

Going paperless

NEXT GENERATION

INTEGRATED ISOLATORS

FOR PHARMACY PRODUCTION PROCESSES







Introducing Envair

World leading clean air and containment systems for healthcare and pharmaceuticals.

Envair has been providing specialist ultra-clean and containment solutions to the healthcare and drug development sectors in the UK and Europe since 1972. At its heart, our mission is to engineer controlled environments to keep your people and processes safe.

That ranges from bespoke rigid isolators for GMP compliant sterile drug dispensing or cytotoxic drug preparation in hospital pharmacies, through to clean air cabinets, fume cupboards or microbiological safety cabinets used in industrial laboratories. We're excited by the possibilities offered by the latest technologies to improve the working lives of our users, including paperless systems and novel validation techniques.

QUALITY SERVICE AS STANDARD

Of course, our involvement doesn't end with the installation, validation and commissioning of your equipment. Our commitment to ensure a lifetime of trouble-free use means our expert engineers are on call 24/7 for service, maintenance and repairs.

Now, as part of Envair Technology, we offer an even wider range of containment systems and benefit from the combined expertise in the group, delivering innovative thinking and further efficiencies for our customers.

PRODUCTS AND SERVICES

- Rigid isolators
- Clean air cabinets and enclosures
- Microbiological safety cabinets
- Service, maintenance and repair
- Validation and commissioning



CDC F range of negative pressure isolators





SAFE ASEPTIC HANDLING OF CYTOTOXICS

This range of negative pressure isolators has been designed to prevent pharmacy and laboratory workers from dangerous exposure to cytotoxic drugs. They also ensure products are protected from microbiological contamination.

With a choice of two or four gloves, wider or narrower working areas and additional exhaust fans and filters, these high performance isolators are easy to set up, operate and maintain.

KEY FEATURES

- Negative pressure for operator protection and safety
- EU GMP Grade A unidirectional airflow work area for aseptic work and product protection
- Transfer chambers with electromagnetic timed interlocks and high air change rates for total suppression of airborne contamination during material transfers in and out, and for rapid evaporation of disinfecting agents
- Automated pressure decay leak test for indicating results and monitoring trends
- PLC controls for easy set up, operation and maintenance
- Good access to all potentially contaminated areas to facilitate cleaning
- Safe to change main (primary) filter
- Two-glove and four-glove, ducted and recirculating models available

Pharm-Assist range of positive pressure isolators



ELIMINATING CONTAMINATION RISKS

The Pharm-Assist range of positive pressure isolators has been created to protect pharmaceutical products being handled in hospital pharmacies and laboratories involved in the drug discovery process and ensure patient safety.

The range is suitable for aseptic preparation, compounding and dispensing of non-hazardous drugs and therapies, such as TPN and CIVAS, as well as Quality Control activities. It provides total suppression of airborne contamination during material transfers in and out.

With a range of models to suit routine processes through to highly complex applications, our engineers put product protection, comfort and ease of use at the heart of our designs.

KEY FEATURES

- Unidirectional airflow in defined critical zone provides EU
 GMP Grade A air quality
- PLC controls for easy set-up, operation and maintenance
- High air change rate D type transfer chambers with electromagnetic timed interlocks
- User friendly automatic pressure decay leak test
- Two-glove and four-glove models available in rigid coated stainless steel or flexible PVC
- Stainless steel base allows users to house equipment such as automatic compounders or sterility testers

Challenges in today's aseptic unit

The COVID-19 pandemic has accelerated the pace of digitalisation, rapidly replacing traditional paper-based processes. And in aseptic units, the stakes are high. Research by the <u>EEPRU</u> in 2018 found that there are an estimated 237 million medication errors per year in the NHS in England. 'Definitely avoidable' adverse drug reactions collectively cost £98.5 million annually and are directly responsible for approximately 700 deaths per year.

