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# VHP (Vaporized Hydrogen Peroxide) Bio-decontamination Technology

Technical Data Monograph - January 2003

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## Introduction

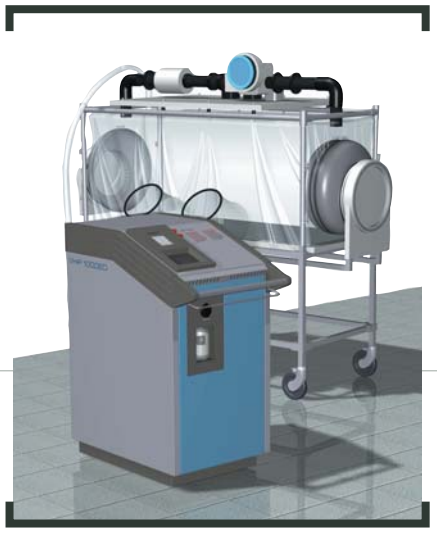
Vaporized hydrogen peroxide (VHP®) systems provide rapid, safe, low-temperature decontamination methods for any enclosed area that may be contaminated with micro-organisms, including spore-forming bacteria. These systems are widely used for decontamination of airborne or surface contaminants, including; rooms, rooms contents (including electrical/electronic equipment), duct work and filters. VHP systems are currently used as rapid, low temperature techniques for decontamination of production filling lines, sterility testing isolators, sealable enclosures, and various types of pass-thru systems within pharmaceutical production, research, and bio-safety laboratory facilities. More recently, the technology has been used for the bio-remediation of enclosed areas, including virus contaminated laboratory research rooms and bacterial/fungal spore contaminated areas. (e.g., Bacillus anthracis spores)

## VHP System Description

A range of VHP delivery and control system are available for the decontamination of small, medium and large enclosed areas.

VHP1000 Bio-decontamination System is a compact, mobile unit which generates and controls VHP delivery into an enclosed environment. The next generation VHP 1000ED has recently been released and offers updated features (Figure 1).

**Figure 1.** VHP 1000ED Bio-decontamination System.



The VHP 1000 has been widely used worldwide for the decontamination of enclosed areas for over 10 years; for example, the system is the most popular method for isolator decontamination and has been used for bio-decontamination of rooms up to 8000 $ft^3$ (230$m^3$). Larger rooms have and can be decontaminated by using multiple generators in tandem. The VHP 1000 is also available as a modular system (VHP M1000), which can be directly integrated into room HVAC system or 'aseptic' filling lines for fixed applications (Figure 2). Under developmental contract, STERIS can modify the basic VHP systems for new projects especially aseptic processing, cleanrooms, food and packaging and other industrial applications.

**Figure 2.** VHP M1000 Bio-decontamination System.

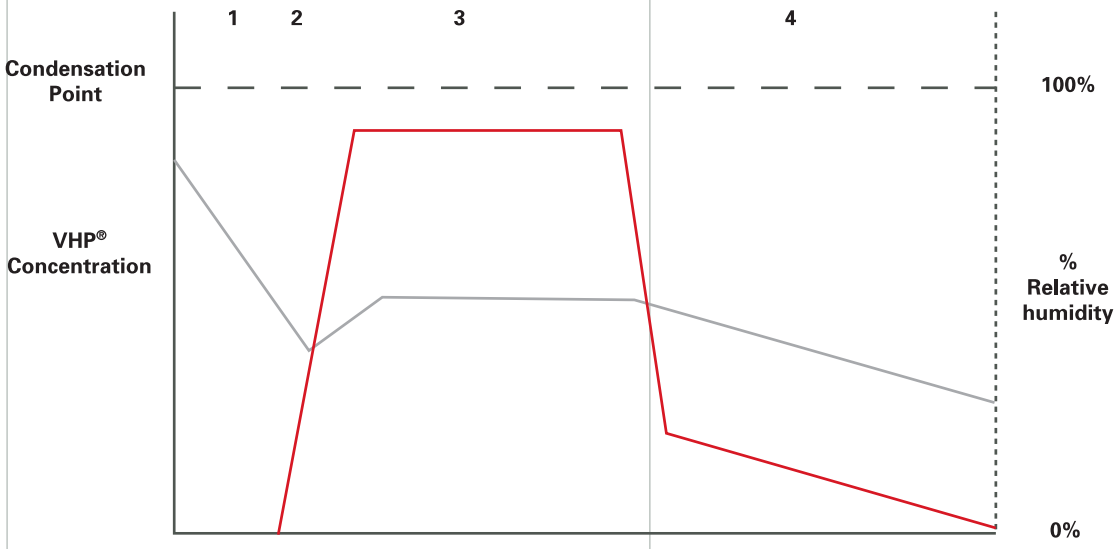
For the decontamination of smaller areas (<70ft3), the VHP 100P Bio-decontamination System is recommended (Figure 3). This mobile system is also available as a modular design (VHP M100).

