



VHP® M100 BIODECONTAMINATION SYSTEM

APPLICATION

The VHP M100 Small Volume Biodecontamination System is a hydrogen peroxide vapor generator for biodecontamination* of clean, dry, sealed Enclosures** used in medical and biological laboratories.

The VHP M100 Biodecontamination System is equally efficient in either closed- or open-loop configurations.

- * 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.
- ** Enclosure must be leak tested according to manufacturer's recommendations.

DESCRIPTION

The VHP M100 Biodecontamination System is designed for biodecontamination of clean, dry surfaces in and permanent mounting to sealed Enclosures. 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® M100 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.



(Typical only - some details may vary.)

To minimize exposure to the liquid hydrogen peroxide during handling, the system uses specially designed disposable cartridges containing approximately 950 mL or bulk containers containing approximately 5 gal (19 L) of Vaprox Hydrogen Peroxide Sterilant.

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

STANDARDS

The VHP M100 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.

The Selections Checked Below Apply To This Equipment

VOLTAGE LANGUAGE OPTIONS CONTROLS ■ 120 Vac, 50/60 Hz English ■ Siemens □ 230 Vac, 50/60 Hz ■ French Allen-Bradley* German **ACCESSORIES OPEN-LOOP STERILANT DELIVERY** Spanish ■ 950 mL Cartridge ■ Reusable Desiccant Cartridge(s) and ■ Italian Regenerator Dutch Bulk Container □ 120 Vac, 50/60 Hz * Available for Open Loop only. **OPTIONS** □ 230 Vac, 50/60 Hz Disposable Desiccant Cartridges and Adapter Closed-Loop Item ■ Mobile Cart Open-Loop Dehumidifier Location(s)_

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 M100 Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. In practice, an aqueous solution of 35% $\rm H_2O_2$ (Vaprox Hydrogen Peroxide Sterilant) is flash vaporized. A heated air stream carries the vapor into the enclosed space requiring biodecontamination. With the VHP M100 Biodecontamination Unit operating as a closed-loop system, air and the VHP antimicrobial are drawn out of the enclosed space and pass through a catalytic converter degrading the VHP antimicrobial into oxygen and water vapor. The air stream then recharges with fresh VHP antimicrobial vapor within the VHP Biodecontamination Unit and returns to the Enclosure.

NOTE: The VHP process can also be operated in an open-loop configuration. Check local regulations regarding environmental hydrogen peroxide discharge.

While operating in a closed-loop configuration (see illustration), the biodecontamination cycle consists of four phases (see illustration):

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 antimicrobial. The internal HEPA filters prevent contamination of internal machine components and prevent recontamination of the Enclosure.

NOTE: Time to reach the targeted humidity corresponds with the initial humidity, temperature and volume 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 (for openloop, 2.0 to 25.0 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.

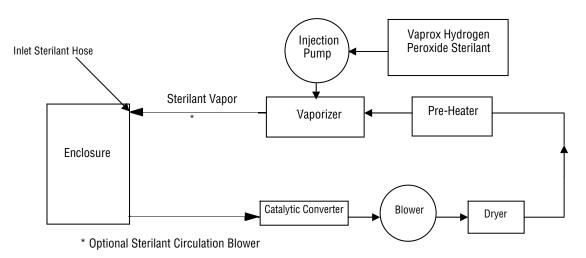
Aeration

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 H₂O₂ vapor concentration within the Enclosure.

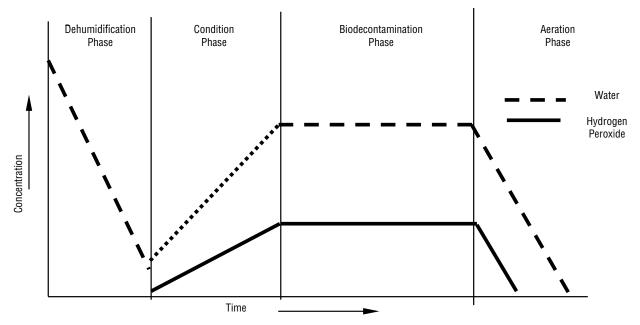
ACCESSORIES

To accomplish the reduction of relative humidity in the Enclosure, either a reusable or disposable desiccant system must be employed.

