VHP Victory™

Biodecontamination System

APPLICATION

The VHP Victory Biodecontamination System offers Customers all the benefits of STERIS' VHP technology and services packaged in a mobile solution for biodecontamination[1] of rooms and clean, dry, sealed enclosures [2].

DESCRIPTION

The VHP Victory is a mobile VHP Biodecontamination Unit designed for use on sealed enclosures and rooms with volumes ranging from 150 to 566 m^3 (5,300-20,000 ft^3) in pharmaceutical production and research applications.

This Unit consists of a hydrogen peroxide generator and control system mounted in an aluminum frame with molded ABS and Kydex T paneling.

The Biodecontamination Unit includes an integrated display and controller that manages the biodecontaminant generation process and provides connections for building or equipment control integration.

This Unit can operate independently or through an interface to building management systems (BMS). The control communication is via discrete I/O or Network interfacing and data can be transferred via USB or Network. In most cases, this interface is used to start and stop cycles, collect system data, and monitor the system status.

To minimize exposure to the Vaprox Hydrogen Peroxide Sterilant during handling, the system uses specially designed disposable cartridges containing 950 mL of Vaprox Hydrogen Peroxide Sterilant.

The system may also be used with higher volume Vaprox Hydrogen Peroxide Sterilant containers for larger spaces.

STANDARDS

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

- 2014/35/EU Low Voltage Products (LVD):
  - EN 61010-1
  - EN 61010-2-040
- Electrical Equipment (Safety) Regulations 2016:
  - BS EN 61010-1:2010+A1: 2009
  - BS EN 61010-2-040: 2015
- 2014/30/EU Electromagnetic Compatibility (EMC) Harmonized standards:
  - EN 61326–1
- Radio Equipment Directive (RED):
  - 2014/53/EU
    - » ETSI EN 301 489-1, ETSI EN 300 330
  - Radio Equipment Regulations 2017
    - » ETSI EN 301 489-1, V2.2.3 (2019–11), ETSI EN 300 330, V2.1.1 (2017–02)
- Restriction of hazardous substances in electrical and electronic equipment (RoHS):
  - EU 2015/863, EN IEC 63000:2018
- Ingress Protection rating: IP20

1. *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 Environmental Protection Agency (EPA) registered labeling of Vaprox Hydrogen Peroxide Sterilant (EPA Reg. No. 58779–4).*
2. *Contained area to be Biodecontaminated (e.g., rooms, facilities, and equipment). Enclosure must be leak tested according to manufacturer's recommendations.*

CONSUMABLES

Vaprox™ Hydrogen Peroxide Sterilant – 35% (EPA Reg. No. 58779-4 and EU BPR Registered) stabilized aqueous solution of hydrogen peroxide designed for use with STERIS VHP™ Biodecontamination Units and Accessories. Refer to Tech Data SD996 and SD992 for further information.

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

Vaprox™ Link provides the user with visual confirmation that their Sterilant has been accepted or not.

Sterilant Delivery Options:

- Cartridge (950 mL)
- Bulk Container (19 L / 5 gal).

SAFETY FEATURES

The Biodecontamination 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.
- Leak detection system to warn user of any possible Vaprox sterilant leaks.

CYCLE DESCRIPTION (TYPICAL)

The STERIS 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 Victory Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. Software automatically runs the selected biodecontamination cycle.

NOTE: Check local regulations regarding environmental hydrogen peroxide discharge.

After starting a cycle at the Human Machine Interface (HMI), the cycle is run automatically.

SMART Cycle and Pre-Configured Cycles

- SMART Cycle (12 Log Reduction or 6 Log Reduction) – The Biodecontamination Unit uses integrated and/or remote biodecontaminant concentration, humidity, and temperature sensor feedback to control the injection rate and cycle time. The cycle automatically adjusts to the enclosure conditions for optimal cycle efficiency.
- Concentration Control Cycles (400 PPM or 250 PPM) – These cycles are for special applications. Biodecontaminant concentration is rapidly increased to the concentration and saturation setpoints and held for the prescribed amount of time.

NOTE: For applications with starting relative humidity greater than 50%, a dryer may be recommended to improve cycle time.

Programmable Cycles (available with Electronic Data Security option) — Includes the following phases:

Dehumidification — This phase includes an absolute humidity target and time period. If the enclosure humidity is already maintained at an acceptable level, the absolute humidity target may be set to 0 and then the phase consists only of an adjustable time period. Drying of ambient air, if necessary, may be achieved using a dehumidifier accessory.

Condition — The flow of air continues while biodecontaminant is injected into the air stream. The condition phase facilitates efficiently reaching the target VHP concentration. Condition time is affected by biodecontaminant injection rate and room or enclosure area volume, contents, and temperature.

Decontamination — The target biodecontaminant concentration is maintained for a specific time period throughout the enclosure. Refer to the Vaprox label and package insert for more information.

Aeration — Vaprox Hydrogen Peroxide Sterilant vapor injection is discontinued and the biodecontaminant concentration may be reduced through the use of an AR1200 Accessory or through facility exhaust.

ACCESSORIES

TS1000 Tri-Scale Sensor — Sensing unit boosts cycle efficiency and effectiveness of Enclosure Biodecontamination by ensuring biodecontaminant is adequately distributed. TS1000 Sensor measures enclosure H2O2 concentration, RH % and temperature. Up to three TS1000 tri-scale sensors may be linked to each VHP Victory Unit.

