STERIS
Life Sciences

VHP® MD140X BIODECONTAMINATION UNIT

APPLICATION

The VHP MD140X Biodecontamination Unit is designed for the application of Vaprox® 59 Hydrogen Peroxide Sterilant to properly prepared (cleaned, rinsed and dried) reusable metal and nonmetal instruments[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 instruments sensitive to heat and moisture.

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

[2] *When using VHP MD140X 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, instruments and reusable instruments 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 MD140X 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 MD140X Biodecontamination Unit performs three programmed Biodecontamination Cycles:

- **Lumen Cycle** (approximately 55 minutes to complete)
- **Non Lumen Cycle** (approximately 28 minutes to complete)
- **Flexible Cycle** (approximately 35 minutes to complete)

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

1. Rigid instruments, with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
2. Single, dual and triple channeled rigid instruments, with the following configurations:
   - Single channeled instruments with a stainless lumen that is ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 500 mm (19-11/16") in length
   - Dual channeled instruments with stainless lumens that are ≥ 0.77 mm (~1/32") ID and ≤ 527 mm (20-3/4") in length
   - Triple channeled instruments with stainless lumens that are either:
     - » ≥ 1.2 mm (~3/64") 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 20 lumens per load. Loads should not exceed this validated number of lumens. Validation studies conducted using validation load of two instrument trays and two pouches for a total weight of 19.65 lb (9.0 kg).*

(Typical only - some details may vary.)

This biodecontamination unit using the **Non Lumen Cycle** can biodecontaminate[4] non-lumened instruments (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 two instrument trays and two pouches for a total weight of 19.65 lb (9.0 kg).*

The Selections Checked Below Apply To This Equipment

ACCESSORIES
- ❑ Seismic Tie Down Kit
- ❑ Trays And Organizer Clips
- ❑ Tray Mats
- ❑ Pouches

MOUNTING
- ❑ Single Door, Cabinet
- ❑ Single Door, Recessed

Item _____
Location(s)_____
_____

This biodecontamination unit using the **Flexible Cycle** can biodecontaminate single or dual lumen flexible instruments in either of the two configurations:

1. Two flexible instruments with a light cord (if not integral to instrument) and mat with no additional load.[1] The flexible instruments may contain either:
   - » A single lumen with an inside diameter of ≥ 1 mm (~3/64") and a length of ≤ 1050 mm (41")
   - » Or two lumens with:
     - One lumen with an inside diameter of ≥ 1 mm (~3/64") and a length of ≤ 998 mm (39")
     - And the other lumen with an inside diameter of ≥ 1 mm (~3/64") and a length of ≤ 850 mm (33")
2. One flexible instrument with a light cord (if not integral to instrument) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps and scissors.[2] The flexible instrument may contain either:
   - » A single lumen with an inside diameter of ≥ 1 mm (~3/64") and a length of ≤ 1050 mm (41")
   - » Or two lumens with:
     - One lumen with an inside diameter of ≥ 1 mm (~3/64") and a length of ≤ 998 mm (39")
     - And the other lumen with an inside diameter of ≥ 1 mm (~3/64") and a length of ≤ 850 mm (33")

[1] *The validation studies were conducted with two flexible instruments, each packaged into a tray with silicone mat and light cord (if not integral to instrument).*

[2] *The validation studies were conducted with a flexible instrument in a tray with silicone mat and light cord (if not integral to instrument). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lb (11 kg).*

The VHP MD140X Biodecontamination Unit also features:

- Unit operates on 208/230 Vac, three-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.
- 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 MD140X Biodecontamination Unit meets the applicable requirements of the following standards:

- **Underwriters Laboratories (UL) Standard UL 61010-1 Second Edition** as certified by INTERTEK Testing Services
- **Canadian Standards Association (CSA): Standard C22.2 No. 61010-1 Second Edition**
- **Pollution Degree: 2**
- **Installation Catagory (OverVoltage Protection): II**

SIZE (W X H X L)

Overall Dimensions:

- 33 x 75-1/8 x 38-5/16" (838 x 1908 x 973 mm)

Chamber Size:

- 17 x 15 x 32-1/2" (432 x 381 x 826 mm)

Chamber Volume:

- 4.8 cubic feet (136 L)

CONSTRUCTION

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

Insulation fitted on chamber wall exterior, door and backhead is 1" (25 mm) thick (nominal), held in place with hook-and-loop closures and is constructed of asbestos-free spin-glass, sealed in an oil and water resistant outer jacket.

Automatic door locking mechanism keeps door locked during entire Biodecontamination Cycle. After cycle completion, air pressure is used to unlock door. This door cannot be opened if either electrical power or air pressure is lost during unit operation. When unit is in Standby mode, there are no door opening restrictions.

Chamber heating is achieved through electric strip heaters attached to 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. System control automatically tracks amount of sterilant used and sterilant expiration date. Control prompts user via control display when new cup is needed.

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

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 and stainless steel.

