

TSI® AEROTRAK® REMOTE PARTICLE COUNTER RESISTANCE TO VAPORIZED HYDROGEN PEROXIDE (VHP)

APPLICATION NOTE CC-108 (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 damage or contaminate the instrument optics. This damage can result in false particle counts, calibration errors or a complete particle counter malfunction.

To address the issue, TSI offers a range of VHP resistant remote particle counters with VHP resistant coatings and materials. The model numbers are listed below:

- AeroTrak Remote 7510-01FV 0.5 µm, 5 µm @ 1 CFM
- AeroTrak Remote 7510-02FV 0.5 µm, 0.7 µm, 1 µm and 5 µm @ 1 CFM
- AeroTrak Remote 7510-A2FV 0.5 µm, 0.7 µm, 1 µm and 5 µm @ 1 CFM, 4-20 mA

This application note details the tests TSI conducted to prove that the performance of the particle counter is not affected when exposed to VHP.

Test Method

To test particle counter resistance to VHP, TSI exposed the entire remote particle counter including optics, enclosures and internal electronic components to real world VHP validated gassing cycles. TSI contracted an industry leading supplier of VHP gassing solutions, Bioquell, to independently conduct the testing.

This testing applies across the entire range of TSI VHP resistant remote particle counter models. All sensors utilize the same key components including optics, internal electronics, tubing and enclosures. Furthermore, to ensure that testing be as rigorous as possible, TSI arranged for an AeroTrak Remote Particle Counter Model 7310-01F (0.3 µm and 0.5 µm @ 1 CFM) to be tested. This particle counter has a 0.3 µm first size channel and is more sensitive to optical component damage as a result of exposure to VHP. Prior to testing, the AeroTrak 7310-01F was calibrated in accordance with the ISO 21501-4 optical particle counter calibration standard.

The AeroTrak Remote Particle Counter was placed into an isolator and VHP sterilized using a Bioquell Clarus VHP generator. During gassing the remote particle counter flow rate was set to 3 L/min to simulate accidental optics 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- see figure 2. 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 cycle is defined in Figure 1 below:

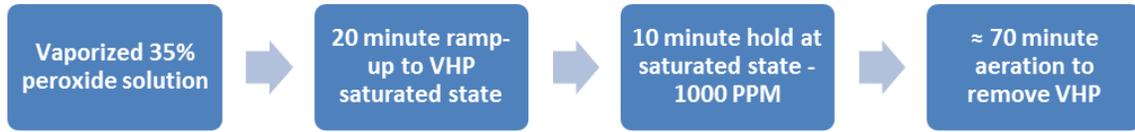


Figure 1: Bioquell VHP Gassing Cycle

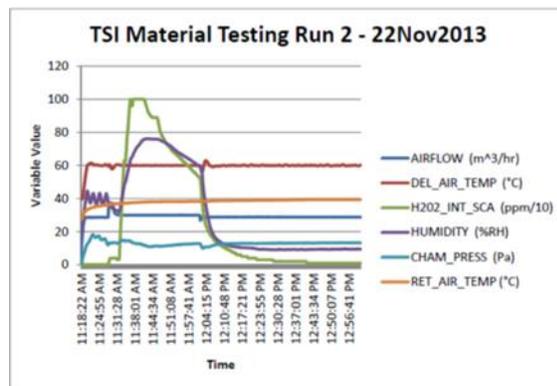


Figure 2: Left to right: The validated gassing cycle and the sensor under test

Results

Calibration

After the VHP gassing cycles were completed, the particle counter calibration was verified per ISO 21501-4. Unit 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 7310-01F

| Counting Efficiency | | | |
|---------------------|-----------------|---------|----------|
| Size | Allowable Range | As Left | As Found |
| 0.3 μm | 50% ± 10 | 50% | 56% |
| 0.5 μm | 100% ± 10 | 99% | 97% |

| Size Error | | | |
|------------|--------------|-------------|-------|
| Channel | Nominal Size | Size Error* | Limit |
| 1 | 0.3 μm | 2.5% | ±10% |
| 2 | 0.5 μm | 0.7% | ±10% |

* compared to *As Left*

| False Count (Concentration) | | |
|-----------------------------|----------------------|-----------------------|
| Upper Limit | As Left | As Found |
| 24.0 / m ³ | 0.0 / m ³ | 3.53 / m ³ |

Physical Inspection

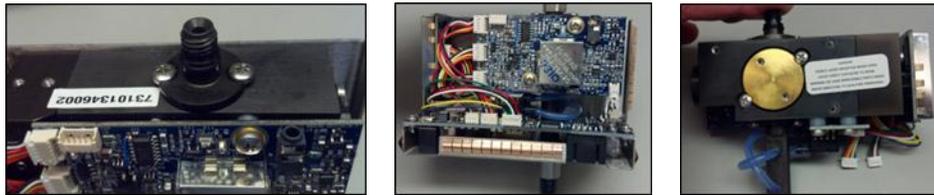
External Case

The outer case shows no visual damage following VHP exposure.



Internal Components

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



Optics Assembly

The mirror and inlet and outlet fittings show no visual damage following VHP exposure.



Conclusion

The TSI AeroTrak Remote –VHP series Particle Counters meets calibration requirements as defined in ISO 21501-4 following exposure to validated VHP gassing cycles. These Particle Counters 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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