STERIS®

AMSCO® V-PRO® MAX LOW TEMPERATURE STERILIZATION SYSTEM (For Use Outside U.S.A. Only)

APPLICATION

The Amsco V-PRO maX Low Temperature Sterilization System is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) reusable metal and nonmetal medical devices used in Healthcare Facilities. The STERIS developed low pressure and low temperature Sterilization Cycles are suitable for sterilizing medical devices sensitive to heat and moisture.

The Amsco V-PRO maX Low Temperature Sterilization System performs three pre-programmed Sterilization Cycles: the **Lumen Cycle** (approximately 55 minutes to complete), the **Non Lumen Cycle** (approximately 28 minutes to complete) and the **Flexible Cycle** (approximately 35 minutes to complete).

This sterilization system using the **Lumen Cycle** can sterilize* the following:

1. Lumened and non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
2. Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:[1]
   - Single channeled devices with a stainless lumen that is ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 500 mm (19-11/16") in length
   - Dual channeled devices with stainless lumens that are ≥ 0.77 mm (~1/32") ID and ≤ 527 mm (20-3/4") in length
   - Triple channeled 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
     - » ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

[1] *Validation testing for all channel/lumen sizes was conducted using a maximum of 20 lumens per load. Hospital loads should not exceed this validated number of lumens. Validation studies were performed using a validation load consisting of two instrument trays and two pouches for a total weight of 8.91 kg (19.65 lb).*

This sterilization system using the **Non Lumen Cycle** can sterilize[2] non-lumened instruments including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with stainless-steel diffusion-restricted areas such as the hinged portion of forceps or scissors.

[2] *Validation studies conducted using validation load of two instrument trays and two pouches for a total weight of 8.91 kg (19.65 lb).*

(Typical - details may vary.)

This sterilization system using the **Flexible Cycle** can sterilize single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of two configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.[3] The flexible endoscopes 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")

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

The Selections Checked Below Apply To This Equipment

UNIT POWER SUPPLY

- ❑ North America: 200-208/230 Vac, 3 phase, 50/60 Hz, 16 Amp
- ❑ Europe/Asia: 400 Vac, 3 phase, 50 Hz, 10 Amp
- ❑ Japan: 200 Vac, 3 phase, 50/60 Hz, 16 Amp

LABELS AND MANUALS

- ❑ French
- ❑ Italian
- ❑ German
- ❑ Spanish
- ❑ Finnish
- ❑ Russian
- ❑ Polish
- ❑ Japanese
- ❑ Danish
- ❑ Portuguese
- ❑ Hungarian

MOUNTING

- ❑ Single Door, Cabinet
- ❑ Single Door, Recessed
- ❑ Double Door, Cabinet

Item _____

Location(s)_____

_____

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps and scissors.[4] The flexible endoscope 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")

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

DESCRIPTION

The Amsco V-PRO maX Low Temperature Sterilization System is specifically designed to only process goods using vaporized hydrogen peroxide under vacuum conditions. The process is fully automated, is compatible with a broad range of materials and has rapid Sterilization Cycle times. There are no toxic by-products created by the Sterilization Cycle – only water vapor and oxygen are produced.

The Amsco V-PRO maX Low Temperature Sterilization System is NOT intended to process liquids, linens, powders or cellulose materials.

The system utilizes specially designed, disposable, multi-use Cartridges (available separately) containing VAPROX® HC Sterilant and is available in either a single door (freestanding or recessed) or double door configuration.

Articles to be sterilized are placed on a racking system within the aluminum chamber. An automated control enables the cycle to be started and monitored by the operator. The touch screen is user friendly and easy to operate.

System installation requires no plumbing, ventilation or air supply – only a dedicated electrical connection is needed. A power cord is supplied for this connection.

STANDARDS

This Amsco V-PRO maX Low Temperature Sterilization System 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

Governing Directive for the affixing of the CE mark:

- Medical Device Directive (MDD) 2007/47/EC

Standards applied to demonstrate conformity to the directives:

- EN 61010-1
- EN 60601-1-2
- EN 14937
- IEC 61010-2-040

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

SIZE (W X H X L)

Overall Dimensions:

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

Chamber Size:

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

Chamber Volume:

- 136 L (4.8 cubic feet)

FEATURES

The chamber and door assembly are aluminum equipped with a silicone rubber gasket for each door and a welded backhead on single door units.

