STERIS
Life Sciences

VHP® M10 BIODECONTAMINATION UNIT

APPLICATION

The STERIS VHP® M10 Biodecontamination Unit is an integrated, small volume, hydrogen peroxide vapor generator for biodecontamination[1] of clean, dry, sealed enclosures[2] such as isolators, chambers, and work cabinets.

The VHP® M10 Biodecontamination Unit can be configured in either closed- or open-loop.

DESCRIPTION

The VHP® M10 Biodecontamination Unit is designed to biodecontaminate clean, dry enclosure surfaces by either permanently mounting the unit to or temporarily connecting the unit to the sealed enclosure. The VHP® M10 Biodecontamination Unit can operate independently as a stand-alone machine but may also be operated through interface to external equipment via discrete I/O interfacing. This interface is used to start biodecontamination cycles, abort cycles, and monitor the biodecontamination unit status.

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

Units are available for operation with 230 Volt or 120 Volt, 50/60 Hz, single-phase electrical (see below for configuration and voltage options) service.

Operator Interface. Allen-Bradley Micro 850 color touch screen. The touch panel is a backlit thin film transistor (TFT) display equipped with graphics and analog touch membrane.

Air Flow Sensor. This sensor monitors air flow and permits the VHP® M10 Biodecontamination Unit to control at a set flow.

Operator Language. VHP® M10 Biodecontamination Unit comes with English, French, Italian, German, Spanish, Dutch, and Japanese languages.

(Typical only - some details may vary)

USB. Cycle data is logged on a USB memory stick in CSV format. This includes airflow, humidity, hydrogen peroxide injection rate, temperature, time and date, cycle phase, cycle number, and alarm code.

STANDARDS

The VHP® M10 Biodecontamination Unit meets the applicable requirements of the following standards:

- **Underwriters Laboratories (UL) 61010-1, 61010-2-040**
- **Canadian Standards Association (CSA) C 22.2 No. 61010-1, 61010-2-040**
- **CE Compliance**
  - » **EMC Directive 2014/30/EU**
  - » **Low Voltage Directive 2014/35/EU**

The Following Sections Are Available to Configure Customer Equipment

VOLTAGES
- ❑ Closed-Loop 230 VAC, 50/60 Hz
- ❑ Closed-Loop with Pressure Control 230 VAC, 50/60 Hz
- ❑ Closed-Loop 120 VAC, 50/60 Hz
- ❑ Open-Loop 230 VAC, 50/60 Hz

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

OPTIONS
- ❑ Pressure Control

DOCUMENTATION
- ❑ Extended Document Package (GAMP)

ACCESSORIES
- ❑ Reusable Desiccant Cartridge(s) and VHP Desiccant Dryer
- ❑ Disposable Desiccant Cartridges
- ❑ Dehumidifier
- ❑ Catalytic Converter
- ❑ Catalytic Converter with 1-1/2" Sanitary Connections
- ❑ High Efficiency Particulate Air (HEPA) Filter
- ❑ High Efficiency Particulate Air (HEPA) filter with 1-1/2" Sanitary Connections
- ❑ Remote Printer Box
- ❑ 1.5" Sanitary SS Connection Kit
- ❑ 1.25" Hose Connection Kit
- ❑ 1.25" Banjo Hose Connection Kit

Item _____

Location(s)_____

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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® M10 Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. In practice, an aqueous solution of 35% hydrogen peroxide (Vaprox® Hydrogen Peroxide Sterilant) is flash vaporized and a heated air stream carries the vapor into the enclosed space requiring biodecontamination. With the VHP® M10 Biodecontamination Unit operating as a closed-loop system (Figure 1), 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.

With the unit operating as an open-loop system (Figure 1), air is drawn from a dehumidified air source. The air stream is HEPA filtered and injected with VHP vapor that is distributed to the enclosure.

The biodecontamination cycle consists of four phases as follows (see Figure 2).

Dehumidification

Dry, High Efficiency Particulate Air (HEPA) filtered air is circulated or fed directly to the enclosure 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 air passes through the dryer* and then is heated to serve as the carrier for the VHP. The HEPA** filter prevents contamination of internal machine components and prevents recontamination of the enclosure.

Time to reach the targeted humidity corresponds with the initial humidity, temperature and volume of the enclosure.

** Closed-loop option uses desiccant cartridge and open-loop option uses a dehumidifier. See Accessories for available options.*

*** HEPA filter is part of the enclosure or is an optional accessory.*

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 5.0 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

For closed-loop units, 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. For open-loop units, the enclosure exhaust system is used to reduce the H_2O_2 vapor concentration within the enclosure.

