



## Frequently Asked Questions about Vaporized Hydrogen Peroxide

### Introduction to VHP

*Q: Where do people use VHP?*

Vaporized Hydrogen Peroxide (VHP, *Also Known As* H<sub>2</sub>O<sub>2</sub>) is a commonly used material for sterilizing pharmaceutical isolators and, in some instances, the cleanroom itself. While a few countries still use formalin gas for this purpose, the use of VHP to kill contaminating bacteria in aseptic manufacturing facilities is growing rapidly worldwide. This use is being accelerated by the determination that formalin (AKA formaldehyde), which once was used for this purpose, is a proven carcinogen.

*Q: How do the pharmas apply VHP?*

Pharmas use VHP to sterilize between batches. All personnel leave the area, all openings are closed, then the VHP is piped in. The VHP forms a mist, with a typical concentration of around 700 ppm; the room is covered in mist for 30-40 minutes, then purged out.

### Impact of VHP

*Q: How does VHP affect the outside of Particle Measuring Systems' particle counters?*

Particle Measuring Systems' (PMS) aerosol particle counters have very strong covers, whether KYDEX<sup>®</sup> (Airnet<sup>®</sup> and Lasair<sup>®</sup> II) or stainless steel (IsoAir<sup>®</sup> and IsoAir PLUS). These covers can resist VHP for years. PMS sample tubing also is very resistant to VHP oxidation.

*Q: How does VHP affect the inside of particle counters?*

VHP is a very strong oxidizer. Over time it will even penetrate through cracks and corrode the insides of rugged products like the Airnet or Lasair II. Eventually this will also happen to an IsoAir or IsoAir PLUS (unless these stainless steel enclosures are purged with nitrogen to protect them from the VHP). Thus, over time VHP will corrode the boards and other metal areas.

*Q: How does VHP affect the optics of particle counters?*

The optics contain a number of components (e.g., lens and mirrors) that will or will not be affected by VHP, depending upon the materials used in their construction.

*Q: How has PMS designed the Airnet XR to resist VHP?*

Where possible, PMS has selected materials that are not affected by VHP. In the other areas, PMS has used a special Teflon coating to protect the vulnerable surfaces.

*Q: How has PMS tested these Teflon-coated parts for resistance to VHP?*

PMS exposed both coated and non-coated parts to a 30% hydrogen peroxide environment for 72 hours. At the end of that time, the non-coated parts showed significant damage, while the coated parts showed no visible effect. The coated sensors were tested in engineering, and no problems with particle counting were detected. (For more information on this testing, please see PMS Technical Note 40<sup>1</sup>, authored by Mark Hallworth)

*Q: How long a warranty does PMS provide for the Airnet XR?*

One year when used with VHP. This is in contrast to the standard Airnet warranty of 3 years.

*Q: What is the warranty on the standard Airnet (without XR) when used in VHP?*

Use of an Airnet with a powerful oxidizer like VHP nullifies the warranty.

*Q: What about using the Airnet XR with other powerful oxidizers?*

Use with other powerful oxidizers voids the warranty, unless PMS conducts internal testing and provides written approval in advance.

### **Designing Systems for Use with VHP**

*Q: Must the particle counter continue to monitor while the clean zone is being exposed to the VHP mist?*

Since the product itself is not exposed to the atmosphere when the VHP is applied, neither the FDA nor the EC GMP requires sampling while VHP is being applied.

*Q: How can one extend the life of an Airnet XR?*

Place the particle counter outside the room and run the sample tubing inside. This will minimize the exposure of the electronics to VHP.

Good design procedure includes returning the exhaust air to a scavenging system. However, it is critical to consider the impact of the sample tubing length and positioning upon large particle transport.

*Q: What maintenance can PMS perform to extend the life of the Airnet XR?*

At the time of annual calibration, PMS can exchange certain parts and mirrors that show significant contamination due to condensation of the vapor over time. PMS does not, however, routinely replace the boards or other electronics.

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<sup>1</sup> Airnet-510 resilience to Hydrogen Peroxide (H<sub>2</sub>O<sub>2</sub>), Mark Hallworth, 2002

*Q: What impact does the VHP have on the central pump?*

As the VHP travels through the sampling tubing, it quickly breaks apart into oxygen and water. Careful pump selection (e.g., with no exposed iron components) will result in minimal impact to the pump.

*Q: Can I use an IsoAir PLUS with VHP?*

PMS has not made the XR option available on the IsoAir PLUS.

### **Operating a System Exposed to VHP**

*Q: Should we cap the particle counter during the application of VHP?*

Particle counters will live longer if capped during VHP application. This is especially true for the optical system of units exposed to VHP. At the same time, while this preserves the optical system, eventually the internal electronics will be impacted.

*Q: What if we have an Airnet XR and do not cap it during the application of VHP?*

Because of the XR design and coating, the Airnet will be much more resistant to damage and should continue working beyond its warranty period of one year.

*Q: Anything else to do if we cap the unit?*

Be sure to turn OFF -- not only the pump --but also the power to the Airnet or IsoAir while it is capped. Otherwise, the heat from the components could reduce the life of the diode. (When the vacuum is provided, this airflow cools the unit, extending the life of the diode.)

*Q: What if we want to sterilize the sample path through the sample tubing or the Airnet?*

The simplest way is to run the Airnet XR uncapped while VHP is present.

Alternatively, and less demanding on the Airnet lifetime, turn the Airnet and vacuum OFF, and rely on the VHP diffusing into the ISP and sample tubing. When the vacuum is restarted, this VHP will be drawn through the tubing and Airnet.

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TP 43, 2005, Bill Belew