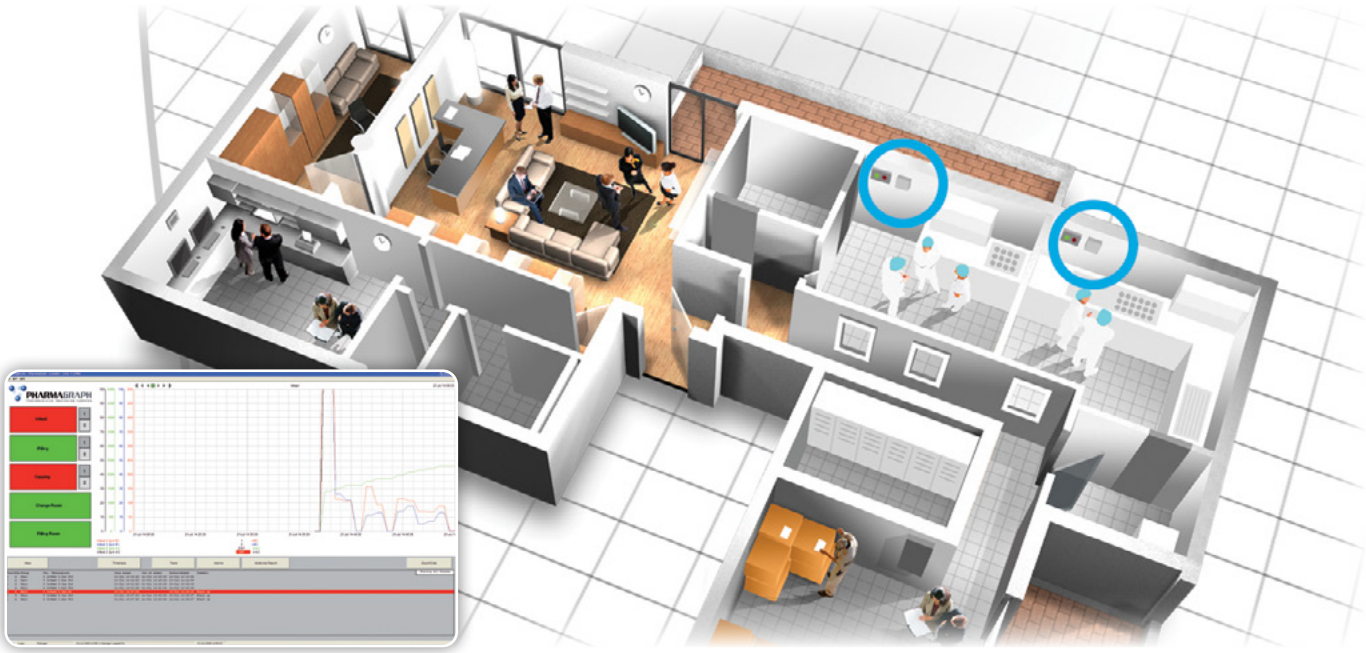
Pharmagraph

enVigil-PnP
System for
Hospital
Pharmacies

PHARMAGRAPH

Pharmagraph enVigil-PnP 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
- Template based Verification Documentation

enVigil-PnP provides a simple to use, cost effective solution which ensures a GMP/GLP compliant system and is ideally suited to modern day hospital pharmacy and IVF clinic operations. With a range of package sizes supporting up to 20 particle counters, 100 active air samplers and up to 160 environmental inputs enVigil-PnP is easy to deploy, verify and validate.

enVigil-PnP is provided with an overview menu with status indicators, trends, alarms, data logging, reports and data to MS Excel. Optional modules are also available to support instrument tracking, batch reporting, network view nodes, OPC server and GSM modem support for data on alarm to email and SMS text.

enVigil-PnP offers support for isolator gassing operations and particle counter “swap-ability” in order to minimise system downtime due to contamination failures. If you do not require particle counting then enVigil-PnP offers a low cost version for environmental or viable (active air sampling) monitoring only.

enVigil-PnP is complete with a simple Verification Protocol that includes a Functional Design Specification and Installation and Operational Acceptance Test Protocols allowing the enVigil-PnP system to be easily designed, configured, installed, commissioned and verified.

