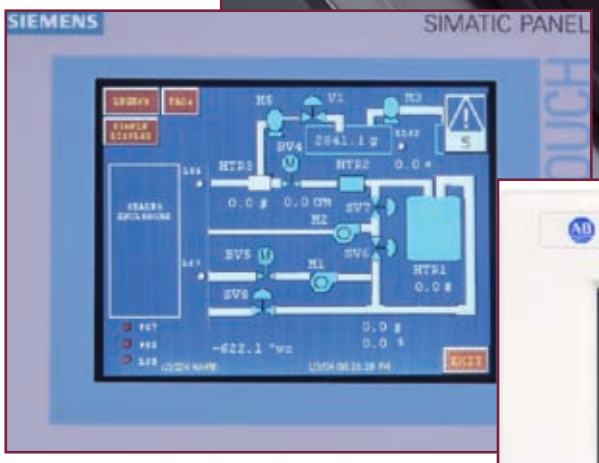
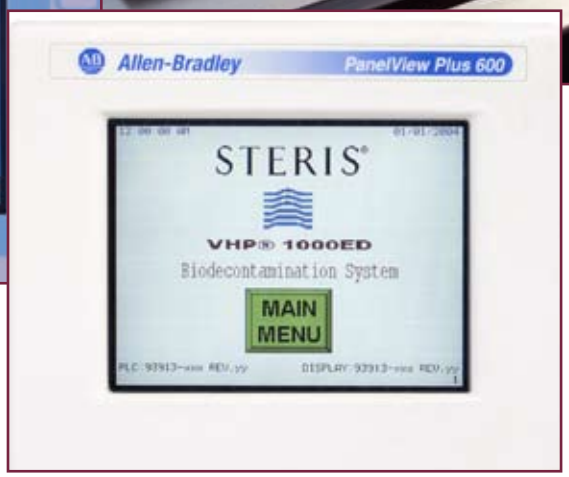
VHP® 1000ED Mobile Biodecontamination System

The proven technology of vaporized hydrogen peroxide biodecontamination validated by our customers worldwide for isolators, rooms and other sealed enclosures





STERIS®

Proven Performance with "Enhanced Design"

Since the introduction of STERIS's vaporized hydrogen peroxide low temperature biodecontamination technology in 1991, VHP® systems have become the predominant choice and industry standard for aseptic processing in research and production applications. With over 1400 VHP® systems installed worldwide, this proven technology is now available with a color touch-screen PLC.

The VHP® 1000ED Biodecontamination System is designed for use in isolators, workstations, aseptic filling lines, and pass-through rooms in research, biological safety and production applications.

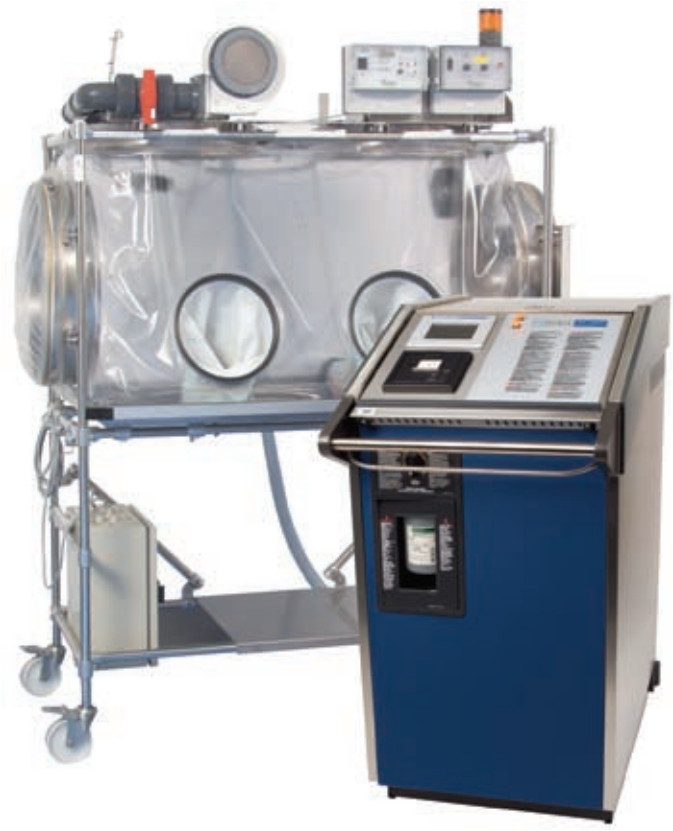
The VHP process is fully controlled, repeatable, and easily validated. This "dry" process operates under low concentration and is highly efficacious. It is fast, safe and offers a wide range of material compatibility.

