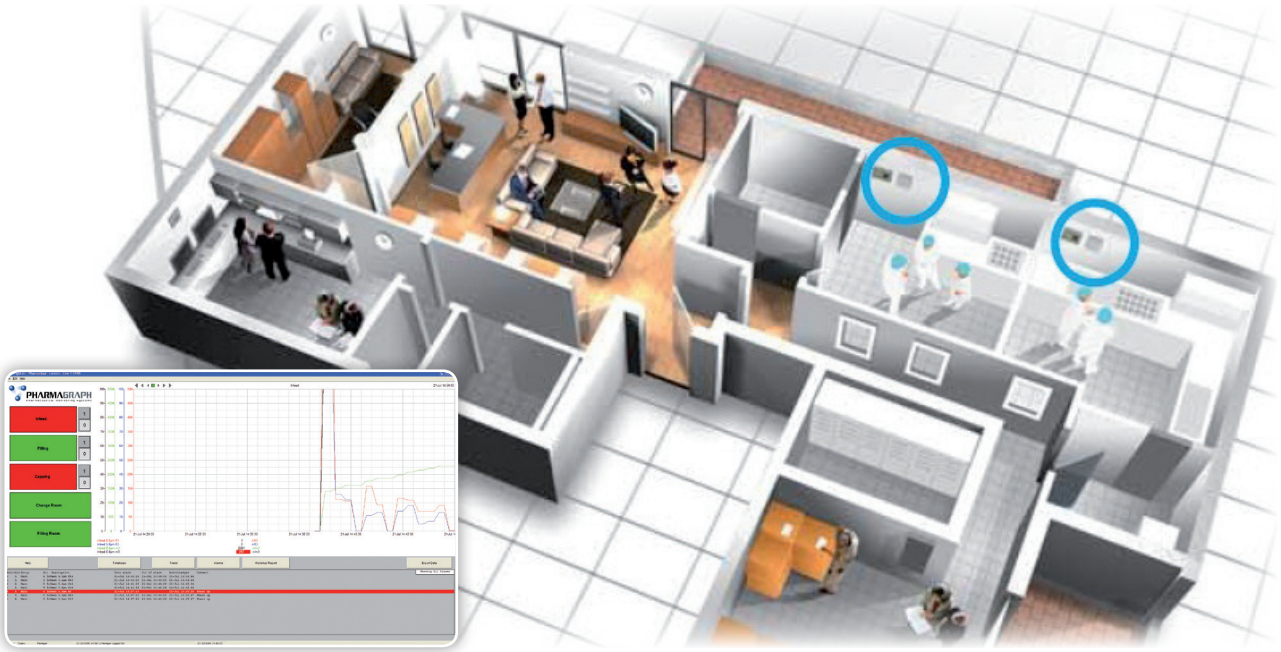
Pharmagraph

GMP/GLP
Monitoring
System

PHARMAGRAPH
Pharmaceutical Monitoring Systems

Pharmagraph GMP/GLP Monitoring System

Demonstrates GMP/GLP compliance for cleanrooms and laboratories



- Monitors, Alarms, Logs and Reports
- Airborne particle counts, temperature, pressure, relative humidity
- Integrated Active Air Sampling
- Cleanrooms, isolators, RABS
- Fridges, freezers, stability trials, incubators
- Automatic audit trail logging
- Multi-level secure log-on
- Built-in data, audit and alarm reports
- Export utility to Microsoft Excel
- Full validation documents available

Pharmagraph publish the enVigil software suite which is deployed specifically for facility and environmental monitoring applications. With a pedigree that has been derived from twenty years' experience in providing EU-GMP compliant monitoring solutions, the enVigil software offers a EU-GMP/GLP compliant monitoring system for a range of applications. From pharmaceutical cleanrooms to satellite manufacturing facilities Pharmagraphs' enVigil systems are deployed worldwide to monitor cleanroom environmental parameters such as airborne particulates, differential pressure, temperature, humidity and air flow. These systems may also be expanded to include equipment monitoring of fridges, freezers and incubators.

The monitored facilities range from pharmaceutical aseptic filling suites, IVF clinics, hospital pharmacies, blood banks, cold chain storage suites and satellite manufacturing facilities.

