VHP® M100 Biodecontamination Systems: Open Loop

The proven technology of vaporized hydrogen peroxide biodecontamination for a variety of applications

STERIS

Proven Technology For High Capacity and Continuous Applications

Since the introduction of STERIS's vaporized hydrogen peroxide technology in 1991, VHP® Biodecontamination Systems have become the predominant choice and industry standard for aseptic processing in research and production applications.

With over 1700 VHP systems installed worldwide, STERIS is proud to provide a product platform that offers both closed loop and open loop** systems for a wide range of applications within production and research facilities.

Biodecontamination Applications Include:

> Isolators

> Glove boxes

> Pass-through chambers

> Aseptic filling

> Clean rooms

> Material air locks

VHP® M100 Open Loop Biodecontamination Systems

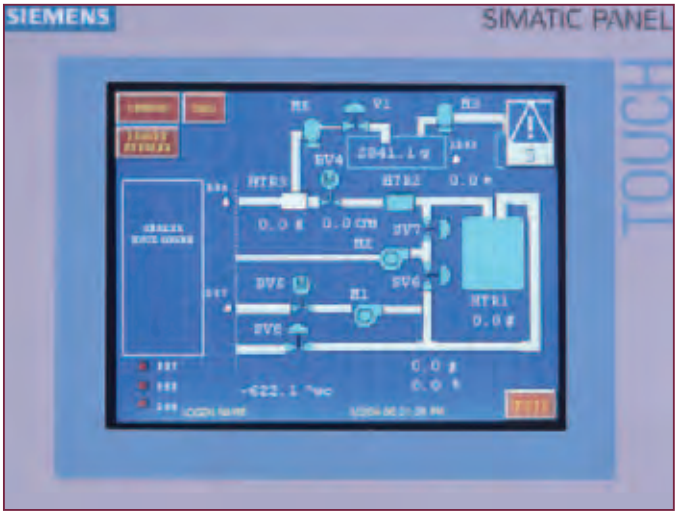
> Modular unit can be conveniently integrated into isolator or room

> AISI 304 (DIN 1.4301) Stainless steel enclosure wall and access door construction

> Continuous Vaprox® sterilant injection features available for open-loop applications

> Easy access design for daily operation, service and maintenance

**Check local regulations regarding environmental hydrogen peroxide discharges.



Material of Construction

AISI 304 (DIN 1.4301) SS enclosure wall and access door construction

Dimensions W x H x D

31" x 26" x 9"
(787 mm x 660 mm x 229 mm)

Weight

160 lbs. (72 kg)

Operating Parameters

Injection Rate: 0.5 – 24 grams per minute
Air flow Range: 8-44 scfm (14-75 cmh)
Pressure Control: N/A

Power Requirements

230 V, 50/60 Hz, Single Phase, 15 Amp

Printer

Ink-on-pad printer provides an easy to read permanent record of all cycle parameters

Control System

> PLC (Allen-Bradley or Siemens) control permits interfacing with existing equipment

> Operator Interface: Allen-Bradley Panel View Plus 600, Siemens TP277

> Custom biodecontamination cycles

> Custom cycle parameter selection

> Cycle alarms for all cycle parameters

> Security access codes

> Help screen

> Battery backup protects cycle memory

> GAMP Software documentation packages available

> Language options:

- Siemens: English, German, French, Dutch, Italian, Spanish and Portuguese
- Allen-Bradley: English, French

