



APPLICATION

The VHP M1000-T4 Biodecontamination System is used for fast, continuous (open-loop) biodecontamination* of clean, dry, sealed Enclosures** used in pharmaceutical, aseptic filling, defense and aerospace applications.

* 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 pre-cleaned, 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 M1000-T4 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 vertical cabinet enabling convenient mounting location for the operator while conserving floor space. Cabinet includes the main control (Siemens), airflow and Vaprox Hydrogen Peroxide Sterilant outlet plumbing, terminations for the Remote Communication Interface (HMI and printer).

The Biodecontamination System can operate independently as a stand-alone machine but may also be operated through interface to external equipment. This interface provides many options, including data communication via communication protocols as well as discrete I/O interfacing. In most cases, this interface is used to start Biodecontamination Cycles, abort cycles and monitor the Biodecontamination System status.

The VHP M1000-T4 Biodecontamination System is only to be operated by trained and certified applicators who have successfully completed the STERIS Training and Certification Course for



(Typical only - some details may vary.)

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 55 gal (208 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.

The Selections Checked Below Apply To This Equipment

VOLTAGE

- 230 Vac, 50/60 Hz
- 380 Vac, 50/60 Hz

ACCESSORIES

- Remote Communication Interface
- Remote Vaprox Supply
- Printer
- Anybus Module

LANGUAGE

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

CONTROLS

- Siemens

STERILANT DELIVERY OPTIONS

- Bulk Container (5 gal/19 L)
- Bulk Container (55 gal/ 208 L)

OPTIONS

- 21CFR Part II Data Security Package

Item _____

Location(s) _____

STANDARDS

The VHP M1000-T4 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.**
- **EMC Directive 2014/30/EU.**
- **Low Voltage Directive 2014/35/EU, 2014/30/EU.**

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 M1000-T4 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 M1000-T4 Biodecontamination Unit operating as an open-loop system, air and the VHP antimicrobial are drawn out of the enclosed space and pass through a facility equipped 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 antimicrobial vapor within the VHP Biodecontamination Unit and 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 four phases:

Dehumidification

Dry air is supplied by an external dehumidifier (equipment available separately, see Accessories) at an acceptable level (typically between 10-60% relative humidity). This permits the necessary target Vaprox Hydrogen Peroxide Sterilant vapor concentration to be maintained below saturation (dew point) levels during the Conditioning and Biodecontamination phases. The dry air is heated to serve as the carrier for the Vaprox Hydrogen Peroxide Sterilant vapor. The maximum airflow through the VHP M1000-T4 Biodecontamination Unit is typically 118 scfm (200 cmh) depending on the electrical supply voltage/frequency and external piping restrictions.

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

Conditioning

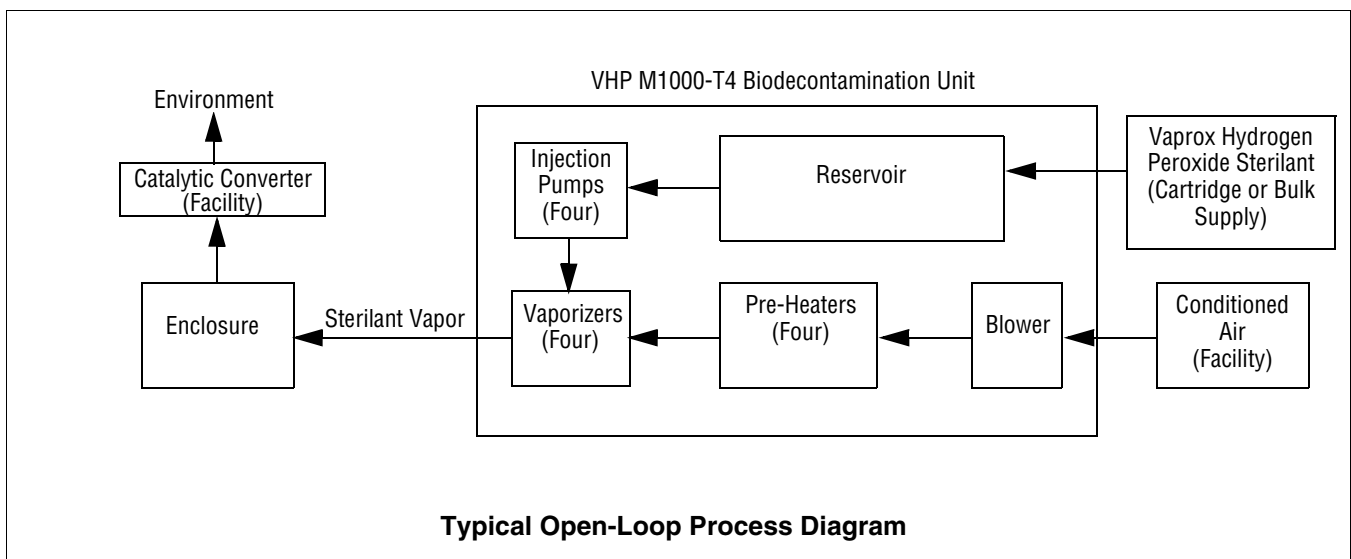
If applicable, the flow of dry air continues while Vaprox Hydrogen Peroxide Sterilant vapor is injected into the air stream just before it leaves the unit. The Vaprox Sterilant injection rate is controllable in the 4 to 99 grams per minute range. The Conditioning phase facilitates reaching the target biodecontamination concentration faster in larger volume sealed Enclosure applications. Conditioning time is affected by Vaprox Hydrogen Peroxide Sterilant injection rate, Enclosure volume, Enclosure contents and temperature.

