

VHP® 100i

Biodecontamination System



APPLICATION

The VHP 100i High Capacity Biodecontamination System is a hydrogen peroxide vapor generator for biodecontamination¹ of clean, dry, sealed enclosures², rooms, isolators, and continuous filling systems. The VHP 100i is configured as an open-loop system for maximum VHP output.

DESCRIPTION

The VHP 100i is installed in a 304SS cabinet that is permanently mounted in the building or enclosure. The VHP 100i 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.



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 Automated Manufacturing Practices (GAMP 5)
- RoHS 2 Compliant: EN IEC 63000:2018, EU 2015/863
- Radio Equipment Directive (RED): (ETSI EN) 301-489-1, 301 489-3, 300 330
- IP54 Ingress Protection Rating: (IEC) 60529: 1989 Ed.2 + A1, A2

SPECIFICATIONS

Controller	Siemens
Dimensions HxWxD in (mm)	28 x 34 x 13 (711 x 864 x 330)
Net Weight lbs (kg)	175 (79)
Input Power:	208V and 230V/1 ϕ /50/60Hz
Airflow/Pressure	12–70 scfm (20–120 cmh) ³
Vaprox Injection Rates:	2-29 g/min
Input Current Amps:	25A (230VAC), 30A (208VAC)
Class	UL, CSA, CE, UKCA

FEATURES

To minimize exposure to the liquid hydrogen peroxide during handling, the system uses specially designed bulk containers

containing approximately 5 gal (19 L) of Vaprox Hydrogen Peroxide Sterilant or 53 gal (200 L) drums.

Units are available for operation on 208V or 230V, 50/60 Hz, Single phase electrical service.

- 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.
- The maximum airflow of the unit is dependant upon piping backpressure in each application. Refer to VHP 100i Equipment drawing for more information on airflow at different pressure conditions.

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.

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

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

CYCLE DESCRIPTIONS

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 and the ability to distribute vapor through piping systems.

The VHP 100i Biodecontamination Unit delivery and control systems provide low-temperature biodecontamination methods for many enclosed areas. In practice, an aqueous solution of 35% H₂O₂ (Vaprox Hydrogen Peroxide Sterilant) is flash vaporized. A heated air stream carries the vapor into the enclosed space requiring biodecontamination. With the VHP 100i Biodecontamination Unit operating as an open-loop system, 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 or room.

While operating in an open-loop configuration, as shown in figure 1, the biodecontamination cycle consists of four phases

Dehumidification — Dry, HEPA-filtered (High Efficiency Particulate Air) air is fed to the unit to dry and heat the VHP distribution system. This permits the necessary target Vaprox Hydrogen Peroxide Sterilant vapor concentration to be maintained below saturation (dew point) levels during the Condition and Decontamination phases. The air passes through the dehumidifier⁴ and then is heated to serve as the carrier for the VHP. The internal HEPA filters prevent contamination of internal machine components and prevent contamination of the enclosure or room.

Condition — 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 2 to 29 grams per minute range. The Condition phase facilitates reaching the target biodecontamination concentration faster in larger volume sealed enclosure or room applications. Condition time is affected by sterilant injection rate, enclosure/room volume, enclosure/room contents and temperature.

Decontamination — 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 enclosure/room HVAC system is used to reduce the H₂O₂ vapor concentration within the enclosure or room.

Auxiliary Aeration - Aeration continues. This phase is intended as an extended aeration to confirm removal of any residual H₂O₂ concentration within the enclosure.

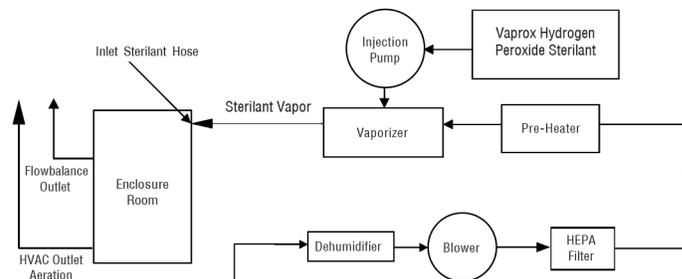


Figure 1: Typical Open-Loop Process Diagram

ACCESSORIES

Dehumidifier - A dehumidifier is an accessory for open-loop configurations to feed dry air to the VHP unit. The dehumidifier includes a desiccant wheel and operates at various capacities depending on the application.

Vaprox Distribution System- Provides a remotely installed Vaprox Hydrogen Peroxide Sterilant Cartridge or connection to Vaprox Hydrogen Peroxide Sterilant bulk supply for the VHP 100i Biodecontamination Unit.

Remote Communication Interface - Provides remote control interface to the VHP 100i Biodecontamination Unit.

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

Anybus Gateway Module - Optional module enabling communication between the STERIS VHP Generator and system network via Modbus, Profibus or EtherNet 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 to 21 CFR Part 11 (Optional).

Software feature enabling audit trail, electronic data capture, user administration, and other features for compliance with FDA 21 CFR 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.

Each bottle of Vaprox Hydrogen Peroxide Sterilant features an RFID tag, Vaprox link, to track lot number, production expiration date and in-use expiration date. This data will be

4. Dehumidifier is not included with the VHP 100i and is a separate accessory ..

available on the batch report and in the control panel interface.

Vaprox link will provide the user with visual confirmation that their chemistry has been accepted or rejected.

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.

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 programs.

NOTES

1. Enclosure must be leak tested according to manufacturer's recommendations.
2. Refer to drawings and Operator Manual for specific installation and operating instructions.
3. Unit should not be installed in an area not compatible with oxidizers. Consult the SDS regarding hydrogen peroxide sterilant.
4. Clearance must be provided to doors on the VHP 100i Biodecontamination System.
5. Space should be allocated for Vaprox bulk container. The container should be placed below the VHP unit.
6. The VHP® 100i 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.

Refer to the Following Equipment Drawing for Installation Details

Equipment Drawing Number	Equipment Drawing Title
11022457	VHP 100i Operator Manual
11958223	VHP 100i Maintenance Manual
PS00000240	VHP 100i Tech Data
11022455	VHP 100i Installation Instructions
11958224	Illustrated Parts Breakdown Manual
11022810	Equipment Drawing
11015864	Electrical Schematic
11022814	Plumbing (System) Schematic
11022456	External Interface Procedure

Selections Checked Below Apply To This Equipment

POWER

230 VAC, 50/60 Hz

208 VAC, 50/60 Hz

ACCESSORIES

Dehumidifier

Vaprox Distribution System

Remote Communication Interface

Anybus Module

Remote Printer Module

OPTIONS

Siemens with Profinet TCP

Siemens with Profinet TCP and Electronic Data

DOCUMENTATION

Extended Document Package (GAMP 5)

LANGUAGE OPTIONS

English

French

German

Spanish

Italian

Dutch

Chinese (User Interface Only)

Japanese (User Interface Only)

Item:	
Locations:	

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

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