



ASEPTIC ISOLATORS

Sterility Test Isolators



.....always in safe hands



## Aseptic Isolators

For a reliable, 6-log reduction of micro-organisms to create a 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 can cost you time, money, and ultimately, your product.

### Benefits of Barrier Isolation

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

- Increased Sterility Assurance Levels (SALs)
- Reduction in false 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 ft<sup>3</sup>/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 results. Consequently, the occurrence of product re-testing and recall is also reduced, saving you time, money, and your product.

### Reduced Operational Costs

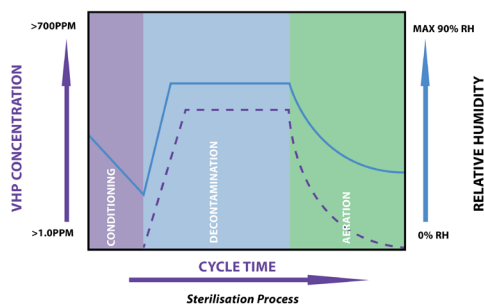
The complete separation of the internal and external environment means that the surrounding area can be operated at a much lower classification, and consequently lower cost.

- Smaller workspace footprint lowers utility costs
- Automated decontamination process
- Reduced gowning and training costs
- Ergonomic space-saving solution

### Aseptic Isolator - Standard Features

- Integrated H<sub>2</sub>O<sub>2</sub> decontamination system
- 6-log reduction of micro-organisms
- Grade A internal environment ISO 14644 Class 4.8
- Positive pressure operation for product protection
- Integrated leak detection system (auto-decay test)
- Controls and operator interfaces





- Double HEPA filters
- Unidirectional airflow
- Fully fabricated stainless steel chamber(s)

#### Optional Extras

- Gassing hatch
- Internal trolley transfer system
- Gloveports available in various sizes, materials and configurations, to accommodate a wide range of ergonomic movement
- Integration of third-party equipment (including Millipore and Sartorius)
- Foot rests
- Raise/lower legs

#### H<sub>2</sub>O<sub>2</sub> Decontamination Systems - BioGen™

The isolator is designed with its own fully integrated BioGen™ decontamination system, controlled via the on-board HMI. All decontamination cycles are automatically sequenced.

Full integration of the BioGen™ system eliminates the need for operators to handle delivery hoses, electrical interfaces, and valves, between decontamination cycles, removing the reliance on SOPs.

BioGen™ includes the Howorth BioSonic™ nano-micro misting process, which is a unique, ultra-high performance liquid shear system. This system provides a perfectly balanced mix of both nano/micro-mist and vapour, and combines exceptional bio-decontamination with outstanding efficacy.

#### 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 an on-board touchscreen HMI (Human Machine Interface).

#### Standard functions

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

#### Bio-decontamination Cycle Time Reduction

In developing any decontamination cycle there is a balance to be made between the need to ensure an adequate bio-decontamination kill rate, and the desire to minimise cycle duration.

Howorth has been able to utilise design techniques, to help with the optimisation of the decontamination cycle. Through the enhancement of the isolator's internal aerodynamic characteristics, we are able to ensure the most effective dispersion of H<sub>2</sub>O<sub>2</sub> within the enclosure to achieve the 6-log reduction of micro-organisms.

#### Transfer Systems

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

#### Commissioning, Validation and Aftermarket Support

Howorth is able to provide a full suite of after-sales support services, including, installation, and commissioning, SAT, and validation (including aseptic validation), together with a complete range of OEM spare parts.





 **WORKSAFE™**

DOWNFLOW BOOTHS



 **ULTRASAFE™**

CONTAINMENT ISOLATORS



 **ENVIROSAFE™**

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