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Safeguarding Particle Counters During VHP Purge Decontamination of Isolators

Synopsis

A variety of methods and antimicrobial agents have been used for the periodic decontamination of critical environments. Conventional wipe down techniques with antimicrobial products can prove time consuming and labour intensive. That's why the industry has moved towards more effective methods and increasingly adopting automated decontamination procedures such as sporicidal gassing using Vapourised Hydrogen Peroxide (VHP). VHP is the vapour form of Hydrogen Peroxide (H₂O₂).

VHP is now widely used to inactivate bio-contamination on surfaces in GMP controlled areas within isolators, RABS, rooms and other critical environments. This process is widely accepted in the market as an environmentally friendly alternative to formaldehyde. But VHP is a powerful oxidizing agent and if drawn into a particle counter can damage or contaminate the instrument's optics. Damage due to VHP exposure can cause

false particle counts, calibration errors or a total particle counter malfunction.

Particle counter protection

Deploying this type of decontamination process presents a challenge to providers of environmental monitoring systems, especially relating to the protection of the Airborne Particle Counter (APC). An APC, specifically its sampling point, must be installed close to the point of interest within the environment being monitored, normally no further than 30cm from the work area. However, these are highly sensitive instruments with optics and sensors that can be damaged if continually exposed to highly chemically reactive products such as VHP.

FMS does supply a remote airborne particle counter in the form of the TSI AeroTrak+ 7000 featuring a VHP-resistant sensor that protects against accidental low-levels of VHP exposure



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To overcome this, FMS engineers developed a high-specification, 3-way isolation valve. FMS consulted with customers and suppliers of decontamination products to provide this robust and reliable solution. It brings together high-end valve hardware, cleanroom applications expertise, installation and commissioning services, and application support as a complete packaged customer solution.

How the FMS solution works

The 3-way isolation valve allows the particle counter to be fully protected from contamination during the VHP gassing cycle. The valve can be in one of two positions: in 'sample' mode that provides a straight through path that minimises particle loss, allowing the APC to monitor the isolator or room; or in 'safe' mode, where the diverter valve mechanism is actuated to open a channel to the VHP cleaning agent while completely shielding the sensitive optics and components of the APC. In its safe position, the flow can be maintained to sterilise the sample probe by dropping to low pressure.

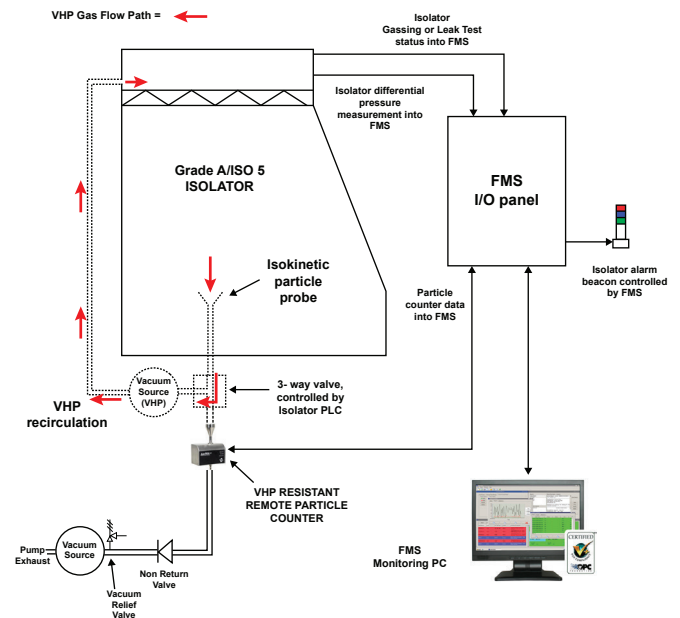
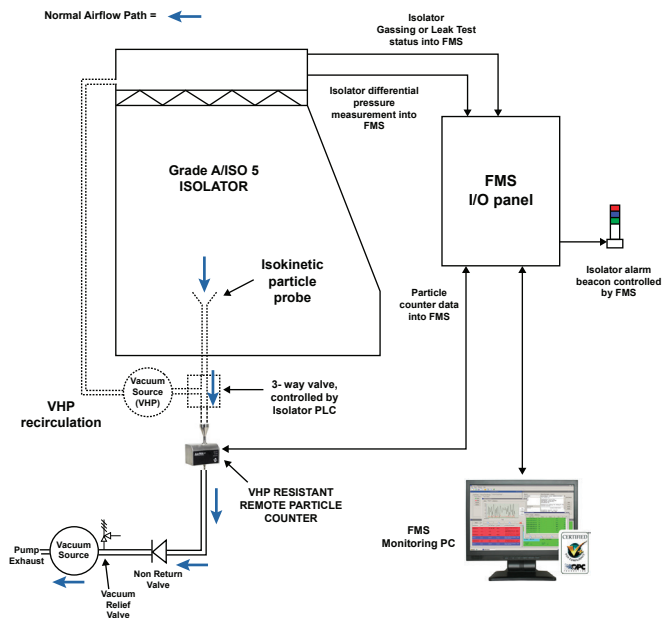
for a short time. However, the counter is not designed to resist high concentrations of VHP passing through the optics, which will quickly degrade and ultimately damage the sensor.