Ergonomically designed for maximum operator comfort and safety, the VHP® 1000ED Biodecontamination System is easily maneuvered for multiple site use.

> Fast – All cycle parameters are quickly and easily customized for the shortest possible cycle time without compromising efficacy.

> Environmentally friendly – Provides a validatable biodecontamination process that yields non-toxic byproducts of water vapor and oxygen.

> Wide range of material compatibility – Hydrogen peroxide vapor has been shown to be compatible with and safe for a wide range of materials including metals (stainless steel, aluminum, and titanium), plastics (polypropylene, polyethylene, and polycarbonate) and other materials (silicone and glass), and even electronics.



The VHP® 1000ED system has been validated by our customers worldwide for sterility testing in isolators, rooms and other sealed enclosures.

Product Features

Industrial Designed Cabinet

Stainless steel shell and piping

Dimensions W x H x D

Inches - 24-1/4 x 48 x 43-3/8

Millimeters - 612.8 x 1219.0 x 1101.3

Weight

Approximately 500 lbs. (227 kg)

Operating Parameters

Injection rate: 1-12 grams per minute

Airflow range: 8-20 scfm (14-34 m^3/h)

Pressure control: +/- 1 inch of water column (250 pascal)

Power Requirements

120 VAC, 50/60 Hz, single phase, 16 A

200 VAC, 50/60 Hz, single phase, 12 A

230 VAC, 50/60 Hz, single phase, 10 A

Operating Temperature Range

60°F – 104°F (16°C – 40°C)

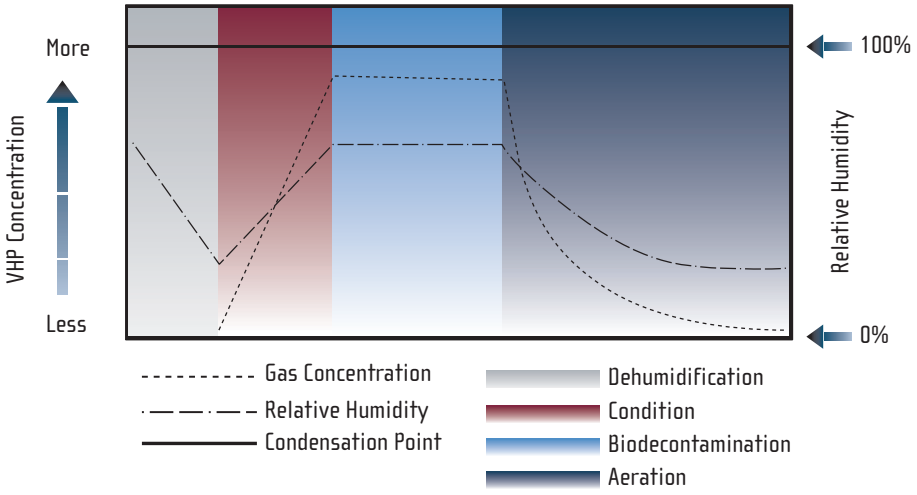
Control System

Select from Allen-Bradley Compact Logix (PanelView Plus 600 display) or Siemens Simatic S7-300 (TP-270 display) color touch-screen Programmable Logic Control (PLC). All control systems provide the precise control and documentation required by GAMP standards.

> Communication port for transfer of data to local or remote data acquisition system
> Standard cycle or custom cycle parameter selection
> Shows real-time status and all current cycle parameters
> Service diagnostics mode for calibration, service, etc.
> Cycle alarms for all cycle parameters
> Security access codes
> Help screen
> Battery back-up protects Allen-Bradley System Data for a minimum of two years, while Siemens System retains data via Flash Memory
> Language options: English, French, German, Italian, Spanish, and Dutch
> GAMP software development documentation package available

Impact printer provides an easy-to-read permanent record of all cycle parameters.