Biodecontamination

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.

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 catalytic converter (equipment not supplied by STERIS) to produce water vapor and ultimately exhausted to the environment. This



exhausting of the vapor/air is used to reduce the Vaprox Hydrogen Peroxide Sterilant vapor concentration within the Enclosure. The VHP M1000-T4 PLC can manage (through discrete outputs and Ethernet connector) external aeration systems as necessary.

ACCESSORIES

Remote Communication Interface - Provides interface to the operator of the VHP M1000-T4 Biodecontamination Unit, but installed remotely to the unit. This interface includes a touch-screen and a printer.

Remote Vaprox Supply - Provides interface of a remotely installed Vaprox Hydrogen Peroxide Sterilant Cartridge or connection to Vaprox Hydrogen Peroxide Sterilant bulk supply for the VHP M1000-T4 Biodecontamination Unit (available as single, 1 to 1 supply, and multi, 2 to 5 supply).

FEATURES

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.

Printer. A 40-column impact printer with paper take-up is available to provide a cycle record.

USB or Memory Card. Cycles and parameters can automatically be generated as PDF files.

21CFR Part II Data Security Package (Optional). Software feature enabling audit trail, electronic data capture, user administration, and other features for use in validation.

CONTROL SYSTEM

The control system provides precise control of the VHP M1000-T4 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 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.

The operator interface allows the user to program the PLC without the need for a Customer-supplied PLC. **Security Codes** are used to prevent unauthorized operation or modification of preset or custom cycle parameters.

CONSTRUCTION

Case: Stainless Steel

Lockable Door: Stainless Steel

Accessories: Stainless Steel

CALIBRATION

STERIS recommends that all VHP M1000-T4 Biodecontamination Systems be calibrated at least once every six months. STERIS Service representatives can provide this service to ensure validatable operation of the unit. All calibration is handled by control.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS concerning our annual maintenance program. Under the terms of this 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 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 for details.

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 M1000-T4 Biodecontamination System.
6. Approximate weight is 600 lb (272 kg).
7. It is the Customer's responsibility to make arrangements for the cycle validation.
8. Enclosure size listed is recommended size. Connecting VHP M1000-T4 Biodecontamination System to larger volumes may increase cycle time.
9. Airflow range is measured exiting VHP M1000-T4 Biodecontamination System. Actual flow rates may vary from variations in local utility power output.

UTILITY REQUIREMENTS

IMPORTANT: Refer to equipment drawing 387355-762 for installation details and specifications.

Electricity:

- 230 Vac, 50/60 Hz, 50 Amps, 1 Phase
- 380 Vac, 50/60 Hz, 25 Amps, 3 Phase

Airflow/Pressure

- Airflow range: 40-100 scfm (68-170 m³/h)
- Maximum output pressure: 2.5 psig. (0.17 bar)

Vaprox Injection Rates:

- Cartridge feed or Bulk-fill: 4-99 grams/minute

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: 10 to 80%

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

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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