# **MEPNN Supplier Scouting Opportunity Synopsis**

Section 1: General I	nformation
Scouting Number Item to be Scouted	2024-256 Steam Sterilizer
Days to be scouted	20
Response Due By	09/18/2024
Description	I. DESCRIPTION: The U.S. Environmental Protection Agency, Research Triangle Park (RTP) Animal Resources Program Office (ARPO) has a requirement for a replacement sterilizer in the RTP vivarium A580 decontamination room. The A580 sterilizer supports the on-going research performed in the Building A animal laboratories. The current sterilizer is a Steris Amsco Eagle 3000SL, double door, through-wall Steam Sterilizer (A580/A580A). The replacement sterilizer shall fit into the existing footprint, wall opening and bioseal space with no additional construction required for tear out or installation. The replacement sterilizer shall have approximately the same throughput capability as the existing sterilizer. The unit will be used to sterilize dirty cages, dirty bedding, and associated waste from studies using primarily BSL2 pathogens.
	II. Salient Characteristics: The contractor shall provide one (1) sterilizer/autoclave with the following characteristics:  • Shall be able to fit into existing wall opening and bioseal space without any new construction. Current bioseal measures 42X76 inches, the current bioseal frame measures 44X77 inches.  • Shall be currently available in the marketplace for the government to buy.  • Shall fit in existing sterilizer footprint and still be able to receive preventative maintenance and servicing.  • Double door, through wall construction with either vertical (preferred) or hinged left hand opening.  Shall have capability to sterilize both solids and liquids.  • Capable of operation utilizing building supplied steam. Building pressure set point is 70 psi, but pressure at unit is decreased due to distance from source.  • Capable of operation utilizing building supplied potable water.  • Autoclave should include a backflow prevention device.  • Sterilizer shall use electric power  • Have an insulated sterilization chamber of sufficient size to sterilize mouse caging (19"L x 10-1/2"W x 6"D) and rat caging (19"L x 10"W x 8 1/2"D).  • Certified and stamped as meeting Underwriters Laboratories Standard 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements  • Certified and stamped as meeting ASME Boiler and Pressure Code Section VIII Division 1.  • Shall be provided with preprogrammed cycles meeting sterilization requirements for infectious waste as required State of North Carolina regulations including a gravimetric, prevacuum, and liquid sterilization cycle.  • Control system permits storage of at least 5 preprogrammed cycles.  • Controls provide the option of requiring an access code or other identification method to operate the sterilizarior or change cycle parameters.  • Controls shall be located so as not to expose the sensitive components to steam and heat.  • Controls shall be capable of providing a printed record of all pertinent cycl

	chamber and save the product in case of power outage. o Chamber door seal interlock and alarm - prevent cycle starting until the door is sealed and aborts the cycle and safely exhausts the chamber if door seal is lost during the cycle. Interlock should also prevent the door from being opened until chamber is vented to a safe pressure. o Excessive condensate/vessel flooding – alarm and interlock to abort the cycle and vent the chamber safely if excessive condensate is sensed within the chamber. o Pressure relief valve – prevent chamber pressure greater than rated pressure. o Under Temperature Alarm - informs the operator that the temperature has dropped the sterilization temperature. o Over Temperature Alarm - informs the operator that the chamber temperature has gone above a set point. o Waste line alarm - informs the operator that drain line temperature is outside the normal range. o Pressure/temperature alarm – informs the operator that chamber pressure or temperature readings are outside the normal steam range during sterilize phase.
Notify Requester Immediately	
State item to be used in	North Carolina

Section 2: Technical Information		
Type of supplier being sought Reason	Manufacturer BABA	
Describe the manufacturing processes (elaborate to provide as much detail as possible)	Electronic / Mechanical Assembly	