At the heart of the enVigil suite of software is the adherence to the requirements of EU-GMP Annex 1, cGMP, GAMP and 21 CFR Part 11 thereby ensuring the installed system can meet current regulatory requirements.

The enVigil suite of software is provided in three variants: **enVigil-Lite**, **enVigil-PnP** and **enVigil-FMS**.

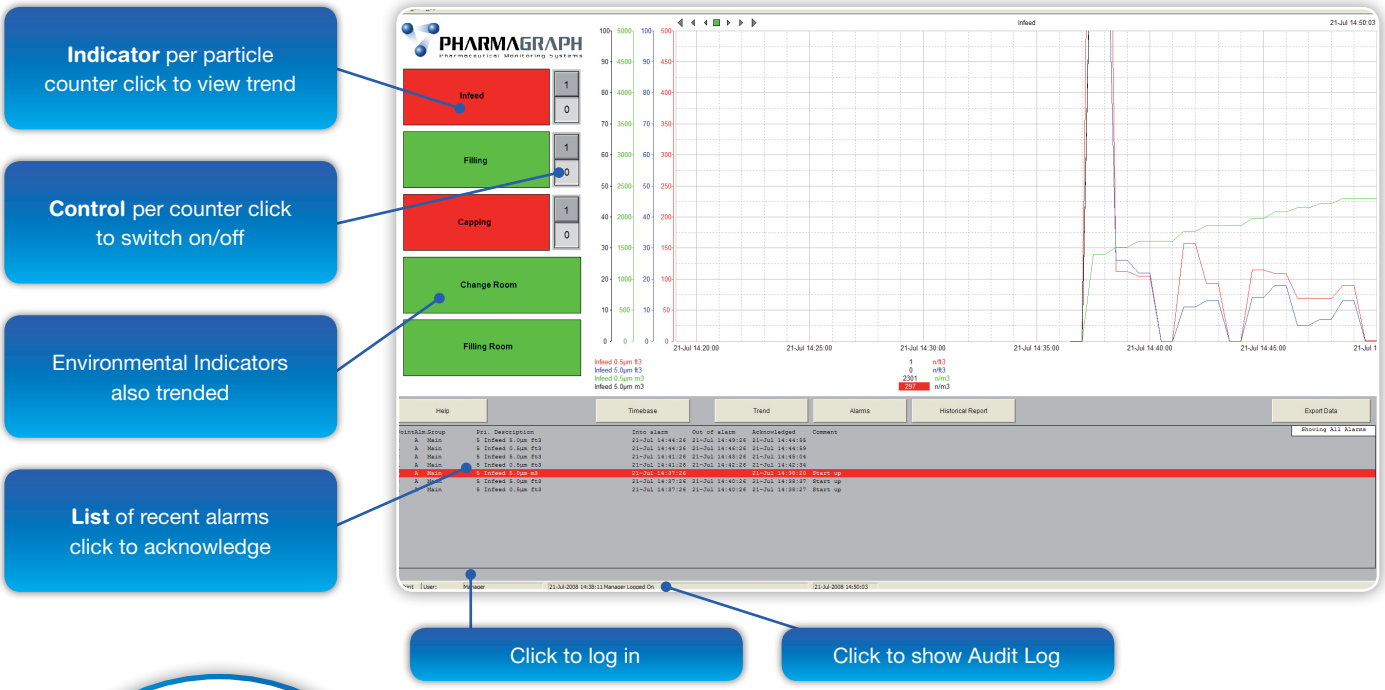
eV-Lite ✔ eV-PnP ✔ eV-FMS ✔

Powerful, secure software

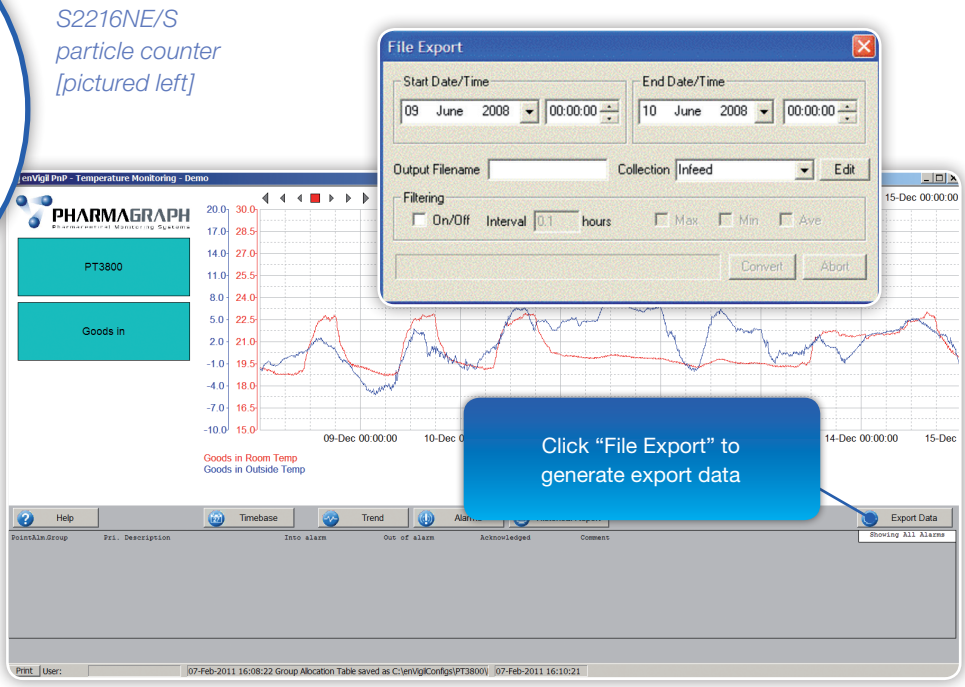
enVigil Software

All GMP/GLP-related parameters can be monitored, alarmed, logged and reported: airborne particle counts, temperature, pressure, relative humidity for cleanrooms, isolators, RABS, fridges, freezers, stability trials and incubators. With automatic audit trail logging, multi-level secure log-on and built-in data, audit and alarm reports this system can deliver a one-stop solution demonstrating compliance with EU-GMP, cGMP and 21 CFR part 11.

EnVigil-Lite/PNP Operator Interface Screen



Pharmagraph S2216NE/S particle counter [pictured left]



Data historian

21 CFR part 11 secure records can be searched by time base for data, alarms and audit trail. Data can be exported to MS Excel, but secure record stays in 21 CFR part 11 compliant system.

Clear facility overview