**Figure 3.** VHP 100P Bio-decontamination System.

## Typical Decontamination cycle

A typical VHP bio-decontamination cycle is shown in Figure 4.

**Figure 4.** Typical VHP Bio-decontamination Cycle.




1. Dehumidification
2. Conditioning
3. Sterilization
4. Aeration

The cycle consists of 4 phases: (1) dehumidification, (2) conditioning, (3) Bio-decontamination or sterilization and (4) aeration, which are controlled and monitored by the VHP 1000 system. VHP is produced by vaporization of 35% liquid hydrogen peroxide (Vaprox™) and is very sporicidal at low concentrations (typically 0.1-3mg/L at 25°C). During the bio-decontamination or sterilization phase, the VHP concentration is maintained at a constant level by continually introducing the vapor into the incoming air and catalytically degrading VHP to water vapor and oxygen in the returning air. The VHP cycle is referred to as a 'dry' process, as the concentration is maintained below the critical condensation point of the vapor. For this reason, VHP is safe for decontaminating a variety of sensitive surfaces, including electronics. Cycle times can be significantly reduced using the room ventilation system following decontamination to assist during aeration. The VHP system microprocessor control continuously monitors the process parameters during each cycle.

VHP is being used for decontaminating a wide variety of rooms and is becoming accepted as an environmentally friendly alternative to other gaseous biocidal methods (e.g., formaldehyde and chlorine dioxide). Other liquid or foam-based methods require significantly longer contact times for sporicidal efficacy, are variable, time consuming and difficult to ensure air/surface contact (e.g., are difficult to apply to ductwork).

## Antimicrobial Efficacy

The broad spectrum efficacy of VHP has been shown against a wide range of micro-organisms over the last 10 years (summarized in Figure 5) and is highly microbicidal even at concentrations as low as 0.1mg/L. The broad-spectrum efficacy of VHP has been widely established and published. VHP has all but replaced formaldehyde as the method of choice for routine decontamination of enclosed areas.

**Figure 5.** Descending order of microbial resistance to VHP.

In addition, VHP has also been shown to neutralize proteinaceous-based toxins (e.g, the botulinum toxin).

**Sporicidal**

VHP is rapidly sporicidal, demonstrating greater efficacy at lower concentration than liquid peroxide, and greater surface compatibility (Block, 1991; example in Table 1).

**Table 1.** Comparison of liquid and vaporized hydrogen peroxide antimicrobial efficacy.

| Test Organism (Spores) | D-value (time to kill one log of test organism in minutes) | |
|---|---|---|
| | Liquid[b] | Vapor |
| | H2O2 Concentration: **370 mg/L** | H2O2 Concentration: **1-2 mg/L** |
| | Temperature: **24-25°C** | Temperature: **24-25°C** |
| B. stearothermophilus a | 1.5 | 1-2 |
| B. subtilis | 2.0-7.3 | 0.5-1 |
| C. sporogenes | 0.8 | 0.5-1 |

**a)** Concentration is >200 times vapor concentration to achieve same antimicrobial activity

**b)** B. steaothermophilus spores are most resistant to vapor, but B. subtilis spores more resistant to liquid and vary considerably.

In general, bacterial spores (in particular Bacillus stearothermophilus spores) have previously been shown to be the most resistant to vaporized hydrogen peroxide, in the presence or absence of an organic soil (5% serum; Klapes & Vesley, 1990; Kokubo et al, 1998).

B. stearothermophilus spores, as the most resistant organism to the process (Kubodo et al, 1998), are generally used to verify and validate bio-decontamination cycles with VHP on site and are available from STERIS in suspension or inoculated onto indicator strips/carriers. Typical bio-decontamination times will depend on the VHP concentration and room temperature (for examples see Table 2).

