STERIS®

VHP® 1000ED-S AND -AB BIODECONTAMINATION SYSTEMS

APPLICATION

Designed for biodecontamination of sealed enclosures* (isolators, work stations, aseptic filling lines, pass-throughs) and rooms in research, biological safety, and production applications.

** Enclosure must be leak-tested at the enclosure manufacturer's recommended pressure.*

DESCRIPTION

The VHP 1000ED (Enhanced Design) Biodecontamination System is a self-contained, hydrogen peroxide vapor generator. The biodecontamination unit operates at ambient temperature and atmospheric pressure to offer operating flexibility.

To avoid exposure to liquid hydrogen peroxide, the system accepts specially designed disposable cartridges (available separately) containing approximately 950 mL of Vaprox® Hydrogen Peroxide Sterilant.

Mounted on rubber wheels and swivel casters, the biodecontamination unit can be moved and repositioned on hard, level surfaces. Units are available for operation on 120 V, 200 V, or 230 V, 50/60 Hz, 1-phase electrical service.

STANDARDS

The biodecontamination unit and control system contain the CE mark and meet the applicable requirements of the following:

- **Underwriters Laboratories (UL) Standard 61010-1, as certified by ETL Testing Laboratories, Inc.**
- **Canadian Standards Association (CSA) Standard C22-2, No. 61010.1:2004, as certified by ETL Testing Laboratories, Inc.**
- **EMC Directive 89/336/EEC, 92/31/EEC, 93/68/EEC.**
- **Low Voltage Directive 73/23/EEC, 93/68/EEC.**

(Typical only - some details may vary.)

FEATURES

Control system provides the precise control and documentation required by Good Automated Manufacturing Practice (GAMP) standards. The Siemens S7-300 (TP-270 display) and Allen-Bradley Compact Logix (Panel View Plus™ 600 Display*) controllers store information such as the desired time for the cycle phases, operating pressure, hydrogen peroxide injection rate, airflow rates, and target relative humidity. The control also monitors the amount of hydrogen peroxide available in the reservoir and the dryer capacity. A prompt notifies the operator when the Vaprox cartridge needs to be changed and when the dryer needs to be refreshed (regeneration).

** PanelView Plus is a trademark of Allen-Bradley.*

The Selections Checked Below Apply To This Equipment

VOLTAGES:

FOR DOMESTIC UNITS:

☐ 120 VAC, 50/60Hz

FOR INTERNATIONAL UNITS:

☐ 200 VAC, 50/60Hz

☐ 230 VAC, 50/60Hz

CONTROLS:

☐ Siemens

☐ Allen-Bradley

LANGUAGE OPTIONS:

☐ **Siemens Control**

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

☐ **Allen-Bradley Control**

- ☐ English
- ☐ French

Item _____

Location(s) _____

_____

Operator interface control panel, consisting of a color touch-screen and impact printer, is located on the top of the unit.

- **Siemens or Allen-Bradley color touch-screen** enables the user to easily program the desired cycle. Program information and operating characteristics are shown on an LCD display. The Siemens screen is 320 x 240 pixel resolution, 5.7" type. The Allen-Bradley screen is 320 x 240 pixel resolution, 6.0" type.

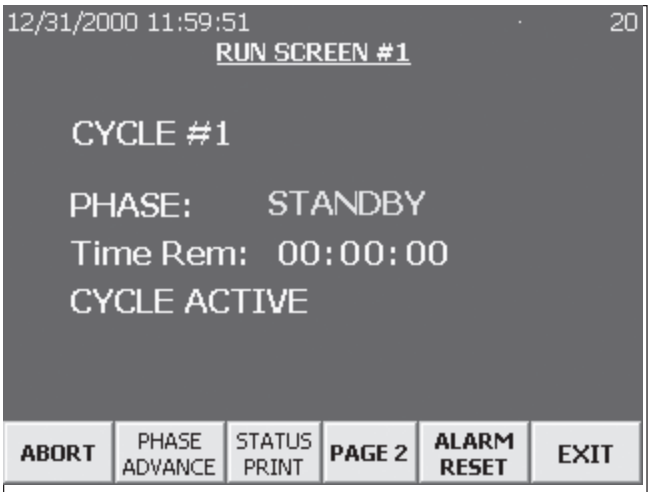
  The display indicates the appropriate control buttons, operator prompts, and status messages necessary to assist in the biodecontamination system operation. All displayed messages are complete phrases with no codes to be cross-referenced. The display also indicates any abnormal conditions that may exist either in or out of a cycle.

- **Ink-on-paper impact printer**, located near the screen, provides an easy-to-read printed record of all pertinent cycle data on 2-1/4" (5.7 mm) wide paper. Data is automatically printed at the beginning and end of each cycle, and at transition points during the cycle.

