PARTICLE MEASURING SYSTEMS
www.pmeasuring.com
5475 Airport Boulevard, Boulder, Colorado 80301-2339
303.443.7100 1.800.238.1801 Fax: 303.546.7380
Customer Service Center 1.877.475.3317
Instrument Service 1.800.557.6363

Airnet® 510 XR Resilience to Vaporized Hydrogen Peroxide

Pharmaceutical manufacturing is performed in batches; between each batch the filling suite is cleaned and sterilized ready for the next batch. This cleaning is done using either hyperchlorite bleaches or alcohol based solvents. A move within the pharmaceutical industry has been toward isolator technologies and enclosed filling lines. A common sterilizing agent used in these closed environments is Vaporized Hydrogen Peroxide (VHP), a strong oxidizing agent. If significant VHP is drawn into most particle counters, it can damage the counter and cause it to malfunction.

Particle Measuring Systems has addressed this issue by coating allcritical components with a stable PFA Teflon® layer.

Testing was done to verify the sensor's resistance to VHP, and to validate its particle counting performance. The baseline instrument was a standard Airnet® 510 that was exposed to the same environment as the unit under test.

Test Method

The two Airnet-510 XR sensors under test were placed outside of an enclosed environment that contained the hydrogen peroxide source.

The tests were designed to prove that the internal optics (NOT the electronic components of the particle counter) withstands oxidation. Bell housing was used to contain the hydrogen peroxide within a local environment. The two particle counters were connected to a vacuum source capable of drawing a sample of 28.3 l/min (1 cfm) through each sensor.

The isokinetic probe from each of the sensors was placed into the test beaker, approximately 6 mm (1/4 inch) above the surface of a solution containing 25% hydrogen peroxide. Thus, the reduced vapor pressure (caused by the vacuum from the sample tubing) would cause the peroxide to be released from the surface of the solution.

The sensors were calibrated prior to the start of the tests and the baseline electronic noise levels measured. After each 24-hour period of testing, the noise levels were measured, and a full calibration was performed at the end of the test period.

Test Results

The tests were run on these sensors, continuously exposing them to high levels of peroxide vapor for over 72 hours. The Teflon-coated sensor used the original aluminum optic block, which allowed the sensor to meet the original CE requirements as it maintains the metal conductivity of the original design. Tests proving the durability of the mirrors had already been performed by a customer, where they immersed the mirrors into a beaker of 30% peroxide for 64 hours with no significant detrimental effect.

The following photographs show the bleaching effect on the non-Teflon-coated elements of the optics chamber, and the same view of the Teflon-coated Airnet-510 XR sensor. Notice the VHP has not visibly affected the chamber of the Airnet-510 XR.

Figure 1. shows that the original black anodized internal components became bleached when exposed to hydrogen peroxide vapor; however the optical chamber retained its black non-reflective properties. Figure 2 shows that in the Teflon-coated chamber all internal components and the optical chamber retain the original optical properties, and are not bleached following exposure to hydrogen peroxide vapor.

Summary

Coating the optical chamber and internal components with Teflon demonstrated the Airnet 510 XR sensor's ability to withstand chemical attack by vaporized hydrogen peroxide without affecting the sensor's ability to count particles at 0.5 and 5.0 mm. The new Airnet-510 XR is now capable of monitoring particles in the isolators where VHP is used as a sterilizing agent.

