VHP® 1000i

Biodecontamination System

APPLICATION

The VHP 1000i Biodecontamination System is used for fast, continuous (open-loop) biodecontamination* of clean, dry, sealed Enclosures.**

*When using VHP® Biodecontamination Systems 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 precleaned, 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.

** Enclosure must be leak tested according to manufacturer's recommendations.

DESCRIPTION

The VHP 1000i Biodecontamination System is designed for permanent mounting to sealed Enclosures. This modular system consists of a hydrogen peroxide generator, plumbing and control interfacing provided in a space saving vertical cabinet. The lockable cabinet includes the operator control interface and PLC, power disconnect, indicator LED, USB and Ethernet ports, Vaprox link interface with injection system, Vaprox link RFID base, HEPA filtered distribution blower, and connections for host control system.

The Biodecontamination System can operate as a stand-alone unit or integrated with a host control system via Industrial communication protocols. These protocols include Profinet TCP and discrete I/O as standard with options available with the Industrial Communication Module accessory. The host control is used to select and start cycles, abort cycles, and monitor the status of the unit.

The VHP 1000i Biodecontamination System is only to be operated by trained and certified applicators who have successfully completed the STERIS Training and Certification Course for applicators of Vaprox Hydrogen Peroxide Sterilant. Certification must be active and in force for all applicators of Vaprox Hydrogen Peroxide Sterilant. Recertification is required every three years.

To minimize exposure to the Vaprox Hydrogen Peroxide Sterilant during handling, the system uses specially designed disposable bulk containers containing approximately 5 gal (19 L) or 53 gal (200 L) of Vaprox Hydrogen Peroxide Sterilant.

Units operate on 230 Volts, 50/60 Hz, Single phase or 380 Volts, 50/60 Hz, Three phase electrical service.

Operator Interface:

- Siemens SIMATIC TP700 - The touch panel is a backlit 7" liquid crystal type (TFT) display equipped with 800 x 480 pixel resolution, 24 bit color graphics and an analog touch membrane.
- USB or Memory Card - Cycles and parameters can automatically be generated as PDF files.
- Electronic Data Security to 21 CFR Part 11 (Optional) - Software feature enabling audit trail, electronic data capture, user administration, and other features for use in validation.
- Remote Operation - Remote operation from computer or tablet device is available using VNC viewer software.

STANDARDS

The VHP 1000i Biodecontamination System meets the applicable requirements of the following standards:

- Underwriters Laboratories (UL): 61010-1, 61010-2-040
- Canadian Standards Association (CSA) Standard C22.2 No. 61010-1, 61010-2-040
- CE Compliance
  - EMC Directive 2014/30/EU
  - Low Voltage Directive 2014/35 EU
  - Radio Equipment Directive 2014/53 EU
- RoHS 2 Compliant

CONSUMABLES

Vaprox® Hydrogen Peroxide Sterilant - 35% stabilized aqueous solution of hydrogen peroxide designed for use with STERIS VHP® Biodecontamination Units and Accessories (EPA Reg. No. 58779-4 and EU BPR Registered). Refer to Tech Data SD996 for further information.

Each container of Vaprox® Hydrogen Peroxide Sterilant features an RFID tag, Vaprox® Link, to track lot number, production expiration date and in-use expiration date. This data will be available on the batch report and in the control panel interface.

Vaprox® Link will provide the user with visual confirmation that their chemistry has been accepted or not.

Sterilant Delivery Options:

- Bulk Container (5 gal/19 L)
- Bulk Container (53 gal/200 L)

SAFETY FEATURES

The unit includes several safety features to ensure operator safety and process integrity. These include:

- Password protected access levels that allows only authorized users to access the unit controls
- Built in fail safe design features and alarms to control the unit to a safe state
- Main power switch that is mechanically interlocked with the cabinet
- Safety contactor device that can be connected to an optional emergency stop switch or contact
- Key locked panel to limit access to authorized personnel
- Leak detection system to warn user of any possible Vaprox steriliant leaks within the enclosure

CYCLE DESCRIPTION (TYPICAL)

STERIS's VHP® Technology produces hydrogen peroxide vapor, a broad spectrum antimicrobial. The biodecontamination process is a dry process resulting in no condensation of the active ingredient onto surfaces. This non-condensation feature provides the additional benefit of a wide range of material compatibility.

