STERIS
Life Sciences

VHP® LS60 BIODECONTAMINATION UNIT

APPLICATION

The VHP LS60 Biodecontamination Unit is designed for the application of Vaprox® 59 Hydrogen Peroxide Sterilant to properly prepared (cleaned, rinsed and dried) reusable metal and nonmetal devices[1] using STERIS's VHP process technology, vacuum conditions and Vaprox 59 Hydrogen Peroxide Sterilant.[2] The low temperature Biodecontamination Cycles are suitable for biodecontaminating devices sensitive to heat and moisture.

[1] *Not for use to reprocess reusable devices for human use.*

[2] *When using VHP LS60 Biodecontamination Units with Vaprox 59 Hydrogen Peroxide Sterilant in the United States of America (USA), the term biodecontamination referred to in this document is defined as sterilization of exposed porous and non-porous surfaces of precleaned, dry, devices and reusable devices for non-human use. Any reference to biodecontamination as it relates to the use of this equipment in the USA does not impart additional claims of effectiveness beyond that approved in the USA Environmental Protection Agency (EPA) registered labeling of Vaprox 59 Hydrogen Peroxide Sterilant (EPA Reg. No. 1043-123).*

DESCRIPTION

The VHP LS60 Biodecontamination Unit uses STERIS's patented VHP process technology. The biodecontamination process is fully automated, is compatible with a broad range of materials and has rapid Biodecontamination Cycle times. There are no toxic by-products created by the Biodecontamination Cycle – only water vapor and oxygen are produced.

The VHP LS60 Biodecontamination Unit performs three programmed Biodecontamination Cycles:

- **Lumen Cycle** (approximately 60 minutes to complete)
- **Non Lumen Cycle** (approximately 28 minutes to complete)
- **Flexible Cycle** (approximately 38 minutes to complete)

This biodecontamination unit using the **Lumen Cycle** can biodecontaminate[3] the following:

1. Rigid devices, with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
2. Single, dual and triple channeled rigid devices, with the following configurations:
   - Single or dual lumened devices with stainless lumens that are ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
   - Triple lumened devices with stainless lumens that are either:
     - » ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (10-55/64") in length
     - » ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (12-13/64") in length OR
     - » ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

[3] *Validation testing was conducted for all lumen sizes using a maximum of 12 lumens per load. Loads should not exceed this validated number of lumens. Validation studies conducted using validation load of one instrument tray and two pouches for a total weight of 11 lb (5 kg).*

(Typical only - some details may vary.)

This biodecontamination unit using the **Non Lumen Cycle** can biodecontaminate[4] non-lumened devices (both non-lumened rigid and those with stainless-steel diffusion-restricted areas such as the hinged portion of forceps or scissors).

[4] *Validation studies conducted using validation load of one instrument tray and one pouch for a total weight of 12 lb (5.4 kg).*

This biodecontamination unit using the **Flexible Cycle** can biodecontaminate devices with a light cord (if not integral to device) and mat with no additional load.[5] The flexible device may contain either a single or dual lumen device with Lumens that are of ≥ 1 mm (~3/64") ID and ≤ 990 mm (38-63/64") in length.

[5] *The validation studies were conducted with one flexible device, each packaged into a tray with silicone mat and light cord (if not integral to device) and no additional load.*

The VHP LS60 Biodecontamination Unit also features:

- Unit operates on 208/230 Vac, one-phase electrical service.
- Unit is equipped with a printer located on front of unit (right side while facing unit). This alphanumeric impact printer provides an easy-to-read permanent record of Biodecontamination Cycle. Printer provides a 2-1/4" (5.7 mm), 24-character wide cycle tape and paper take-up.

The Selections Checked Below Apply To This Equipment

UNIT POWER SUPPLY

- ❑ North America: 120 Vac, 1 phase, 60 Hz, 20 Amp
- ❑ Europe/Asia: 230 Vac, 1 phase, 50/60 Hz, 10/8 Amp
- ❑ Japan: 200 Vac, 1 phase, 50/60 Hz, 12 Amp

INSTALL OPTIONS

- ❑ Single Door, Counter Mounted
- ❑ Single Door, Cart Mounted

Item _____

Location(s)_____

_____

- Unit utilizes specially designed, disposable, multi-use cups (available separately) containing 0.03 gal (113 mL) Vaprox 59 Hydrogen Peroxide Sterilant, a broad-spectrum anti-microbial. Proprietary cup is equipped with a data matrix code to ensure correct cup is used in unit and cup contents are not expired; no cup code (or other information) needs to be entered by user.
- Unit verifies expiration date of sterilant, tracks days it has been opened and tracks number of cycles per cup that have been performed. Ready, Status, Standby and Cup Empty screens include a cup level indicator in lower right corner. Each bar represents approximately four cycles.
- Unit is available with single door in either a freestanding or recessed configuration.
- Unit installation requires no plumbing, ventilation or air supply – only a dedicated electrical connection is needed. A power cord is supplied for this connection.
- Unit is equipped with a racking system for articles to be biodecontaminated.
- Unit is equipped with automated control enabling cycle to be started and monitored by operator. Control touch screen is user friendly and easy to operate.

