STERIS®

V-PRO® 60 LOW TEMPERATURE STERILIZATION SYSTEM

APPLICATION

The V-PRO 60 Low Temperature Sterilization System with VAPROX® HC Sterilant is a vaporized hydrogen peroxide Sterilizer intended for use in the terminal Sterilization of properly cleaned, rinsed and dried reusable metal and nonmetal medical devices used in Healthcare Facilities. The pre-programmed Sterilization Cycles (**Lumen Cycle, Non Lumen Cycle** and **Flexible Cycle**) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

The V-PRO 60 Sterilizer's **Lumen Cycle** can sterilize*:

1. Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
2. Non-Lumened devices including non-lumened rigid and semi-rigid endoscopes.
3. Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:[1]
   - 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

* *Validation studies for all lumen configurations were conducted using a maximum of 12 lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and two pouches for a total weight of 11 lb (5.0 kg).*

The V-PRO 60 Low Sterilizer's **Non Lumen Cycle** can sterilize†:

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless-steel or titanium diffusion-restricted spaces such as the hinged portion of forceps or scissors.

† *The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lb (5.4 kg).*

The V-PRO 60 Low Sterilizer's **Flexible Cycle** can sterilize‡:

- One flexible surgical endoscope or bronchoscope with a light cord (if not integral to scope) and mat without any additional load.‡ The flexible endoscope may be a single or dual lumen device with Lumens that are of ≥ 1 mm (~3/64") ID and ≤ 990 mm (38-63/64") in length.

‡ *The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.*

(Typical only - some details may vary.)

NOTE: Single-Use, medical grade polyethylene (PE) and Teflon®** tubing†† with internal diameter ≥ 1 mm and length ≤ 4 m may be sterilized in the Flexible Cycle. Up to 26 pieces of tubing with no additional load may be sterilized.

** *Teflon is a registered trademark of E. I. duPont de Nemours and Company.*

†† *Tubing claims have not been reviewed by the US FDA.*

DESCRIPTION

The V-PRO 60 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 V-PRO 60 Low Temperature Sterilization System is NOT intended to process liquids, linens, powders or cellulose materials.

The system utilizes specially designed, disposable, multi-use cups (available separately) containing VAPROX HC Sterilant and is available with single door in either a counter or cart mounted configuration.

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

OPTIONS

- ❑ Single Door, Counter Mounted
- ❑ Single Door, Cart Mounted
- ❑ IQ/OQ/PQ Protocol (10088229)
- ❑ Seismic Tie-Down Kit (10084158)*

* *Conforms to the California Code of Regulations.*

Item _____

Location(s)_____

_____

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 V-PRO 60 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 61326-1:2006, 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 L X H)

Overall Sterilizer 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)

FEATURES

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

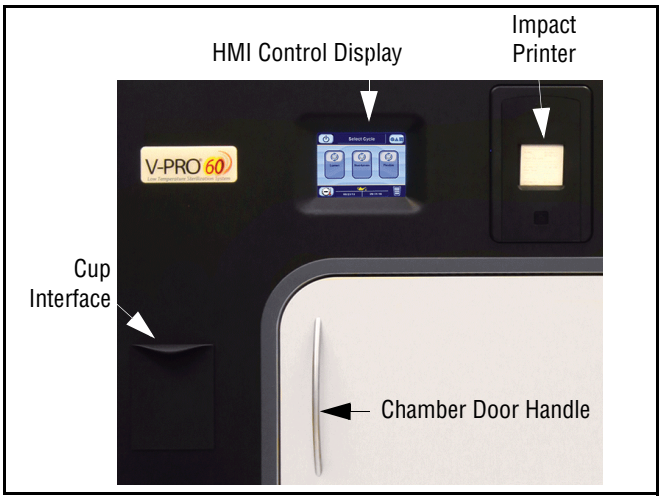
Insulation fitted on the chamber wall exterior, door and backhead is 1/2" (13 mm) thick (nominal). Insulation is held in place with adhesive.