Aerator AR1200 — The AR1200 is a portable, high capacity catalyzation unit designed to shorten cycle time in rooms. The high-capacity blower and catalyst assist in expediting the aeration phase. Up to two AR1200 units can be powered and controlled by the Victory or can operate as a stand-alone unit.

Munters Dehumidifiers – Dehumidification systems available for permanent installation and portable operation.

Hydrogen Peroxide Sensors — Draeger or similar hydrogen peroxide vapor sensors are available for safety monitoring.

Output Cable Assembly — Cable includes a 19 pin connector with flying leads and is 9 m /30 ft in length. Allows for communication from Biodecontamination Unit to Customer equipment or to control external accessories.

Input Cable Assembly — Cable includes an 8 pin connector with flying leads and is 9 m / 30 ft in length. Allows for Customer equipment communication to Biodecontamination Unit.

Vaprox Bulk Container Siphon Cap Assembly — The siphon cap is designed to interface directly with the Vaprox Sterilant 18.9 L (5 gal) bulk container opening. Includes peroxide compatible plastic cap, stainless-steel couplings for 1/4" or 1/8" diameter hose, and a drum wrench. Vaprox Bulk Container Siphon Tube must be purchased with this option. This option is only required if bulk feed kit option is used.

Vaprox Bulk Container Siphon Tube — The siphon tube is designed to interface directly with the Vaprox Sterilant Bulk

Container Siphon Cap Assembly. The length of the tube is designed for the 18.9 L (5 gal) bulk container. Includes peroxide compatible plastic tube and interface cap. This option is only required if bulk feed kit option is used.

Braided Stainless-Steel Interconnecting Hose — Teflon hose (multiple lengths are available) with stainless-steel over-braid for transfer of Vaprox Sterilant from a bulk container to the Biodecontamination Unit. The hose has 1/4" MNPT stainless-steel connections at both ends. This option is only required if bulk feed kit option is used.

OPTIONS

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

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

A standard, commercially available programmable logic controller (PLC) is utilized in this Biodecontamination System. The control hardware consists of the B&R Industrial Power Panel C80 control system and HMI. The operator can configure, start, monitor, and abort cycles through interaction with the HMI touch screen.

CONSTRUCTION

Frame: Aluminum and stainless steel.

Case: Scratch and crack resistant, molded in color, ABS or Kydex T plastic.

Casters: Front swivel, back fixed, lockable and non-marking.

CALIBRATION

STERIS recommends that all VHP Victory Biodecontamination Systems be calibrated at least once every six months. STERIS Service representatives can provide this service to ensure validatable operation of the Biodecontamination 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. Enclosure must be leak tested according to manufacturer's recommendations.
2. STERIS recommends a dedicated, grounded electrical circuit be provided for each Biodecontamination Unit.
3. Unit should not be installed in an area not compatible with oxidizers. Consult the SDS regarding hydrogen peroxide sterilant.
4. Refer to Equipment Drawings and Operator Manual for specific installation and operator instructions.
5. Biodecontamination System must be on a hard, level surface.
6. It is the Customer's responsibility to make arrangements for the cycle validation.
7. This Biodecontamination Unit is only to be operated by Trained and Certified Applicators who have successfully completed both STERIS Training and Certification Course for Applicators of Vaprox Hydrogen Peroxide Sterilant.

UTILITY REQUIREMENTS

IMPORTANT: Refer to Equipment Drawing for installation details and specifications.

Electricity:

- 120 Vac, 50/60 Hz, 15 Amps, 1 Phase
- 230/240 Vac, 50/60 Hz, 7.5 Amps, 1 Phase

Vaprox Injection Rate:

- 5-25 g/min

Vaprox Fill Rate:

- Max fill rate is 0.5 L/min.

ENVIRONMENTAL FACTORS

Ambient Conditions:

- Room Temperature: 16-40 C (60-104 F)
- Relative Humidity: 0 to 50%

Unit Specifications:

- 540 x 1014 x 988 mm (21 x 40 x 39")
- Weight:
  - Unit: 63.5 kg (140 lb)
  - Shipping: 92 kg (202 lb)

Selections Checked Below Apply To This Equipment

VOLTAGE

- ☐ 120 Vac, 50/60 Hz
- ☐ 230/240 Vac, 50/60 Hz

LANGUAGE OPTIONS

- ☐ English
- ☐ French
- ☐ Italian
- ☐ German
- ☐ Spanish
- ☐ Dutch[3]
- ☐ Portuguese[3]
- ☐ Japanese[3] - User Interface Only
- ☐ Chinese[3] - User Interface Only

OPTIONS

- ☐ Electronic Data Security to 21 CFR Part 11

DOCUMENTATION

- ☐ Extended Document Package (GAMP 5)

ACCESSORIES

- ☐ TS1000 Tri-Scale Sensor
- ☐ Aerator AR1200
- ☐ Munters Dehumidifiers
- ☐ Output Cable Assembly
- ☐ Input Cable Assembly
- ☐ Hydrogen Peroxide Sensors
- ☐ Vaprox Bulk Container Siphon Cap Assembly
- ☐ Vaprox Bulk Container Siphon Tube
- ☐ Braided Stainless-Steel Interconnecting Hose

Item:	
Locations:	

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3. *Available only with the 21CFR version.*