Typical Biodecontamination Cycle



The VHP biodecontamination cycle operates in a closed-loop configuration where the enclosure is subjected to four phases:

> Dehumidification – Reduction of relative humidity to a pre-determined level

> Condition – Rapid increase to desired VHP concentration

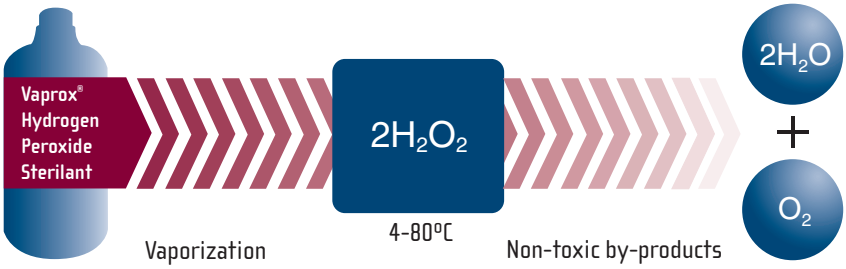
> Biodecontamination – Maintenance of desired VHP concentration and relative humidity (for retention of vapor phase)

> Aeration – Rapid reduction of hydrogen peroxide vapor

Cycle times vary with initial temperature and humidity, enclosure type, volume and load. The process is fully automated, and all cycle parameters are monitored and recorded for process validation.

The on-board dehumidification system periodically requires a regeneration cycle to refresh the drying system. The unit can be programmed to automatically regenerate on shutdown or when convenient.

How VHP Biodecontamination Works



Sporicidal at low concentrations
(Typically 0.1-2 mg/l at 25°C)

Advantages of VHP Biodecontamination

> Biodecontamination within low temperature range of 4-80°C

> Proven efficacy against a wide range of microorganisms

> Excellent material compatibility

> Environmentally friendly process yielding only water vapor and oxygen as by-products

STERIS can provide technical assistance with feasibility studies, efficacy studies, and material and packaging compatibility testing. In addition, assistance with determining cycle parameters, load configuration, and sizing is available.

Training, Technical Support and Service

> Full operator training is provided either on-site or at a STERIS training facility.

> Application engineers are available to assist with onsite operator training, hands-on demonstrations, custom cycle development and validation training.

> Field service engineers are available to assist with IQ/OQ, calibration, start-up and preventive maintenance.

The STERIS Life Sciences Group takes pride in its extensively trained professionals. Rigorous classroom, factory, and field training yield experts who specialize in your products, your systems, and your industry.

System Requirements

> Dedicated grounded electrical circuit

> Vaprox® 35% Hydrogen Peroxide Sterilant (EPA Registration No. 58779-4), formulated to provide optimum equipment performance.

> VHP™ Chemical and Spordex® Biological Indicators

NOTE: The user is responsible for ensuring that enclosures are properly sealed before using any VHP Biodecontamination System.

Standards

The unit and control systems have been designed to meet applicable requirements of the following:

> Underwriters Laboratories (UL) Standard 61010-1 2nd Edition as certified by ETL Testing Laboratories, Inc.

> Canadian Standards Association (CSA) Standard C22.2 No. 61010-1:2004 as certified by ETL Testing Laboratories, Inc.

> Designed to meet all applicable electrical requirements and international electrical codes.

> EMC Directive: 89/336/EEC, 92/31/EEC, 93/68/EEC; Low Voltage Directive: 73/23/EEC, 93/68/EEC, and bears the CE mark.

Vaprox Hydrogen Peroxide Sterilant is specially formulated to maintain optimum equipment performance.

To minimize exposure to the liquid hydrogen peroxide during handling, the system uses specially designed disposable cartridges (available separately) containing approximately 950 ml of Vaprox 35% Hydrogen Peroxide (H_2O_2) Sterilant.

Spordex Biological Indicators (*Geobacillus stearothermophilus*) and VHP Chemical Indicators are available for use with Vaporized Hydrogen Peroxide distribution, efficacy studies, and sterility testing.

When using VHP® equipment with Vaprox Hydrogen Peroxide Sterilant in the United States, the term biodecontamination referred to in this document is defined as sterilization of exposed porous and non-porous surfaces in a pre-cleaned, dry, sealed enclosure. Any reference to biodecontamination as it relates to the use of this equipment in the United States does not impart additional claims of effectiveness beyond that approved in the EPA-registered labeling of Vaprox Hydrogen Peroxide Sterilant.

STERIS®

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