A clear, mimic-style overview of the production facility can be provided, giving clear warning to facility QC and management of status of the production environment. These screens can be configured to show just those areas of interest, or the entire facility. Drill-down buttons allow the user to view trend data and acknowledge alarms for any area.

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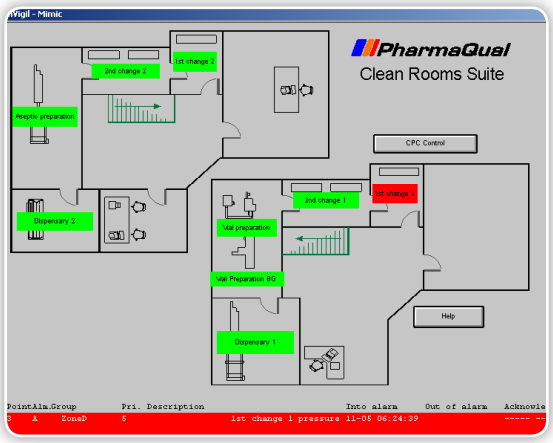

EnVigil-FMS Clear facility overview

Reconciled Alarm Reporting

Alarm excursions are captured to succinct records with "Into Alarm", "Out of Alarm", "Alarm Acknowledgement" and "Time in Alarm" events being detailed with time /date and period information. The record is complete with alarm acknowledgement comments which are entered during the alarm acknowledgement activity either by free typing and/or selected from a drop down list. The reconciled alarm report provides detailed records of significant alarm events in an easy to read format with signature boxes for sign off. Compliance can easily be demonstrated through the absence of alarm conditions during production periods. Any alarm excursions that are reported are easily generated for sign off allowing succinct reports to be printed and kept. Batch reporting can be provided as an optional extra.