**Table 2.** Effect of VHP concentration and time

| Temperature (°C) | Concentration (mg/L) | Concentration (ppm) | Typical D-value |
|---|---|---|---|
| 4 | 0.1-0.5 | 350 | 8-12 mins |
| 25 | 1-2 | 700-1500 | 1-2 mins |
| 37 | 3-4 | 2000-3000 | 0.5-1 min |
| 55 | 10-12 | 7000+ | 1 sec |

**Note:** the dew point concentration/condensation point of VHP increases as temperature increases.

The typical range for room decontamination is 20-30°C at 0.1-3mg/L VHP.

The VHP process, as an EPA registered sterilant, has also been shown to pass the AOAC sporicidal test (Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC), 15th ed. 1990, Chapter 6, Section 966.04, Sporicidal activity of disinfectants), which includes two carrier materials (porcelain penicylinders and silk suture loops) inoculated with Clostridium sporogenes and Bacillus subtilis in the presence of organic and inorganic soils and subsequently desiccated. Of the >800 carriers tested in two studies, all demonstrated no growth following exposure to VHP.

Of particular note, VHP has been validated for use for decontaminating research laboratory rooms/enclosures against B. anthracis spores.

**Virucidal**

VHP has been shown to be virucidal against a range of viral families (Figure 5). The efficacy of VHP against a series of viral families has previously been published (Heckert et al, 1997). The most resistant viruses to the process are the non-enveloped/non-lipid viruses, due to the nature of these viruses (McDonnell & Russell, 1999. Clin. Micro. Rev. 12:147-179). Recent case studies have confirmed the efficacy of VHP against representatives of these viral families, in the environmental control of parvoviridae in research laboratories.

Parvoviridae are generally considered as having low sensitivity to chemical biocides and are recognized as the most resistant viral family to disinfectants and sterilants. Due to their ability to survive adverse environmental conditions, parvovirus is particularly contagious and difficult to eradicate from critical environments. A 5600 $ft^3$ (~170$m^3$) rectangular room was shown to be successfully decontaminated in just over 3 hours (total cycle time), with no adverse material compatibility observed. Triplicate cycles were evaluated with VHP biological ($10^5$ Bacillus stearothermophilus spores) and chemical indicators randomly distributed around the room, on the walls, ceiling and floor. In addition, mouse parvovirus carriers ($10^3$ viable virus particles dried in the presence of 10% serum onto the surface of plastic petri plates) were randomly positioned around the room. A total of sixty biological indicators, thirty chemical indicators and seven parvovirus carriers were evaluated and no growth observed following a 3 hour (total time) decontamination cycle (McDonnell et al, 2001). Parallel successful validation studies were performed at this site for 1700 $ft^3$ (~50 $m^3$) rooms with the following test organisms:

- Canine parvovirus (CPV)
- Bovine Viral Diarrhea (BVD)
- Avian Reovirus (ARV)
- Clostridium tentani spores
- Bacillus stearothermophilus spores
- Escherichia coli

**Bactericidal**

VHP is effective against Gram positive and negative bacteria (Figure 5). Recent studies have focused on key nosocomial and environmental pathogens, including:

- Food-based pathogens
  - Escherichia coli
  - Escherichia coli O157: H7
  - Listeria monocytogenes
  - Salmonella choleraesuis
  - Staphylococcus
  - Bacillus cereus
- Nosocomial/Environmental pathogens
  - Methicillin-resistant Staphylococcus aureus
  - Vancomycin-resistant Enterococcus
  - Klebseilla pneumoniae
  - Legionella pneumophilia

A recent example of the application of VHP for environmental control of bacteria has been published for the food industry (McDonnell et al, 2002)

