STERIS®

VHP® M100S BIODECONTAMINATION SYSTEM

APPLICATION

The VHP M100S Small Volume Biodecontamination System is a hydrogen peroxide vapor generator for biodecontamination[1] of clean, dry, sealed enclosures, and isolators[2] used in pharmaceutical applications and biological laboratories.

The VHP M100S Biodecontamination System is configured in a closed-loop configuration to easily connect with a variety of enclosures, isolators, and smaller devices.

DESCRIPTION

The VHP M100S is installed in a 304SS cabinet enclosure that is mounted on the enclosure. A mobile cart is also available for use with multiple enclosures. The M100S can operate independently as a stand-alone machine and can be operated with external equipment such as a host PLC or building management system via an external interface. This interface provides many options, including data communication via several 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.

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

Units are available for operation on 120 or 230 Volts, 50/60 Hz, Single phase electrical service.

Operator Interface - Siemens Simatic TP700 - The touch panel is a backlit 7" liquid crystal type (TFT) display equipped with 800 x 480 pixel resolution, 256 color graphics and an analog touch membrane.

Printer. An impact printer with paper take-up is available to provide cycle records, machine configuration data, and calibration values.

(Typical only - some details may vary.)

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

Inlet HEPA Filter - An internal H14 HEPA filter is included.

STANDARDS

The VHP M100S 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**
- **CE Compliance**
  - » **EMC Directive 2014/30/EU**
  - » **Low Voltage Directive 2014/35/EU**
- **Good Automation Manufacturing Practices (GAMP5)**
- **RoHS 2 Compliant**

The Following Sections Are Available to Configure Customer Equipment

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

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

OPTIONS
- ❑ Siemens with Profinet TCP
- ❑ Siemens with Profinet TCP and Electronic Data Security to 21 CFR Part 11
- ❑ Mobile Cart

DOCUMENTATION
- ❑ Extended Document Package (GAMP 5)

ACCESSORIES
- ❑ Reusable Desiccant Cartridge(s) and Regenerator
  - ❑ 120 Vac, 50/60 Hz
  - ❑ 230 Vac, 50/60 Hz
- ❑ Disposable Desiccant Cartridges and Adapter
- ❑ Anybus Module

Item _____

Location(s)_____

_____

CYCLE DESCRIPTION

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 M100S Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. In practice, an aqueous solution of 35% H_2O_2 (Vaprox Hydrogen Peroxide Sterilant) is flash vaporized. A heated air stream carries the vapor into the enclosed space requiring biodecontamination. With the M100S Biodecontamination Unit operating as a closed-loop system, air and the VHP are drawn out of the enclosed space and pass through a catalytic converter degrading the VHP into oxygen and water vapor. The air stream then recharges with fresh VHP vapor within the VHP Biodecontamination Unit and returns to the enclosure.

While operating in a closed-loop configuration, the biodecontamination cycle consists of four phases as shown in Figure 1.

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 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 6.0 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.

ACCESSORIES

To operate the unit properly, either a reusable or disposable desiccant system must be selected.

Reusable Desiccant Cartridge(s) and Regenerator - The reusable cartridge containing desiccant is constructed of aluminum and is easily installed in the VHP M100S Biodecontamination System. Following use, a prompt notifies the operator that it is time to remove the cartridge and install it in the regenerator to refresh the desiccant. An indicator on the regenerator signals the user that the cartridge is ready for reuse.

Disposable Desiccant Cartridges and Adaptor - The disposable cartridge containing desiccant is constructed of plastic and is easily installed in the VHP M100S Biodecontamination System using a stainless-steel adaptor. Following use, a prompt notifies the operator that it is time to discard and replace the cartridge.