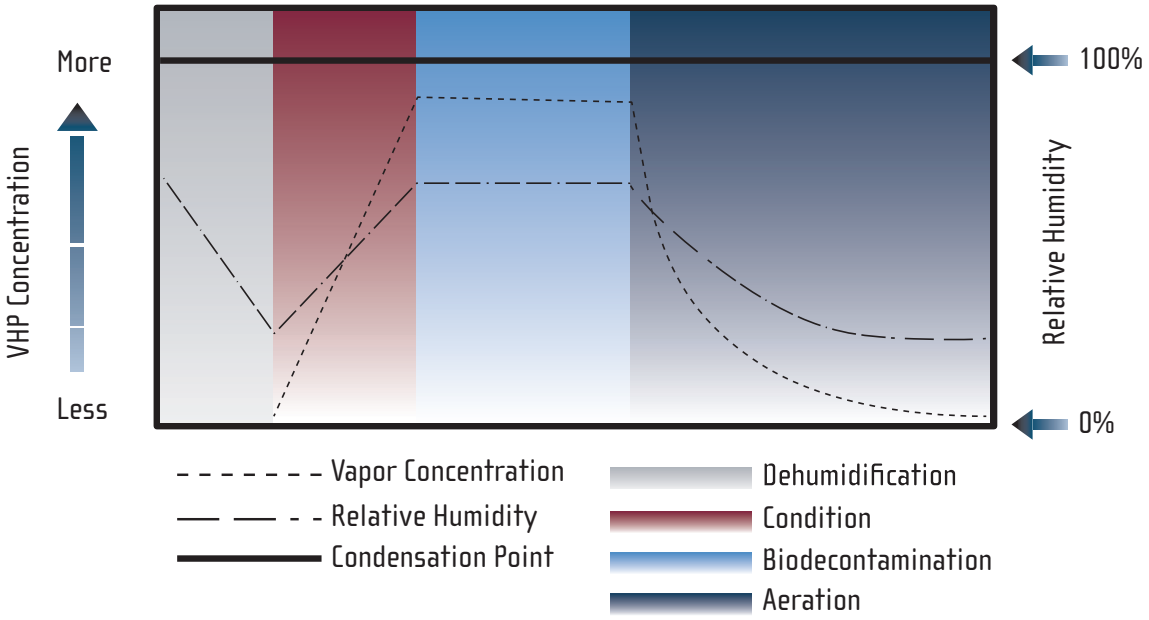
Vaprox® Interface

> 1 L cartridge interface as an option; bulk supply as standard

Dehumidification System

> Customer supplied desiccant wheel

About VHP Biodecontamination Cycle



A typical cycle operates in a closed-loop or open-loop configuration where the enclosure is subjected to four phases:

- Dehumidification - reduction of relative humidity to 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

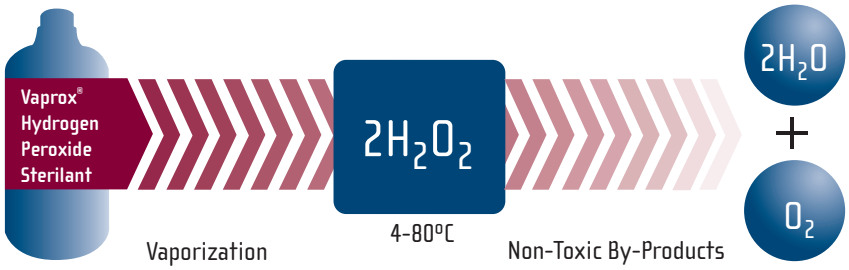
Cycle times vary with initial temperature and humidity, enclosure type, size and configuration, and load. The process is fully automated. All cycle parameters are monitored and recorded for process validation.

With water vapor and oxygen as by-products, VHP® Biodecontamination Systems offer your best formaldehyde replacement option.

Advantages of STERIS VHP Biodecontamination Systems

- Biodecontamination under ambient conditions
- Proven efficacy against a wide range of microorganisms
- Broad range of material compatibility, including metals, plastics and elastomers
- Environmentally friendly process yielding water vapor and oxygen as by-products

How VHP Biodecontamination Works



Sporicidal at Low Concentrations

System Requirements

> Customer supplied desiccant wheel and aeration system

> 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.

Training, Technical Support, and Service

> Specialists are available to assist with onsite 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.