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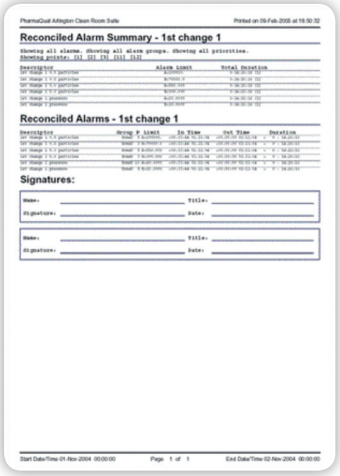
Reconciled Alarm Summary - 1st change 1

Reconciled Alarms - 1st change 1

Signatures:

Reconciled alarm report

Innovative hardware design

Preventing data gaps

Data gaps through particle counter failure/damage can leave holes in the data to support that the area was in compliance during a batch. Pharmagraph counters overcome this issue by being 'hot-swappable' by cleanroom staff without the need for support from facility maintenance or IT support teams. Additionally, in the event of data link failure, particle count data will be stored in the particle counters and automatically uploaded to the central system once communications are restored.

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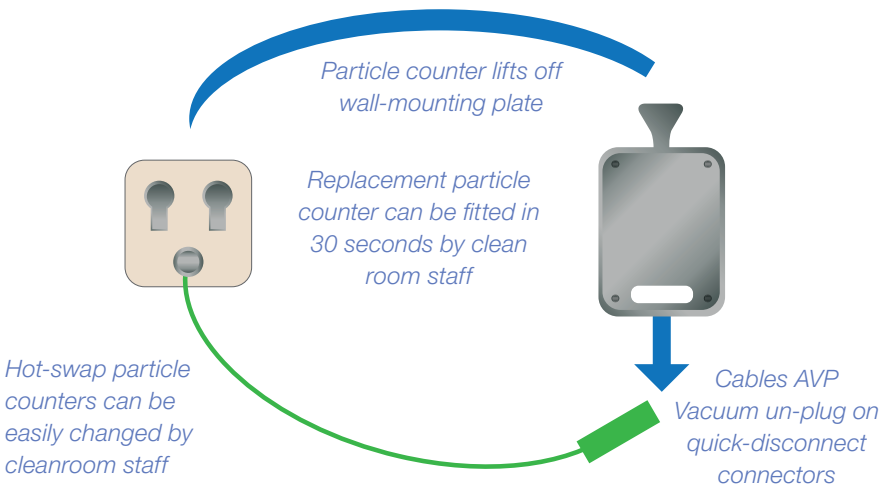
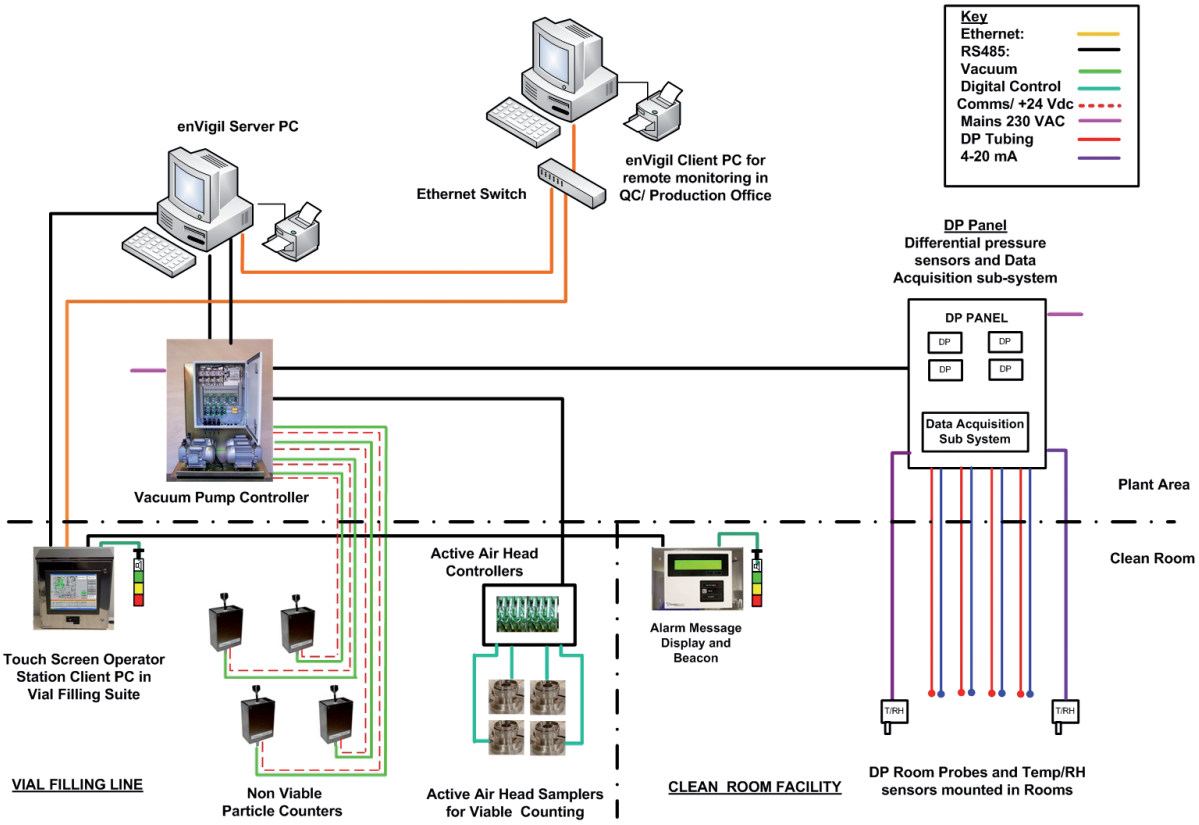