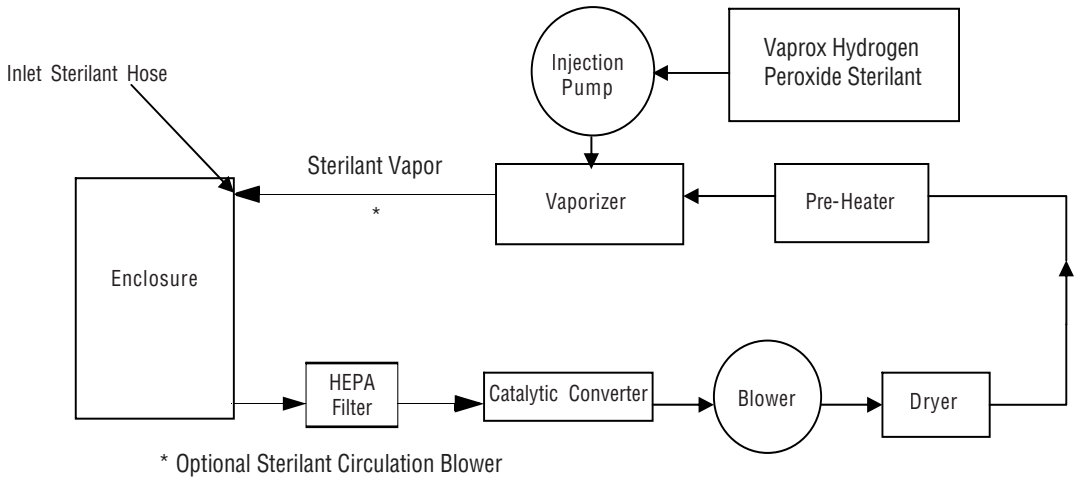

Figure 1 - Typical Closed-Loop Process Diagram

Anybus Gateway Module - Optional module enabling communication between the STERIS VHP Generator and system network via Modbus, Profibus, EtherNet/IP, or BACnet/IP communication protocols.

Extended Document Package - This option provides additional risk-based verification documentation, in compliance with GAMP 5 guidelines, to support Customers in the validation of their products and/or production processes.

OPTIONS

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

E-Stop Push Button Electronic Disconnect - Discrete signal sent to safety relay which shuts power off. Can be ordered through special sales quote process.

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.*

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

The control system provides precise control of the VHP M100S Biodecontamination System and uses the Siemens S7 Series controller.

The PLC control stores and controls to information such as the time for each phase, operating pressure, hydrogen peroxide injection rate, air flow rate and target relative humidity. The control also monitors the amount of hydrogen peroxide available for the next cycle. A prompt notifies the operator to change the hydrogen peroxide cartridge when there is insufficient hydrogen peroxide volume to run the next cycle. Additionally, the control monitors the capacity available in the desiccant cartridge and will flag the user when change-out is necessary for the next cycle. All calibration is also handled by the control.

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. Standard communication protocol is Profinet TCP for Siemens.

CONSTRUCTION

Case: Stainless Steel

Lockable Door: Stainless Steel

Hydrogen Peroxide Cartridge Interface: Flame-Resistant Plastic

Disposable Desiccant Cartridge: Plastic

Reusable Desiccant Cartridge: Aluminum

Reusable Desiccant Cartridge Regenerator Enclosure and Doors: Painted Steel

CALIBRATION

STERIS recommends that all M100S Biodecontamination Systems be calibrated at least once every six months. STERIS Service representatives can provide this service to ensure validatable operation of the unit.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS concerning our annual 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 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. 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.
3. Refer to drawings and Operator Manual for specific installation and operating instructions.
4. Unit should not be installed in an area not compatible with oxidizers. Consult the SDS regarding hydrogen peroxide sterilant.
5. Hoses must be supported to keep them from resting on the floor or other cold surfaces.
6. Clearance must be provided to doors on the VHP M100S Biodecontamination System and regenerator.
7. Access must be provided for desiccant cartridge installation and removal.
8. The VHP® M100S Biodecontamination Unit is only to be

operated by trained and certified applicators who have successfully completed the STERIS Training and Certification Course for 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.

UTILITY REQUIREMENTS

IMPORTANT: *Refer to equipment drawings 356257-509 for installation details and specifications.*

Electricity

- *M100-S and M100-S (Mobile Cart):*

120 Vac, 20A, 50/60 Hz, 1-PH

230 Vac, 15A, 50/60 Hz, 1-PH

- *Reusable Desiccant Cartridge Regenerator:*

120 Vac, 8A, 50/60 Hz, 1-PH

230 Vac, 4A, 50/60 Hz, 1-PH

Airflow/Pressure

- Airflow range: 5 -20 scfm (8-34 cmh) Closed-Loop
- Maximum control pressure: 2.3 W.G. (572 Pa)

Vaprox Injection Rates:

- 1 - 6 grams/minute

ENVIRONMENTAL FACTORS

Ambient Conditions

- Room Temperature: 68 - 86°F (20 - 30°C)
- Relative Humidity: 10 to 80%

Conditioned Air Inlet

- Temperature: 64 - 104°F (18 - 40°C)
- Humidity: 0 to 30%

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

STERIS Corporation, Mentor 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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