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

Automatic door locking mechanism keeps the sterilization system door locked during the entire Sterilization Cycle. After cycle completion, the door is electrically unlocked. The sterilizer door cannot be opened if electrical power 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 122°F (50°C).

Sterilant cup interface only accepts VAPROX HC Sterilant 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 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.

There are two Cup options available:

- Ground Shipped (good for approximately 20 Cycles)
- Air Shipped (good for approximately five Cycles)

Once Cup is punctured by the Sterilization System, it has a 14-day “in Unit” shelf life. After use, empty Cups may be disposed in regular waste.

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 sterilization system design to simplify piping and increase serviceability.
- **Chamber Air Supply and Vacuum Filters** are supplied to ensure air entering chamber is High Efficiency Particulate Air (HEPA) filtered (prevent chamber recontamination) and air exhausted from vacuum pump is free of entrapped oil and odor.
- **High Power Vacuum Pump** produces cycle vacuum pulses that remove air and moisture from chamber. The direct drive rotary vane pump is quiet (56 dB) with low vibration. A powerful 1.0 HP (0.75 kW) motor produces a displacement of 21 CFM (35 m^3/hr) and helps alleviate moisture sensitivity in the sterilization unit. The Sterilizer operating pressure is from atmospheric pressure down to less than 1 Torr.

- **Sterilization System Panels** are constructed of plastic.
- **Sterilization System Frame** and support system is constructed of welded carbon steel with protective paint.

CONTROL DESCRIPTION

The V-PRO 60 Low Temperature Sterilization System is equipped with a proprietary 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, 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, Sterilize Phase - Blue and 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. For normal operation (with VAPROX HC 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 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 2-1/4" (5.7 mm), 24-character wide cycle tape and paper take-up.

CYCLE DESCRIPTION

The V-PRO 60 Low Temperature Sterilization System is equipped with three pre-programmed Sterilization Cycles: Lumen Cycle (approximately 60 minutes to complete), Non Lumen Cycle (approximately 28 minutes to complete) and Flexible Cycle (approximately 38 minutes to complete). Each Sterilization Cycle proceeds through three phases: CONDITION, STERILIZE and AERATION.

- **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.
- **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.

Some of the V-PRO 60 Low Temperature Sterilization System preventive maintenance is usage-based. Vacuum pump preventive maintenance is due every 750 cycles or six months. An oil can (yellow) appears on the screen when it is almost due for maintenance. Can changes to red when maintenance is required.