Scalable, modular solution

Pharmagraph's monitoring systems can start small, saving initial investment, then scale up as the facility grows, building on existing hardware and monitoring sensors and providing additional monitoring stations as the system grows.
Initial systems can start as small as a single environmental parameter and scale up to an entire facility of parameters because of it's modular nature

Particle Monitoring System:
Integrated Non-Viable and Viable Particle Monitoring System



Avoiding additional cost of ownership

Particle counters are extremely sensitive optical devices designed to accurately measure and count particles that the human eye cannot see. It is very common that they are damaged when cleaning takes place and the particle counter is left running – the sample vacuum draws the cleaning fluid into the sensitive optical chamber and, at best the optics need to returned to factory for cleaning, at worst the contamination renders the optics beyond repair. Either way, contamination issues can lead to an unforeseen additional cost of ownership. Always select a system that allows you to turn off individual counters during cleaning. Systems that deploy a central vacuum pump may not have this feature.

What if the central monitoring PC fails?

Imagine the central monitoring PC fails, is unplugged by accident or simply crashes? Other systems can continue to show green lights in the cleanroom, whereas the Pharmagraph system can employ an innovative 'PC Watchdog' which monitors the central PC and generates audible and visible alarms in the event that anything goes wrong.

Data integrity for stability programs

Long-term product stability programs require safe data storage and integrity. Commonly used chart recorders can run out of paper, ink or even memory, leaving data gaps and compromising the stability testing data integrity. Pharmagraph systems deploy a 21 CFR part 11-safe data historian that can be automatically backed-up to secure data storage ensuring the success of product stability testing programs.

Temperature monitoring accuracy

Many temperature controlled storage facilities require the environment to be controlled and monitored to +/- 2ºC. Pharmagraph systems employ unique sensor and interface designs to ensure that accuracy on the monitoring systems achieve +/- 0.1ºC.

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Unique temperature sensor interface ensures system accuracy to +/-0.1ºC [pictured left]

How do the cleanroom/isolator/incubator users know it is safe to manufacture?

Typically, the central monitoring PC is located in the Quality Control office. Pharmagraph systems deploy unique AN1440 messaging and alarm indicators to alert cleanroom/isolator users if any single parameter goes out of compliance.
In addition, the AN1440 can drive 'traffic light' beacons.