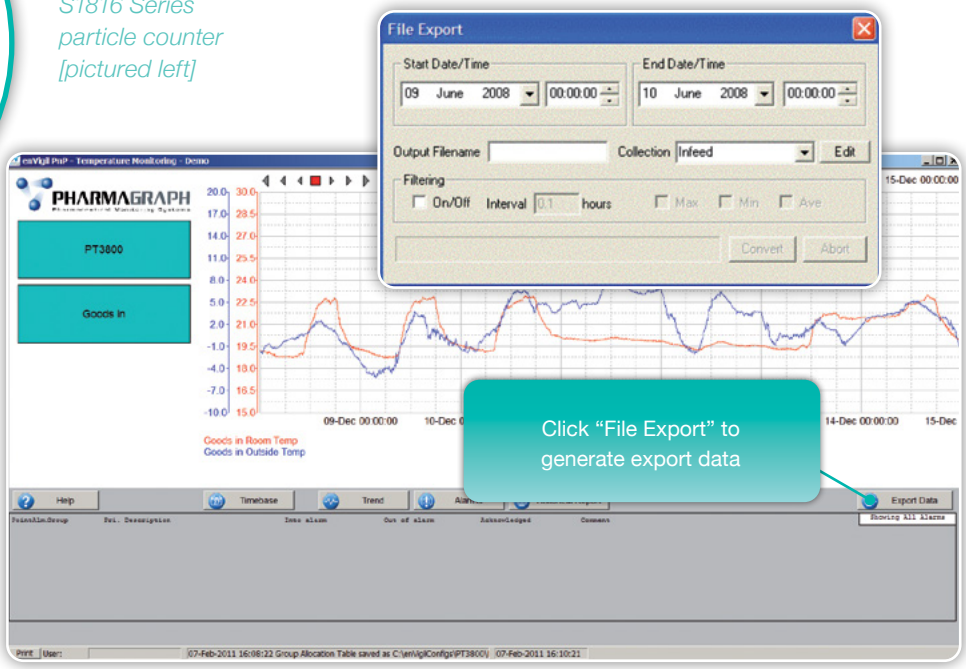
Powerful, secure software

enVigil-PnP 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-PnP Operator Interface Screen

Pharmagraph S1816 Series 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.

Particle Counting

enVigil-PnP supports two particle counters detailed as follows:

Pharmagraph S1816 Series Particle Counter

The Pharmagraph S1816 series particle counter contains a Met One 6015 sensor and is housed in a stainless steel enclosure suitable for pharmaceutical applications. The S1816 particle counter offers either Ethernet or RS485 Serial communication protocols. The Met One 6015 sensor is compliant with the ISO 21501-4 calibration standard for particle counters. The Met One 6015 sensor provides >0.5µm and >5.0µm size channels at a 1.0 cfm (28.3 L/min) flow rate. The S1816VS serial version offers “swap-ability” when deployed with Pharmagraph vacuum pump controllers (P4150-4G/CC9058). This aids quick replacement if the sensor requires a calibration service or becomes contaminated, as the particle counter network address is determined by the sampling position and not the individual sensor. This in turn reduces system downtime.

S1816VS [pictured above]
Met-One 6015P [pictured below]

Met-One 6015P Particle Counter

The Met-One 6015P particle counter offers a particle counter with an integrated vacuum pump and is compliant with the ISO 21501-4 calibration standard for particle counters. The 6015P provides >0.5µm and >5.0µm size channels at a 1.0 cfm (28.3 L/min) flow rate and offers Ethernet connectivity. The Met-One 6015P provides an integrated pump particle counter solution which reduces installation costs and can easily be fitted to Isolators, Micro Biological Safety Cabinets and LAF workstations.

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 also be provided as an optional module.

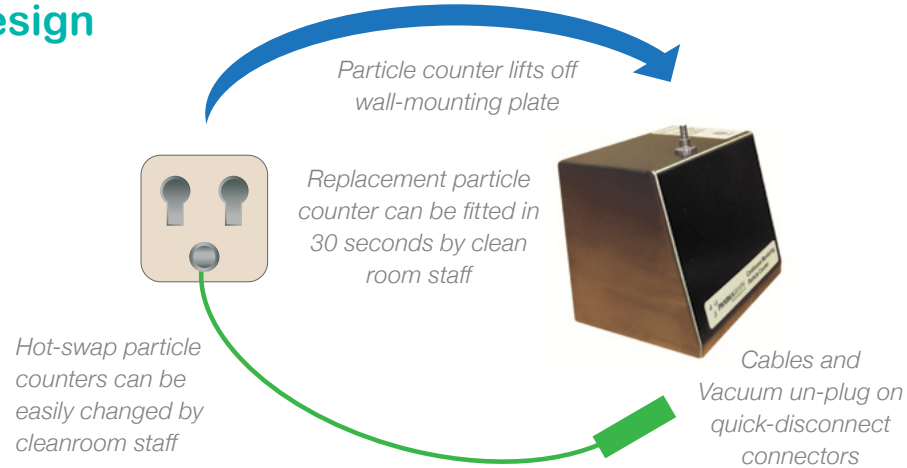
Reconciled Alarm Summary - 1st change 1
Reconciled Alarms - 1st change 1
Signatures:

Reconciled alarm report

Innovative hardware design

Preventing data gaps

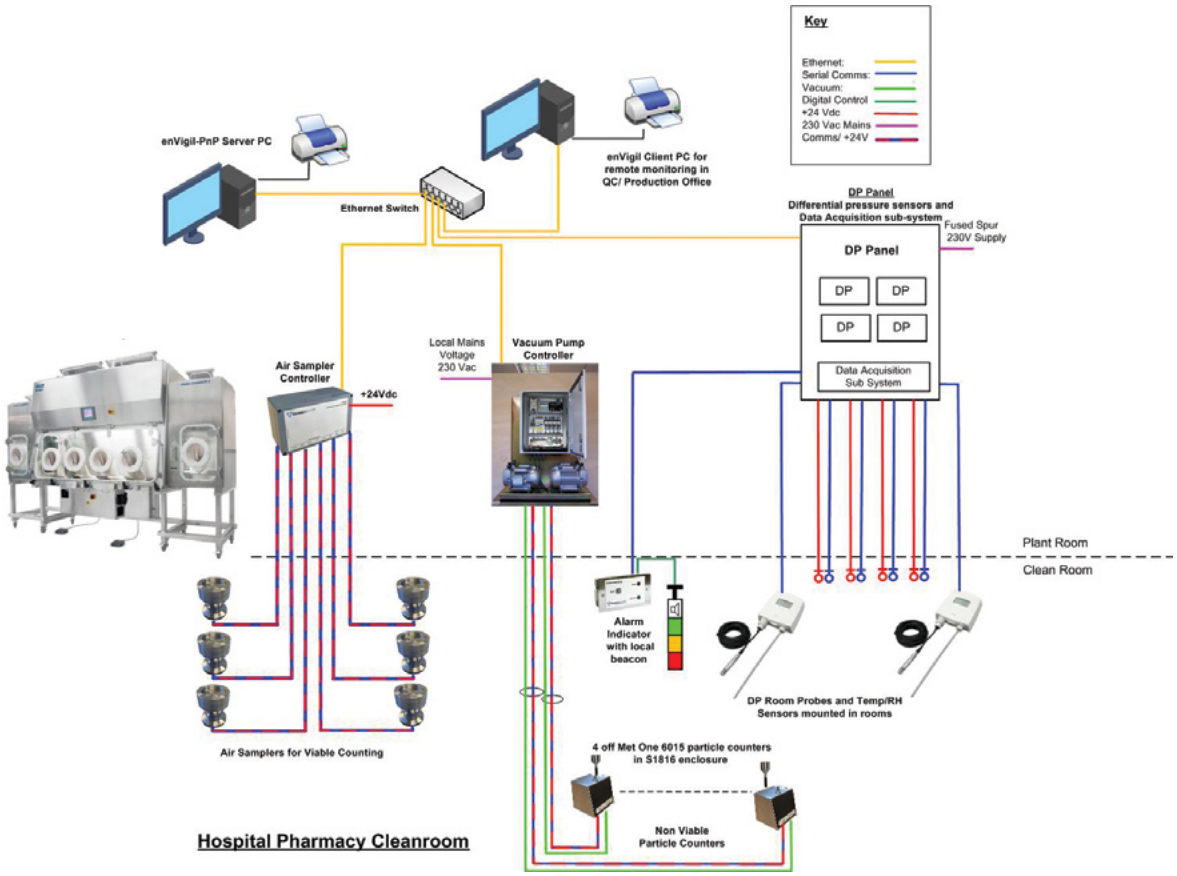
Data gaps through particle counter failure/damage can leave holes in the data to support that the area was in compliance during a batch. Pharmagraph counters overcome this issue by being ‘hot-swappable’ by cleanroom staff without the need for support from facility maintenance or IT support teams.



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

enVigil-PnP 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.

Environmental Sensors

The Pharmagraph Series 2000 I/O system connects to sensors to accurately measure differential pressure, temperature, humidity and air flow. Equipment storage facilities are also catered for and temperature accuracies of +/- 0.1 ºC can be achieved for the monitoring of fridges, freezers and incubators.

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.

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

Remote alarms with GSM Modem

Pharmagraph systems can provide instant messaging to alert staff by text or email 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. The GSM Modem option offers call schedules to suit staff working patterns and shift rotas.