**** Catalytic converter is part of the enclosure or is an optional accessory..*

ACCESSORIES

HEPA Filter. A H14 HEPA filter is available for in-line use (external to VHP® M10 Biodecontamination Unit). Connections are available for 1.5" sanitary or flexible hose. The filter is shipped separately and disconnected by others to the M10 and enclosure piping.

Catalytic Converter. A catalytic converter is available for in-line use (external to VHP® M10 Biodecontamination Unit). Connections are available for 1.5" sanitary or 1.25" FNPT. The catalytic converter is shipped separately and is connected by others to the M10 and enclosure piping.

Remote Printer Box. The remote printer box connects to the VHP M10 via Ethernet to provide a print out of the cycle record. A separate 100-240 VAC power source is required.

Desiccant System. To accomplish the reduction of Relative Humidity (RH) in the enclosure, either a reusable or disposable desiccant system must be employed.

- **Reusable Desiccant Cartridge(s) and VHP Desiccant Dryer for Closed-Loop Unit** – The reusable 600-gram cartridge containing desiccant is constructed of aluminum and is easily installed in the VHP® M10 Biodecontamination Unit. Following use, a prompt notifies the operator that it is time to remove the cartridge and install it in the dryer to dry the desiccant.
- **Disposable Desiccant Cartridges and Adaptor for Closed-Loop Unit** – The disposable 270 gram cartridge containing desiccant is constructed of plastic and is easily installed in the VHP® M10 Biodecontamination Unit using a stainless-steel adaptor. Following use, a prompt notifies the operator that it is time to discard and replace the cartridge.
- **Dehumidifier for Open-Loop Unit** - The dehumidifier is used to feed dry air to the VHP unit. The dehumidifier includes a desiccant wheel and operates at various capacities depending on the application.
- **1.5" Sanitary SS Connection Kit**. The 1.5" sanitary connection kit includes two (2) 304SS 1.5" to 1" MNPT adapters for the inlet and outlet of the unit. Two (2) sanitary gaskets, blank flanges, and wing clamps are also included.

- **1.25" Hose Connection Kit**. The 1.25" hose connection kit includes two (2) 1.25" hose barb to 1" MNPT adapters for the inlet and outlet of the unit. Four (4) hose clamps and two (2) 10ft. (4m) 1.25" hoses are also included.
- **1.25" Banjo Hose Connection Kit**. The 1.25" banjo quick connect hose connection kit includes two (2) 1.25" banjo to 1" MNPT adapters for the inlet and outlet of the unit. Two (2) 1.25" banjo to 1.25" hose barb female adapters, four (4) hose clamps, and two (2) 10ft (4m) 1.25" hoses are also included.

OPTIONS

Pressure Control. The control is mounted internal to VHP® M10 Biodecontamination Unit to control positive and negative pressure control of smaller enclosures.

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® M10 Biodecontamination Unit and uses the Allen-Bradley PLC and color touch screen.

The PLC stores and controls the time for each phase, operating pressure, hydrogen peroxide injection rate, air flow rate and target 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, for closed-loop models, the control monitors the capacity available in the desiccant cartridge and flags the user when change-out is necessary for the next cycle. All calibration is handled by the control.

The operator interface allows the user to program the PLC without the need for a Customer-supplied computer. Security Codes are used to prevent unauthorized operation or modification of preset or custom cycle parameters. Up to 5 configurable cycles are available with 2 cycles that can be initiated in remote mode using the discrete I/O connections.

CONSTRUCTION

Case: Stainless Steel
Service Door: Stainless Steel
Hydrogen Peroxide Cartridge Interface: Flame-Resistant Plastic

Disposable Desiccant Cartridge: Plastic

Reusable Desiccant Cartridge: Aluminum

CALIBRATION

STERIS recommends that all VHP® M10 Biodecontamination Units be calibrated at least once every six months. STERIS Service representatives can provide this service to ensure validatable operation of the unit.