Unit Frame and support system is constructed of welded carbon steel with protective paint.

High Power Vacuum Pump is supplied to produce cycle vacuum pulses that remove air and moisture from chamber. Direct drive rotary vane pump is quiet (<60 dB) with low vibration. Powerful 3 HP (2.2 kW) motor produces a displacement of 53 CFM (90 m^3/hr) and helps alleviate moisture sensitivity in biodecontamination unit. Biodecontamination unit operating pressure is from atmospheric pressure down to less than 1 Torr.

CONTROL DESCRIPTION

The VHP MD140X Biodecontamination Unit is equipped with an Allen-Bradley Compact Logix™ (PanelView Plus™ 6 1000 Display[1]) control. PLC features a 10.4" color TFT display with touch screen.

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 Unit permits no manual control of the Biodecontamination Cycles.

[1] *CompactLogix™ and PanelView™ Plus 6 1000 are trademarks of Allen-Bradley, a Rockwell Automation Company.*

CYCLE DESCRIPTION

The VHP MD140X Biodecontamination Unit is equipped with three programmed Biodecontamination Cycles: Lumen Cycle (55 minutes), Non Lumen Cycle (28 minutes) and Flexible Cycle (35 minutes). Each Biodecontamination Cycle proceeds through three phases: CONDITION, BIODECONTAMINATION and AERATION.

Basic description of a Biodecontamination Cycle (example):

- **CONDITION** — This cycle phase is a set time 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 repeated.

  NOTE: If Condition phase fails the second 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.

NOTE: Automatic door locking mechanism keeps chamber locked during entire Biodecontamination Cycle.

STERILITY 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 Process Indicator – Chemical indicator designed for use with hydrogen peroxide vapor.

Steraffirm® PCC050 Process Indicator – Chemical indicator designed for use with hydrogen peroxide vapor.

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

ACCESSORIES

Seismic Tie Down Kit – Required for seismic installations for safe operation of Biodecontamination Unit.

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

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

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 MD140X 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 instruments for human use.
3. Refer to equipment drawing 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 MSDS regarding hydrogen peroxide sterilant.
5. STERIS recommends maintaining and operating Biodecontamination Unit in area where temperature ranges from 41-104°F (5-40°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 MSDS, label and package insert for information regarding storage and handling of Cups.
8. Unit weight – 850 lb (386 kg) recessed and 1020 lb (463 kg) free-standing.
9. Heat loss at 70°F (21°C) – Peak=1,046 BTU/hr; Avg.=942 BTU/hr.
10. Electrical Consumption, per cycle=2.2 kW-hr average; out of cycle=0.7 kW-hr average.

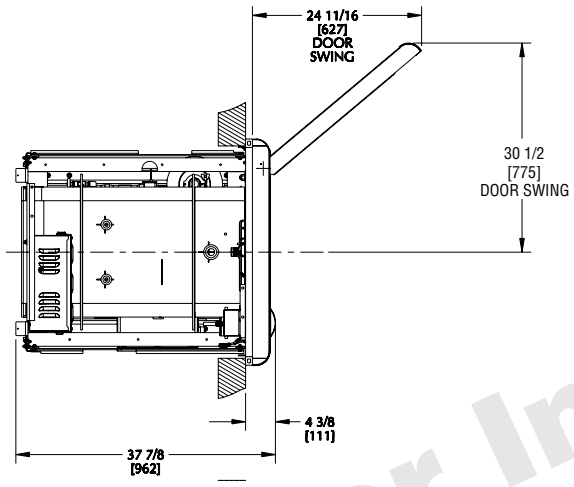

Vis-U-All
Low Temperature* Tyvek
Sterilization Tubing
872041
POUCH SIZE 4" x 100' (10.2 cm x 3048 cm)
*Not intended for Steam Sterilization


ETO CAP MB-156

EQUIPMENT DRAWINGS (REQUIRED FOR INSTALLATION)

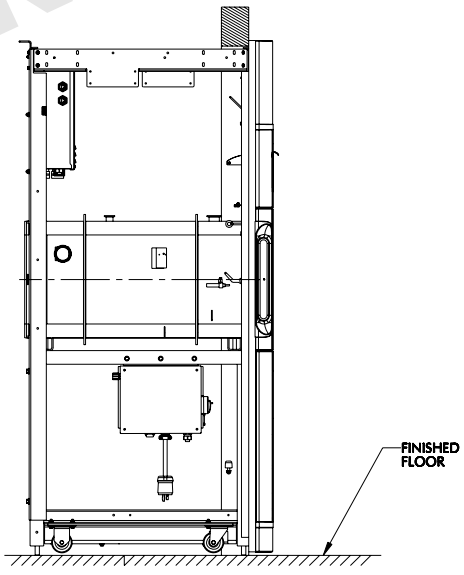
Equipment Drawing Part Number	Equipment Drawing Title
387358-924	Single Door, Recessed
387358-923	Single Door, Cabinet

Dimensions are typical.
Drawing is not to scale.