STANDARDS

This VHP LS60 Biodecontamination Unit meets the applicable requirements of the following standards, **as certified by INTERTEK Testing Services**:

- Underwriters Laboratories (UL) Standard UL 61010-1 Second Edition
- Canadian Standards Association (CSA) CAN/CSA 22.2 No. 61010-1 Second Edition

Each biodecontamination unit is designed, fabricated, assembled and tested in accordance with all applicable sections of UL and CSA.

SIZE (W X L X H)

Overall Dimensions:

- 31 x 31 x 28" (787 x 787 x 711 mm)

Chamber Size:

- 13 x 28 x 10" (330 x 711 x 254 mm)

Chamber Volume:

- 2.1 cubic feet (60 L)

CONSTRUCTION

The chamber and door assembly are aluminum equipped with a silicone rubber gasket for the door and a welded backhead for the chamber.

Insulation fitted on the chamber wall exterior, door and backhead is 1/2" (13 mm) thick (nominal). Insulation is held in place with adhesive.

Insulation is constructed of asbestos- and chloride-free, oil and water resistant (silicone impregnated) fiberglass.

Automatic door locking mechanism keeps the door locked during the entire Biodecontamination Cycle. After cycle completion, the door is electrically unlocked. The door cannot be opened if electrical power is lost during unit operation. When Biodecontamination Unit is in Standby mode, there are no door opening restrictions.

Chamber heating is achieved through electric strip heaters attached to the chamber sides, bottom wall, door and backhead. Operating temperature is approximately 122°F (50°C).

Sterilant cup interface only accepts Vaprox 59 Hydrogen Peroxide Sterilant Cups. The system control automatically tracks the amount of Vaprox 59 Hydrogen Peroxide Sterilant used and the Sterilant expiration date. The control prompts the user on the control display when a new cup is needed.

The proprietary cup is equipped with a data matrix code to ensure the correct cup is used in the sterilization unit and that the cup contents are not expired; no cup code (or other information) needs to be entered by the user.

Catalytic converter receives outflow from chamber during all cycle phases. Catalytic converter converts hydrogen peroxide into water vapor and oxygen.

Other Components:

The following are furnished to obtain a complete working unit, ready for (but not including) connection to the facility service lines:

- **Resistance Temperature Detectors (RTDs)** are installed for sensing and displaying temperature control of vaporizer and chamber. Signals from all system RTDs, converted into electrical impulses, provide accurate control inputs and readouts throughout the entire cycle.
- **Pressure Transducers** are installed for sensing and displaying chamber pressure control. Signals from all system pressure transducers, converted into electrical impulses, provide accurate control inputs and readouts throughout the entire cycle.
- **Solenoid Valves and Switches** are used in the biodecontamination unit design to simplify piping and increase serviceability.
- **Chamber Air Supply and Vacuum Filters** are supplied to ensure air entering chamber is HEPA (High Efficiency Particulate Air) filtered (prevent chamber recontamination) and air exhausted from vacuum pump is free of entrapped oil and odor.
- **Unit Panels** are constructed of plastic.
- **Unit Frame** and support system is constructed of welded carbon steel with protective paint.

CONTROL DESCRIPTION

The VHP LS60 Biodecontamination Unit is equipped with a proprietary control system and an impact printer.

- **Control Display Panel** is located on the front of the Biodecontamination Unit in the center while facing the unit. This color touch panel provides user information and allows user inputs. The display is a 640 x 480 pixel resolution, 5.7" screen. Use of this panel and associated screens is normally self-explanatory. The screens are color coded for operator convenience as follows:
  - Control Screens:
    - » Condition Phase - Green,
    - » Biodecontamination Phase - Blue
    - » Aeration Phase - Violet

- Service Screens - Light Blue
- Option Screens - Purple
- Alarm Screens - Red

NOTE: This Biodecontamination System permits no manual control of the Biodecontamination Cycles.

The Ready, Status, Standby and Cup Empty screens include a cup level indicator (similar to a cell phone battery indicator) in the lower right corner. For normal operation (with Vaprox 59 Hydrogen Peroxide Sterilant), each bar represents approximately five cycles remaining (e.g., four bars means cup contains enough sterilant for 16 - 20 cycles).

Printer is located on the front of the biodecontamination unit on the right side while facing the unit. This alphanumeric impact printer provides an easy-to-read permanent record of the Biodecontamination Cycle. Printer provides a 2-1/4" (5.7 mm), 24-character wide cycle tape and paper take-up.