NOTES

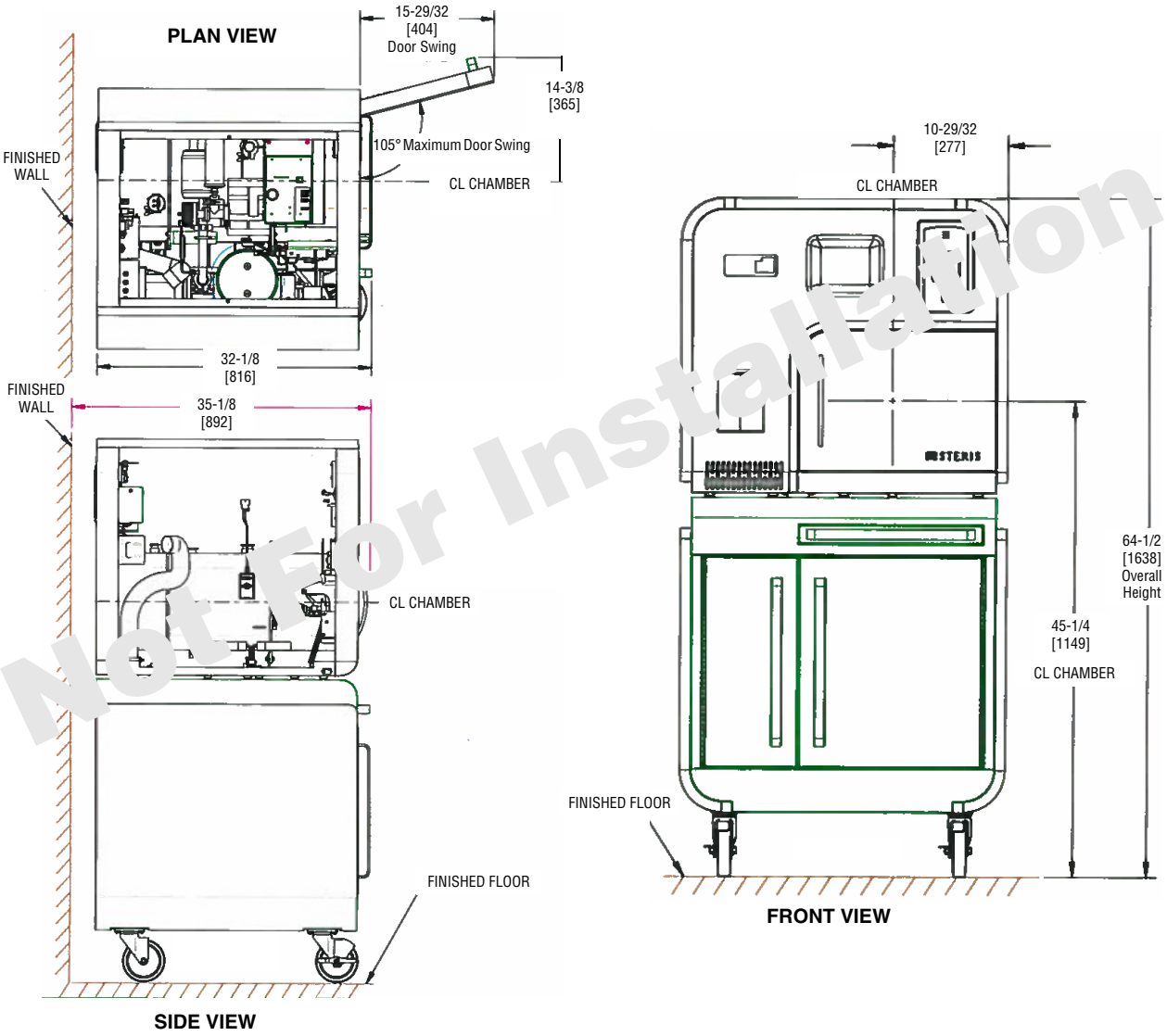
1. For general installation information, refer to STERIS General Notes for Sterilizers (drawing 062941-091). This drawing should always accompany the equipment drawing.
2. Refer to equipment drawing showing all utility and space requirements for actual installation specifications. Clearances shown are 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 86°F (30°C). Per AAMI ST58:2013, it is also recommended to have a 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 SDS regarding storage and handling of VAPROX HC Sterilant Cups.
6. Approximate unit weight – 120 Vac units: 255 lb (116 kg); 230 Vac units: 259 lb (117 kg).
7. Approximate cart weight – 255 lb (116 kg).
8. Heat loss at 70°F (21°C) – Peak = 271.10 BTU/hr; Avg. = 95.83 BTU/hr.
9. Electrical Consumption, per cycle = 1.0 kW-hr average; out of cycle = 0.4 kW-hr average.
10. STERIS assumes no responsibility for changes to the Sterilizer made necessary through failure to observe the supplied necessary specifications (e.g., incorrect facility power supply).

EQUIPMENT DRAWINGS (REQUIRED FOR INSTALLATION)

Equipment Drawing Part Number	Equipment Drawing Title
129603-007	V-PRO 60 LOW TEMPERATURE STERILIZATION SYSTEM

Dimensions are typical. Drawing is not to scale.

Dimensions are in inches [mm]



SINGLE DOOR, CART MOUNTED SHOWN

For Further Information, contact:

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