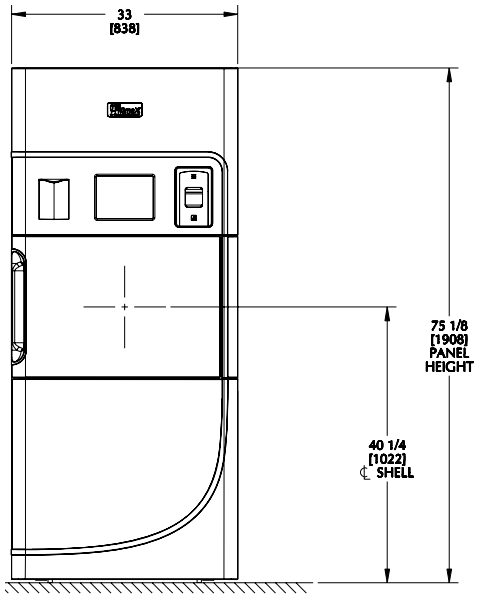


PLAN VIEW

Dimensions are in inches [mm]



SIDE VIEW



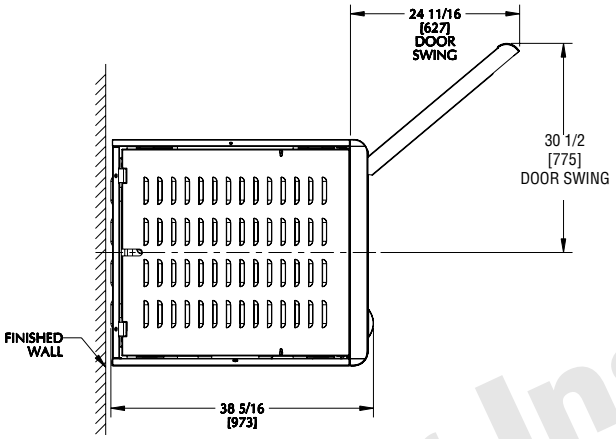
FRONT VIEW

SINGLE DOOR, RECESSED MODEL SHOWN

EQUIPMENT DRAWINGS (REQUIRED FOR INSTALLATION)

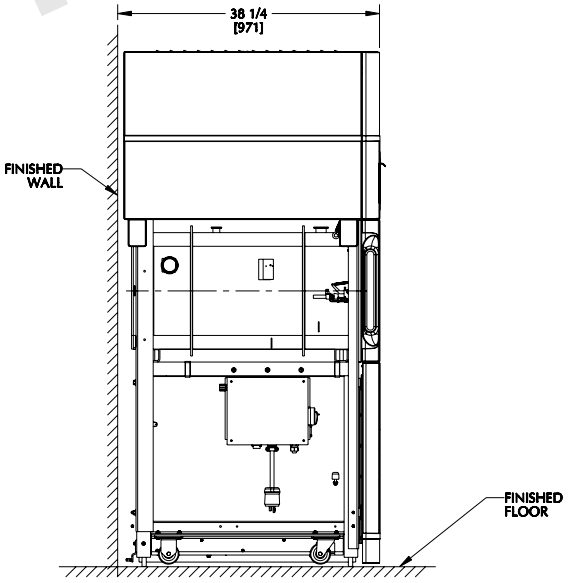
Equipment Drawing Part Number	Equipment Drawing Title
387358-924	Single Door, Recessed
387358-923	Single Door, Cabinet

Dimensions are typical. Drawing is not to scale.

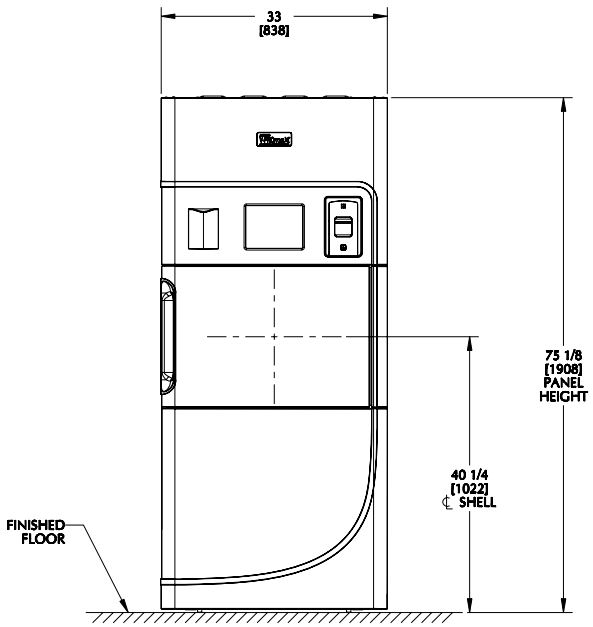


PLAN VIEW

Dimensions are in inches [mm]



SIDE VIEW



FRONT VIEW

SINGLE DOOR, CABINET MODEL SHOWN

For Further Information, contact:

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