



# 21 CFR part 11 compliant Facility Monitoring Software

## The Software

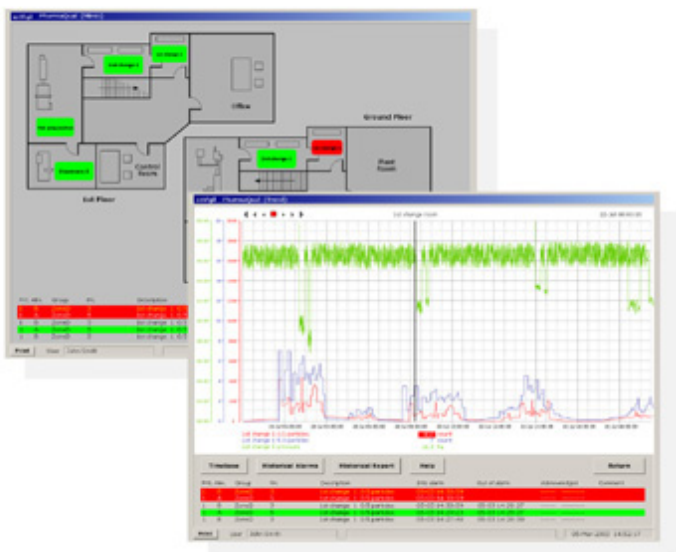
enVigil software runs under Microsoft Windows 2000/XP, gathering results from environmental monitoring and particle counting instruments and displaying them in clear, easily understood screens.

Template-based software allows individual requirements to be met by configuring a small number of highly functional modules. This simplifies qualification, controls costs and reduces learning curves while allowing for future expansion. Each module has been subjected to a full qualification procedure offering unrivalled reliability.

The system is extremely easy to use; an overview screen shows a simplified floor plan of the facility where the rooms or equipment being monitored are green when within limits and red when in alarm.

Clicking on the room of interest shows a trend graph of the parameters within that room together with their numeric values, colour coded by their alarm state. The trend duration is chosen simply by clicking a button or you can zoom or pan interactively by dragging within the graph.

The trend graph seamlessly integrates real-time and historical data letting you jump to any period in history by selecting the date on a calendar.



## Simple, Reliable and Secure

- Simple to use
- Password protected operation
- Secure data logging
- Automatic audit trail

## Monitor, Log and Report

- Temperature
- Relative Humidity
- Differential Pressure
- Particle Counts
- Air Flow





## Built-in Diagnostics

While qualifying a system, the entire map of input and outputs is visible at a glance, allowing you to validate the 'raw' values as they arrive from the sensors. Even before real devices are attached to the system, you can inject test values directly or use simulated devices to verify correct system behaviour.

## Security

With security features built-in, you can restrict or open up facilities to different operators, assuring you that only those people allowed to perform a certain task are able to do so. Activities such as alarm limit modification or the switching off of particle counters during cleaning activities are typical operations protected by system security.

## Connectivity

enVigil incorporates powerful networking features offering real-time and historical data access from slave or 'View Node' PCs. An optional communications package even allows you to keep in touch via your pager or mobile phone; different priority alarm messages can be directed to different maintenance or management staff, allowing them to take appropriate action.

## Automatic file maintenance

Behind the scenes, enVigil automatically archives vital records to local backup devices or file server based storage. It can even automatically delete data older than a selected age, providing it has been successfully archived, giving you almost maintenance free operation.

## Alarm reporting

Full alarm logging and printing is built-in as standard, showing alarms in the sequence they occur. An optional alarm reconciliation module lets you quickly generate 'out of compliance' reports over a specific period. Transitions into alarm and out of alarm are reconciled automatically and can be printed and signed off to support batch records. These concise reports show exactly how long each area or machine was out of compliance, or clearly state that no out of compliance results were recorded over the period of interest.

## 21 CFR part 11 compliance

enVigil software has been written from the ground up to comply with the tough demands of 21 CFR part 11 (with regard to electronic records) through the use of tight security, proprietary format data logging and provision of an audit trail. The software system is secured via unique user names and passwords, with automatic log out when the system is left idle. A secure binary format is used for data log files making it virtually impossible to alter records. An audit trail logger automatically tracks changes to the system configuration, recording what has been changed, by whom, when and for what reason. The audit trail logger also records operator log in and log out activity, including failed log in attempts.

## Quick and Simple Configuration

Configuring enVigil screens is as simple as importing a CAD drawing of the floor plan and filling in rows in a few forms. Alarm indicators are automatically created for you; all you have to do is drag them into position on the floor plan. All the rooms' trend graphs and reports are automatically created and connected to the alarm indicators - no more configuration is needed.

## True Client/Server Architecture

enVigil employs a flexible client/server architecture allowing a wide range of system topologies to be created; from a single standalone PC, to a network of PCs including touch screen panel PCs and desktop PCs offering different 'views' onto the system. These 'views', or clients, can be deployed with minimal re-qualification due to the well defined split between the server (data acquisition, alarm checking and logging) and client (data display, trending and reporting) configurations. All client licence management is performed by a single hardware key attached to the server PC and is field-upgradable to allow additional clients to be readily attached.

enVigil is available in development, run-time and network client versions, with various package sizes. Please consult the sales office for more details.

---

## System Requirements

- Microsoft Windows XP Professional (SP1 or greater) or Microsoft Windows 2000 Professional (SP3 or greater)
- 256MB minimum system memory (512MB or greater recommended for XP)
- Networking services (required even for a standalone PC)
- CD-ROM drive for software installation
- Spare parallel port or USB port for hardware security key



Pharmagraph, 3 Lakeside Business Park, Swan Lane, Sandhurst, Berkshire, UK, GU47 9DN

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

Pharmagraph is a division of Acquisition Systems Ltd.