Provide dimensions / size / tolerances / performance specifications for the item	See attached AMSCO Small LS Series CSI Spec 8-16-24 and Technical Brochure SD1026_6-20 8-16-24, both attached, for specifics.
	Basic information pulled from CSI Spec 8-16-24 includes the following, but is incomplete:
	Construction Shell Assembly: Two Type 316L stainless steel shells, welded one within the other, to form the sterilizer vessel. End Frame(s): Type 316L stainless steel, welded to door end. Single door chamber back: Type 316L stainless steel formed head, welded to back of chamber. Vessel: ASME rated at 50 psig (3.2 bars). [(16"x16" and 20" x 20" unit only) 1" NPT welded chamber bushing included on the 250LS only. Baffle: Shield steam-supply opening inside chamber by a Type 316L stainless steel baffle Passivated internal chamber and door surfaces to maximize corrosion protection. Chamber Door: Type 316L stainless steel; formed from single sheet; insulated. Door Seal: Steam activated; construct from long-life rubber compound. Compressed air back up to door seals provided on double door units. Manual door operation; cable-supported, counterweight mechanism. Insulation: One inch (25 mm) thick, fiberglass insulation sleeve is sealed and held in place with Velcro closures. Insulation is asbestos-free with a silicone impregnated, oil- and water-resistant cover. Steam Piping: Constructed of brass; includes steam strainer, shutoff valve, and brass pressure regulator. Pipe, valve, and trap sterilizer to receive [building-] [electric steam generator-] [pure steam generator-] supplied steam Piping: All piping and electrical connections to terminate within the confines of the sterilizer.  a. Solenoid Valves: Located in manifold with DIN Connectors. Pneumatic valves are provided for units with Stainless Piping.  b. Manual Shutoff Valves: Pressure rated at 125 psig (862 kPa) for saturated steam. Valve handles to be low-heat conducting. Support sterilizer on height-adjustable carbon steel stand, shop-coated for corrosion protection Exterior Enclosure: Stainless steel side panels and louvered stainless steel top panel to enclose sterilizer body and piping.
List required materials needed to make the product, including materials of product components	See Salient Characteristics. Most of this is listed above.
Are there applicable certification requirements?	Yes
Certification(s) required	UL
Details	Certified and stamped as meeting Underwriters Laboratories Standard 61010- 1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use - Part 1: General Requirements
Are there applicable regulations?	Yes
Details	Shall be provided with preprogrammed cycles meeting sterilization requirements for infectious waste as required State of North Carolina regulations including a gravimetric, prevacuum, and liquid sterilization cycle. Required to meet BSL2 standards.
Are there any other stndards, requirements, etc.?	Yes
Details	Certified and stamped as meeting ASME Boiler and Pressure Code Section VIII Division 1.
NAICS 1	541715 Research and Development in the Physical, Engineering, and Life Sciences
NAICS 2	

Additional Technical Comments	Please see salient characteristics. This thing needs to fit into our space without interrupting active use of the facility. No construction. It has to fit through the doors to get to where it's going. We can't tear walls out to accommodate it. This is a replacement item for an actively functional site.
	Also of note: This item is needed now. We have lentivirus vectors in use in the vivarium as we speak. We have found work arounds to keep staff safe, but having a functioning starilizer would make this a much more viable project.

	having a functioning sterilizer would make this a much more viable project.	
Section 4: Business Information		
Estimated potential business volume	1 sterilizer.  We need 1 sterilizer to replace the existing unit that is 20+ years old and quite dead. This one unit will also hopefully last at least 10 years.	
Estimated target price / unit cost information (if unavailable explain)	\$98,835.70	
When is it needed by?	We have a current need right now, but can live with receiving the sterilizer by Feb 15, 2025	
Describe packaging requirements	Leave safe packaging of this equipment to the vendor. It will be heavy, and they are generally shipped in crates. The vendor will know best how to do this. The crate(s) will need to be shipped to the warehouse listed below.  Tractor trailers cannot fit into the loading dock of most other buildings on the EPA RTP campus, though box trucks can fit.	
Where will this item be shipped?	US EPA Shipping and Receiving Warehouse Durham, NC 27703	

