LIGHTHOUSE
WORLDWIDE SOLUTIONS

VAPORIZED HYDROGEN PEROXIDE AND APEX INSTRUMENTS

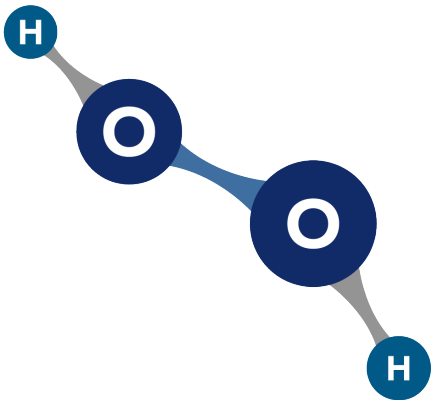
Lighthouse Worldwide Solutions

Overview

Vaporized Hydrogen Peroxide (VHP) is a powerful chemical used to sterilize surfaces and equipment in the cleanroom, specifically in the medical equipment and pharmaceutical industries. It can cause deterioration and breakdown of equipment. Due to the nature of the industries in which it is used, VHP is often used to sterilize equipment while the cleanroom is in use. Thus, tools used in a cleanroom with VHP must be uniquely designed to withstand exposure. Lighthouse's Apex particle counters have been tested against VHP and show no significant or out of the norm wear when exposed to VHP.

What is VHP?

Vapor Hydrogen Peroxide VHP (H^2O^2) is registered by the U.S. Environmental Protection Agency as a sterilant. The EPA defines a sterilant as "a substance that destroys or eliminates all forms of microbial life in the inanimate environment, including all forms of vegetative bacteria, bacterial spores, fungi, fungal spores, and viruses". As a sterilant, VHP is one of the chemicals approved for decontamination of anthrax spores from contaminated buildings, such as during the 2001 anthrax attacks in the U.S. It has also been shown to effectively remove exotic animal viruses, such as avian influenza and Newcastle disease from equipment and surfaces. VHP is used in Hospitals and in the Pharmaceutical Manufacturing Industry.



[Source – EPA website]

Why Is VHP Used In Cleanrooms?

Cleanrooms that manufacture drugs, biological products, and medical devices undergo vigorous sterilization processes. The use of hydrogen peroxide to disinfect surfaces is perhaps the most critical disinfection procedure. Product safety and quality, as well as human health, depends on the quality and thoroughness of a surface disinfection wipe-down. Some manufacturing processes run 24/7 to keep up with the demands for pharmaceutical products and avoid product shortages. Thus, off-line shutdowns are short and most of the sterilization is done in-situ. It is, therefore, important to select equipment that it is compatible and VHP tolerant.

What Are The Potential Impacts On Particle Counters?

VHP is produced by the vaporization of liquid hydrogen peroxide at 120°C to create a mixture of VHP and water vapor. As a 'dry' process, the concentration of VHP is maintained below a given condensation point. This is dependent on the area temperature. For room decontamination, VHP is generally maintained well below the saturation concentration at 0.1-1.5mg/L at 25°C. For medical device sterilization, higher concentrations can be used at higher process temperature, generally up to 60°C.

When the concentration of VHP increases above the saturation point for a given temperature, hydrogen peroxide will preferentially condense out. This forms concentrated peroxide on a surface, as peroxide has a lower vapor pressure than water. In this situation, although the condensate may be antimicrobial, the process may become variable and damage surfaces.
This is the scenario that poses a danger to all process equipment in a cleanroom, including but not limited to particle counters.

Are Lighthouse Apex Particle Counters And VHP Contamination Compatible?

Fifteen or 20 years ago, the answer to this would be a resounding no; however, Lighthouse has developed our particle counter technology to tolerate the effects of VHP. Lighthouse's Apex particle counters are designed to seal the housing and display to prevent any VHP from getting inside the unit. This stops the sensitive electronic boards and pumps. We have also designed our sensors to be VHP tolerant. Our components have been rigorously tested to verify VHP does not cause any corrosion inside the sensor. Additionally, our Apex particle counters have self-diagnostics to alert you if your sensor health is suffering for any reason.