Insulation fitted on the chamber wall exterior, door and backhead is 25 mm (1") thick (nominal). Insulation is held in place with hook-and-loop closures.

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

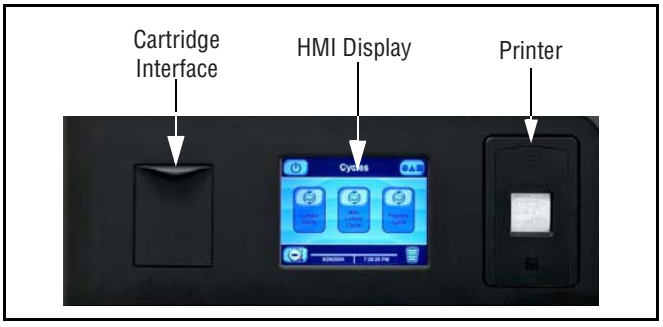
Automatic door locking mechanism keeps the sterilization system door locked during the entire Sterilization Cycle. After cycle completion, air pressure is used to unlock the door. The sterilizer door cannot be opened if either electrical power or air pressure is lost during sterilizer operation. When sterilization system 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 50°C (122°F)

Sterilant cartridge interface only accepts VAPROX HC Sterilant Cartridges (Cups). The system control automatically tracks the amount of VAPROX HC Sterilant used and the Sterilant expiration date. The control prompts the user on the control display when a new Cup is needed.

The proprietary Cartridge 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:

- **Resistive Thermal 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.
- **Pneumatic and Solenoid Valves and Switches** are used in the sterilization system design to simplify piping and increase serviceability.
- **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.
- **Sterilization System Panels** are constructed of plastic and stainless steel.
- **Sterilization System 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 the chamber. The direct drive rotary vane pump is quiet (<60 dB) with low vibration. A powerful 2.2 kW (3 HP) motor produces a displacement of 90 m^3/hr (53 CFM) and helps alleviate moisture sensitivity in the sterilization unit. The Sterilizer operating pressure is from atmospheric pressure down to less than 1 Torr.

Typical Operator Screens

CONTROL DESCRIPTION

The Amsco V-PRO maX Low Temperature Sterilization System is equipped with an Allen-Bradley Compact Logix™ (Panel View Plus™ 6 1000 Display[1]) control system and an impact printer.

- **Control Display Panel** is located on the front of the sterilization 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, 10.4" 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
    - » Sterilize Phase - Blue
    - » Aeration Phase - Violet
  - » Service Screens - Light Blue
  - » Option Screens - Purple
  - » Alarm Screens - Red

  NOTE: This Sterilization System permits no manual control of the Sterilization 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 (see Typical Operator Screens). For normal operation, each bar represents approximately four cycles remaining (e.g., four bars means cup contains enough sterilant for 13-16 cycles).
- **Printer** is located on the front of the sterilization unit on the right side while facing the unit. This alphanumeric impact printer provides an easy to read permanent record of the Sterilization Cycle. Printer provides a 5.7 cm (2-1/4"), 24-character wide cycle tape and paper take-up.

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

CYCLE DESCRIPTION

The Amsco V-PRO maX Low Temperature Sterilization System is equipped with three pre-programmed Sterilization Cycles: Lumen Cycle (approximately 55 minutes to complete), Non Lumen Cycle (approximately 28 minutes to complete) and Flexible Cycle (approximately 35 minutes to complete). Each Sterilization Cycle proceeds through three phases: CONDITION, STERILIZE and AERATION.

- **CONDITION** – *Lumen Cycle:* 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 repeats.
  Non Lumen Cycle: This cycle phase is a vacuum pulse to remove air and moisture from the chamber. When set point is reached, load is tested for acceptable moisture content. If content is acceptable, cycle proceeds. If not, Condition pulse as identified for Lumen Cycle is initiated.
  Flexible Cycle: This cycle phase is a vacuum pulse to remove air and moisture from the chamber. When set point is reached, load is tested for acceptable moisture content. If content is acceptable, cycle proceeds. If not, Condition pulse as identified for Lumen Cycle is initiated.

