enVigil PnP v4

Facility Monitoring Software



enVigil PnP

- Monitors, Alarms, Logs and Reports
- Up to 20 particle sampling locations, including gassing support
- Up to 20 environmental locations (up to 160 channels)
- Up to 96 microbiological monitoring locations
- Up to 10 remote network clients (View Nodes)
- Automatic audit logging
- Secure operation using Windows user names and passwords
- Offers trends, alarm reports and tabular data reports
- Export XML data to Microsoft Excel
- Includes system verification documents in PDF format
- Compliant with EU GMP Annex 1 and 21 CFR part 11

enVigil 'Plug and and Play' Facility Monitoring Software allows you to configure a fully featured particle monitoring system in minutes. Offering a clear status overview with one click access to trends, concise alarm reports and data export to Microsoft Excel™, enVigil PnP delivers the information you need to maintain compliance without tedious configuration and documentation. An intuitive configuration wizard guides you through a few simple steps to define the locations being monitored and the regulatory classes being applied – enVigil PnP does the rest. Password protected operation and an automatic audit trail logging system make the system compliant with 21 CFR part 11 straight out of the box.

Operation

enVigil PnP presents a simple and consistent user interface divided into three panes; a grid of indicators, the main report and a scrolling alarm list.

The indicators on the left depict the current state of particle sampling or environmental locations and clicking an indicator shows the report for that location ont the right. The default format is a trend, but one click offers historical alarm reports or historical tabular data instead and you can readily change the time base for any report using familiar calendar controls.

For particle counting locations, control buttons allow you to start and stop each counter or a group of counters, with an automatic delay before counting starts to allow the sample path to be purged of 'old' air.

Indicators, values and alarm entries are all color coded according to their state; green when in compliance, red when out of compliance and flash until they have been acknowledged. Unique colors indicate inactive counters or errors such as flow or sensor failure at a glance.

The built-in reconciled alarm facility offers the most concise report of compliance over a period of time. A summary at the top clearly shows the total time each parameter spent out of compliance, while the lower section details the individual events that contributed to that total time.

In addition to the reports available for each particle counter, a global audit report is available showing login activity and any changes made to the configuration. Reports can be printed with a single click and include signature boxes allowing them to be used for batch sign off.

Data can also be exported to Microsoft Excel over a selectable period and includes data, alarm transitions and audit entries over that period.
item of hardware that they refer to.

Remote PCs can connect via an Ethernet network to provide different views in different departments, for example in Production, QC and Microbiology.

PHARMAGRAPH
Pharmaceutical Monitoring Systems

Configuration

enVigil PnP offers the quickest and simplest configuration mechanism available. The configuration wizard offers a series of 'tabs' that map directly onto the hardware you are configuring. By supplying a few details on each tab and clicking the 'run' button, you can be up and running in minutes:

- In the first tab you enter descriptive information about the system that is to be included in the header of printed reports.
- A second tab lets you define the particle counting locations to be monitored and the alarm limits to be applied. Pre-defined sets of standard limits such as 'Grade A' are available, or you can define your own. If using particle counters without intergral pumps, another tab allows you to configure vacuum sources for the counters.
- A further tab offers environmental monitoing locations such as fridges or freezers and uses styles that can be defined once and applied to all measurements of the same type.
- Another tab lets you define the location of optional alarm beacon hardware and which locations contribute to their alarm state.

For the ultimate in system confidence you can use the optional watchdog facility. When The watchdog constantly monitors the health of the enVigil PnP processes on the PC and alerts staff on the external watchdog hardware if system integrity is compromised.

Documentation Templates

Document templates are included on the CD to address the system Functional Design Specification and Installation/Operation Acceptance Test. Also included are individual test sheet templates for particle counters, environmental locations and alarm indicators.

Using this pre-printed document set, system verification can be carried out without creating bespoke documents, by simply filling in the forms in the master documents and completing a test sheet per item of hardware that they refer to.

Supported Hardware

- Up to 20 Pharmagraph Series 2000/3000 Modules each with up to 8 channels
- Up to 20 Particle Counters that use Modbus RTU protocol with either serial or Ethernet communications. Serial and Ethernet counters cannot be mixed in a single system.
  - Pharmagraph S1816DS particle counter
  - Pharmagraph S1816DE particle counter
  - Pharmagraph GP6015 particle counter with gassing support
  - Met One 3400/6000/7000 series particle counter
- Up to 20 Pharmagraph Alarm Indicators/Beacons/Displays
- Up to 96 Pharmagraph VF8023 active air samplers for microbiological monitoring

System Requirements

- Microsoft Windows 7™ or Windows 10™ (32 or 64 bit versions)
- Minimum monitor resolution 1024x768 pixels*
- CD-ROM Drive
- USB port for security key when not using virtual machines
- Ethernet port

Ordering Information

- EPS-00 supports environmental inputs only
- EPS-02 supports up to 2 particle counters
- EPS-05 supports up to 5 particle counters
- EPS-10 supports up to 10 particle counters
- EPS-15 supports up to 15 particle counters
- EPS-20 supports up to 20 particle counters

- ENV-CL1 adds 1 remote network client licence
- ENV-CL3 adds 3 remote network client licences
- ENV-CL5 adds 5 remote network client licences
- ENV-CL10 adds 10 remote network client licences

Specification

enVigil PnP v4
Facility Monitoring Software

Pharmagraph is a division of Acquisition Systems Ltd

Pharmagraph, 39 Ivanhoe Road, Hogwood Industrial Estate, Finchampstead, Berkshire, UK, RG40 4QQ
Tel: +44 (0) 1252 861700 Fax: +44 (0) 1252 861155
www.pharmagraph.co.uk e-mail: sales@pharmagraph.co.uk

PHARMAGRAPH
Pharmaceutical Monitoring Systems

* enVigil PnP software is optimised for wide screen layout but will run on a 4:3 monitor

Windows 7, Windows 10, Excel are registered trademarks of Microsoft Corporation. enVigil is a registered trademark of Acquisition Systems Ltd
Document 49101101 Rev E © Acquisition Systems Ltd 2018