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

GSM Modem offers SMS text and email on alarm. [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.

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

Avoiding becoming an accidental contamination source

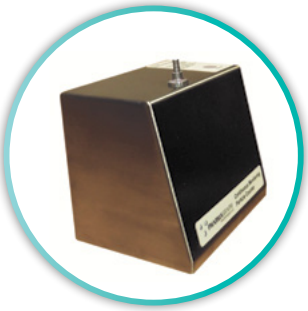
The sample pathway through the particle counter passes into the adjacent service/utility rooms. Should the sampling vacuum pump fail, then the sampling pathway can provide an accidental pathway for contamination to pass back up the sample tube from the service/utility rooms into the isolator, especially 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

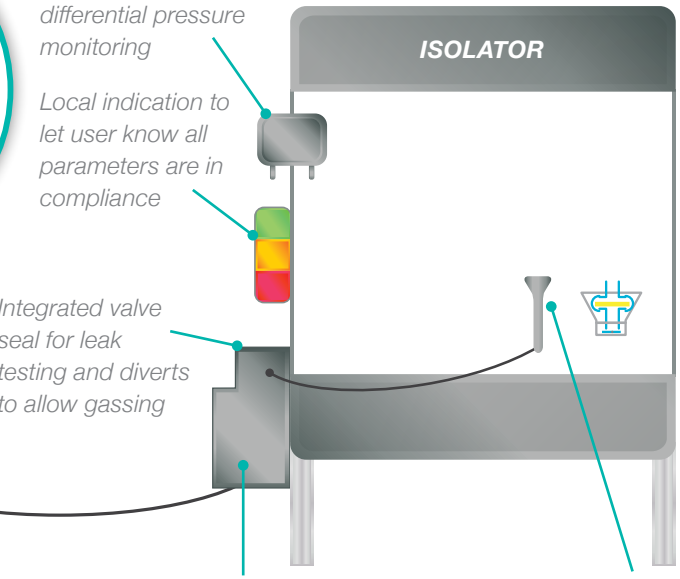
For systems where all that is required is a simple go/no-go compliant indication and secure data historian, Pharmagraph have developed enVigil-PnP which is a bounded version of the Pharmagraph enVigil-FMS product. enVigil-PnP offers GMP/GLP compliance by using a template approach to the Verification Documentation. This reduces overall cost by avoiding application specific documentation but without compromising GMP compliance. An ideal approach which saves significant costs in deployment 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.



Optional S1816VS particle counter with remote vacuum pump and easy maintenance



Isolator temp & differential pressure monitoring

Local indication to let user know all parameters are in compliance

Integrated valve seal for leak testing and diverts to allow gassing

Met-One 6015P particle counter provides an integrated vacuum pump. [pictured above]

Individual vacuum pump for each counter allows individual control of vacuum to each isolator for leak testing/gassing etc

Particle counter can be changed by cleanroom staff without need for I.T or maintenance assistance

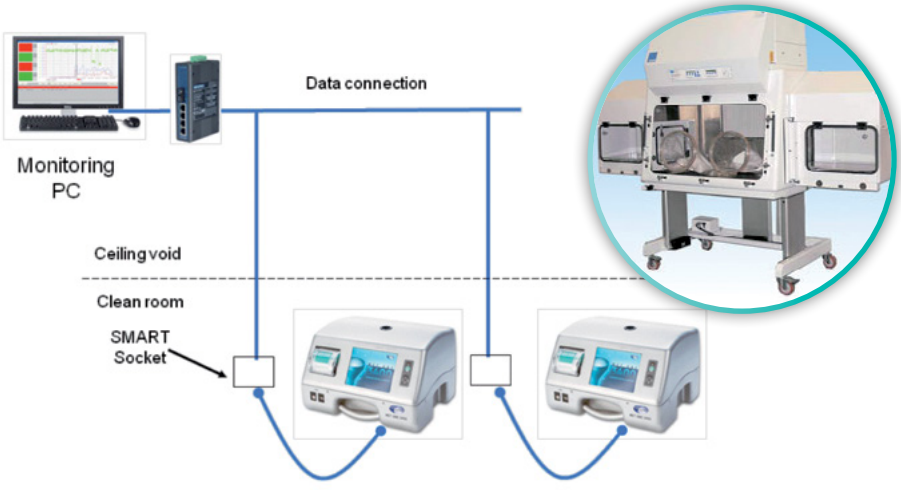
Non-viable and viable counting integrated by central monitoring system and can be gassed in place

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 enVigil-PnP 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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