  NOTE: If Condition phase fails the second moisture check, the cycle Aborts.
- **STERILIZE** – This cycle phase is a series of four pulses. Each pulse consists of: vacuum pulled to setpoint; VAPROX HC 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.

PREVENTIVE MAINTENANCE

Customers are encouraged to contact STERIS 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 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.

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

NOTES

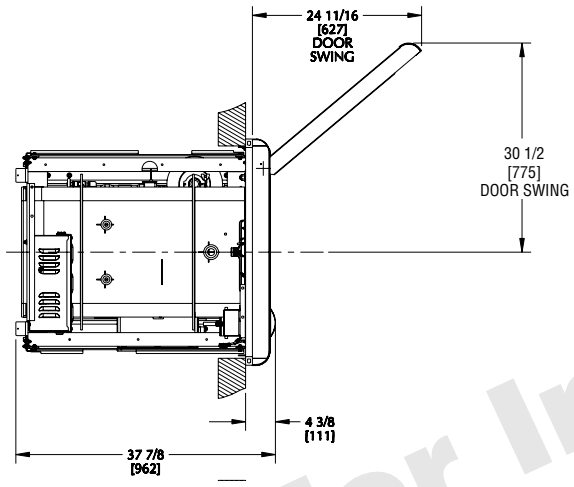
1. For general installation information, refer to STERIS General Notes for Sterilizers (drawing 062941-091). This drawing should always accompany the equipment drawing.
2. Refer to equipment drawing showing all utility and space requirements for actual installation specifications. Clearances shown are minimum required for servicing equipment. Floor surface must be hard and level.
3. STERIS recommends maintaining and operating sterilization system in area where temperature does not exceed 40°C (104°F) and has ventilation system exchanging area air at least 10 times per hour.
4. STERIS recommends a dedicated, grounded electrical circuit be provided for each unit. Use of an extension cord is not recommended.
5. Consult MSDS regarding storage and handling of VAPROX HC Sterilant Cartridges (Cups).
6. Unit weight: Single Door – 386 kg (850 lb) recessed and 463 kg (1020 lb) free-standing; Double Door – 562 kg (1240 lb) recessed one wall.
7. Heat loss at 21°C (70°F) – Peak=1,046 BTU/hr; Avg.=942 BTU/hr.
8. Electrical Consumption, per cycle=2.2 kW-hr average; out of cycle=0.7 kW-hr average.
9. STERIS assumes no responsibility for changes to the Sterilization Unit made necessary through failure to observe the supplied necessary specifications (e.g., incorrect facility power supply). Specifications are subject to change without notice.


VAPROX™ HC
Sterilant
STERIS
Cycles

EQUIPMENT DRAWINGS (REQUIRED FOR INSTALLATION)

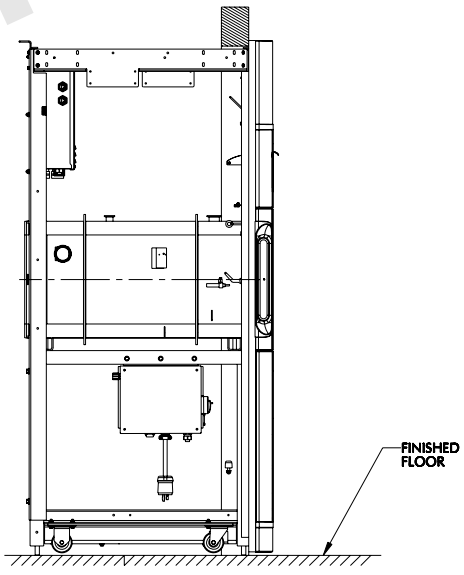
Equipment Drawing Part Number	Equipment Drawing Title
129385-449	Single Door, Recessed
129385-450	Single Door, Cabinet
129385-451	Double Door, Cabinet

Dimensions are typical.
Drawing is not to scale.

