VHP™ Flex™

Biodecontamination System

APPLICATION

The VHP Flex Biodecontamination System offers Customers all the benefits of STERIS' VHP technology and services packaged in a compact, mobile Decontamination Unit offering flexibility for biodecontamination[1] of small to medium size rooms and clean, dry, sealed enclosures[2].

DESCRIPTION

The VHP Flex is a mobile VHP Biodecontamination Unit designed for use on sealed enclosures, such as isolators, pass through chambers, and rooms in pharmaceutical production, research, and biological safety applications.

This Unit consists of a hydrogen peroxide generator and control system mounted in an aluminum frame with stainless-steel paneling.

The Biodecontamination Unit includes an integrated main control system that controls the sterilant generation process, Vaprox Hydrogen Peroxide Sterilant injection system, and connections for building or equipment control integration.

The VHP Flex 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 Unit 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 bulk sized Vaprox Hydrogen Peroxide Sterilant for larger spaces.

STANDARDS

The VHP Flex 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
- Electromagnetic Compatibility Regulations: 2016
  - BS EN 61326–1: 2013
- Radio Equipment Directive (RED):
  - 2014/53/EU
    - » ETSI EN 301 489-1, ETSI EN 301 489-3, ETSI EN 300 330
  - Radio Equipment Regulations 2017
    - » ETSI EN 301 489-1, V2.2.3 (2019–11), ETSI EN 301 489-3, V2.1.1 (2019–03), 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
  - RoHS 2012, BS EN IEC 63000:2018

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 EPA registered labeling of Vaprox Hydrogen Peroxide Sterilant.*
2. *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) and 59% (EPA Reg. No. 1943–123) 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 (5 gal/19 L).

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.
- Key locked panel to limit access to authorized personnel.
- Leak detection system to warn user of any possible Vaprox sterilant leaks within the enclosure.

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 Flex Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. In practice, an aqueous solution of Vaprox Hydrogen Peroxide Sterilant is flash vaporized. A heated air stream carries the vapor into the enclosed space requiring biodecontamination. 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 blower initializes and cycle is run automatically.

Cycle proceeds through the following phases:

Dehumidification — Dry HEPA-filtered air is passed through the system to reduce the humidity to a range that will allow the target Vaprox Hydrogen Peroxide vapor concentration to be maintained below saturation (dew point) levels during the subsequent Condition and Decontamination phases. The return air is dried as it passes through the drying accessory and then is heated to serve as the carrier for the hydrogen peroxide. The internal HEPA filters prevent contamination of internal machine components and prevent recontamination of the room or enclosure.

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

Condition — The flow of dry, HEPA-filtered air continues while sterilant is injected into the air stream just before it leaves the Biodecontamination Unit. The condition phase facilitates reaching the target VHP concentration faster. Condition time is affected by sterilant injection rate and room or enclosure area volume, contents, and temperature.

Decontamination — The target sterilant 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 recirculating flow of dry, HEPA-filtered air continues through the catalytic converter to reduce the sterilant concentration within the room or enclosure. Room or enclosure return air circulates, during all phases, through a catalytic converter inside the Biodecontamination Unit which converts vaporized hydrogen peroxide into water vapor and oxygen. The room or enclosure HVAC system may also be used to remove sterilant from the area and enhance aeration time.

SMART Cycle — This Biodecontamination System is available with a SMART Cycle that uses integrated and/or remote VHP sterilant, humidity, and temperature sensor feedback to control the injection rate, and cycle time. SMART Cycle automatically adjusts to the enclosure conditions and uses the worst-case sensor conditions if multiple sensors are used.

ACCESSORIES

VHP Wireless Tri-Scale Sensor — The VHP Wireless Tri-Scale Sensor includes VHP sterilant, humidity, and temperature sensors to provide feedback to the Biodecontamination Unit control. The sensors can be used for monitoring or to control the Unit using the SMART Cycle feature. Up to four sensors can be connected to the Unit using wireless or wired connection. Sensors are independently identified by the control system.

