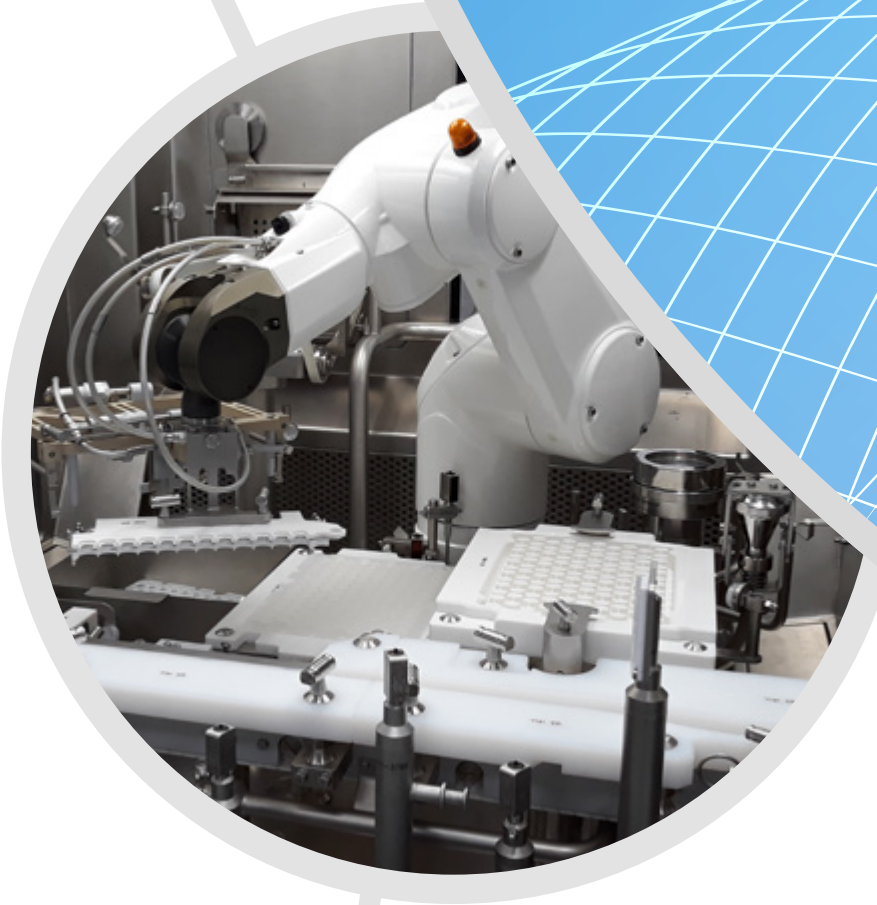


enVigil-IMS Isolator Monitoring System



enVigil-IMS Isolator Monitoring System

Pharmagraph offers a complete, integrated environmental monitoring solution for process critical isolators and enclosures. Whether it's a sterility test isolator or a multiple zone integrated filling machine isolator, enVigil IMS monitors key environmental and process parameters, including particle counts, active air samples, pressure, temperature, and humidity.

The enVigil-IMS application provides a data historian function maintaining historic information for alarms, periodic data and audit logs, all of which are maintained in an FDA/EU-GMP compliant environment.

The software offers:

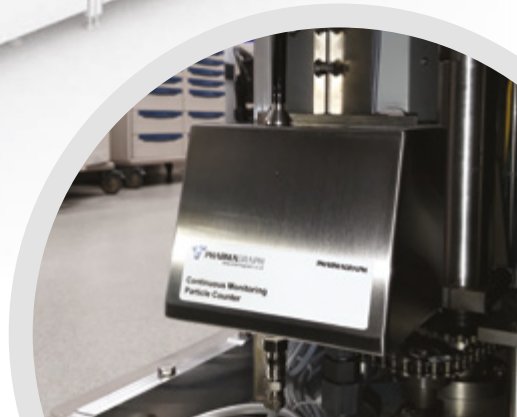
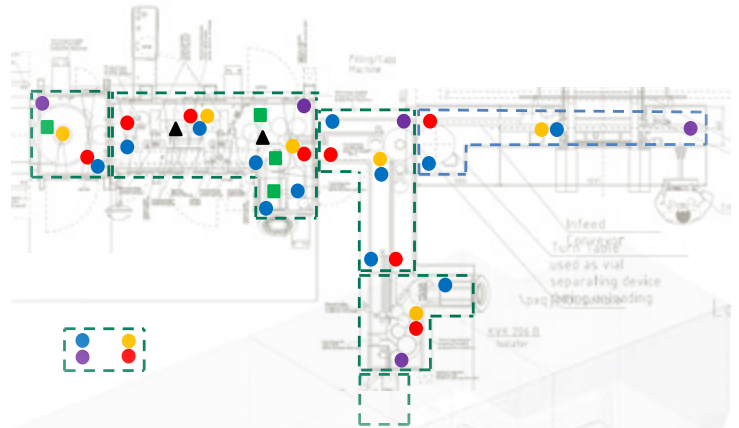
- An easy-to-use graphical interface
- High level system mimics and alarm displays
- Trending of real-time and historical data
- Batch reporting with electronic signatures
- Compliance prediction tools
- Reconciled alarm reports with Trend Metrics
- Powerful reporting and data analytics
- 2-way connectivity to the isolator HMI/PLC controller
- Compatibility with multiple particle counters, air samplers and environmental sensors

Intelligent Pump Controller

A central component of the enVigil-IMS system is the intelligent pump controller, this is located in the technical area, normally above the cleanroom facility.

The intelligent pump controller is able to monitor and control continuous particle counters – supplied by a central vacuum pump, active air samplers and a digital control interface to the isolator filling machine PLC.

- Active Air Sampler
- Particle Counter
- Settle Plates (Monitoring)
- Settle Plates (Classification)
- Contact Plates (Critical Surfaces and Gloves)
- ▲ Swaps (Filling Needles, Stopper Guides and VHP Load Point Contacts)



Non-Viable Sampling

Our enVigil-IMS monitoring software is compatible with a wide range of particle counter manufacturers allowing for easy integration with new or existing sensors, these include:

- Beckman Coulter
- PMS
- Lighthouse
- Climet

Each particle counter sampling position returns results as counts per cubic feet (28.3 L/min) and counts per cubic metre for $>0.5\mu\text{m}$ and $>5.0\mu\text{m}$ size channels to meet event and compliance monitoring.

Each particle counter is protected from hydrogen peroxide contamination by a stainless-steel diverter ball valve and is controlled by the isolator.

In the UK, Pharmagraph is a distributor for Beckman Coulter Met One particle counters, and we manufacture our own enclosures to ensure they are cleanroom compliant.

Viable Active Air Sampling

The enVigil-IMS system offers active air samplers which are mounted in predefined sampling positions as determined by the risk assessment.



For non-toxic applications we offer our iVAS range of intelligent air samplers, which provide:

- Unrivalled efficiency and consistency in microbial monitoring
- Integrated HPV tolerant controller measuring actual flow and sample volume
- Compatibility with 90mm media plates
- Regulatory compliance to EU-GMP Annex 1 and USP 797 requirements.

For toxic applications we integrate third party air samplers with an external vacuum source.

- PMS
- MBV
- Veltek



Project Management

At Pharmagraph we work closely with our OEM partners to ensure a seamless solution to the client. Our dedicated team of IMS Engineers collaborate with OEM engineering teams from initial system integration and documentation all the way through to on-site validation. Working alongside our OEM partners we can assist on specific projects where required too.



Design



Project Management



Validation

The enVigil IMS software is capable of communication and data exchange by various standard protocols such as Modbus, OPC UA/DA or Web API allowing integration with a wide range of third-party systems.



Quality and Compliance at Pharmagraph

Pharmagraph aims to deliver products and services that meet or exceed our customers' expectations, and that comply with all statutory and regulatory requirements for the industry. Our aim is to provide the customer with goods and services to the agreed requirement in accordance with the scope and price.

Pharmagraph are committed to achieving and maintaining Quality and Compliance.

Our Quality Management System is certified as meeting the requirements of ISO 9001:2015 and we can offer ISO 17025:2017 accredited calibrations. Giving our customers confidence in the high quality of products and services we provide.



Accreditation

Our attainment of the following accreditation demonstrates our commitment to work to the highest industry standards, as well as our dedication to continuous improvement.

- ISO 9001:2015
- ISO 17025:2017
- Cyber Essentials
- Safe Contractor
- Constructionline
- JOSCAR Registered



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