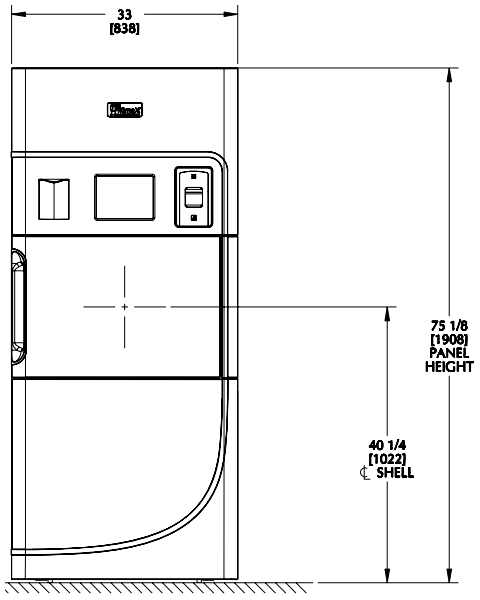


PLAN VIEW

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
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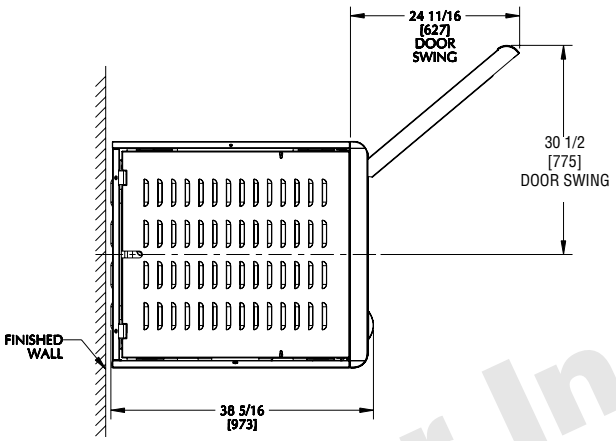

PLAN VIEW

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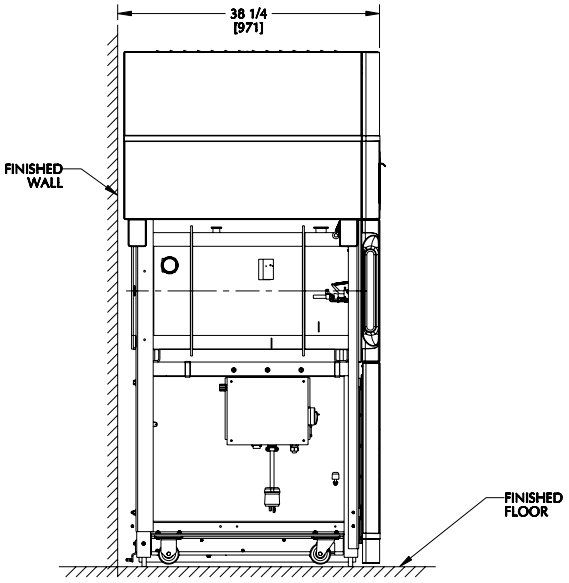
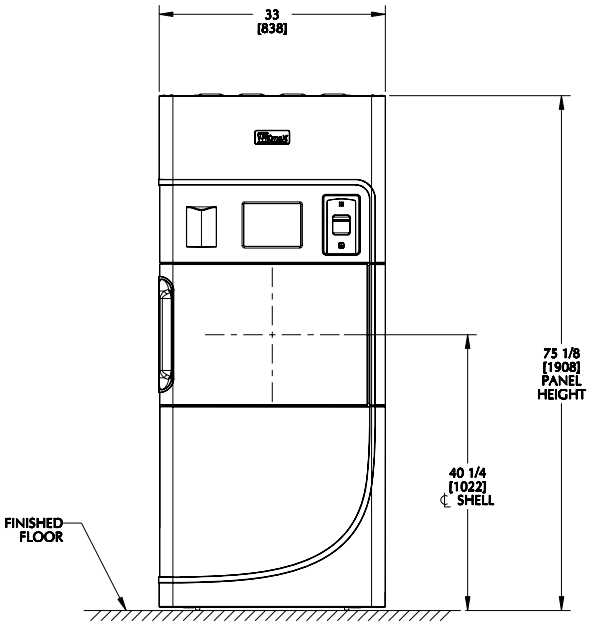


SIDE VIEW



FRONT VIEW

SINGLE DOOR, CABINET MODEL SHOWN

For Further Information, contact:

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