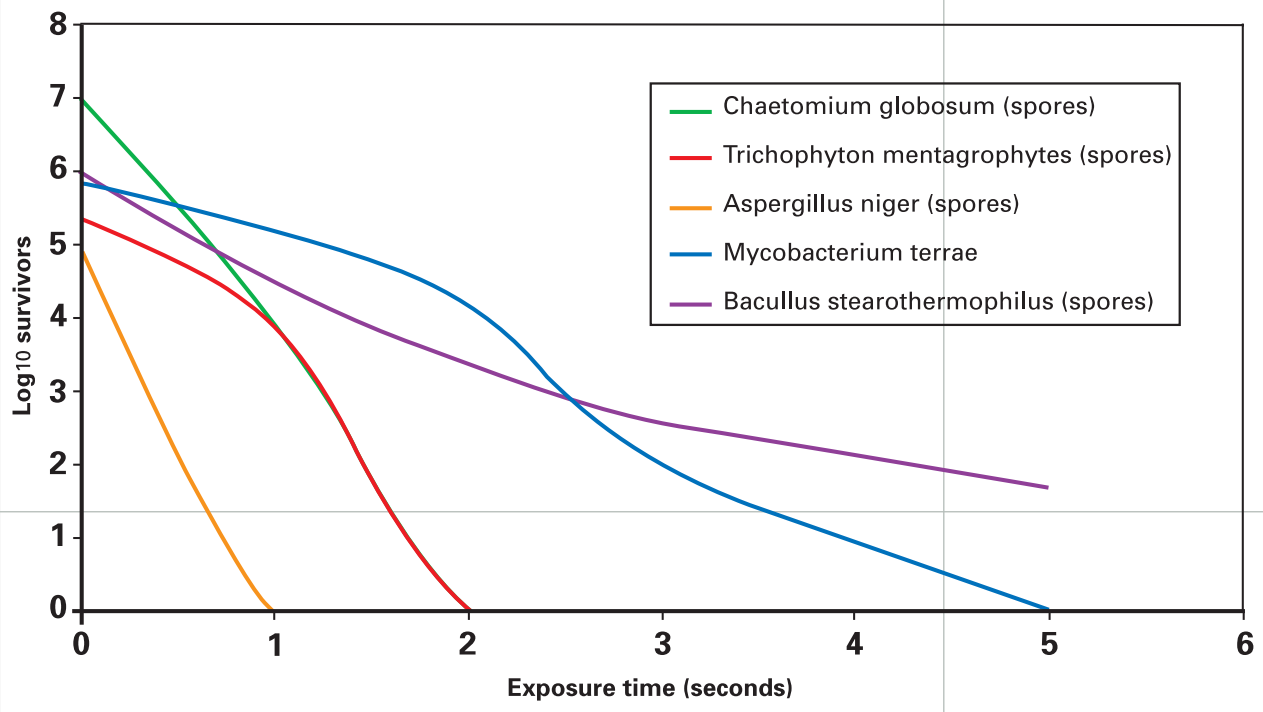
**Fungicidal**

VHP has been shown to be effective against a wide range of fungi (including moulds and yeasts), including key fungal environmental contaminants and pathogens:

- Molds
  - Aspergillus
  - Fusarium
  - Penicillium
  - Stachybotrys
  - Chaetomium
  - Trichophyton
  - Fusarium
- Yeasts
  - Candida
  - Saccharomyces
  - Rhodotorula

VHP is rapidly effective against fungal vegetative forms and spores; bacterial spores are significantly more resistant than fungal spores as shown in Figure 6 (at ~1mg/L VHP):

**Figure 6.** Efficacy of VHP over time against specific micro-organisms.



**Tuberculocidal**

Despite the intrinsic resistance of the mycobacterial cell wall, VHP has been shown to be rapidly effective against mycobacteria, and other microorganisms with similar cell wall structures:

- Mycobacterium tuberculosis
- Mycobacterium bovis
- Mycobacterium terrae
- Mycobacterium smegmatis
- Nocardia

An example of mycobactericidal efficacy is shown in Figure 6.

**Nematodes eggs**

The group nematoda consists of approximately 20,000 described species, with actual estimates of 40,000 – 10 million species in existence.
The taxonomic groups of Rhabodita, Ascaridida, Oxyyurida, and Spirurida pose parasitic health problems to humans and other vertebrates.
For example, nematode egg contamination in research facilities can cause significant material, time, and financial loss. To determine the efficacy of VHP against nematodes, Caenohabditis elegans, from the taxonomic group Rhaboditida, was used as a surrogate marker for other parasitic nematodes like Enterobius (pinworms), Syphacia, Aspicularis and Ascaris. C. elegans has proven to be a useful model for this type of application because it is non-parasitic to humans, rodents, and other vertebrates, but demonstrates equal resistance to decontamination. For example, for these studies, nematode eggs were isolated and remain viable on exposure to 0.5-1% bleach for 10 minutes. In a 2000 $ft^3$ (60 $m^3$) room study, following a four hour total decontamination cycle with VHP, total kill of C. elegans eggs, larvae, and adult forms was confirmed (Gustin et al, 2002). The efficacy of VHP has been also confirmed against Syphacia muris and Syphacia obvelata. A further study on the efficacy of VHP against nematodes has recently been published (Riedesel et al, AALAS 2002).

