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Positive Isolator Success

Traditionally known for their renowned range of Containment Isolators – both rigid and flexible – Extract Technology has rapidly become known as a respected and reliable supplier of Isolators for the Aseptic market. Increasingly active in this market for the past few years (and being backed by Walker Barrier their US sister company who have over 20 years experience in this field), Extract has already built up an impressive portfolio of installations spanning Europe and South Africa.

Extract’s valuable experience in designing and supplying Containment Isolators, has meant that the transition has been a smooth one. This has resulted in successful projects for the Pharmaceutical, Veterinary and Healthcare industries for the installation of Sterility Test, Processing and Filling Line Isolators (see cover shot).

The Isolators vary from turbulent to unidirectional flow, with air classification to ISO5 with many of the Isolators supplied with validated bio decontamination systems.

With an expanding database of standard Isolator ‘component’ designs they are able to offer customers either standard or bespoke tailored solutions from their in-house manufacturing facility. Whatever your Isolator requirement is, there will be a solution.

Active Product Dispensing Isolator for China

Extract Technology recently completed the installation and commissioning of another Active Product Dispensing & Mixing Isolator in China, achieving nanogram containment levels.

Xi’an-Janssen Pharmaceutical Ltd were working on a containment project, and had identified the need for an Isolator to protect their operators when handling a new potent compound. The subsequent Purchase Order was based not only on Extract’s growing expertise in this area, but also on the success of previous installations for Downflow Booths and Isolators for this customer.

The highly specialised Isolator had many special features, and critical to the success of the project were the ergonomic features that included an inclined front face to the Isolator as well as round glove ports and large areas of glazing, all designed with the comfort of the operators in mind and the access they needed.

The Isolator also included a jacketed vessel with a heater integrated into the base, allowing the operators to dispense the compound straight into the vessel, from where it was transferred under vacuum into a process reactor.

The Xi’an Janssen Project Manager on site commented; “Both the operators and the maintenance personnel are very pleased with the completed installation, and we can confirm that on any future projects that you will be a priority vendor.”
Flexible and Rigid Screens for Improved Containment

Extract Technology Downflow Booths have for many years had additional design features built into them to allow improved/increased containment levels to be achieved. These designs were incorporated into Booths in the early 1990’s in detraying and dispensing applications when OELs of <10μg/m³ (task duration) were achieved.

These designs were the forerunner to the Flexible Containment Screen (patented) and the Rigid Containment Screens that are increasingly being adapted in current applications, where the screen acts as an additional barrier between the active product and the operator.

The Flexible Containment Screen is a cost effective solution manufactured in anti-static PVC that allows the operator to handle the potent compound through glove ports, (the customer/operator defining the number of positions), whilst also allowing full flexibility of movement so the operator does not feel restricted. The glove ports are generally welded PVC sleeves with lightweight cuff rings and nitrile rubber gloves, but can be adapted to suit the application.

For those customers who prefer a Rigid Containment Screen, the clear perspex or glass viewing panel has a full 4-axis range of movements. The screens also incorporate the PharmaPort glove ports used on the Extract Rigid Isolators, with a range of gloves (neoprene/vinyl/latex etc) to suit the customer’s specific application.

Recent tests undertaken on Booths as far afield as Brazil, Australia, Saudi Arabia and closer to home in Ireland, have confirmed levels as low as 1μg/m³ (task duration) can be achieved dependent upon the application.

Servicing and Equipment Upgrades

Servicing of your installed containment equipment has always been highly recommended to ensure its continuing functionality, and suitability for the application in question. Extract Technology offers a planned Preventative Maintenance Programme with validated documentation, but now it has gone a step further, with information from the HSE guidelines (HSG 258) now included into the Extract servicing documentation.

Extract’s Maintenance Programme provides a scheduled visit to undertake recommended tests and any minor adjustments and is designed to minimise any production disruptions. Additionally, upgrade services are available for any containment equipment. This will include the Containment Screens mentioned above, but could also include cooling packages, replacement gloveports/glazing panels, as well as equipment relocations.
## Extract Pyramid - Containment Banding

The Extract Pyramid has helped many customers understand the theory of containment, and guide them through their applications to successfully choose the correct containment devices. The pyramid has recently been updated, but still the underlying principles from its launch in 1999 remain the same.

The pyramid was the forerunner to the idea of "Containment Banding" which pharmaceutical companies have now all adopted.

To use the system follow these steps:

1. Select the exposure potential of the product(s) in question, the quantity being handled, the duration of the task operation and having a view on how dusty the product is.

2. Select the containment band into which the product falls. Most companies tend to have their own OEL “banding system”, but using this generic banding may help.

3. Finally, consider which control approach or equipment will suit your needs.

Remember, there can be significant overlaps in using the system so use this as a starter tool before contacting Extract Technology for additional/detailed help.

Also, remember the upgrade options, which can be offered on existing equipment no matter who the original manufacturer was. Extract’s Aftermarket division will help and advise on all your requirements.