Every sample is validated for sensor health with 8 diagnostic checks. If any one of these checks are out of tolerance, then the data is flagged as questionable. Inside our sensor the 8 diagnostic parameters cover flow, location, calibration, laser, and photodetector health been continuously monitored. No other particle counter on the market has this level of diagnostics to ensure data integrity.

Every sample has been validated to ensure data integrity is intact

What Do Lighthouse Apex Particle Counter HEALTH CHECK Diagnostics Mean In The Real World?

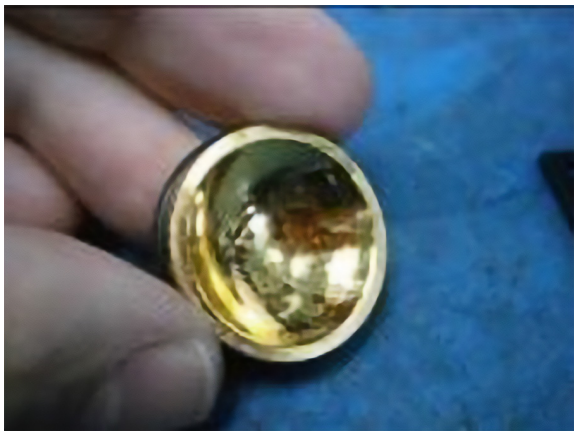
With this level of diagnostic feedback, the Apex sensor alerts to the presence of contamination inside the sensor. The Apex models continuously monitors the background voltages, photodetector status, and laser current to ensure your data's integrity remains intact. If any of these parameters are compromised, the particle counter will send out a service alarm.

If VHP or any other aerosol condenses on the sensor, the background voltages are affected, which triggers an alarm to the operator. This allows the affected sensor to be taken out of service immediately.

The particle counter can be sent out for investigation and a newly calibrated particle counter can be rotated into service and the downtime is kept to a minimum. This practice prevents a compromised sensor from sending out invalid data. Why would the data be invalid? If the sensor is contaminated with condensed VHP or cleaning solution aerosol, 9 times out of 10 it will fail the "as found" calibration for sizing accuracy and counting efficiency. This means it is sending out bad data. The Lighthouse Apex sensor technology diagnostics has been designed to mitigate against this issue.

When spraying cleaning solution near particle counters be careful to avoid the aerosol from entering the particle counter as the solution can deposit on the sensor optics and cause inaccurate particle count data and also fail the as found calibrations.

What would happen if your particle counter did not have this level of sensitivity? Without your knowledge, the data coming from the sensor would be inaccurate. If the mirrors and optics inside the sensor are coated in VHP residue or cleaning solution, the light scattering of each particle will be affected. This can mean sizing errors and count accuracy issues. Particle Counters use light scattering to convert the particle size into an electric signal (voltage) that can be scaled to represent the size of the particle. The particle is pulled through the sensor using an internal pump or an external vacuum pump (if the particle counter is a remote unit without an internal pump).



Example of a sensor mirror coated in cleaning solution residue

Without the self-diagnostics built into your particle counter, you would not know until the unit is sent for calibration that there was a problem with bad data. To make matters worse, you would not be able to tell when this error occurred. That would mean the data from this particle counter used to support batch releases would be questionable. That is a QA Managers nightmare which could cost your company hundreds of thousands of dollars in lost revenue and delays in production.

What Should You Do If A VHP Process Requires The Particle Sensor and Sample Tubing Be Sterilized?

Over the years we have seen more of our customers asking this question. With our Apex particle counters and the studies we have undertaken, we can advise it is safe to run VHP through our Apex particle counter. As you can see below, our advanced design with a sealed housing allows us to make this statement with confidence.

In one of the many studies, we ran VHP cycles with our ApexZ portable particle counter and our ApexR remote particle counter. Before the test was undertaken, we calibrated the units. VHP exposure was run through the sensors with multiple cycles to represent a year of VHP decontamination in the cleanroom. The particle counters were then recalibrated. The data compared to the pre calibration indicated that post calibration data was still within tolerance (ISO 21501-4 Calibrations were applied to ISO 17025 accreditation).