**Penentration and decontamination under worst case conditions**

A series of tests were completed to verify the efficacy of VHP under worst case test conditions:

**1)** Verification of bacterial spores as the most-resistant to VHP

A study was conducted to assess the different microbial resistances to 1.0 mg/L VHP.
The organisms selected for the evaluation included Aspergillus niger spores, Bacillus stearothermophilus spores, Klebsiella pneumoniae, Mycobacterium terrae, Staphylococcus aureus, Trichophyton mentagrophytes spores and the T2 bacteriophage (phages are used as indicators of viral efficacy due to their unusual resistance to biocides). The organisms were prepared in 10% bovine serum, inoculated onto the surfaces of stainless steel coupons, and dried for 50 minutes. Coupons were exposed to the sterilization phase of a VHP cycle for 1, 2 and 5 minutes, and log reductions determined. Average log reductions were determined and clearly showed the bacterial spores as the most resistant (Table 3):

**Table 3.** Microbial D-values* when exposed to VHP at 1mg/L and in the presence of 10 serum.

| Test Organism | D-value (seconds) |
|---|---|
| B. stearothermophilus spores | 150 |
| Mycobacterium terrae | < 50 |
| Staphylococcus aureus | < 50 |
| Aspergillus niger | < 24 |
| Klebsiella pneumoniae | < 24 |
| Trichophyton mentagrophytes | < 24 |
| T2 bacteriophage | < 24 |

*D-value: time to kill one log of test organism

**2)** Verification of Bacillus stearothermophilus spores as the most resistant to VHP.

Testing was repeated as described above with bacterial spore suspensions (in the absence of serum) to confirm the most resistant bacterial species (Table 4). As previously published, B. stearothermophilus spores were clearly the most resistant to VHP.

**Table 4.** Confirmation of the most resistant microorganism to VHP.

| Test Spore Species | D-value (seconds) |
|---|---|
| Bacillus stearothermophilus | 42 |
| Bacillus subtilis | 19 |
| Clostridium sporogenes | 16 |
| Bacillus circulans | 14 |
| Bacillus cereus | 10 |

**3)** Identification of the most resistant material to VHP.

Testing was repeated as described above with $10^6$ B. stearothermophilus spores dried onto a variety of materials to identify the most resistant material to decontamination by VHP (Table 5). The antimicrobial activity of any biocide will vary depending on the contact surface and is often underestimated in the evaluation of antimicrobial processes

**Table 5.** Confirmation of the most resistant material to VHP.

Its is clear from these results that paper (in this case Whatman No.2 filter paper) presented the worst case surface for VHP decontamination; due to its cellulosic nature, paper will breakdown VHP, but despite this a 6 log reduction was observed within one hour expose to VHP. In general, the presence of cellulosics in any area for VHP decontamination requires special consideration and cycle development.

| Material | Exposure Time – Avg. Counts (cfu) | | | | |
|---|---|---|---|---|---|
| | 10 min | 20 min | 30 min | 45 min | 60 min |
| Stainless Steel | <10 | 0 | 0 | 0 | 0 |
| Anodized Aluminum | 0 | 0 | 0 | 0 | 0 |
| Optical Glass | 15 | 12 | 0 | 0 | 0 |
| Ceramic Tile | 0 | 0 | 0 | 0 | 0 |
| Beechwood | 0 | 0 | 0 | 0 | 0 |
| PET | 0 | 0 | 0 | 0 | 0 |
| LDPE | 63 | <10 | 0 | 0 | 0 |
| Polypropylene | <10 | 0 | 0 | 0 | 0 |
| Silicone | <10 | 0 | 0 | 0 | 0 |
| Paper | $2.3 \times 10^5$ | $1.2 \times 10^5$ | 86 | <10 | 0 |
| Fiberglass | 18 | 0 | 0 | 0 | 0 |
| PVC | <10 | 0 | 0 | 0 | 0 |
| Polyurethane | $1.8 \times 10^4$ | <10 | 0 | 0 | 0 |
| Neoprene | <10 | 0 | 0 | 0 | 0 |
| Viton | $3.7 \times 10^3$ | <10 | 80 | 0 | 0 |
| EPDM | 0 | 0 | 0 | 0 | 0 |

**4)** Demonstration of efficacy of VHP to decontaminate the most resistant organism on the most resistant material, in the presence of blood.