The VHP 1000i Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. In practice, an aqueous solution of 35% Vaprox Hydrogen Peroxide Sterilant is flash vaporized. A heated air stream carries the vapor into the enclosed space requiring biodecontamination. With the VHP 1000i Biodecontamination Unit operating as an open-loop system, air and VHP antimicrobial are drawn out of the enclosed space and pass through a facility equipped vent system to atmosphere. The vent system maybe equipped with an optional catalytic converter (equipment not supplied by STERIS) degrading the VHP antimicrobial into oxygen and water vapor and then exhausted into the environment. The air stream continuously charges with fresh VHP supplied to the Enclosure.

NOTE: *Check local regulations regarding environmental hydrogen peroxide discharge.*

While operating in an open-loop configuration (see illustration), the biodecontamination cycle consists of five phases:

Dehumidification

Dry air is supplied by an external dehumidifier (equipment available separately, see Accessories) at an acceptable level (typically between 0–30% relative humidity). This permits the necessary target Vaprox Hydrogen Peroxide Sterilant vapor concentration to be maintained below saturation (dew point) levels during the Condition and Decontamination phases. The dry air is heated to serve as the carrier for the Vaprox Hydrogen Peroxide Sterilant vapor. The maximum airflow through the VHP 1000i Biodecontamination Unit is typically 118 scfm (200 cmh) depending on the electrical supply voltage/frequency and external piping restictions.

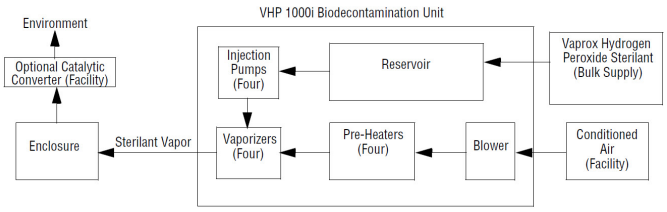
NOTE: *Time to reach the targeted humidity corresponds with the initial humidity, temperature and volume of the Enclosure.*

Condition

If applicable, the flow of dry air continues while Vaprox Hydrogen Peroxide Sterilant vapor is injected into the air stream just before it leaves the unit. The Vaprox Sterilant injection rate is controlled by the unit to ensure consistent VHP flow to the Enclosure. The Conditioning phase facilitates reaching the target biodecontamination concentration faster in larger volume sealed Enclosure applications. Conditioning time is affected by Vaprox Hydrogen Peroxide Sterilant injection rate, Enclosure volume, Enclosure contents and temperature.

Decontamination

A constant flow of the Vaprox Hydrogen Peroxide Sterilant vapor/air mixture is maintained at the selected hydrogen peroxide injection rate for a specific period.



Typical Open-Loop Process Diagram

Aeration

Vaprox Hydrogen Peroxide Sterilant vapor injection is stopped and the flow of dry air continues. This vapor/air mixture exhausts from the Enclosure through the facility equipped vent system to atmosphere. This exhausting of the vapor/air is used to reduce the Vaprox Hydrogen Peroxide Sterilant vapor concentration within the Enclosure. The VHP 1000i can communicate with host control systems as necessary during all cycle phases.

Auxiliary Aeration

Aeration continues. This phase is intended as an extended aeration to confirm removal of any residual H2O2 concentration within the enclosure.

ACCESSORIES

Vaprox Distribution System - Provides interface of a remotely installed connection to Vaprox Hydrogen Peroxide Sterilant bulk supply for the VHP 1000i Biodecontamination Unit.

Remote Printer Module -The remote printer module connects to the VHP 100i and 1000i via Ethernet to provide a print out of the batch report. A separate 100-240 VAC power source is required.

Industrial Communication Module- is available to communicate via Ethernet/IP, PROFIBUS, Modbus TCP, BACnet/IP or OPC UA.

Dehumidifers - Dehumidification units are available to feed dry air to the VHP Unit. This is to ensure proper air supply and optimal VHP output.

Hydrogen Peroxide Vapor Sensors - Fixed and portable hydrogen peroxide vapor sensors are available for high concentration and low concentration measurements. Safety sensors are also available.

