STERIS®

VHP® 1000ED BIODECONTAMINATION UNIT

APPLICATION

The STERIS VHP® 1000ED Biodecontamination Unit is designed for mobile biodecontamination[1] of clean, dry, sealed enclosures[2] such as isolators, chambers, and small rooms using STERIS's VHP process technology, featuring Vaprox® Hydrogen Peroxide Sterilant.

DESCRIPTION

With its mobile design and multi-purpose features, the VHP® 1000ED is one of the most versatile pharmaceutical grade Biodecontamination Units on the market today. The Biodecontamination Unit uses STERIS patented VHP process technology. The process uses hydrogen peroxide vapor as a broad-spectrum antimicrobial without condensation of active ingredient onto surfaces. This non-condensation feature provides additional benefit of a wide range of material compatibility.

The VHP® 1000ED Biodecontamination Unit features easy operation with an easy to use operator interface and other key built-in design features like dehumidification, pressure control, Vaprox cartridge interface and aeration module for an All-In-One unit. Once the Customer cycle is selected, the control system automatically completes the desired biodecontamination cycle.

Additionally, the VHP® 1000ED Biodecontamination Unit offers an impact printer for hard copy of the cycle data as well as a USB port for electronic biodecontamination cycle capture.

The unit includes a connection kit with four (4) Banjo 1.25" couplings and 25 ft. (7.6 m) of tubing for connecting to enclosures or rooms.

STANDARDS

The VHP® 1000ED Biodecontamination Unit meets the applicable requirements of the following standards:

- **Underwriters Laboratories (UL): UL 61010-1** and **UL 61010-2-040**

(Typical only - some details may vary)

- **Canadian Standards Association (CSA): Standard C22.2 No. 61010-1** and **C22.2 No. 61010-2-040**
- **Ingress Protection Rating (IP) 20**
- **CE Compliance:**
  - » **EMC Directive (2014/30/EU)**
  - » **Low Voltage Directive (2014/35/EU)**

CYCLE DESCRIPTION

An aqueous solution of 35% hydrogen peroxide (Vaprox® Hydrogen Peroxide Sterilant) is vaporized and a high velocity air stream disperses it throughout the enclosure. Software automatically runs the selected biodecontamination cycle.

Basic description of example biodecontamination cycle:

After starting 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 (High Efficiency Particulate Air) air is circulated to reduce humidity to a predetermined level in the 10-60% relative humidity range. This permits the necessary target Vaprox® Hydrogen

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The Following Sections Are Available to Configure Customer Equipment

VOLTAGES
- ❑ 120 Vac, 50/60 Hz
- ❑ 230 Vac, 50/60 Hz

LANGUAGE OPTIONS
- ❑ English
- ❑ French
- ❑ German
- ❑ Spanish
- ❑ Italian
- ❑ Dutch

OPTIONS
- ❑ Hydrogen Peroxide Concentration Sensors - Integrated
- ❑ Siemens with Profinet TCP
- ❑ Siemens with Profinet TCP and Electronic Data Security to 21 CFR Part 11

DOCUMENTATION
- ❑ Extended Document Package (GAMP)

ACCESSORIES
- ❑ Enclosure Pressure Monitor Kit
- ❑ Adapter Kit, 1.5" Sanitary Clamp
- ❑ Hydrogen Peroxide Concentration Detector Kit
- ❑ AC Output Cable Assembly
- ❑ DC Interface Cable Assembly

Item _____

Location(s)_____

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Peroxide Sterilant vapor concentration to be maintained below saturation (dew point) levels during the Conditioning and Biodecontamination phases. The return air passes through the dryer and then is heated to serve as the carrier for the VHP. The internal HEPA filters prevent contamination of internal machine components and prevent recontamination of the enclosure.

Conditioning

The flow of dry, HEPA-filtered 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 controllable in the 1.0 to 12.0 grams per minute range. The Conditioning phase facilitates reaching the target biodecontamination concentration faster in larger volume sealed enclosure applications. Conditioning time is affected by sterilant injection rate, enclosure volume, enclosure contents and temperature.

Biodecontamination

The target VHP antimicrobial concentration is maintained for a specific period of time throughout the enclosure.

Aeration

Vaprox® Hydrogen Peroxide Sterilant vapor injection is stopped and the recirculating flow of dry, HEPA-filtered air continues through the catalytic converter to reduce the H_2O_2 vapor concentration within the enclosure. The enclosure exhaust system may also be used to accelerate aeration time.

Biodecontamination Cycle information is saved to USB and/or printer.

ACCESSORIES

Enclosure Pressure Monitor Kit - External pressure monitor and hardware, with two independent "dry contact" alarm setpoints, that can be connected directly to the enclosure and VHP® Unit. Hi and Lo pressure alarms will occur if the enclosure is outside the pressure range.