  Printer take-up spool stores an entire roll of paper, providing cycle records which can be saved for future reference. Three paper tape rolls are furnished with each unit.

Cycle configuration is performed by accessing the Cycle Values menu through the touch screen. Up to 19 cycles may be configured; one additional cycle (20) is available for remote programming/operation by a host PLC. In addition to adjustment of cycle values, the following operating parameters can also be changed through the Cycle Values menu:

- **User name and access code.** A 10-character alpha-numeric user name and four-digit numerical password are required when entering the operator, supervisor, or service mode. Operating the biodecontamination system, starting a cycle, or accessing the Cycle Values menu causes the display to request the entry of an access code. If the access code is not properly entered, the display returns to the standby or main menu screen, denying the user access to the biodecontamination system or programming.
- **Temperature display and printout units** are Celsius (°C) or Fahrenheit (°F). Temperature is set, displayed, controlled, and printed to the nearest 0.1°. Recalibration is not required when changing temperature units from °F to °C, and vice versa.
- **Pressure/vacuum display and printout units** are inches W.C. or Pascals. Recalibration is not required when changing pressure units.
- **Cycle airflow display and printer units** are in ft^3/m or m^3/h. Recalibration is not required when changing cycle air flow units.



Typical Touch Screen Display

- **Liquid hydrogen peroxide injection rate** can be set from 1.0 to 12.0 grams per minute. Variable speed blowers can be set to deliver an airflow ranging from 8 to 20 scfm (14 to 34 m^3/h).

  NOTE: The operating pressure selected must not exceed the pressure specifications set by the enclosure manufacturer.

Technical Data

The control system consists of PLC control cards and a control rack located within the upper bay.

Cycle data is stored on battery-backed RAM or flash memory. Estimated life of the replaceable battery is two years. If a power failure occurs during a cycle, the battery backup system assures that the cycle memory will be retained and proper cycle completion will occur once power is restored.

CONSTRUCTION

The VHP 1000ED biodecontamiation unit is constructed with a 1/8" (3 mm) painted aluminum frame and stainless-steel side and top panels. The cartridge interface system, printer, and control bezel are molded of flame-resistant plastic. The self-activating spring brake mechanism has a release bar conveniently located beneath the push handle.

The liquid hydrogen peroxide is metered with a precision motor-driven pump. The mass flow of the hydrogen peroxide is measured with a weighing device.

Four customer relay contact outputs (maximum 1A at 24 V), and three optically isolated switch inputs are provided for connection to external devices which can be activated during a cycle or during an alarm.

Interfacing to external equipment is possible for the Siemens Control System by using Profibus/MPI communications and for the Allen-Bradley Control System by using Ethernet/IP communications.

Internal HEPA (High Efficiency Particulate Air) filters prevent contamination of internal machine components and prevent recontamination of the enclosure.

CYCLE DESCRIPTION

After the reservoir is filled, the Decontamination cycle proceeds through four phases: Dehumidification, Condition, Decontamination, and Aeration.

Reservoir Fill. Hydrogen peroxide is pumped from the cartridge to a reservoir. If the amount of hydrogen peroxide required for the cycle is greater than the capacity of the reservoir (1950 grams), the cycle is disabled.

Dehumidification Phase. Dry, HEPA- filtered air is circulated to reduce humidity to a predetermined level in the 10-30% relative humidity range. This permits necessary H_2O_2 vapor concentration to be maintained below saturation levels during the Condition and Decontamination phases. Time to reach the targeted humidity increases with the volume of the enclosure.

Condition Phase. The flow of dry, HEPA-filtered air continues while the H_2O_2 vapor is injected into the air stream just before it leaves the biodecontamination system. The injection rate is controllable in the 1 to 12 grams per minute range. The Condition phase facilitates reaching the desired decontamination concentration more quickly in larger sealed enclosures. Condition time is affected by sterilant injection rate and enclosure volume. The Condition phase is optional, and can be selected for the purpose of reducing total cycle time, especially for larger applications. Use of the Condition phase does not reduce the time of exposure during the Decontamination phase.

Decontamination Phase. A constant flow of the H_2O_2 vapor/HEPA-filtered air mixture is maintained at the selected hydrogen peroxide injection rate, within the controllable range.

Aeration Phase. H_2O_2 vapor injection is stopped and the recirculating flow of dry HEPA-filtered air continues to reduce the vapor concentration within the enclosure.

Following the Decontamination cycle, the drying system may need to be refreshed. Time required to refresh the drying system depends upon cycle parameter selection, initial relative humidity, humidity set points, and enclosure size.