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Local AN1440 audio/ visual display for cleanroom staff [pictured right]

Remote alarms with auto dialer

Pharmagraph systems can provide instant messaging to alert staff by text or pre-recorded voice messaging of any imminent out-of-specification environmental parameter, for example giving staff at an IVF facility time to recover stock and re-locate it to a safe environment.

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'Traffic light' beacon for cleanroom staff [pictured right]

Auto dialer option can notify remote staff in emergency [pictured left]

Integral viable monitoring

Active microbial air sampling can be added as an integral part of Pharmagraph's solution, removing the need for using portable air samplers and providing secure logging of viable sampling program timing to support batch release. Continuous or interrupted active air sampling regimes are supported. The internal impeller fan speed is monitored and controlled to ensure the correct sample volume and d50 values are maintained. Active Air Samplers are available with a variety of mounting and sample head options.

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Active microbial sampling heads can be added as an integral part of the system [pictured right]

Avoiding becoming an accidental contamination source

The sample pathway through the particle counter passes into the adjacent service/utility rooms. Should the sampling vacuum pump fail, then the sampling pathway can provide an accidental pathway for contamination to pass back up the sample tube from the service/utility rooms into the isolator, especially for negative-pressure isolators. By providing a non-return valve in the sample pathway, Pharmagraph systems automatically seal off the sample pathway in the event of pump failure, preventing any risk of accidental contamination.

Bounded version available for low-cost deployment and validation

For systems where all that is required is a simple go/no-go compliant indication and secure data historian, Pharmagraph have developed enVigil-Lite/PnP which are a bounded version of this powerful software and have all the GMP/GLP monitoring requirements for compliance, but without the complex validation requirements, saving significant costs in deployment and validation.

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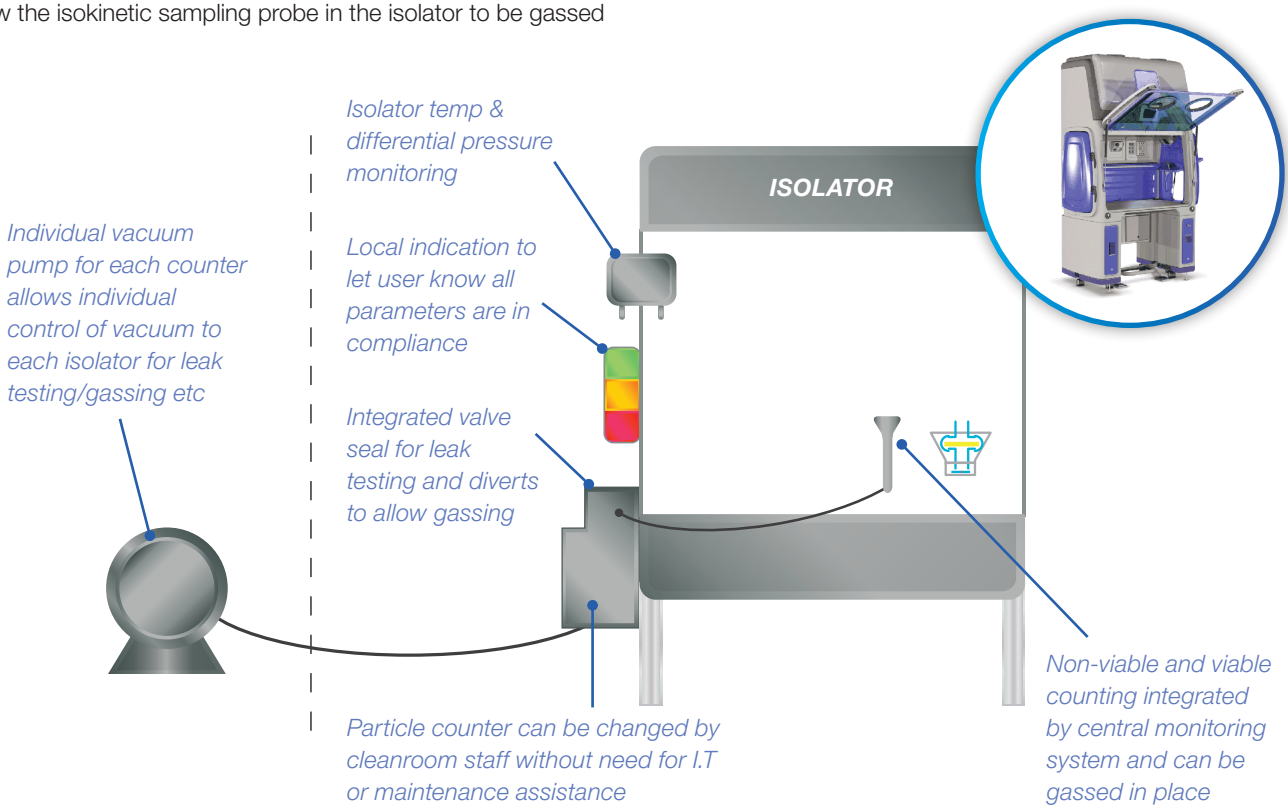
Note: enVigil-FMS is provided with an Application Specific documentation suite designed to meet the GMP/GAMP requirements for system verification and validation.