The ability of VHP to decontaminate an enclosed area under worst case conditions was confirmed by inoculating $10^6$ of the most resistant organism (B. stearothermophilis spores) in the presence of 50% whole blood onto the most resistant material (Whatman No.2 filter paper). These coupons were dried and placed at various locations in one rigid (SPACE Bio-safety Cabinet; Envair Ltd., Lancashire, England) and one flexible-walled ($21ft^3$ ,$0.7m^3$ flexible isolator, Model No. I56143; La Calhene, Rush City, MN) isolator. These combination of conditions combine a worst case physical, chemical and microbial challenge to the fumigation process.
Both isolators were decontaminated with a standard VHP 1000 cycle for a total cycle time of ~2.5 hours (45-60 minute sterilization phase). All coupons were recovered and found to be sterile following incubation.

**Bioterrorism remediation**

VHP decontamination has been shown to be an effective method for bioremediation of rooms and buildings, including HVAC systems. VHP 1000 and higher capacity delivery and control systems have been developed and used for the remediation of area contaminated with Bacillus anthracis spores. Case studies have been successfully completed on the remediation of enclosed areas up to 1, 500, 000 $ft^3$ (43,000 $m^3$). Research is ongoing into the use of VHP for HVAC (air-handling) decontamination and for chemical weapon remediation.

## Chemistry

**VAPROX**

VHP is produced by vaporization of 35% liquid hydrogen peroxide (VAPROX), which is provided in easy to use 950mL thick walled polyethylene bottles with vented cap. The bottles have been specifically designed to permit direct insertion into a VHP system, which draws the liquid hydrogen peroxide directly from the bottle. The operator is not required to dispense or transfer the hydrogen peroxide, thereby limiting direct exposure and reducing the risk of spillage. Hydrogen peroxide liquid is a colorless, odorless liquid. An MSDS is provided for reference. Vaprox is a registered sterilant for use in STERIS VHP equipment (EPA Reg. No. 58779-4).

**Environment**

The half-life of VHP in the environment is relatively short and rapidly breaks down into water and oxygen in the environment.

The VHP decontamination process includes an aeration phase utilizing a catalytic converter in which vapor levels in the treatment area are reduced in concentration to below the established Permissable Exposure Level (PEL) of 1 ppm.

**Material Compatibility**

VHP bio-decontamination is a 'dry' process and used at much lower concentrations than alternative oxidizing agent-based liquids (bleach, hydrogen peroxide/peracetic acid combinations) or gaseous alternatives, which also require significant humidification (>70%) for activity. VHP is compatible with a wide range of materials, including electronic components and equipment. A list of the most common materials encountered during decontamination processes and their respective compatibility is provided in Table 6. Compatibility is defined as the materials ability to undergo exposure to VHP with no significant changes in physical, or chemical properties (i.e., no changes in strength, flexibility, chemical composition, corrosiveness, etc.). For example, the VHP 1000 has been used for over 10 years in a variety of pharmaceutical and industrial applications and is highly regarded as being safe and compatible for use for surface decontamination. Most of the experience with VHP in practice has been repeated exposures for validated isolator or room applications.

**Table. 6.** Examples of materials demonstrating compatibility with VHP.

| **Metals** |
|---|
| Aluminum |
| Stainless steel (all grades) |
| Titanium |
| **Plastics** |
| Polycarbonate |
| Nylon |
| ABS |
| PVC |
| Polypropylene |
| **Elastomers** |
| Viton |
| Polyurethane |
| **General** |
| Oil and Latex paint |
| Olefin blend and polyester blend carpet |
| Ceiling tiles, including compressed wood, elluose-based, fiber glass and plaster-based |
| Electronics (including computers, calculators, scanners, equipment) |

Enclosed areas that may contain significant absorptive or proteinaceous materials (e.g. celluosics) require specific cycle development. Prolonged exposure over multiple applications may cause some discoloration (fading) on some surfaces over time, for example color fading on x surfaces.

**Sensors/Indicators**

Sensors and indicators are available to detect the concentration and presence of VHP during a bio-decontamination process.