Standards

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

> Underwriters Laboratories (UL) Standard 61010-1

> Canadian Standards Association (CSA) Standard C22.2 No. 61010.1

> 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

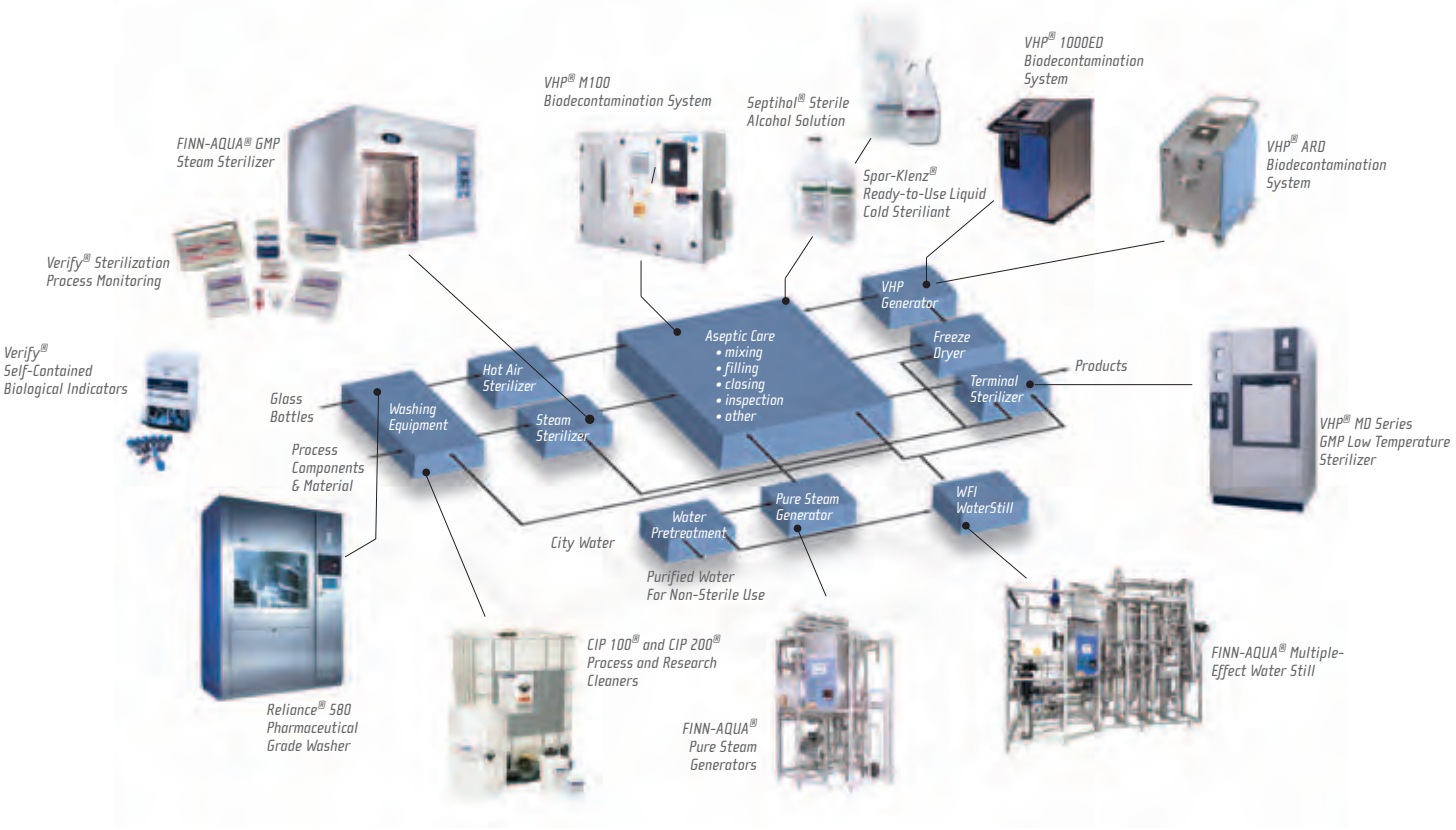
To minimize exposure to the liquid hydrogen peroxide during handling, the system uses specifically designed disposable cartridges (available separately) containing approximately 950 ml or bulk containers containing approximately 5 gallons (19L) of Vaprox 35% Hydrogen Peroxide (H_2O_2) Sterilant.

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

STERIS provides solutions to help prevent contamination in your manufacturing or research process. Our systems are specially designed to answer the contamination challenges in research laboratories, animal facilities, aseptic processing and bulk biopharmaceutical manufacturing.

Our expert resources offer integrated solutions to help you achieve faster process validation, more efficient operations and greater cost control. We provide onsite training, educational seminars and technical support where and when you need it through our worldwide manufacturing presence and broad distribution channels.

STERIS is a leading provider of infection and contamination prevention, microbial reduction and surgical support systems, products, services and technologies to healthcare, life sciences, research, food and industrial customers throughout the world.



* 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.

Manufactured exclusively by STERIS Corporation in our ISO-9001 certified Mentor, Ohio facility.

Mixed Sources

Product group from well-managed forests, controlled sources and recycled wood or fiber

Printed with Soy based inks and water based coatings on FSC/Green Seal-certified paper.

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