downtime.
- Simplicity of air handling making RABS easier to install.
- Flexible alternative to isolators and facilitate intervention where necessary.
- Lower initial cost out-lay in comparison with brand new clean room facilities
- Suitable for integration into new and existing facilities

- Assists in ensuring your compliance with current regulatory requirements.
- Easy to use because a RAB system does not require its own bio-decontamination system

Principles of a RAB system

A Restricted Access Barrier System (RABS) is an advanced aseptic processing system that can be utilized for many applications in a fill-finish area.

RABS provides an enclosed environment which reduces the risk of contamination to product, containers, closures and product contact surfaces.

Active & Passive RABS

There are fundamentally two types of RAB systems, Active and Passive, both of which provide a combination of physical and aerodynamic barriers.

Passive RABS

The unidirectional air supply for the system is provided by the Cleanroom ceiling. There is no integrated air-handling system as part of the RAB enclosure.

Active RABS

These systems have an integrated air handling system that provides the unidirectional air supply to the RABS enclosure.

“A Pods”

Howorth has developed the concept of an Active RAB system with the introduction of ‘airflow pods’ or A Pods. A Pods are attached to the canopy exterior and provide a unidirectional, HEPA filtered quality of air to the adjacent environment. This means, that in the rare instance of intervention, the risk of contamination will be reduced.

Modular Flexibility

A Howorth RAB system consists of individual modules, each manufactured to a standard specification, but completely configurable depending on the space that you have to work with. It can cover small or large filling and packaging lines, by simply adding more modules.

Intervention Flexibility

RAB systems can provide a level of aseptic quality similar to that of an isolator but facilitate intervention as and when necessary.

In these rare instances, appropriate measures must still be taken to ensure protection is maintained.

Product Features

- Integrated smoke generator & pipe manifold for DOP testing
- Gloveports for aseptic intervention
- Access doors with Pneumatic Interlock and inflatable seal
- Lock door access control
- Local Network Control Panel
- Hotwire for measurement of real time airflow
- Light Pods with external access
- Static video camera’s for recording interventions
- Service plate for Electrical & Pneumatic Connection
- Photo-electric sensor for monitoring gloveport access
- Removable access covers for maintenance filling



Aseptic Isolation Booths

For a reliable, sterile environment for the testing of pharmaceutical products, you need a solution that provides uncompromised, total barrier isolation

Sterility testing is one of the most crucial steps in ensuring the safety of your products. The introduction of contaminants through equipment failure and human error, resulting in false positives can cost you time, money and ultimately, your product.

Benefits of barrier isolation

The use of aseptic barrier isolation technology can produce significant benefits:

- Increased Sterility Assurance Levels (SALs)
- Reduction in false positive results and consequent product wastage
- Cost savings

Product protection

People are the biggest source of contamination in cleanrooms, even under optimal conditions, a gowned, motionless human may generate 100,000 particles per ft³/min. Aseptic barrier isolation technology offers the complete separation of personnel from the test sample ensuring pure protection for your products.

Increased Sterility Assurance

Using an aseptic isolator will completely separate the product from possible sources of contamination, giving you the peace of mind that your product is being tested under aseptic conditions.

Reduce Product Wastage

Product testing within isolated conditions reduces the frequency of generating false positive results. Consequently, the occurrence of product re-testing and recall is also reduced, saving you time, money and your product.

Reduced Operational Costs

The complete separation of the internal and external environment means that the surrounding area can be operated at a much lower classification and consequently lower cost.

- Smaller workspace footprint lowers utility costs
- Automated decontamination process
- Reduced gowning & training costs
- Effective alternative to cleanroom construction
- Ergonomic space saving solution

Aseptic Isolator - Standard Features

- Single chamber with a range of construction materials
- Operated under positive or negative pressure
- Turbulent or zonal airflow
- Grade A internal environment (ISO 5)
- HEPA filters
- Controls & operator interfaces
- Integrated HPV decontamination system
- Integrated leak detection system (auto-decay test)

Optional Extras

- Raise/lower legs
- Sharps container interface
- Foot rests
- Pass box
- Internal trolley transfer system
- Gloveports available in various sizes, materials & configurations to accommodate a wide range of movement
- Double HEPA exhaust filtration

H₂O₂ Decontamination Systems (Hydrogen Peroxide Vapor)

The isolator is designed to interface both mechanically and electrically with a range of proprietary HPV generation systems providing a seamless, automatic integration between the isolator and generator. The isolator is equipped with an automatically operated air inlet and outlet, sealing valves and chamber HPV distribution valves ensuring safe operating conditions and correct HPV distribution.

This eliminates the need for operators to handle delivery hoses and electrical interfaces and operate valves between decontamination cycles removing the reliance on SOPs.

Transfer Systems

Howorth can offer an extensive range of transfer systems. Whether our own proprietary designs or third party solutions, we are sure to have a transfer solution to meet with your process and ergonomic needs.

Controls & Operator Interface

The isolator is equipped with a PLC control system interfaced with all system hardware and sensors, developed in accordance with the GAMP guidelines. The isolator is operated from a touch screen HMI (Human Machine Interface) control panel.

Standard functions

- Operating mode and status displays
- Parameter monitoring displays
- System alert/warning/alarm displays & audible sounder
- Automatic integrity testing function
- Automatic decontamination mode controls and displays
- Restricted access supervisor and engineering functions





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