

VHP and Lighthouse Apex Particle Counter Exposure

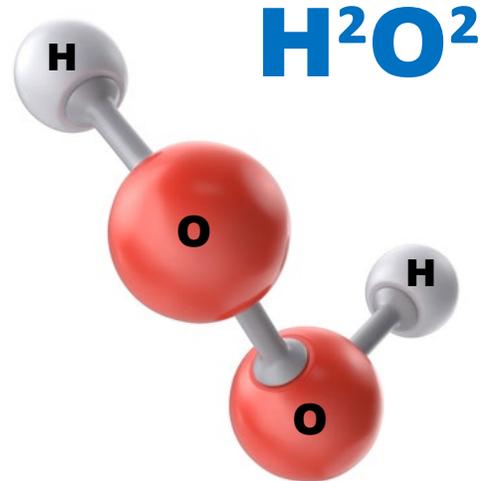
by Jason Kelly

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What is VHP?

Vapor Hydrogen Peroxide VHP (H^2O^2) is registered by the U.S. Environmental Protection Agency as a sterilant, which the EPA defines 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 occurred during the 2001 anthrax attacks in the U.S. It has also been shown to be effective in removing 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 it used in cleanrooms?

All cleanrooms that manufacture drugs, biological products and medical devices, go through vigorous sterilization processes. Disinfection of Surfaces with Hydrogen Peroxide of all the contamination control activities in a cleanroom, is perhaps the most critical of disinfection procedures. Product safety, quality and human health depends on the quality and thoroughness of a surface disinfection wipe-down. With some manufacturing processes running 24/7 to keep up with the demands for pharmaceutical products to avoid product shortages, off-line shut downs are short and most of the sterilization is done in-situ. Therefore it is important in the selection of process equipment that it is compatible and VHP tolerant.

What are the potential impacts on Particle Counters?

VHP is produced by the vaporization (at 120°C) of liquid hydrogen peroxide to give a mixture of VHP and water vapor. As a 'dry' process, the concentration of VHP is maintained below a given condensation point, which 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 forming 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 damaging to surfaces.

This is the scenario that needs to be controlled when using VHP in-situ to decontaminate cleanrooms and all process equipment in the cleanroom not just particle counters.

Can you keep running Lighthouse Apex Particle Counters while VHP is decontaminating a room?

If we were asked this question 15 or 20 years ago the answer would be NO! However Lighthouse has been developing our particle counting technology to be tolerant to the effects of VHP. If you look at the design of Lighthouse Apex particle counters you can see our focus on sealing the housing and display to prevent ingress of VHP from getting inside the unit where sensitive electronic boards and pumps are housed and in the sensor flow path we have designed our sensors to be VHP tolerant. We have rigorously tested our components to verify VHP does not cause any corrosion inside the sensor. Our Apex particle counters have also self-diagnostics built into our technology in terms of sensor health. 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



Sensor Health Check

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

**Minimize Risk
and Increase
Data Integrity**

What do the HEALTH CHECK diagnostics in Lighthouse Apex Particle Counters mean in the real world?

With this level of diagnostic feedback the Apex sensor alerts to the presence of contamination inside the sensor. Background voltages, photodetector status and laser current are continuously monitored ensure your data's integrity remains intact. It is this key concept with this level of sensitivity and the 8 diagnostic measurements that provide the Apex the ability to send out a service alarm if any of these parameters are compromised.

This is a critical feature which allows a service notification to be sent out if the sensor is potentially compromised. If VHP or any other aerosol condenses on the sensor the background voltages are effected and this triggers an alarm to the operator to say that the unit will require a service or further investigation. This allows the effected 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 then 9 times out of 10 it will fail the “as found” calibration for sizing accuracy and counting efficiency. Which 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.

Imagine 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 then the light scattering of each particle will be affected which 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).

Without the self-diagnostics built into you would not know till 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 and that would mean the data from this particle counter used to support batch releases would be questionable. That is a QA Managers



Example of a sensor mirror coated in cleaning solution residue

nightmare that could cost your company hundreds of thousands of dollars in lost revenue and delays in production.

What do we recommend if a VHP process requires the particle sensor and sample tubing to be sterilized?

Over the years we have seen more of our customers asking this question and 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 with our advanced design with a sealed housing we can make this statement with confidence. In one of the many studies undertaken we tested our ApexZ Portable Particle Counter and our ApexR remote particle counters running VHP cycles and before the test was undertaken the units were calibrated. 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 internal parts and circuit boards were closely examined. There were no observations of corrosion or residue build up inside the sensors. With the test conducted and particle counters running, VHP was prevented from condensing inside the sensor. Therefore Lighthouse can 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 by-pass 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 and 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) then 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.

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.



A 3-Way Bypass solenoid Valve for VHP decontamination processes. We do not recommend using by-pass valves for VHP decontamination processes instead recommend running VHP through the Apex sensor.

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 services 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 services where cleaning solution can build up and moisture accumulate.

3

Sealed smart bracket that can actually 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.

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