One reason to avoid such exposure is attributed to the wide variations in the purity of the Hydrogen Peroxide solution that's vapourised. Perhaps more critical is the likelihood of changes in pressure, temperature and humidity the particle counter optics may encounter between the VHP supply and the zone being decontaminated, which may cause the gas to condense excessively and leave residues. Ultimately, this will result in the sensor requiring removal for cleaning or possible replacement, which negates the advantage of a VHP-resistant sensor.

With the remote APC physically positioned outside the isolator, the process uses sample tubing from the isokinetic particle probe to the APC sensor. Such tubing is typically one metre in length but can be greater, depending on the equipment configuration. The Gassing Valve is designed to sit in that pathway but immediately adjacent to the remote particle counter. This means that when the valve is actuated to allow the gassing cycle to commence, the entire sample flow path comprising the inside surfaces of the isokinetic probe and the sample tubing will also be fully decontaminated by the VHP as far as the valve hardware, before the gas is recovered or recirculated back to the isolator.

Normal Air Flow

VHP Gas Flow



The Gassing Valve mechanism is available in electrically or pneumatically actuated variants. The valve hardware is identical in both cases.

Positional feedback

Position sensor switches are built into the valve mechanism. These are robust mechanical switches for maximum reliability. The switches provide feedback via volt-free contacts to confirm that the valve is positioned in 'sample' or 'safe' mode. This reliable feedback can be used by an FMS system or by the PLC fitted to the isolator to automate the decontamination process. The Gassing Valve can operate as a stand-alone mechanism. It does not need to be used with FMS software.

Installation configuration

The FMS Gassing Valve solution is more than simply the hardware mechanism. Where needed, the package includes system design, installation

and equipment configuration expertise. In some decontamination configurations observed, for example, there can be a risk associated with air flowing back towards the critical area should the particle counter vacuum source cease to function. FMS ensures that the system features non-return valves installed in the correct location in the vacuum source tubing as a control measure to eliminate this risk.

Failsafe

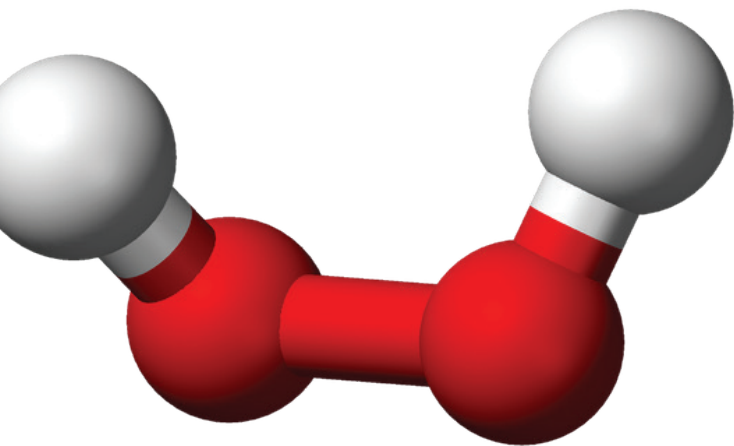
In the event of power loss for electrically operated variants, or air pressure loss for pneumatically operated variants, the valve mechanism will default to its 'safe' mode.



