

Written By:
Mike Hopfe, Air Product Manager - Hach Ultra

Met One Sensors Resistant to Vaporous Hydrogen Peroxide (VHP)

Background

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 affects of VHP on the sensor in Met One remote air particle counters, Hach Ultra conducted testing on the sensor body, components and mirror. This testing included the following:

Internal Sensor Surfaces

- The Optical black coating patented by Hach Ultra on the sensor body and internal optical components
- Mirror coated with gold plating

Test Method: Sensor

- Prior to testing the sensor was calibrated, and the threshold voltages for 0.3 and 0.5 micron 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 to be 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 a like comparison with the testing performed by Particle Measuring Systems (PMS).
- The sensors were 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 and 0.5 µm-sized particles was observed. This is depicted in the consistency in calibration voltage and noise over time in Figure 1, Appendix A.

Mirror

- Figures (2-3, Appendix A) 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.

Comparison of Testing Conducted by PMS

The exposure time for the testing conducted by Hach Ultra was more rigorous than the testing completed by PMS. Comparisons are included in Figure 4, Appendix A.

Conclusion

The critical sensor components found in the following Hach Ultra products can be characterized as VHP-resistant: Met One 45XX, 48XX, 49XX, 58XX, 59XX and 23XX.

Hach Ultra recommends that the product intake be capped during sterilization practices, as neither the US FDA, nor EU GMP requires sampling during disinfection.

Caution

Please note the following:

- The Met One 23XX includes a pump, filter and other components 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 could be placed outside the clean room with tubing extending through the wall and into the clean room.
- All Met One remote air particle counting instruments carry a one-year warranty with the exception of the Met One 4500, which carries a two-year warranty. When used in the presence of VHP or other oxidizing sterilization agents, the warranty for the sensor is limited to one year. Corrosion of the electronic components due to exposure to oxidizing chemicals is not included in the warranty of any air particle counter.

Appendix A

STANDARD OPTICAL BLACK COATING

DATE	CAL VOLTAGE (VOLTS)	NOISE	0.3 MICRON PEAK VOLTAGE	0.5 MICRON PEAK VOLTAGE
21-APR-2006	1	17	34.65 MV	335.26 MV
25-APR-2006	0.998	17	34.65 MV	334.52 MV
1-MAY-2006	0.95	17	34.40 MV	337.45 MV
31-MAY-2006	0.952	17	34.65 MV	335.01 MV

Figure 1



Figure 2



Figure 3

		Hach Ultra Testing	PMS Testing
Sensor	Simulated VHP Disinfection Cycles	1,090	96
Mirror	Submergence in 30% Aqueous H ₂ O ₂ (Days)	25	2.67

Figure 4

Global Headquarters

6, route de Compois
 C.P. 212, CH-1222 Vesenaz
 Geneva, Switzerland
 Tel: 41 22 855 91 00 / Fax: 41 22 855 91 99

Americas Headquarters

481 California Avenue
 Grants Pass, Oregon 97526 USA
 Toll Free 1 800 866 7889
 Tel: 1 541 472 6500 / Fax: 1 541 479 3057

www.hachultra.com

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