Adaptor Kit, 1.5" Sanitary - A 1.5" stainless steel sanitary adapter is provided for a flexible connection hose. Includes swivel clamp, gasket, and hose band clamp. Inlet/Outlet connections require 1 kit each.

Hydrogen Peroxide Concentration Detector Kit, Tee in Return Line - A barbed tee connection is provided that fits into the flexible hose return of the VHP® Unit. The tee connection includes a cap and insert for an optional external hydrogen peroxide concentration sensor.

AC Output Cable Assembly - A 30 ft. (9.1 m) cable is provided to interface the VHP® Unit output with closed dry contacts. If 120 Vac output is required, a kit is available.

DC Interface Cable Assembly - A 30 ft. (9.1 m) cable is provided to interface the VHP® Unit input/output with a 24 VDC device or signal.

OPTIONS

Hydrogen Peroxide Concentration Sensors - Includes 2 integrated hydrogen peroxide vapor monitoring sensors for measuring high and low concentrations of peroxide in an enclosure. The sensors will automatically switch to high or low version depending on concentration. If enabled, Aeration will not end until the low sensor hits the configured set point. The sensor reading is included in the batch report.

Electronic Data Security 21 CFR Part 11 - Software feature enabling audit trail, electronic data capture/transfer, and other features for use in validation and complying with 21 CFR Part 11.

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 bottle of Vaprox® Hydrogen Peroxide Sterilant features a 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 the H2O2 they are using has been accepted or rejected.

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

Provides precise control of the VHP® 1000ED Biodecontamination Unit required by Good Automated Manufacturing Practice (GAMP) and allowing for Operator, Supervisor, Service, and Administrator level access to the biodecontamination unit operations and functions.

Siemens Model - Siemens TP700 HMI color display with Simatic S7-1500 control and profinet TCP, or discrete I/O interface.

Cycle data is stored on flash memory. If a power failure occurs during a cycle, flash memory ensures cycle memory is retained and proper cycle completion occurs once power is restored.

CONSTRUCTION

Frame - Constructed of welded aluminum.

Case - Stainless-steel top and side panels. Powder coated aluminum front and back panels.

Casters - Front swivel, back fixed, lockable and non-marring.

Blower - Variable speed, internal 8-25 scfm (14 - 42 m^3/h) blower.

Injection Pump - Injection rates from 1.0 - 12.0 grams/min.

Reusable Desiccant Tank - 2000 g.

Aeration Module - Platinum metal group catalyst.

CALIBRATION

STERIS Life Sciences Service recommends that the VHP® 1000ED Biodecontamination Unit be calibrated at least once every six months. STERIS Life Sciences Service representatives can provide this service to ensure valid operation of the unit.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS Life Sciences Service concerning a maintenance program. Under the terms of the program, preventive maintenance, adjustments and replacement of worn parts are provided on a scheduled basis to help ensure optimal equipment performance and to help minimize untimely or costly schedule interruptions. STERIS Life Sciences Service maintains a worldwide staff of well-equipped, factory-trained technicians to provide these services, as well as on-site installation, training and expert repair services. Contact STERIS Life Sciences Service* for details.

** 1 (800) 444-9009 or www.sterislifesciences.com.*

NOTES

1. When using VHP® Biodecontamination Unit 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.
3. Refer to drawings and Operator Manual for specific installation and operator instructions.
4. Unit should not be installed in an area not compatible with oxidizers. Consult Safety Data Sheet (SDS) regarding hydrogen peroxide sterilant.
5. The VHP® 1000ED 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 and the VHP® 1000ED Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox® Hydrogen Peroxide Sterilant.
6. Floor must be a hard, level surface.
7. Access to power switch and hose connectors located at rear of unit must be provided.
8. Rear hose clearance must be adequate to prevent kinks and strains on connectors.
9. Hoses must be supported to them from resting on floor or other cold surfaces.
10. Refer to Vaprox® Hydrogen Peroxide Sterilant package label for additional information and Application instructions.

UTILITY REQUIREMENTS

IMPORTANT: *Refer to equipment drawing 387352-121 for installation details and specifications.*

Electricity

120 Vac, 60 Hz,1 Phase, 18 Amp

230 Vac, 50-60 Hz, 1 Phase, 9 Amp

Airflow Rates

8-25 scfm (14 - 42 m^3/h)

Vaprox Injection Rates

1.0-12.0 g/min

ENVIRONMENTAL FACTORS

Ambient Conditions

Room Temperature: 60-104F (6 - 40C)

Relative Humidity: 10-85%

Size (W x H x D)

24-1/4 x 43-3/8 x 48" (613 x 1101 x1 219 mm)

Weight: 470 lbs. (213 kg)

Shipping Weight: 570 lbs. (259 kg)

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

STERIS Corporation, Mentor (Hopkins) Ohio is an ISO 9001 certified facility.

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

For Further Information, contact:

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