For detection of low level (safety) concentrations Draeger Pac III hand held or wall mounted monitors (e.g., P/N4530010 with hydrogen peroxide Sensor Head P/N 6809170) sensor system (handheld) or Draeger Chemical indicator Tubes 9 (such as Part #81 01 041) with a hand-aspirated pump are available to monitor VHP in adjacent areas or to confirm adequate aeration in a given area. Other hydrogen peroxide gas sensors are available from Analytical Technology Inc. (ATI)

Electrochemical and spectro-photometric sensors are available for detection and monitoring of higher VHP concentrations during a bio-decontamination process.

Chemical indicators that indicate the presence of VHP at effective concentrations over time are available for routine monitoring or validation of VHP decontamination processes.

## Safety Issues

### Toxicity

Of all the gaseous methods currently available for room decontamination, VHP has the best safety and environmental profile. In general, a limit of 1ppm (0.0014 mg/L) in air for an 8-hour time averaged over an 8 hour work shift for worker exposure to hydrogen peroxide vapor has been established (i.e., OSHA Permissible Exposure Limit (PEL)). The short-term danger level for hydrogen peroxide vapor is 75ppm (0.0105 mg/L) for 30 minutes (i.e., the IDLH for short term exposure). Hydrogen peroxide vapor becomes apparently irritating at levels over 1ppm (, so it is unlikely for personnel to unknowingly be exposed. These risks are considered as part of cycle development for an application provided by STERIS. Simple, hand-held methods and sensors are available for rapidly quantifying low levels of peroxide. Further, VHP rapidly degrades in the environment to water vapor and oxygen, both innocuous no-toxic byproducts.

Note as a reference point that hydrogen peroxide at 3% (30,000ppm) is used as a skin and oral antiseptic, and 6% (60,000ppm) as an antiseptic and hair colorant. 1% (10,000ppm) is approved by the EPA for direct food use with no significant toxicity. Further, hydrogen peroxide is listed as GRAS (Generally Regarded As Safe).

Hydrogen peroxide is non-flammable and so the vapor does not present a risk for explosion and hence no explosion limits are set. At the concentrations of hydrogen peroxide used in the STERIS VHP process, the oxygen concentration released by the hydrogen peroxide will cause an increase of the atmospheric oxygen concentration of less than 0.2%, a negligible difference.

### Wet versus Dry

Hydrogen peroxide vapor systems may be classified as ‘wet’ or ‘dry’ processes. Hydrogen peroxide vapor can be introduced into a given area up to a certain concentration, dependant on the isolator temperature and humidity, to a saturation level or dew point. If the concentration of hydrogen peroxide increases above this level it will condense onto the surfaces of the isolator (‘condensation’ or ‘micro-condensation’). This has been well established physically and chemically for over 50 years. In the case where micro-condensation is formed and maintained during the cycle, this is considered a ‘Wet’ process. If the vapor concentration is maintained below the dew point during the cycle, it is essentially a ‘Dry’ process (as described for the VHP systems). The antimicrobial efficacy, cycle characteristics, material compatibility and safety aspects for both processes are distinct and should be considered separate. VHP is designed as a dry process. Wet processes can be variable (due to uneven deposition on surfaces), difficult to validate, very corrosive to surfaces and can pose a safety risk. The cycle times are also significantly longer, due in particular to the longer aeration times needed to remove the condensed hydrogen peroxide and water from surfaces. A comparison of wet and dry processes is given in Table 7.

**Table 7.** 'Wet' versus 'Dry' Hydrogen peroxide vapor

| | VHP 'Dry' | Alternative 'Wet' |
|---|---|---|
| Sterilization process | Dry | Wet (condensation) |
| Repeatable process, easily validated | Yes | No, especially larger volumes |
| Reach low humidity levels | Yes | No |
| Control of H2O2 concentration | Yes | No, only condensation level at one point in an area |
| Typical use concentrations | 0.1-2 mg/l | Unknown, variable |
| Aeration time | Short | Very Long |
| Material compatibility | Very Good | Poor |
| Capacity | Range for small areas to very larger areas | Up to 3500 ft3 |
| Mobile | Yes | Yes |
| Available as a modular system | Yes | No |
| Safe on electronics | Yes | Not recommended |
| Number of units validated | >500, worldwide | Few, at this writing |

Independent case studies directly comparing the safety, efficacy, compatibility and total cycle time of wet and dry processes are available for review.

## Case studies and reference accounts

A variety of case studies and reference accounts are available for review. Published references are also provided below.

