

Introduction to Vaporized Hydrogen Peroxide Sterilization

Sterilization with hydrogen peroxide vapor (V-PHP, VHP, or vH_2O_2) is a relatively rapid, low-pressure, low-temperature, nontoxic process that uses hydrogen peroxide in a gaseous form to reduce the level of infectious agents. A 35% solution of liquid H_2O_2 is introduced to the generator via a precision pump, heated by a vaporizer and injected into the environment to be treated by means of a blower. In hospitals and pharmaceutical manufacturing this process is preferred for products that cannot withstand the heat of typical autoclave sterilization (such as plastics). Additionally, enclosed spaces such as clean rooms, patient isolation rooms or public spaces can also be treated. The main parameters to be monitored are temperature, humidity (RH) or relative saturation (RS) and H_2O_2 vapor concentration (PPM). A starting temperature $> 20^\circ C$ and starting Relative Humidity $< 70\%$ is ideal for a successful cycle.

The total length of the process can vary, but it is most dependent on the size (volume) of the environment being treated and the required killing effectiveness. For instance, typical gas dwell times for a Biosafety Cabinet (BSC), or pharmaceutical manufacturing isolator are approximately 1 hour to achieve a 6-log kill, a level of effectiveness commonly associated with sterility. To treat an enclosed space (clean room, patient isolation room or public space), gas dwell times can be anywhere from 2 hours ($50 m^3$) to eight hours ($500 m^3$), again depending on the volume of the space. And generally, the longer the gas dwell time, the longer the aeration time required to bring the concentration (PPM) down to a safe level. This process can be accelerated by using the building ventilation system or by using an external catalyst/blower.

VHP sterilization is safe and effective. And because hydrogen peroxide breaks down to water and oxygen, aeration times are typically shorter compared with other bio-decontamination technologies such as formaldehyde or chlorine dioxide. Additionally, as long as care is taken to avoid condensation of the vapor back into a liquid, V-PHP is also friendly to plants and sensitive electronics.

To ensure harmful liquid condensation is avoided, the Amira Bioreset® family of VHP decontamination systems employ a Temperature and Relative Humidity (Relative Saturation) monitoring probe for cycle control. The system senses when the H₂O₂ vapor concentration is approaching the dew point, and the injection of 35% liquid H₂O₂ is paused, and when the probe detects lower Relative Saturation values, liquid H₂O₂ injection restarted. While the process is compatible with a wide range of medical instruments and materials, material compatibility issues do exist. For example, cellulose cannot be sterilized because the hydrogen peroxide is completely absorbed by the fibers. Absorption causes variability in the gas dwell and the aeration times that cannot be modeled or predicted. In the case of room decontamination, for spaces containing only (or mostly) hard, non-porous surfaces, absorption isn't an issue, and those spaces can be frequently decontaminated using VHP. In spaces containing large amount of porous surface areas (carpeting or upholstered furniture, for example), absorption due to running frequent gassing cycles will cause aeration times to become prohibitively long to allow a cycle to be completed overnight.

Vaporized hydrogen peroxide has proven to be highly effective in killing bacteria, fungi and viruses. VPHP sterilization is a material friendly, useful sterilization method that can be used at ambient pressures. However, with any sterilization technology there are limitations, whether it be steam (high temperature), ClO₂ (toxic, flammable) or UV (line of sight effectiveness, safety). But when compared to other sterilization methods VHP is a practical alternative. When used properly, it is a safe and cost-effective sporicidal agent that kills all types of microorganisms when it comes into direct contact with them.

Safety Summary Table – Select Chemical Bio-Decontaminants

	H ₂ O ₂ Vapor	EO/EtO	NO ₂	ClO ₂	Peracetic Acid	O ₃	Formaldehyde Gas
IDLH* (Immediate Danger to Life and Health)	✓	✓	—	✗	✗	✗	—
TWA** (Time Weighted Average)	✓	✓	✓	✗	✗	✗	—
Non-Carcinogenic	✓	✗	—	—	—	—	✗
Non-Explosive	✓	✗	✓	—	✓	✓	✗
Non-Toxic	✓	✗	✗	✗	✓	✗	✗
Environmentally Friendly	✓	✗	✗	✗	✗	✓	✗

***Immediate Danger to Life and Health (IDLH)** is a limit set by NIOSH (National Institute of Occupational Safety and Health), a non-regulatory organizational component of the Centers for Disease Control and Prevention, charged with ensuring safety and health for all people in the workplace through research and prevention.

****Time weighted average (TWA)** is the average workplace Permissible Exposure Limit (PEL). The PEL or **OSHA PEL** is a legal, regulatory limit on the quantity or concentration of any hazardous contaminant or agent an employee can be exposed to, using the baseline of an 8 hour per day or 40 hours per week work schedule.

Advantages of Vapor Hydrogen Peroxide Decontamination

	High-Log Efficacy	Compatible with Electronics	No-Touch Disinfection	No Bleach, Chlorine, Acid, Dyes	No Mixing	Evenly Dispersed	Small Micron Size	Quick Application	No Residue
VHP**	✓	✓	✓	✓	✓	✓	✓	✓	✓
iHP***	✓	✓	✓	✓	✓	✗	✗	✓	✓
AHP***	✗	✓	—	—	—	✗	✗	✗	✓

V-PHP

VHP (Vaporized Hydrogen Peroxide) is a registered trademark of Steris Corporation. The process is likely to be operated in an environment with fairly well controlled conditions of temperature and humidity (normally 50% RH and 20°C). A 35% solution of hydrogen peroxide is evaporated, introduced into a stream of air being directed into an enclosure such as a biosafety cabinet, isolator, cleanroom or public space, where it acts to kill viable micro-organisms inside the enclosure. V-PHP, HPV and vH₂O₂ are all acronyms that are used interchangeably with VHP*. The basic processes are relatively similar.

HPV

****iHP*** (Ionized Hydrogen Peroxide) is a registered trademark of Astro Pak Corporation. It is a relatively new process. The technology is being applied for surface decontamination as an alternative to conventional Vapor Phase Hydrogen Peroxide and other technologies used for bio-decontamination. It uses a 6%-10% concentration of hydrogen peroxide, creating a mist of ionized hydrogen peroxide via an ultrasonic nozzle. These positively charged hydroxy ions act as the mechanism to destroy micro-organisms.

vH₂O₂

*****AHP** – (Aerosolized Hydrogen Peroxide) decontamination systems use pressure to push hydrogen peroxide (sometimes in combination with other additives to improve efficacy) through an atomizer. The atomizer pushes the H₂O₂ through a nozzle that helps form and disperse small droplets (mist) of H₂O₂ in the enclosure. These droplets range in size from 5 -30 µm. These large droplets may wet surfaces with a concentration of 6% -10% hydrogen peroxide. Although this differs from true VHP, many people refer to AHP as VHP. It is also often referred to as a "Dry Fog" process.