

# Lighthouse Apex Particle Counters compatibility with Vaporized Hydrogen Peroxide

by Jason Kelly

## Lighthouse Apex Particle Counters compatibility with Vaporized Hydrogen Peroxide (VHP), cleanroom wipe down solutions and our guarantee of Data Integrity.

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### What is Vaporized Hydrogen Peroxide (VHP)?

VHP is a vapor from hydrogen peroxide H<sub>2</sub>O<sub>2</sub>. VHP is produced from a solution of liquid H<sub>2</sub>O<sub>2</sub> and water, by generators specifically designed for the purpose. These generators initially dehumidify the ambient air, then produce VHP by passing aqueous hydrogen peroxide over a vaporizer, and circulate the vapor at a programmed concentration in the air. VHP systems can be used to decontaminate facilities, isolators or small enclosures and pharmaceutical companies generally use VHP in between batches. VHP has been proven to be easily dispersed as it is in a vapor form and has been shown to have an effective 6-Log reduction ratio. To look at in terms of reduction of the CFUs, a reduction of

- 1 Log (90%) reduces CFUs on a test area from 1,000,000 CFUs to 100,000,
- 2 Log (99%) reduces 1,000,000 to 10,000 CFU's,
- 3 Log (99.9%) from 1,000,000 to 1,000 CFU's
- 6 Log reducing 1,000,000 down to 1 CFU

Therefore with its 6-Log reduction ratio VHP is widely used in Hospitals and Cleanrooms to assist in keeping harmful bio-burden contamination at bay.



Fig 1. ApexZ Portable Particle Counters

## **VHP oxidation effects**

VHP is a strong oxidizer as it will have a chemical reaction with most materials it is in contact with.

Some grades of stainless steel have been shown to oxidize with H<sub>2</sub>O<sub>2</sub> turning it a light brownish color, the same can be seen with aluminum air sampler heads that turn a greenish color. Therefore material compatibility is very important especially when bringing equipment into a cleanroom.

## **How can VHP effect a Particle Counter?**

As VHP disperses very effectively as a vapor this vapor can get almost everywhere as it was designed to do just that as it deposits on surfaces. At Lighthouse Worldwide Solutions we have tested and designed our particle counters to be VHP resistant externally and internally. Our Apex range come as standard with VHP resistance and a 3 year warranty based on a non-condensing VHP process.

### On the outside - Particle Counter Enclosure

Apex Z portable particle counter has a polycarbonate sealed enclosure which was designed specifically to meet the pharmaceutical industry requirements on enclosure wipe down. Making it very durable for cleanroom wipe downs and VHP exposure. The design of the ApexZ enables an easy wipe down with a sealed enclosure and sealed communication ports and power outlets. Without any open crevices where particles and contamination can build up users can be assured the ApexZ is one of the cleanest particle counters on the market.

### On the inside -Particle Counter

With the high grade sealing technology used in Lighthouse Particle Counter designs the probability of VHP finding its way into the inner workings of our particle counters is extremely low. VHP will eventually corrode many surfaces it touches and our seals can be tested and replaced easily during routine service of the instruments. Protecting the insides of a particle counter is very important and needs a lot of consideration in the design. Circuit boards and other sensitive electronics are all susceptible to corrosion. Luckily the Apex range of particle counters have been designed with that in mind and are still the latest generation on the market with this added protection designed into the structure preventing any ingress inside the main enclosure.

### The Apex Flow Path

The flow path is the physical path a sample of air would pass through the particle counter sensor as particles in the sample make their way through the laser and optics to be counted and finally exhausted from the sensor. Although there is no FDA or GMP requirement to run a particle counter through a VHP cycle some customer SOP's require all processes to be fully decontaminated. Therefore Lighthouse Worldwide Solutions when designing the next generation particle counters made sure that the sensor would not be compromised and data integrity would be intact. Sensor Self-Diagnostics were built in to detect sensor contamination and if contamination was present a service alarm would be activated. Service reports on sensors used in the field which have VHP run through the flow path all have indicated no significant issues and calibration as found data has remained positive and no out of tolerances were observed as long as there has been no VHP condensing and the VHP process has been validated thoroughly by the VHP vendor.

## Testing Summary and Overview for Chemical Compatibility and exposure H2O2.

The ApexZ portable particle counters is used for monitoring and certification applications in cleanrooms are made up of a polycarbonate enclosure material have other enclosure materials which were all submerged in the following cleaning solutions;

- Sodium Hypochlorite (Bleach) 8.25%
- Isopropyl Alcohol 70%
- Hydrogen Peroxide 35%
- Spore Klenz (from Steris) 1% H<sub>2</sub>O<sub>2</sub> and 0.08% peroxyacetic acid

The tests were conducted over a 1 week period where the outer body sample materials of the ApexZ were fully submerged in each solution. These tests were accelerated tests to keep the materials in contact with the chemicals for 1 week. However in the real world the instrument would receive a wipe down for disinfection control based on the user guidelines which could be a couple of times a day or week depending on usage.

Each day each sample material was visually inspected and the thickness of each material was checked against the starting thickness. Over the week the thickness of material did not have any significant impact and there was no discoloration observed on the material or any signs of degradation. Below are the summaries of testing completed on the enclosure parts of the ApexZ.