So whilst digital pharmacies can clearly save resources, time and money, the benefits for patients' health and safety are even more compelling. In the aseptic unit, where negative pressure isolators are used for chemotherapy and positive pressure isolators are used for CIVAS preparation, the reliance on paper causes particular challenges:



SOUND FAMILIAR?

- It's difficult to identify what stage of preparation a product is at, or the patient's status and where they are in the process, increasing the risk of errors and patient waiting times
- Information stored in multiple systems such as nursing and pharmacy flow, prescriptions, lab results, protocols or EMRs
- Valuable staff time is consumed with locating, retrieving, filing and storing paper files, whilst maintaining GMP and GDPR compliance
- Tasks are needlessly duplicated by nurses, doctors and pharmacy
- Workflows and audit trails are complicated and time consuming
- Maintenance status records of your isolator are paper-based, making it hard to investigate who used the isolator, what for and when, in the event of a micro-failure
- · Long periods of downtime and recommissioning when isolators need to be replaced or retrofitted

In collaboration with medical technology specialists BD™, Envair now supports paperless pharmacy production.

Medication workflow solution



The Envair range of isolators is now available with integrated BD Cato™ medication workflow solution.

This cutting-edge technology standardises intravenous therapies prescription, compounding and administration processes such as order review, medication picking and dose preparation. In the aseptic unit, this improves medication safety, product quality, streamlines the pharmacy workflow and increases efficiency.



The software solution supports physicians and nurses when creating and executing individual long-term therapies for patients, as well as pharmacists and pharmaceutical technicians during the entire compounding workflow. BD Cato™ can operate as a stand-alone application in aseptic units or as an end-to-end solution for the IV medication workflow, either at a single hospital or across multiple sites.

KEY BENEFITS OF BD CATO™

- · Automates calculations, technical checks, gravimetric compounding and barcode confirmation
- Provides clear visibility of the status of each step of the process to minimise errors
- In the event of a micro-failure, thanks to product tracking and full audit trail, BD Cato[™] allows easy identification
 of affected preparations
- Available already integrated with Envair isolator range, ready to go into service as soon as commissioned
- End-to-end solution thanks to different modules (BD Cato[™] Prescribe, BD Cato[™] Pharmacy and BD Cato[™] ReadyMed) keeps all data in one place
- Simple integration with other platforms
- Documentation available at the touch of a button
- Auto scheduled workflow ensures visibility of process, helping to avoid duplication or omission of tasks

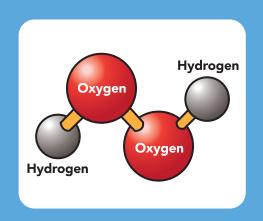
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Other integrated solutions

HYDROGEN PEROXIDE VAPOUR (VH2O2) BIO-DECONTAMINATION

Our isolators and clean air technology devices can offer integrated solutions for hydrogen peroxide vapour (vH2O2) bio-decontamination. In collaboration with proven market leading, vH2O2 partners, we offer clients automated 6-log sporicidal kill on all exposed surfaces inside the isolator to generate a contamination free working environment.

This technology is compliant with the BPR in Europe (EU Regulation 528/2012) and the Hydrogen Peroxide Sterilant is a registered EPA Sterilant (registration number 72372-1- 86703), including efficacy data in line with NFT 72-281:2014.



PARTICLE MONITORING

Integrated solutions for viable and non-viable particle counting are also available from Envair. We can provide particle monitoring for gassing and non-gassing systems, active air sampling, trending, reporting, alarm notification and audit trails.

We enable our clients to meet current regulatory requirements including the EU-GMP Annex 1, cGMP, GAMP and 21 CFR Part 11. Envair is committed to providing solutions to meet the ever-changing needs of the pharmaceutical industry.







FOR MORE INFORMATION OR TO REQUEST PRICING DETAILS:

T: +44 (0) 1706 228 416

E: info@envair.co.uk

W: envair.co.uk

