



MET ONE Particle Sensors Resistance to Vaporous Hydrogen Peroxide (VHP)



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The use of Vaporous Hydrogen Peroxide (VHP) is commonplace in the pharmaceutical industry for disinfecting sterile manufacturing cores. Since VHP is a strong oxidizing agent it can be damaging to certain internal components in optically based air particle counting instruments. The MET ONE series of air particle counters have been specifically designed to utilize materials that will not be damaged by exposure to VHP. The testing outlined in this paper demonstrates the resistance of these components and stability of the instrument over an extended period of exposure time.

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Introduction

Pharmaceutical manufacturers often require an aseptic production environment to minimize the presence of microbes and their potential contamination of the manufactured product. One common method of disinfection is the use of vaporous hydrogen peroxide (VHP). VHP is a strong oxidizer and excellent disinfectant. A typical clean room disinfection cycle consists of a 3% VHP exposure for 45 minutes.

There is a concern that the use of VHP in the presence of optical particle counters can cause damage. When introduced into an air particle counter, VHP could bleach the internal surfaces of the sensor and cause corrosion of the mirror surface, which would increase reflections within the sensor. This in turn, can cause false particle counts.

To better understand the effects of VHP on the sensor in Met One air particle counters, testing was conducted on a Met One 4803 remote air counter sensor body, components and mirror. This testing included the following:

Internal Sensor Surfaces

- The patented Optical black coating on the sensor body and internal optical components
- Mirror coated with gold plating
- Other components in the sample flow path (injector nozzle, differential pressure sensor interface, critical orifice, exhaust fitting)

Test Method: Sensor

- Prior to testing the sensor was calibrated, and the threshold voltages for 0.3 μm and 0.5 μm sized particles were measured.
- A clean vessel was partially filled with an aqueous solution of 30% Hydrogen Peroxide and deionized water. The VHP concentration was measured using a Gastec Dosimeter tube at 5-6%.
- The test sensor was placed outside the vessel and connected by tubing to an isokinetic probe placed 6 mm from the surface of the aqueous solution.
- After 72 hours of continuous exposure, the sensor was checked to determine sensor diagnostic stability.
- The sensor was then exposed again for 744 hours prior to final evaluation. This exposure was equivalent to 1,090 disinfection cycles of 45 minutes duration.

Test Method: Mirror

- In addition to the vaporous hydrogen peroxide test above, the mirror was placed in an aqueous solution with 30% Hydrogen Peroxide.
- The mirror was left submerged in this solution for 600 hours.
- After 25 days, the mirror was removed from the solution and visually examined.
- After visual examination, the mirrors were reinstalled in the sensor to determine if changes in calibration occurred.

Results

Sensor

No significant difference in the sensor's ability to accurately count 0.3 μm and 0.5 μm -sized particles was observed. This is depicted in the consistency in calibration voltage and noise over time in Figure 1.

Test Runtime	Calibration Voltage	Noise	0.3 Micron Peak Voltage	0.5 Micron Peak Voltage
Pre-test	1	17 mV	34.65 mV	335.26 mV
72 hours	0.998	17 mV	34.65 mV	334.52 mV
192 hours	0.950	17 mV	34.40 mV	337.45 mV
816 hours	0.952	17 mV	34.65 mV	335.01 mV

Figure 1 – Sensor performance over time

Mirror

- Figures 2 & 3 (below) are photographs of the mirror after 600 hours direct exposure to the 30% aqueous solution of hydrogen peroxide.
- Negligible degradation can be observed on the reflective surface of the mirror.
- Some degradation can be observed on the edges, which are not functional optical surfaces.



Figure 2 - Mirror condition over time



Figure 3 - Mirror condition over time

Applicability of testing to other MET ONE instruments

This testing was conducted on the optical and flow path components of a Met One 4803 remote air particle counter. The materials that make up these components are identical in all Met One air particle counting instruments. Although formal testing has not been performed on all the models below Beckman Coulter/MET ONE are confident in the VHP tolerance of these instruments and offer the same warranty against damage as the instrument tested.

- MET ONE 4000 series remote air particle counters
- MET ONE 3400 series portable air particle counters
- MET ONE 6000 and 6000P series remote air particle counters
- MET ONE 7000 series remote air particle counters

Conclusion

The critical sensor components found in the above MET ONE products can be characterized as VHP-resistant.

Best Known Practices

Although proven that VHP will not damage the internal components of the MET ONE air particle counting instrument, it is still possible to contaminate the optics to the point of requiring service to become operational. Beckman Coulter recommends that the sample inlet of the instrument be capped during sterilization processes, as neither the US FDA, nor EU GMP requires sampling during disinfection. In situations where this is impractical, MET ONE offers an instrument (the 7000 series) that utilizes a sealed 316l stainless steel enclosure and an automatic vacuum shut off valve that stops the sample flow through the instrument when sampling is ceased by the software. This is an effective method to keep VHP from contaminating the optics of the instrument.

Please note the following:

- The Met One 6015P remote and the 3400 series portable air counters include a vacuum pump, and filter that have not been tested and may be susceptible to damage by oxidizers such as VHP.
- All instruments include electrical components, which when exposed to oxidizers can corrode and be damaged. To minimize the risk of damaging the instrument, the particle counter should be placed outside the clean room with tubing extending through the wall and into the clean room. The exception to this would be the 7000 series of remote air particle counter.
- All Met One remote air particle counting instruments carry a one-year warranty. When used in the presence of VHP or other oxidizing sterilization agents, the warranty for damage to the sensor is limited to one year. Corrosion of the electronic components due to exposure to oxidizing chemicals or service (cleaning) due to contamination is not included in the warranty of any MET ONE air particle counter.

About the author

Ted Lawrence is a Global Marketing Manager for Beckman Coulter Life Sciences. In this role he manages the MET ONE product line of remotes air particle counters. He is also responsible for Beckman Coulter Particle Counting and Characterization Lifecycle Management and MET ONE Systems Solutions products. Ted has 20 years experience in applications development and marketing for the particle counting industry serving the electronics, pharmaceutical, aerospace and industrial markets.

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