CALIBRATION

STERIS recommends that all VHP 1000ED Biodecontamination Systems be calibrated at least once every six months. STERIS can provide this service to assure validated operation of the unit.

PREVENTIVE MAINTENANCE

A global network of skilled service specialists can provide periodic inspections and adjustments, to help ensure low-cost peak performance. STERIS representatives can provide information regarding annual maintenance agreements.

NOTES

1. STERIS recommends that a dedicated, grounded electrical circuit be provided for each unit. Use of an extension cord is not recommended.
2. The system should not be installed in an area which is not compatible with oxidizers. Consult the MSDS regarding the hydrogen peroxide solution or Vaprox Hydrogen Peroxide Sterilant.
3. The floor must be a hard, level surface.
4. Access to the power switch and hose connectors located at the rear of the unit must be provided.
5. Rear 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.
7. Moving the VHP 1000ED Biodecontamination System requires more than one person. The unit weighs approximately 500 lbs (227 kg).
8. The VHP 1000ED Biodecontamination System normally operates at airflows ranging from 8.0 scfm (13 scmh) to 20 scfm (34 scmh). The airflow that the VHP 1000ED is capable of maintaining is dependent on the pressure drop in the sterilant delivery and return lines.
9. Request VHP 1000ED equipment drawing for acceptable operating condition recommendations.

STERIS Corporation, Mentor, (Hopkins) Ohio is an ISO 9001 and ISO 13485 certified facility.

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

UTILITY REQUIREMENTS

Electricity (E)

- 120 V, 1-Phase, 50/60 Hz, 20 Amps
- 200 V, 1-Phase, 50/60 Hz, 10 Amps
- 230 V, 1-Phase, 50/60 Hz, 10 Amps

Connections

① Sterilant Output HOT

② Sterilant Return

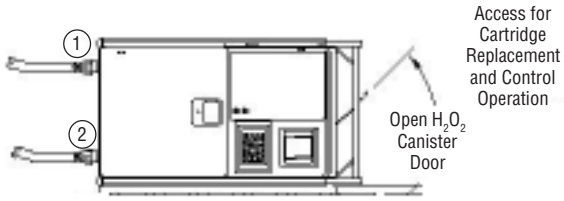
Environmental Factors

- Room Temperature: 60-104°F (16-40°C)
- Relative Humidity: 10-80% relative humidity, non-condensing

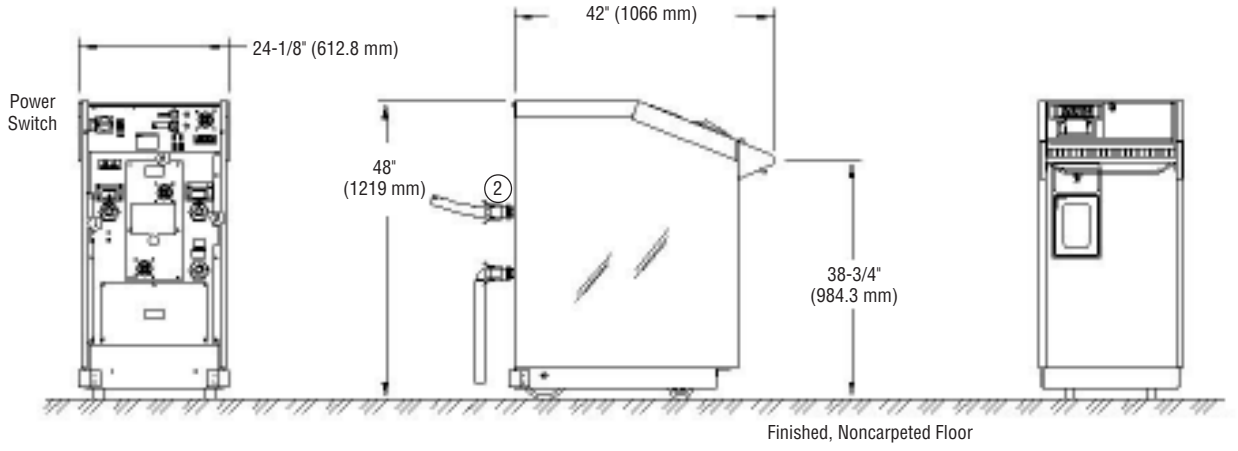
CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH APPLICABLE LOCAL AND NATIONAL CODES AND REGULATIONS.

Reference the following equipment drawings for installation details.	
Equip. Dwg. No.	**Equipment Drawing Title**
387352-121	VHP 1000ED-S/AB

Dimensions are typical – drawing is not to scale.



TOP VIEW



REAR VIEW **SIDE VIEW** **FRONT VIEW**

For further information, please contact:

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