CYCLE DESCRIPTION

The VHP LS60 Biodecontamination Unit is equipped with three programmed Biodecontamination Cycles: Lumen Cycle (60 minutes), Non Lumen Cycle (28 minutes) and Flexible Cycle (38 minutes). Each Biodecontamination Cycle proceeds through three phases: CONDITION, BIODECONTAMINATION and AERATION.

Basic description of a Biodecontamination Cycle (example):

- **CONDITION** — This cycle phase consists of the reservoir filling and a timed vacuum pulse to remove air and moisture from the chamber. When setpoint is reached, load is tested for acceptable moisture content. If content is acceptable, cycle proceeds. If not, Condition pulse repeats.

  NOTE: If Condition phase fails the third moisture check, the cycle Aborts.

- **BIODECONTAMINATION** — This cycle phase is a series of four pulses. Each pulse consists of: vacuum pulled to setpoint; Vaprox 59 Hydrogen Peroxide Sterilant vapor drawn into chamber; hold for programmed time; filtered air is introduced to setpoint; hold for programmed time; deep vacuum pulled to setpoint.
- **AERATION** — This cycle phase pulls a vacuum to setpoint and continues to evacuate for programmed time to reduce chamber vapor concentration. Once Aeration phase is complete, chamber pressure returns to atmospheric and chamber door is unlocked.

BIODECONTAMINATION ASSURANCE PRODUCTS

Vaprox 59 Hydrogen Peroxide Sterilant – 59% stabilized aqueous solution of hydrogen peroxide designed for use with VHP Biodecontamination Units and Accessories (EPA Reg. No. 1043-123). Order PB033US (113 mL).

Steraffirm® PCC049 Indicator – Chemical indicator designed for use with hydrogen peroxide vapor.

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Spordex® NA340 S24 Self-Contained Biological Indicator – E6 *Geobacillus stearothermophilus* 24-hour self-contained biological indicator designed for use with hydrogen peroxide vapor.

ACCESSORIES

Trays And Organizer Clips – Trays are lightweight, durable and available in a variety of sizes to fit your devices while organizer clips anchor devices in-place for transportation.

Tray Mats – Mats are lightweight, durable and feature flexible prongs which loosely grip devices.

Pouches – Vis-U-All™ pouches combine durable Tyvek with a clear 2.0 mL film to offer a wide variety of pouch sizes and styles in heat-seal, self-seal and customizable roll tubing.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS Life Sciences concerning annual maintenance programs. Preventive maintenance, adjustments and replacement of worn parts are provided on a scheduled basis to help ensure optimal equipment performance and help minimize untimely and costly interruptions. STERIS Life Sciences 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 Life Sciences[2] for details.

[2] *(800) 444-9009 or www.sterislifesciences.com*

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

NOTES

1. Unit is only to be operated by Trained and Certified Applicators who have successfully completed both STERIS Vaprox Training and Certification Course and LS60 Biodecontamination Unit Operator Course. Certification must be active and in force for all Applicators of Vaprox 59 Hydrogen Peroxide Sterilant.
2. Biodecontamination Unit is NOT intended to process liquids, linens, powders or cellulose materials. Biodecontamination Unit is NOT intended to process reusable devices for human use.
3. Refer to equipment drawing (10066139) showing all utility and space requirements for actual installation specifications. Clearances shown are minimum required for servicing equipment. Floor surface must be hard and level.
4. Biodecontamination Unit should not be installed in an area not compatible with oxidizers. Consult the SDS regarding hydrogen peroxide sterilant.
5. STERIS recommends maintaining and operating Biodecontamination Unit in area where temperature does not exceed 86°F (30°C) and has ventilation system exchanging area air at least 10 times per hour.
6. STERIS recommends a dedicated, grounded electrical circuit be provided for each Biodecontamination Unit. Use of an extension cord is not recommended.
7. Consult Vaprox 59 Hydrogen Peroxide Sterilant SDS, label and package insert for information regarding storage and handling of Cups.
8. Approximate unit weight – 120 Vac units: 255 lb (116 kg); 230 Vac units: 259 lb (117 kg).
9. Approximate cart weight – 255 lb (116 kg).
10. Heat loss at 70°F (21°C) – Peak=1,046 BTU/hr; Avg.=942 BTU/hr.
11. Electrical Consumption, per cycle=1.0 kW-hr average; out of cycle=0.4 kW-hr average.
12. STERIS assumes no responsibility for changes to the Biodecontamination Unit made necessary through failure to observe the supplied necessary specifications (e.g., incorrect facility power supply).

For Further Information, contact:

STERIS Life Sciences

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.STERISLifeSciences.com