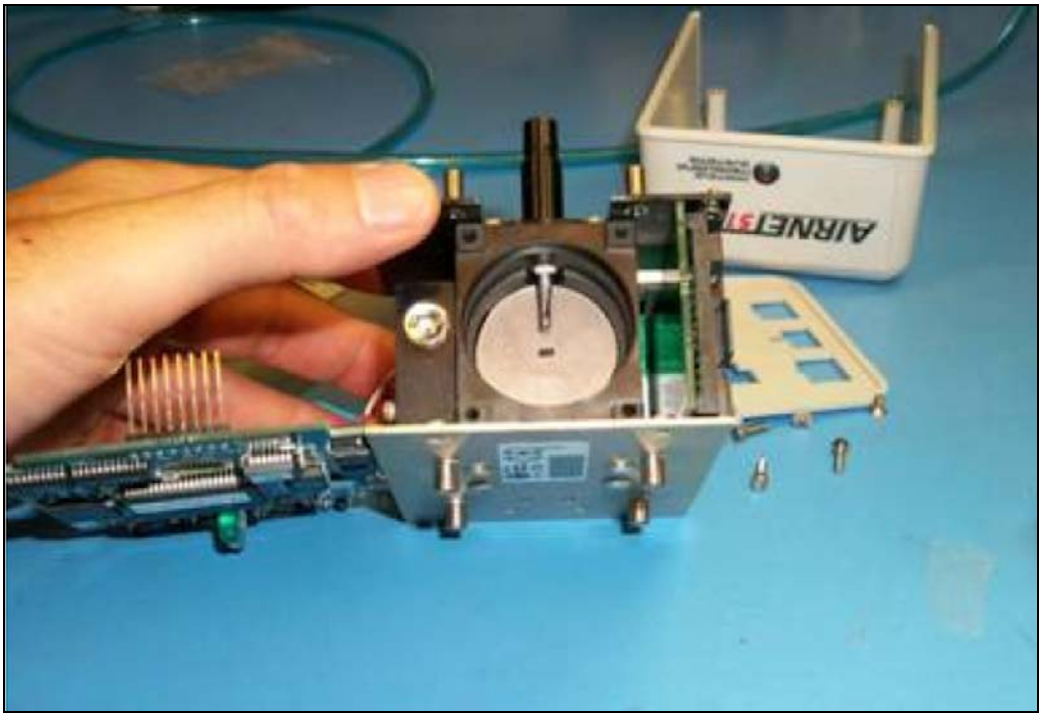

Figure 1. Non-Teflon-coated Airnet-510 XR internal components.

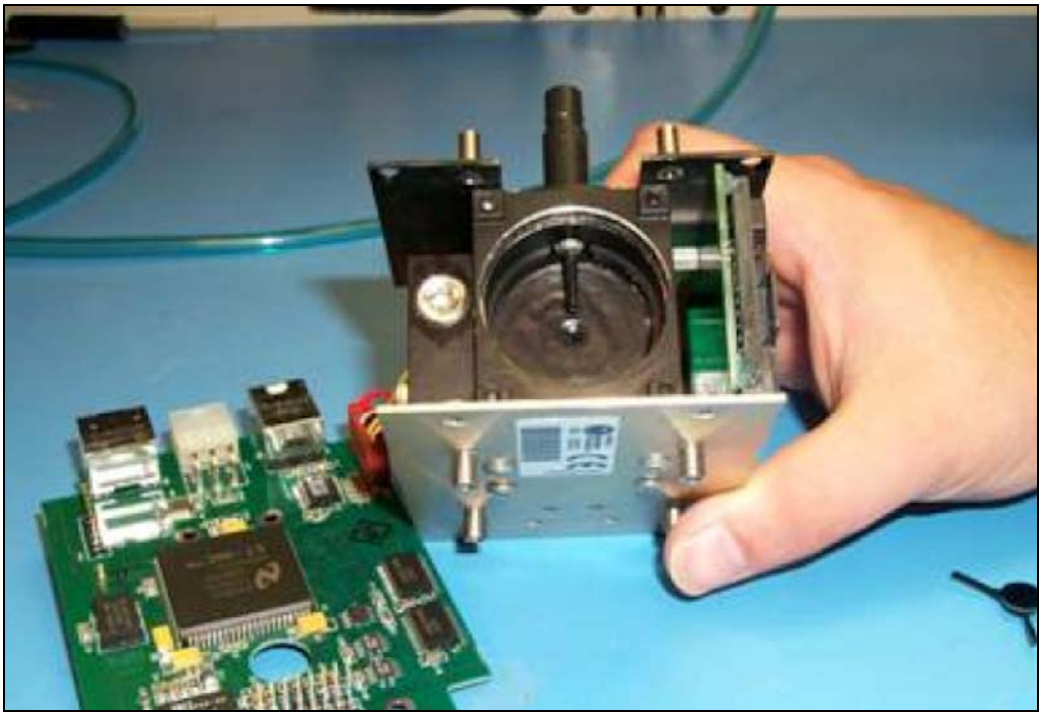

Figure 2. Teflon-coated Airnet-510 XR optics chamber and internal components.
