STERIS®

VHP® 1000ED BIODECONTAMINATION UNIT

APPLICATION

The STERIS VHP 1000ED Biodecontamination Unit is designed for mobile Biodecontamination[1] of clean, dry, sealed Enclosures[2] using STERIS's VHP process technology, featuring OptiaPhase software technology, and Vaprox® Hydrogen Peroxide Sterilant.

[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.*

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. 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 OptiaPhase software technology and other key design built-in design features like dehumidification, pressure control, Vaprox cartridge interface and aeration module for an All-In-One unit. Once the Customer validated biodecontamination cycle is selected, OptiaPhase software technology takes over and completes the desired biodecontamination cycle.

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

The VHP 1000ED Biodecontamination Unit is only to be operated by Trained and Certified

(Typical only - some details may vary.)

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.

STANDARDS

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

- **Underwriters Laboratories (UL): UL61010-1 Second Edition** as certified by Intertek Testing Services, Inc.
- **Canadian Standards Association (CSA): Standard C22.2 No. 61010-1 Second Edition**.
- **Ingress Protection Rating (IP) 21** as certified by Intertek Testing Services, Inc.
- Governing Directives for Affixing the CE Mark:
  - » **EMC Directive (2004/108/EC, 92/31/EEC, 93/68/EEC)** as certified by Intertek Testing Services, Inc.
  - » **Low Voltage Directive (2006/95/EC, 93/68/EEC)** as certified by Intertek Testing Services, Inc..

The Selections Checked Below Apply To This Equipment

VOLTAGES

FOR DOMESTIC UNITS:

☐ 120 Vac, 50/60 Hz

FOR INTERNATIONAL UNITS:

☐ 230 Vac, 50/60 Hz

CONTROLS

☐ Siemens

☐ Allen-Bradley

LANGUAGE OPTIONS

☐ **Siemens Control**

- ☐ English
- ☐ French
- ☐ German
- ☐ Spanish
- ☐ Italian
- ☐ Dutch

☐ **Allen-Bradley Control**

- ☐ English
- ☐ Spanish

Item _____

Location(s)_____

_____

CYCLE DESCRIPTION (Typical)

In practice, 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.

NOTE: Refer to Vaprox Hydrogen Peroxide Sterilant package label for additional information and Application instructions.

Basic description of example Biodecontamination Cycle:

After starting Cycle at the Human Machine Interface (HMI), the blower initializes and OptiaPhase software technology is engaged.

Cycle proceeds through the following phases:

1. **Dehumidification** - Enclosure is dehumidified to a Relative Humidity (RH) of ~10-50% using a reusable desiccant tank within the Unit. Upon reaching the desired relative humidity, the Cycle advances to Condition phase.
2. **Condition** - Hydrogen Peroxide Sterilant vapor is added to sealed Enclosure until target concentration needed for full Biodecontamination phase is reached.
3. **Biodecontamination** - Enclosure is filled with Hydrogen Peroxide Sterilant vapor. Cycle continues for a pre-determined amount of time based upon Operator selections to achieve a minimum of a 6-log bioburden reduction. Upon reaching desired time, Cycle advances to Aeration phase.
4. **Aeration** - Hydrogen Peroxide Sterilant vapor is catalyzed into water vapor and oxygen. Cycle continues for pre-determined amount of time based upon the cycle selected to achieve a minimum concentration of $\leq$ 1ppm. Upon reaching desired time, Cycle advances to Cycle Complete.

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

OPTIONS

21CFR Part 11 / Annex 11 - Optional software feature enabling audit trail, electronic data capture/transfer, and other features for use in validation (SIEMENS ONLY).

Fill-On-The-Fly - Optional software feature enabling fill-on-the-fly for large enclosure decontamination.

Bulk Fill - Optional hardware feature enabling sterilant fill from a bulk supply.

Drager H2O2 Sensors/Monitors - Hydrogen peroxide vapor sensors for permanent installation and portable operation.

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). *Refer to Tech Data SD996 for further information.*

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 and Service level access to the Biodecontamination Unit operations and functions.

Siemens Model

Siemens TP700 HMI color display with Simatic S7-300 control.

Allen-Bradley Model

Panel View™ Plus 6 600 HMI color display with CompactLogix™ control[1].

Cycle data is stored on a battery-backed RAM / flash memory. Estimated life of the battery is about two-years. If a power failure occurs during a cycle, battery backup system ensures cycle memory is retained and proper cycle completion occurs once power is restored.

[1] *CompactLogix and PanelView Plus 6 600 are trademarks of Allen-Bradley, a Rockwell Automation Company.*

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 7-24 scfm (12-40 m^3/h) blower.

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

Reusable Desiccant Tank - 2000 g.

Reservoir - 0.53 Gal (2L).

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. STERIS Life Sciences Service recommends a dedicated, grounded electrical circuit be provided for each unit. Extension cord use is not recommended.
2. Unit should not be installed in an area not compatible with oxidizers. Consult Safety Data Sheet (SDS) regarding hydrogen peroxide sterilant.
3. Floor must be a hard, level surface.
4. Access to power switch and hose connectors located at rear of unit must be provided.
5. Rear hose clearance must be adequate to prevent kinks and strains on connectors.
6. Hoses must be supported to them from resting on floor or other cold surfaces.
7. Moving unit requires more than one person. Unit weighs approximately 500 lb (227 kg).
8. Enclosure size listed is recommended size. Connecting VHP 1000ED Biodecontamination Unit to larger volumes may increase cycle time.
9. Airflow range is measured exiting VHP 1000ED Biodecontamination Unit. Actual flow rates may vary from variations in local utility power output.

UTILITY REQUIREMENTS

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

Electricity

120 Vac, 60 Hz, 1 Phase, 16 Amp

230 Vac, 50-60 Hz, 1 Phase, 10 Amp

Airflow Rates

7-24 scfm (12-40 m^3/h)

Vaprox Injection Rates:

1.0-12.0 g/min

Temperature:

60-104F (16-40C)

Relative Humidity:

10-80%

Size (W x H x D):

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

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

STERIS Corporation, Mentor (Hopkins) Ohio is an ISO 13485 and 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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