Special integration for gassing isolators

Isolators using the increasingly-common hydrogen peroxide vapour decontamination technique represent significant challenges for particle counters. Pharmagraph counters provide a solution to these applications with an integrated valve that can allow the isokinetic sampling probe in the isolator to be gassed without contaminating the sensitive optics inside the particle counter. This avoids drawing hydrogen peroxide vapour out of the isolator, thus potentially compromising the efficacy of the gassing decontamination program.



Supporting leak testing for isolators

The particle counter isokinetic sampling probe draws an air sample out of the isolator to allow the particle counter to sample and count particles. This forms a potential leakage path leading to failure of isolator leak testing. Pharmagraph's innovative sampling valve seals the isokinetic sampling probe allowing successful isolator leak testing and preventing damage to the isolator. In addition, individual particle counters can be turned off during leak testing, allowing the other particle counters to continue to work independently to demonstrate compliance in other still operational areas. Non-viable particle counting and active air sampling within the isolator allows a fully integrated monitoring system to be deployed. The EnVigil software provides simple operator feedback of the current status of the isolator.

Paperless data from routine monitoring programs – saving time and money

Portable particle counters for routine monitoring can be connected to the Pharmagraph system to upload data real-time, avoiding the time consuming paper trail and manual data entry associated with these monitoring programs.

Paperless routine monitoring program [pictured right]

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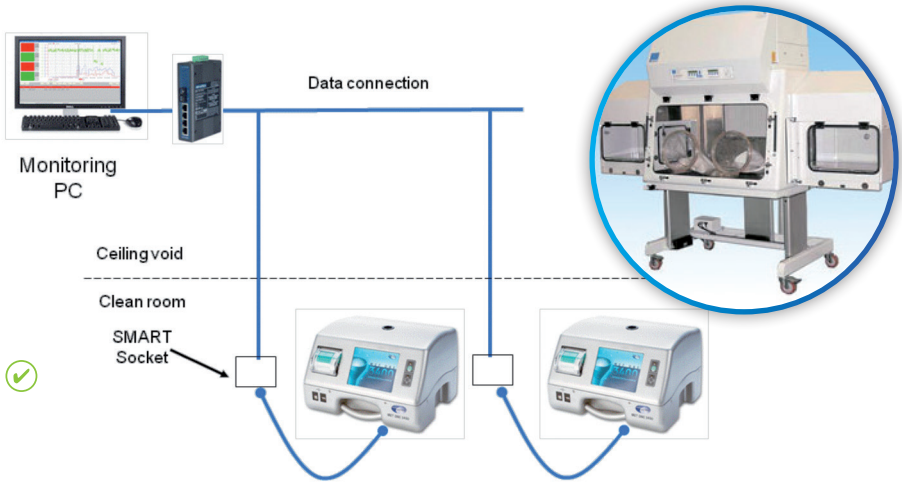

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Pharmagraph

39 Ivanhoe Road
Hogwood Industrial Estate
Finchampstead
Berkshire RG40 4QQ
United Kingdom

Pharmagraph is a division of Acquisition Systems Ltd

Tel: +44 (0) 1252 861700
Fax: +44 (0) 1252 861155
sales@pharmagraph.co.uk

www.pharmagraph.co.uk