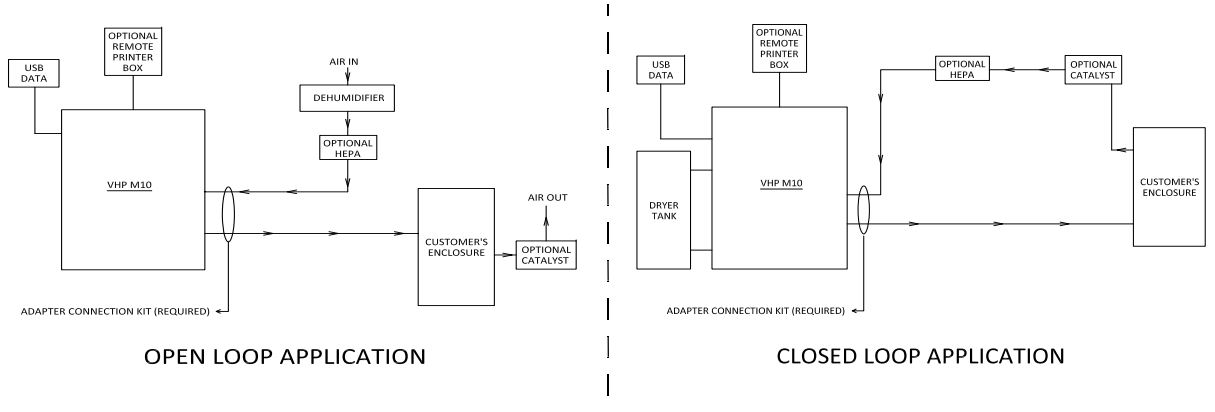

Figure 1 - Typical Process Diagrams

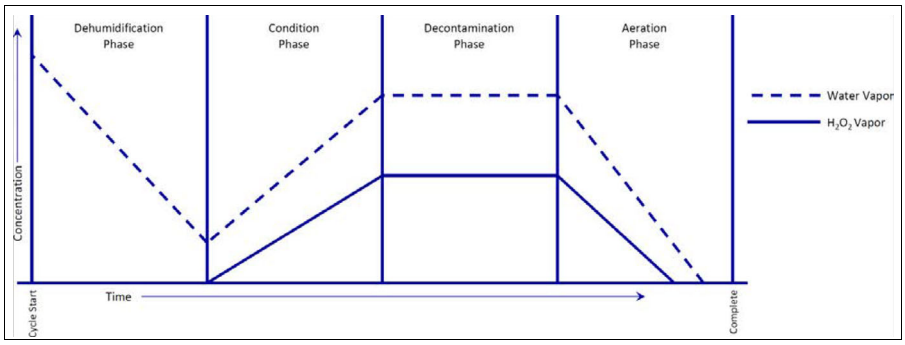

Figure 2 - Typical VHP® M10 Biodecontamination Unit Four Phase Cycle

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 ensure optimal equipment performance and to 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. In this document, when referring to the use of VHP® Biodecontamination Units with Vaprox®Hydrogen Peroxide Sterilant in the United States, the term biodecontamination 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 of America (USA) does not impart additional claims of effectiveness beyond that approved in the USA Environmental Protection Agency (EPA) registered labeling of Vaprox® Hydrogen Peroxide Sterilant.
2. Contained area to be biodecontaminated (e.g., rooms, facilities and equipment). Enclosure must be leak tested according to manufacturer's recommendations.
3. Refer to drawings and Operator Manual for specific installation and operation instructions.
4. Unit should not be installed in an area not compatible with oxidizers. Consult the Safety Data Sheet (SDS) regarding hydrogen peroxide sterilant.
5. Hoses must be supported to keep them from resting on the floor or other cold surfaces to avoid condensation.
6. Clearance must be provided to rear panel on the VHP® M10 Biodecontamination Unit.
7. Access must be provided for desiccant cartridge installation and removal.
8. The VHP® M10 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 drawing 11007509 and Figure 1 for installation details and specifications.*

Electricity

120 VAC, 50/60 Hz, 1PH, 15 Amp. Includes power cord with NEMA 5-20P plug

230 VAC, 50/60 Hz, 1PH, 10 Amp. Includes power cord - Customer to supply plug per local codes

Airflow/Pressure

Airflow Range: 8 - 20 scfm (14 - 34 cmh)

Maximum Control Pressure: 2.3 W.C. (572 Pa)

Vaprox Injection Rates

1.0 - 5.0 grams/minute

ENVIRONMENTAL FACTORS

Ambient Conditions

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

Relative Humidity: 10 to 80% non-condensing

Weight

110 lb. (50kg) without dryer cartridge (shipping weight)

80 lb. (36.3kg) without dryer cartridge (installation weight)

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

STERIS Corporation, Mentor Ohio is an and ISO 9001 certified facility.

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

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