## References

The following references are provided as an example of published information on VHP:


**Akers JE, Agalloco JP, Kennedy CM.** 1995. Experience in the design and use of isolator systems for sterility testing. PDA J Pharm Sci Technol. 49(3):140-4.

**Corveleyn S, Vandenbossche GM, Remon JP.** 1997. Near-infrared (NIR) monitoring of H2O2 vapor concentration during vapor hydrogen peroxide (VHP) sterilisation. Pharm Res. 14(3):294-8.

**Graham GS, Rickloff JR.** 1992. Development of VHP sterilization technology. J Healthc Mater Manage.10(8):54, 56-8.

**Gustin, E.J., G.E. McDonnell, G. Mullen, and B.E. Gordon.** 2002. The efficacy of vapor phase hydrogen peroxide against nematode infestation: the Caenohabditis elegans model. American Association for Laboratory Animal Science (AALAS), Annual meeting, San Antonio, TX. October 27-31, 2002.

**Heckert, R.A., M. Best, L.T. Jordan, G.C. Dulac, D.L. Eddington and W.G. Sterritt.** 1997. Efficacy of vaporized hydrogen peroxide against exotic animal viruses. Appl. Environ. Microbiol. 63: 3916-3918.

**Jahnke, M., and G. Lauth.** 1997. Bio-decontamination of a large volume filling room with hydrogen peroxide. Pharm. Eng. 17: 96-108.

**Johnson, J.W., J.F. Arnold, S.L. Nail, and E. Renzi.** 1992. Vaporized hydrogen peroxide sterilization of freeze dryers. J. Parent. Sci. Techn. 46: 215-225.

**Klapes, N.A., and D. Vesley.** 1990. Vapor-phase hydrogen peroxide as a surface decontaminant and sterilant. Appl. Environ. Microbiol. 56: 503-506.

**Kokubo, M., T. Inoue, and J. Akers.** 1998. Resistance of common environmental spores of the genus Bacillus to vapor hydrogen peroxide vapor. PDA J. Pharm. Sci. Technol. 52: 228-231.

**Krause, J., G. McDonnell and H. Riedesel.** 2001. Bio-decontamination of animal rooms and heat-sensitive equipment with Vaporized Hydrogen Peroxide. Cont. Topics. 40:18-21.

**Lentine, K.R., and R.J. Keller. 2003.** The effect of vaporous phase hydrogen peroxide on sterility test devices. Pharm. Techn. Europe. February 2003. p31-42.

**Malmborg, A., M. Wingren, P. Bonfield, and G. McDonnell.** 2001. Room decontamination with vaporized hydrogen peroxide. Cleanrooms. Nov, 2001.

**Manzati C.** 1995. Gas sterilization with gas hydrogen peroxide: a new technology in the pharmaceutical industry. Boll Chim Farm. 134(8):413-33 < Italian>.

**McDonnell, G.** 2002. Vaporized Hydrogen Peroxide (VHP®) decontamination and sterilization processes for Pharmaceutical, Laboratory Research and Medical Device Applications. Cleanroom Technology. Oct/Nov 2002. p13-16.

**McDonnell, G.** 2002.
Sterile environment. Manufacturing Chemist. Sept. 2002. p. 69-71.

**McDonnell, G.** 2002.
Decontamination of workstations and enclosed areas with Vapor Phase Hydrogen Peroxide (VHP). Hospital Pharmacy Europe Winter 2002.

**McDonnell G., G. Grignol, and K. Antloga.** 2002.
Vapor phase hydrogen peroxide decontamination of food contact surfaces. Dairy, Food Environ. Sanit. 22: 23-28.

**McDonnell G, B. Belete, C. Fritz, and J. Hartling.** 2001.
Room decontamination with Vapor Hydrogen Peroxide VHP for environmental control of parvovirus. American Association for Laboratory Animal Science (AALAS), Annual meeting, Baltimore, MD, October 21-25, 2001.

**McDonnell G, B. Belete, C. Fritz, E. Gustin, J. Hartling.** 2001.
Room decontamination with Vapor Hydrogen Peroxide VHP7 for environmental control of parvovirus. American Biological Safety Association (ABSA), Annual meeting, New Orleans, LA, October 21-24, 2001.

**McVey, I, E. Gustin, and G. McDonnell.** 2002.
Large area volume biological remediation with Vaporized Hydrogen Peroxide (VHP) technology. 45th Annual American Biological Safety Association meeting, October 22, 2002; San Francisco, CA, USA.

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