

# enVigil™ Lite Cleanroom Monitoring Systems

**Affordable and easy compliance  
for small aseptic production**

## Features and Benefits

### Configures a compliant monitoring system in minutes using an easy-to-use intuitive wizard

enVigil Lite Facility Monitoring Software allows you to configure a fully featured particle monitoring system in minutes using a simple, intuitive wizard. The drop down menu allows for the cleanroom class or grade to be selected for FDA cGMP or EU GMP compliance. For example, choosing "Grade A" automatically loads the pass/fail criteria in accordance with the EU GMP Annex 1.

### Monitors up to 20 locations on a single screen

enVigil Lite presents a simple and consistent user interface for controlling all MET ONE particle counters and indicating their current state. Clicking on an indicator reveals the historical data trend, alarms or tabular data for the individual counter. In addition to the individual reports, a global audit report is available showing login activity and any changes to the configuration. As a result, enVigil Lite delivers the information you need to maintain compliance without tedious configuration and documentation.

### Provides secure operation using Windows user names and passwords

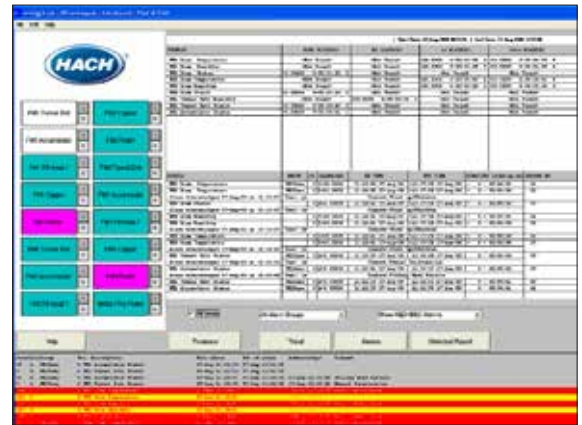
enVigil Lite is password protected and employs an automatic audit trail logging system that enables 21 CFR Part 11 compliance out of the box.

### Includes system verification documents

enVigil Lite also includes documentation templates to address the system functional design specification (DQ), as well as installation and operational acceptance testing (IQ/OQ). Using this pre-printed document set, system verification can be completed without the need to recreate the documents.

### Reporting and data export

enVigil Lite offers a clear status overview with one click access to trends, concise alarm reports and data export to Microsoft® Excel®. Reports can be printed with a single click, and include signature boxes allowing them to be used for batch sign off.



Consolidated Alarms Display



Particle Trends Display

*enVigil Lite is ideal for smaller FMS installations consisting of 20 or fewer monitoring locations. The primary advantage of enVigil Lite is that it provides a turnkey software solution without requiring expensive customization.*

## Specifications

### System Description

- Continuous measurement of particle counts
- Remote start/stop of particle counters
- Vacuum control
- Alarm output to indicator devices
- Audit trail recording
- Secure user interface
- Alarm indication via colour change on the operator screen
- Alarm acknowledgment via operator screen
- Trend views of live and historic data
- Tabular reports of historic data
- Reconciled alarm reports
- Compliance with 21 CFR part 11 with respect to electronic records
- Supports up to 160 inputs for Analog/Digital sensors (differential pressure, temperature, air velocity, etc.)

### Languages

- French
- German
- Spanish
- Italian

### Supported Hardware

- Up to 20 each MET ONE 6000/7000/3400 series particle counters
- Up to 20 alarm indicators, alarm beacons and/or alarm displays
- 1 single, or up to 20 individual vacuum controllers
- Supports modules for analog and digital inputs and outputs in several configurations

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For configurations requiring more than 20 counters, contact your local Hach sales representatives

### Computer System Requirements

- Configured as standalone system or network supported
- Microsoft Windows XP® or Vista® OS
- Monitor resolution 1280 x 800 pixels
- CD-ROM drive
- USB port for security key
- Ethernet port

### Ordering Information

|              |                            |
|--------------|----------------------------|
| 200-600-7005 | Up to 5 Particle Counters  |
| 200-600-7010 | 6 to 10 Particle Counters  |
| 200-600-7015 | 11 to 15 Particle Counters |
| 200-600-7020 | 16 to 20 Particle Counters |

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Lit. No. 5246  
B10 Printed in USA

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