

TSI® AEROTRAK® REMOTE WITH PUMP RESISTANCE TO VAPORIZED HYDROGEN PEROXIDE (VHP)

APPLICATION NOTE CC-109 (US)

Introduction

A widely used method to inactivate bio-contamination on surfaces in GMP controlled areas is sporicidal gassing using vaporized hydrogen peroxide (VHP). This decontamination process uses a free radical reaction to kill microorganisms on surfaces. VHP is a powerful oxidizing agent and if drawn into a particle counter it can potentially damage or contaminate the instrument optics. This damage can result in false particle counts, calibration errors or a complete particle counter malfunction.

To address this issue, TSI offers a range of VHP resistant AeroTrak® Remote Particle Counters with integrated pumps that have VHP resistant coatings and materials. This application note details the tests TSI conducted to prove that the performance of the particle counter is not affected when inadvertently exposed to VHP.

The model numbers are listed below:

- AeroTrak Remote Particle Counter 6510 0.5 µm, 0.7 µm, 1 µm, and 5 µm @ 1CFM
- AeroTrak Remote Particle Counter 6310 0.3 µm, 0.5 µm, 0.7 µm, and 1 µm @ 1CFM

Test Method

To test particle counter resistance to VHP, TSI exposed the entire particle counter optics and flow path components to real world VHP standard gassing cycles. TSI contracted an industry leading supplier of VHP gassing solutions, Bioquell, to independently conduct the testing.

This testing applies to both TSI VHP-resistant remote particle counter with pump models, as they utilize the same key sensor and flow path components. Furthermore, to ensure rigorous testing, nonstandard AeroTrak portables models 9500 (0.5 µm @ 100 L/min) and 9350 (0.3 µm @ 50 L/min) with identical enhanced VHP-resistant sensor and flow path components were tested. These particle counters have high sample flow rates and are more sensitive to optical sensor component damage as a result of VHP exposure. Prior to testing, the instruments were calibrated in accordance with the ISO 21501-4 calibration standard.

The AeroTrak Portable Particle Counters and power supplies were placed into an isolator and VHP sterilized using a Bioquell Clarus VHP generator. During gassing the particle counters were powered up and set to sample continuously to simulate sensor and flow path exposure during a VHP gassing cycle.



The efficacy of the gassing cycle was validated by Bioquell using Biological Indicators achieving a 6 log reduction (kill) in the test isolator. Any possible damage to components due to VHP exposure will have been exhibited within fifteen VHP cycles. For this reason a total of fifteen VHP gassing cycles were performed:

The VHP gassing cycle is defined below:

- Vaporized 35% peroxide solution
- 20 minute ramp-up to VHP saturated state
- 10 minute hold at saturated state -1000 PPM
- ≈ 70 minute aeration to remove VHP