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About VHP gassing

VHP sporicidal-gassing decontamination takes advantage of a free radical reaction to kill microorganisms on surfaces. Free radicals are molecules or atoms that possess an unpaired electron. Electrons don't like to be unpaired, so they steal an electron from another molecule or atom in order to become paired. As stated earlier, this makes VHP highly chemically reactive towards other substances, but is also what makes it an extremely effective biocide.



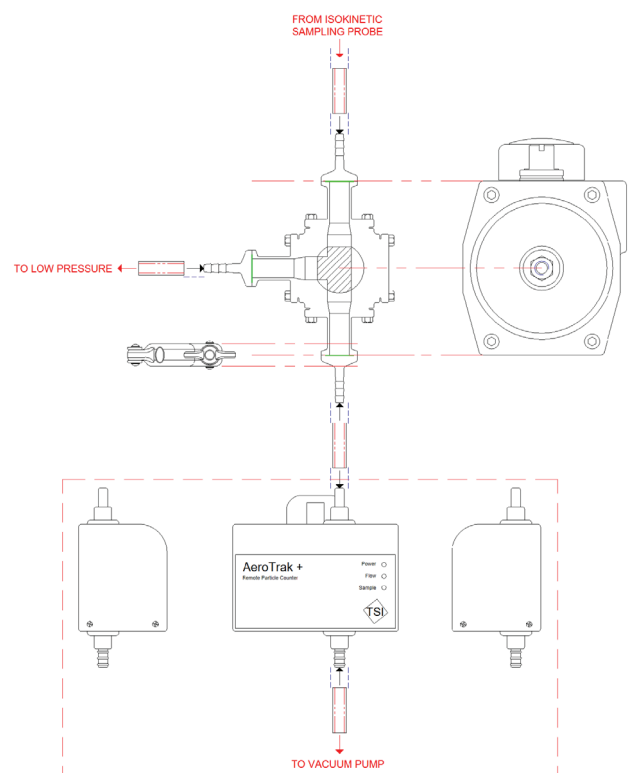
VHP is circulated or passed through the area at a programmed concentration and for a specified period. This is the gassing cycle. VHP gassing cycles are carefully optimised to achieve a kill or reduction to six orders of magnitude (1,000,000:1) of predetermined numbers of microbes on Biological Indicators (BIs), determined during validation studies.

Gassing cycle times and concentrations vary according to factors such as overall isolator volume, surface area, the microbiological flora, and the temperature and relative humidity of the environment being decontaminated. Typical VHP concentrations range from 140ppm to

1400ppm, while 75ppm is considered an immediate threat to life or health in humans. The permissible occupational exposure limit (OEL) is just 1ppm for 8 hours. Cycle times can be a few seconds or minutes to several hours in length.

Gassing Valve specification overview

The valve uses industry standard tri-clover fitting to eliminate the need for tools to remove and reinstall the valve assembly for maintenance. FMS engineers selected a superior, industrial-grade valve assembly featuring high purity hardware, comprising primarily chemically inert 316 stainless steel construction, PTFE (Teflon) coating for all wetted interior surfaces to prevent the shedding of any particles, and Viton (FKM synthetic rubber and fluoropolymer elastomer) materials in its seals. The FMS 3-way isolating valve is supplied assembled and functionally tested.





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Gassing Valve Technical Spec.

½" Full bore 3-way ball valve	AP3 spring return (10 springs) for pneumatic actuated variant
Rotated T-port configuration	5 bar recommended air supply
CF8M stainless steel body construction	APL-210N valve position monitor with 2 limit switches
Cavity filled PTFE seats	Enclosure rated to IP67
800psi pressure rating	Beacon indicator & plastic dome to suit 3-way T-port valves
Tri-clamp end connections	

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