Reusable Desiccant Cartridge(s) and Regenerator - The reusable cartridge containing desiccant is constructed of aluminum and is easily installed in the VHP M100 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.



Typical Closed-Loop Process Diagram



Typical VHP M100 Biodecontamination System Four Phase Cycle

Disposable Desiccant Cartridges and Adaptor - The disposable cartridge containing desiccant is constructed of plastic and is easily installed in the VHP M100 Biodecontamination System using a stainless-steel adaptor. Following use, a prompt notifies the operator that it is time to discard and replace the cartridge.

NOTE: Reusable or disposable desiccant cartridges are not available on the open-loop configured VHP M100 Biodecontamination Units.

Dehumidifier - A compact, low profile design, desiccant dehumidifier is an accessory for open-loop moderate volume configurations to aid in moisture removal. This non-cycling sorption dehumidifier with single desiccant rotary structure operates at 53 scfm (90 m³/h).

FEATURES

Operator Interface. Two are available.

- 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.
- Allen-Bradley PanelView™ Plus 600¹ The touch panel is a 6.5" active matrix TFT display equipped with 640 x 480 pixel resolution, 18 bit color graphics and resistive touch membrane. Available for Open Loop only.

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

Inlet HEPA Filter. An internal HEPA filter is included.

CONTROL SYSTEM

The control system provides precise control of the VHP M100 Biodecontamination System and uses either the Siemens S7 Series or Allen-Bradley CompactLogix^{™1} controller.

PanelView and CompactLogix are trademarks of Allen-Bradley, a Rockwell Automation Company. Available for Open Loop only.

The PLC control stores and controls such information 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.

CONSTRUCTION

Case: Stainless Steel

Lockable Door: Stainless Steel

Hydrogen Peroxide Cartridge Interface: Flame-Resistant Plastic

NOTE: The liquid hydrogen peroxide is metered with a precision pump.

Disposable Desiccant Cartridge: Plastic Reusable Desiccant Cartridge: Aluminum

Reusable Desiccant Cartridge Regenerator Enclosure and

Doors: Stainless Steel

CALIBRATION

STERIS recommends that all VHP M100 Biodecontamination System 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

- STERIS recommends a dedicated, grounded electrical circuit be provided for each unit. Extension cord use is not recommended.
- Unit should not be installed in an area not compatible with oxidizers. Consult the SDS regarding hydrogen peroxide sterilant
- 3. Regenerator must be on a hard, level surface.
- 4. Access must be provided to power switch and hose connectors.
- Hose clearance must be adequate to prevent kinks and strains on the connectors.
- 6. Hoses must be supported to keep them from resting on the floor or other cold surfaces.
- Clearance must be provided to doors on the VHP M100 Biodecontamination System and regenerator.
- 8. Access must be provided for desiccant cartridge installation and removal.
- 9. Enclosure size listed is recommended size. Connecting VHP M100 Biodecontamination System to larger volumes may increase cycle time.
- 10.Airflow range is measured exiting VHP M100 Biodecontamination System. Actual flow rates may vary from variations in local utility power output.

UTILITY REQUIREMENTS

IMPORTANT: Refer to equipment drawings 356257-509 and 356257-535 for installation details and specifications.

Electricity

• M100-ABX:

230 Vac, 50/60 Hz, 15 Amps

• M100-S and M100-S (Mobile Cart):

230 Vac, 50/60 Hz, 15 Amps

• M100-SX:

230 Vac, 50/60 Hz, 15 Amps

• Reusable Desiccant Cartridge Regenerator:

120 Vac, 50/60 Hz, 1-Phase, 8 Amps 230 Vac, 50/60 Hz, 1-Phase, 4 Amps

Airflow/Pressure

Airflow range: 5 -11 scfm (9-19 cmh) Closed Loop; 8 -44 scfm (14-75 cmh) Open Loop

Maximum control pressure: 2.3 W.G. (572 Pa).

Vaprox Injection Rates:

- Closed-Loop, cartridge feed, cartridge desiccant:
- 1 6 grams/minute
- Open-Loop, bulk-fill with external continuous operation:
- 2 25 grams/minute

ENVIRONMENTAL FACTORS

Ambient Conditions

• Room Temperature: 68 - 86°F (20 - 30°C)

• Relative Humidity: 10 to 80%

Conditioned Air Inlet (Open Loop)

• 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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