As well as pre and post calibrations during the testing, no abnormalities were seen on the particle counters externally and internally. The particle counters were taken apart and the sensors and

or residue build up inside the sensors. With the test conducted and particle counters running, VHP was prevented from condensing inside the sensor. Lighthouse can, therefore, recommend VHP to be run through its Apex sensors with confidence assured. See test images in Appendix 1.

On the other hand, we do not recommend the use of solenoid valves to bypass VHP around a particle counter. We have advised against this approach and for good reason. Recently, we had a customer who had issues with their system where they used a bypass system against our advice. Their ApexR sensors were flagging service alarms. When investigated, the sensors were contaminated with VHP residue and were failing "as found" calibration checks. After sending a Lighthouse engineer onsite to investigate further, we found the bypass valve system when closed during the VHP cycle was collecting VHP residue (VHP was condensing as there was a temperature difference). When the VHP cycle was finished and the valve opened the residue liquid was pulled into the ApexR sensor when sampling started. After discussions with the customer, the bypass valve system was removed. Since then the customer has been running VHP through their VHP sensors without further issues.

A 3-Way Bypass Solenoid Valve for VHP decontamination processes. We do not recommend using bypass valves for VHP decontamination processes. Instead we recommend running VHP through the Apex sensor.

In Conclusion

Lighthouse can assure VHP exposure externally and internally with its Apex particle counter models. Internal and external studies have verified this conclusively as long as the VHP process is non-condensing, and a by-pass valve system is not used. Lighthouse Apex models have been designed to meet harsh cleaning and disinfection programs and tested rigorously against cleanroom cleaning agents. Below are images of ApexZ and ApexR particle counters highlighting the special design in the housing to prevent particle traps and with highly engineered seals to prevent liquid or VHP ingress.

ApexZ Remote Particle Counter with Sealed Housing

1. **Sealed sample inlet base – avoids buildup of wipe down excess and potential particle trap and difficult area to keep free from ingress debris and potential home for bacteria.**
2. **Sealed housing seam with internal O-ring. Waterproof sealed housing seam without any cervices where cleaning solution can build up and moisture accumulate.**
3. **Sealed glass touchscreen eliminates problematic push buttons and promotes easy operator interface.**
4. **Sealed printer cover with easy access for paper replacement and alignment.**

ApexR and ApexRP Remote Particle Counter with Smart Bracket Technology

1 Sealed sample inlet base – avoids buildup of wipe down excess and potential particle trap and difficult area to keep free from ingress debris and potential home for bacteria.

2 Sealed housing seam. Waterproof sealed housing seam without any cervices where cleaning solution can build up and moisture accumulate.

3 Sealed smart bracket that can withstand low pressure water shower with ID location built into the smart bracket.

4 Concealed tubing and cables that normally hang out at the bottom of the unit and crate particle traps and are difficult to clean.

Appendix 1.