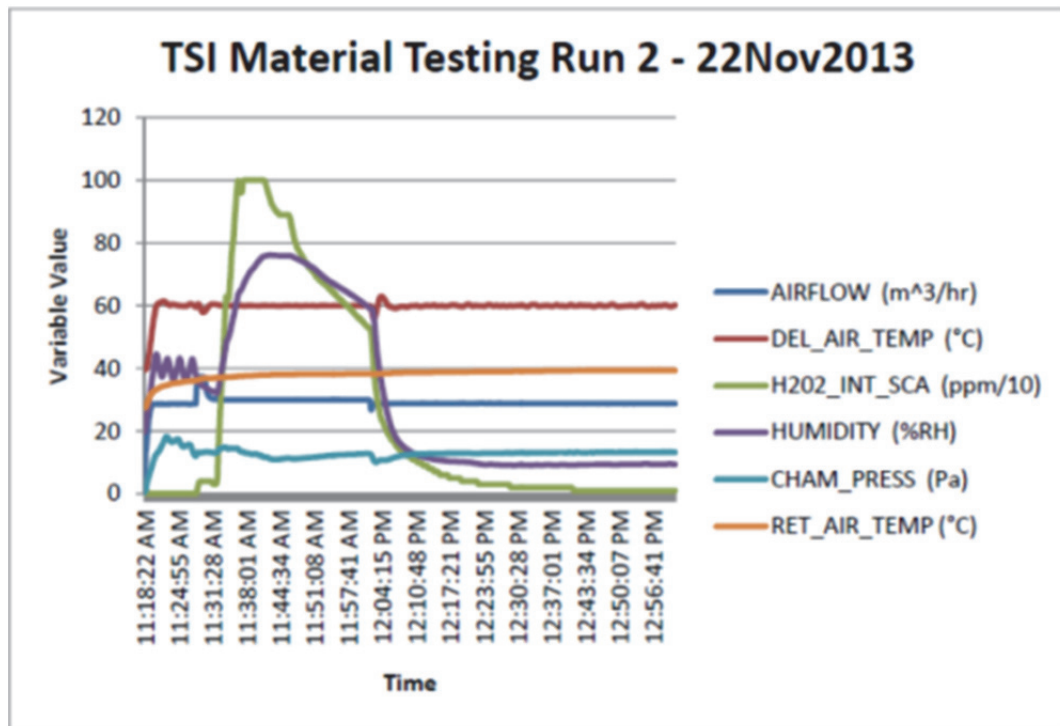


Figure 1: Left to right: The VHP gassing cycle

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Results

Calibration

After the VHP gassing cycles were completed the particle counter calibrations were checked per ISO 21501-4. In each case the calibration was found to easily meet ISO 21501-4 requirements. See calibration data below, *As Left* is before testing and *As Found* is post testing data.

AeroTrak Model 9500-01

Counting Efficiency			
Size	Allowable Range	As Left	As Found
0.5 µm	50% ± 10	50%	48%
1.0 µm	100% ± 10	94%	100%

Size Error			
Channel	Nominal Size	Size Error*	Limit
1	0.5 µm	0.0%	±10%
5	5.0 µm	0.0%	±10%

* compared to As Left

False Count (Concentration)		
Upper Limit	As Left	As Found
24.0/m ³	0.2/m ³	0.5/m ³

AeroTrak Model 9350-02

Counting Efficiency			
Size	Allowable Range	As Left	As Found
0.3 µm	50% ± 10	52%	52%
0.5 µm	100% ± 10	95%	94%

Size Error			
Channel	Nominal Size	Size Error*	Limit
1	0.3 µm	0.0%	±10%
2	0.5 µm	0.0%	±10%
6	5.0 µm	-2.7%	±10%

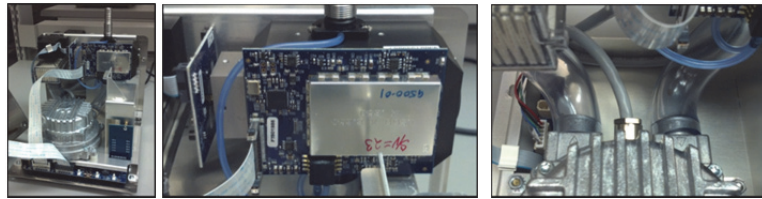
* compared to As Left

False Count (Concentration)		
Upper Limit	As Left	As Found
24.0/m ³	0.0/m ³	0.33/m ³

Physical Inspection

Internal Components

The optics block, sample inlet, tubing, all electrical boards, connectors and vacuum pump show no visual damage following VHP exposure.



Optics Assembly

Left to right: mirror, inlet and outlet fittings and beam dump show no visual damage following VHP exposure.



Conclusion

The TSI AeroTrak Remote Particle Counter with Pump sensor meets calibration requirements as defined in ISO 21501-4 following real world VHP gassing cycles. The AeroTrak Remote Particle Counter with Pump sensors and flow path components were found to be resistant to VHP exposure and are suitable for use in environments that are sanitized using Vaporized Hydrogen Peroxide in life science applications.



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