<b>Polycarbonate Enclosure</b> (the body of the ApexZ)	Bleach 8.25% Sodium Hypochlorite	Hydrogen Peroxide 35%	Isopropanol 70%	Spor-Klenz® Ready-to-use
Starting Thickness	0.112	0.113	0.122	0.113
After 7 days	0.115	0.113	0.124	0.116
% Deviation	2.6%	0%	1.6%	2.6%
<b>Thermoplastic Olefin</b> (Covers power jack, I/O cover and sample inlet)	Bleach 8.25% Sodium Hypochlorite	Hydrogen Peroxide 35%	Isopropanol 70%	Spor-Klenz® Ready-to-use
Starting Thickness	0.067	0.067	0.066	0.067
After 7 days	0.066	0.066	0.065	0.067
% Deviation	1.5%	1.5%	1.5%	0%
<b>Steralloy</b> (ApexZ handle)	Bleach 8.25% Sodium Hypochlorite	Hydrogen Peroxide 35%	Isopropanol 70%	Spor-Klenz® Ready-to-use
Starting Thickness	1.028	1.027	1.032	1.028
After 7 days	1.026	1.022	1.032*	1.023
% Deviation	0.2%	0.5%	0%	0.5%

**Table 1. ApexZ Enclosure Testing Results**

\* Test criteria for each material was set at a deviation of 3%. ApexZ handle was wiped down with isopropanol every day and showed no signs of swelling or discoloration during the week of wipe down testing

## What was learned from the testing and from field testing?

This testing backed up a lot of feedback from our Customers who currently use our particle counters in VHP decontamination processes and we have also seen instruments come back after flow path exposure and some with no visible effects and the “as found” calibrations had passed all tests meaning the data from the particle counters had not been compromised. Some customers after every batch flush out the particle counter with VHP and it runs through the sampling flow path. From observations over the last couple of years we have found no failures on calibrations where VHP has been exposed through the flow path or evidence of oxidation internally if the VHP does not condense or if there are no physical constraints like bypass valves that collect the VHP residue and dump it into the sensor when the valve is opened up to allow normal sampling activities resume.

Lighthouse we do not actively encourage this practice and we have seen issues with bad bypass check valve designs where VHP has condensed and as soon as the bypass valves open the condensed liquid is pulled into the sensor and deposits onto mirrors and in this situation we have seen a cloudy staining of the mirrors and a trigger of the sensor service light. Upon inspection we find that the sensor fails as found calibration and when the sensor is stripped down we can clearly see the contamination.

Example of a contaminated mirror with VHP condensed and stained on the surface. Unless the process has been properly validated to ensure no condensing occurs then our recommendation is to cap the sensor and switch off the vacuum during the decontamination process.

However we have seen if the process is properly validated to ensure no condensing occurs and the VHP vapor disperses in the flow stream then data integrity remains intact.

We have had confirmation of this with independent studies which also looked at pre and post calibration data and verified that the sterilization process did not cause any “bad data” and there were no visible signs of any oxidation.



## Conclusions

The ApexZ enclosure materials and flow path have all been tested with cleaning solutions and the flow path has been exposed to VHP. The tests conducted on the enclosure verify that the materials are not affected by any oxidation or swelling. With its light and durable enclosure with tight sealing the ApexZ is very well adapted for pharmaceutical cleanroom operations and sterile wipe downs using the most common cleaning solutions found in cleanrooms.

For VHP exposure because of the unknown nature of the VHP process and environment we recommend caution when running VHP through a particle counter. Although the sensor can resist the VHP in some cases when this vapor condenses it can contaminate the sensor leading to bad data and calibration failure. Therefore unless the process has been fully validated by the customer we would advise the end user to cap the sample inlet and turn off the internal pump or vacuum when using a remote particle counter. There is no GMP or FDA requirement to use a particle counter during cleaning cycles. With the risk of condensing and the high probability of bad data and introduction of contamination into the sensor not monitoring during cleaning cycles is a prudent choice and one that will be a less expensive option and keep your particle counter from needing costly repairs.

## How does the Apex sensors assist with Data Integrity?

With data integrity been critical it was important to verify that H<sub>2</sub>O<sub>2</sub> and other chemicals tested had no significant impact on the data coming from the particle counter.

The ApexZ and ApexR models have many health checks built into the sensors with Lighthouse self-diagnostic technology. Lighthouse has designed these features based on over over 30+ years' experience and from taking our customer feedback and developing the most advanced particle counter sensor with self-diagnostics and sensor checks to determine the validity of every data record.

### Every data record SHOULD include a health check of all sensor components

**Data Integrity**  
**Self Diagnosis Test**  
**Risk Mitigation**  
**Accurate Data**  
**Reliable Data**  
**Location ID check**

**Sensor Health Check**

- Laser Power
- Laser Current
- Laser Supply
- Photodetector
- Optics Health
- Location ID
- Flow Status
- Calibration Status

Every Apex data record has 8 independent checks that verify Good Data is being sent from the particle counter. From location ID with smart bracket technology™ to validating the health of the sensor to flow, laser, photodetector to calibration status you can be assured that the data you get from these top of the range particle counters is indeed valid data all of the time.

The Apex Z supports and exceeds the FDA ALCOA requirements with the most advanced sensor on the market that can guarantee you're Data's Integrity.

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- Attributable**

Clearly indicates who recorded the data or performed the activity – Signed / dated - Who wrote it and when.
- Legible**

It must be possible to read or interpret the data after it is recorded. – Must be permanent record – No unexplained hieroglyphics – Properly corrected if necessary.
- Contemporaneous**

Data must be recorded at the time it was gathered – Close proximity to occurrence.
- Original**

Data must be preserved in its unaltered state – If not, why not – Certified copies.
- Accurate**

Data must correctly reflect the action / observation made – Data checked where necessary – modifications explained if not self – evident.