Aerator AR1200 — The AR1200 is a portable, high capacity catalyzation unit designed to shorten cycle time in rooms. The high capacity blower delivers 1200 cfm (2039 cmh). The AR1200 can be started from the Biodecontamination Unit through a 24 Vdc contact or can operate as a stand alone unit.

Reusable Desiccant Cartridge — The 600-gram reusable desiccant cartridge is constructed of aluminum and is easily installed in the Biodecontamination Unit. The reusable desiccant is regenerated in a separate desiccant dryer.

Disposable Desiccant Cartridge — The 270-gram disposable cartridge is constructed of PVC and is easily installed in the Biodecontamination Unit using an adaptor (separate accessory).

Desiccant Regeneration Unit — The desiccant regeneration unit is used to regenerate the 600-gram reusable desiccant cartridge. This includes a door to protect the user from hot

surfaces during the regeneration cycle. An indicator light notifies the operator when the cycle is completed or if there is an alarm condition.

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

Adaptor Kit — A 1" stainless-steel adapter is provided for a flexible connection hose. Inlet/Outlet connections require one kit each.

Output Cable Assembly — A 30 ft (9 m) cable is provided to interface the Biodecontamination Unit output.

Input Cable Assembly — A 30 ft (9 m) cable is provided to interface the Biodecontamination Unit input.

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 Siemens SIMATIC S7-1500 control system and the Siemens SIMATIC HMI TP700 Comfort Panel graphics terminal. The operator can configure, start, monitor, and abort cycles through interaction with the TP700 Comfort Panel HMI touch screen.

CONSTRUCTION

Frame: Extruded aluminum.

Case: Stainless-steel side panels. Aluminum reinforced plastic top cover and lower skirts.

Lockable Control Panel: Aluminum.

Casters: Front swivel, back fixed, and lockable.

CALIBRATION

STERIS recommends that all VHP Flex 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, 18 Amps, 1 Phase
- 230/240 Vac, 50/60 Hz, 10 Amps, 1 Phase

Airflow/Pressure:

- Airflow range: 6-25 scfm (10-42 scmh)

Vaprox Injection Rate:

- 1.0-12.0 g/min.
- Injection rate range is available at listed voltages (up to -10%) and across all conditioned air inlet temperature and humidity ranges.

Vaprox Fill Rate:

- Max flow rate is 0.5 L/min.

ENVIRONMENTAL FACTORS

Ambient Conditions:

- Room Temperature: 60-104 °F (16-40 °C)
- Relative Humidity: 15 to 85%

Unit Specifications:

- Size (W x H x D): 26" x 26" x 47" (660 mm x 660 mm x 1194 mm)
- Weight:
  - Unit: 215 lb (98 kg)
  - Shipping: 420 lb (191 kg)

Selections Checked Below Apply To This Equipment

VOLTAGE

☐ 120 Vac, 50/60 Hz

☐ 230/240 Vac, 50/60 Hz

LANGUAGE OPTIONS

☐ English

☐ French

☐ German

☐ Spanish

☐ Italian

☐ Dutch

☐ Japanese - User Interface Only

☐ Portuguese

☐ Chinese - User Interface Only

OPTIONS

☐ Siemens with Profinet TCP and Electronic Data Security to 21 CFR Part 11

DOCUMENTATION

☐ Extended Document Package (GAMP 5)

ACCESSORIES

☐ VHP Wireless Tri-Scale Sensor

☐ Aerator AR1200

☐ 600g Reusable Desiccant Cartridge

☐ 270g Disposable Desiccant Cartridge

☐ Desiccant Regeneration Unit

☐ Hydrogen Peroxide Sensors

☐ Adaptor Kit

☐ Output Cable Assembly

☐ Input Cable Assembly

☐ Vaprox Bulk Container Siphon Cap Assembly

☐ Vaprox Bulk Container Siphon Tube

☐ Braided Stainless-Steel Interconnecting Hose

Item:	
Locations:	

For Further Information, contact:

STERIS Corporation
5960 Heisley Rd.
Mentor, OH 44060–1834 ▪ USA
440–354–2600 ▪ 800–548–4873
www.sterislifesciences.com

The base language of this document is ENGLISH. Any translations must be made from the base language document.

CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.