OPTIONS

Electronic Data Security to 21 CFR Part 11 (Optional) - Software feature enabling audit trail, electronic data capture, user administration, and other features for compliance with FDA 21 CFR Part 11.

Domain Password Access - Domain password access is available as an option through the Siemens Simatic Logon features.

STERILITY ASSURANCE PRODUCTS

Steraffirm® VH2O2 Process Indicators (PCC051 and PCC060) - Chemical indicators designed for use with hydrogen peroxide vapor.

Spordex® VH2O2 Biological Indicator (NA333) - E6 Geobacillus stearothermophilus (12980) biological indicator designed for use with hydrogen peroxide vapor.

Spordex® Biological Indicator Media (NA117) - TSB culture media designed for use with Spordex biological indicators.

CONTROL SYSTEM

The control system provides precise control of the VHP 1000i Biodecontamination System and uses the Siemens S7–1500 Series Controller.

The PLC control stores and controls such information as the time for each phase, operating temperature and pressure, Vaprox Hydrogen Peroxide Sterilant injection rate, air flow rate and target relative humidity. The control also monitors the amount of Vaprox Hydrogen Peroxide Sterilant available for the next cycle.

CONSTRUCTION

Case: Stainless Steel

Lockable Door: Stainless Steel

CALIBRATION

IQ/OQ, SAT, Training and Cycle Development. These services are available to aid in proper operation and qualification of the unit.

STERIS recommends that all VHP 1000i Biodecontamination Systems be calibrated at least once every six months. STERIS Service representatives can provide this service to ensure validatable operation of the unit.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments to help ensure low-cost peak performance. STERIS representatives can provide information regarding annual maintenance programs.

NOTES

1. STERIS recommends a dedicated, grounded electrical circuit be provided for each unit.
2. Unit should not be installed in an area not compatible with oxidizers. Consult the SDS regarding hydrogen peroxide sterilant.
3. Biodecontamination System must be on a hard, level surface.
4. Access must be provided to power switch and pipe connectors.
5. Clearance must be provided to doors on the VHP 1000i Biodecontamination System.
6. Approximate weight is 700lb (318 kg).
7. It is the Customer's responsibility to make arrangements for the cycle validation.
8. Enclosure size listed is recommended size. Connecting VHP 1000i Biodecontamination System to larger volumes may increase cycle time.
9. Airflow range is measured exiting VHP 1000i Biodecontamination System. Actual flow rates may vary from variations in local utility power output. See equipment drawing for flow rate curves and details.

UTILITY REQUIREMENTS

IMPORTANT: Refer to equipment drawing 11031653 for installation details and specifications.

Electricity:

- 230 Vac, 50/60 Hz, 50 Amps, 1 Phase
- 380 Vac, 50/60 Hz, 35 Amps, 3 Phase

Airflow/Pressure:

- Airflow range: 24-118 scfm (40-200 m^3/h)

Vaprox Injection Rates:

- Bulk fill: 4-70 grams/min (injection rate range is available at listed voltages (up to -10%) and across all conditioned air inlet temperature and humidity ranges. Additional injection capacity is available with listed voltages (up to +10%) and optimal conditioned air inlet temperature and

humidity. Please contact your STERIS representative for additional details.)

Conditioned Air Inlet:

- Humidity: 0-30% RH
- Temperature: 64-104°F (18-40°C)
- Maximum Pressure: 1 psig (69 mbar)

ENVIRONMENTAL FACTORS

Ambient Conditions:

- Room Temperature: 59-95°F (15-35°C)
- Relative Humidity: 15 to 80%

Selections Checked Below Apply To This Equipment

VOLTAGE

☐ 230 VAC, 50/60 Hz

☐ 380 VAC, 50/60 Hz

LANGUAGE OPTIONS

☐ English

☐ French

☐ German

☐ Spanish

☐ Italian

☐ Dutch

☐ Danish

☐ Chinese- User Interface Only

OPTIONS

☐ Electronic Data Security to 21 CFR Part 11

DOCUMENTATION

☐ Extended Document Package (GAMP 5)

ACCESSORIES

☐ Vaprox Distribution System- Single

☐ Remote Printer Module

☐ Industrial Communication Module

☐ Dehumidifier

Item:	
Locations:	

For Further Information, contact:

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