VHP Testing of ApexZ and ApexRP / ApexR test results

Scope of Test

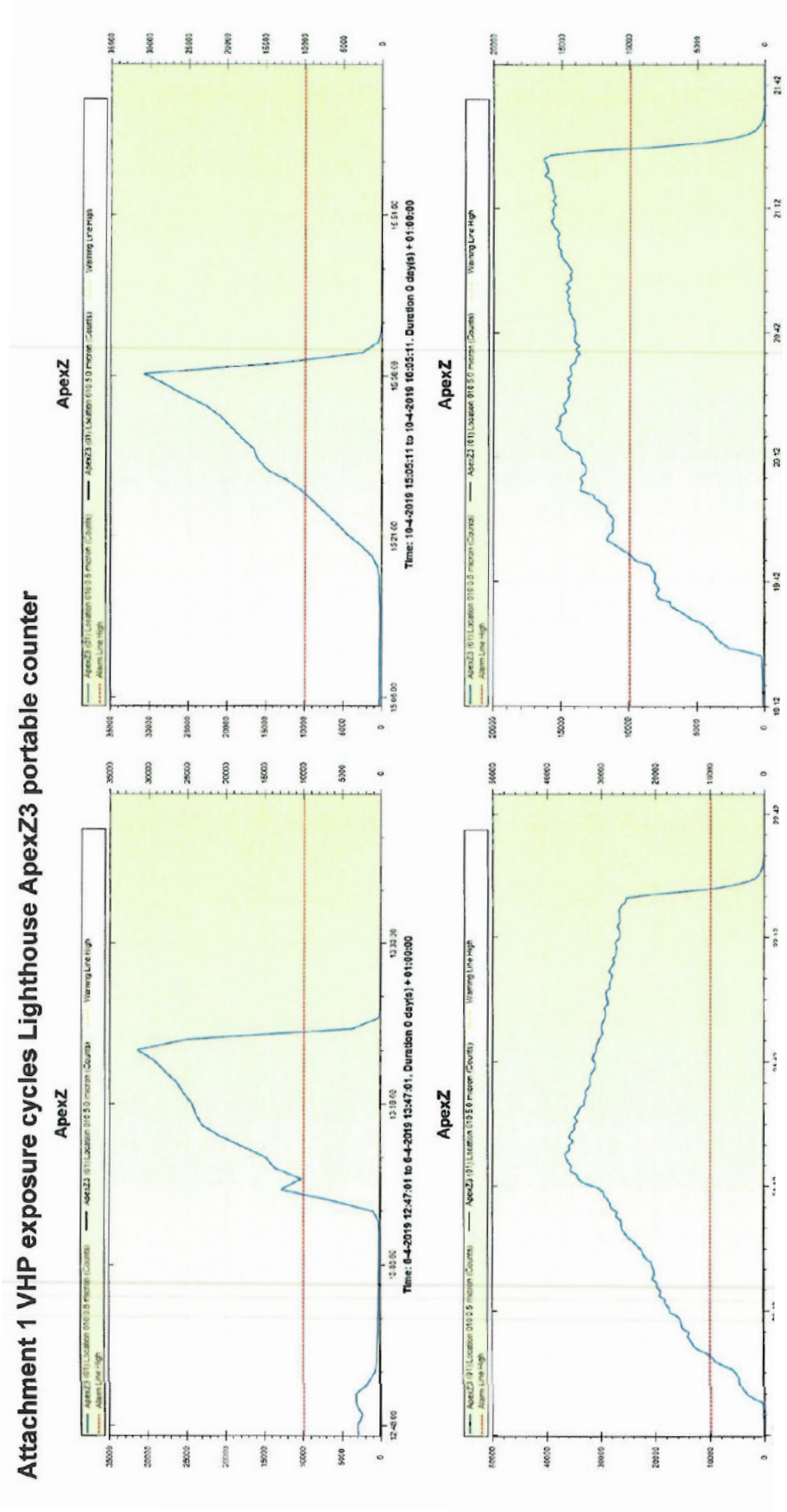
Off the factory line ApexZ, ApexR, and ApexRP particle counters were calibrated. Prior to calibration, the sensor parts were verified as clean, and images were taken of internal parts. The particle counters were setup in a cleanroom and VHP was released into the environment. The particle counters were running and sampling during the VHP decontamination cycle. The VHP exposure was indicated in the particle counters, as the counts which started at a zero-baseline jumped up to an average range of 30,000 to 40,000, indicating VHP exposure inside the sensor. Each VHP run lasted up to 2.5hrs (accelerated testing). An average of 36 VHP exposure cycles were run for each particle counter.

Test Observations

During the testing no defects, staining, or abnormalities were seen on the particle counter housing or inside the sensors. The particle counters were examined mid testing and "as found" calibration was determined. At the end of the testing the as found calibrations were again tested and the sensors were stripped down and the internal sensor parts were again examined.

Appendix 1.

ApexZ data from VHP exposure during run cycle lasting 2.4hrs



Appendix 1.

Overall and from the test data, it is clear that VHP had no effects on the Apex model particle counters for portables and remotes. Visual inspections during and after exposure back up this conclusion as well as calibration data. As long as the VHP process is non-condensing and the temperatures of the room and particle counters is constant, the VHP process will remain a dry process and room temperatures remain below 25°C.

Test Images at start of study, mid study and end of study.