# **Additional Comments** Department of Commerce Point of Contact information for questions including Is there other information you would like to include? BABA/Buy American compliance: Pamela Gillikin U.S. Environmental Protection Agency Office of Research and Development (ORD) Gillikin.Pamela@epa.gov Please copy scouting@nist.gov on all correspondence 1. There are other sterilizer manufacturers. Consolidated Sterilizer Systems came on site but required we tear up a wall. Getinge (https://www.getinge.com), Steelco (https://www.steelcogroup.com), Tuttnauer (https://tuttnauerusa.com) all make sterilizers. The big issue is the requirement that the equipment fit within the exitisting sterilizer bioseal and require no further construction. Components are generally a mixed bag, made all over the world and not necessarily viable for the Made in America Act requirements and how EPA chooses to implement them. Good luck. 2. I have absolutely no idea what an appropriate NAICS code would be, and your form doesn't let me leave it blank. This sterilizer is for a vivarium. A research lab or hospital that works with pathogens might have similar requirements, so that's the best I can offer. I would not recommend actually using those NAICS codes for much of anything, since they do not fit the application.

# SECTION 11622

# AMSCO 250LS SMALL STEAM STERILIZERS

## PART 1 – GENERAL

# 1.1 SECTION INCLUDES

- A. [Pre-Vacuum] [Isothermal] steam sterilizer(s).
- B. Optional features for sterilizer(s).
- C. Accessories for sterilizer(s).

# 1.2 RELATED SECTIONS

- A. Section [15100] [ ] Plumbing: Domestic water, sanitary waste and vent piping.
- B. Section [15800] [15810] [ ] Heating, Ventilating, and Air Conditioning Equipment: Ducts.
- C. Section [16100] [16200] [ ] Electrical: Power, wiring, and devices.

# 1.3 REFERENCES

- A. Standards
  - a. Canadian Standard Association (CSA), CAN/CSA-C22.2 No. 61010-1, Second Edition. CSA C22.2 No 61010-2-040 (ed 1)
  - b. Underwriters Laboratory (UL), UL 61010-1, Third Edition
- B. Governing Directives for Affixing the CE Mark
  - a. Low Voltage Directive (2014/35/EU)
  - b. EMC Directive (2014/30/EU)
  - c. Machinery Directive (2006/42/EEC)
- C. Standards Applied to Demonstrate Conformity to the Directives
  - a. EN/IEC 61010-1: Third Edition
  - b. IEC 61010-2-040: 2005 (ed.1)
  - c. IEC 61326-1: 2012
  - d. FCC CFR47 Part 15 Subpart B: 2/2016

## 1.4 SYSTEM DESCRIPTION

A. Sterilizers using steam-under-pressure as the sterilizing agent; designed for sterilization of certain materials used in laboratories and research facilities.

# B. Configuration(s):

[1. Pre-vacuum: Designed for efficient, high-volume sterilization of porous, heat- and moisture-stable materials at 100°C to 141°C (212°F to 285°F). Prevacuum cycle utilizes a mechanical air evacuation system. Includes Gravity, Liquid, Waste Bag, Continuous Program (requires power door), USP 660 Cycle, ATF cycles, leak test, DART and Bowie-Dick test cycles]

# 1.5 SUBMITTALS

- A. Follow Section [01300] [01330] [ ].
- B. Product Data: Describe unit construction, size and finish.
- C. Shop Drawings: Show entire assembly, materials, components, dimensions and gauges. Show wiring and piping diagrams and electrical, plumbing and exhaust ductwork service requirements including rough-in dimensions.
- D. Informational Submittals:
  - 1. Field Service Report.
  - 2. Demonstration and Instruction Statement from Owner.
  - 3. Operation and Maintenance Data: Include parts manual, control diagram, wiring diagrams and procedures for maintenance.

# 1.6 DELIVERY, STORAGE, AND HANDLING

- A. Schedule delivery of laboratory equipment only after wet operations in building are completed.
- B. Provide receiving, distribution, and storage areas of sufficient size and capacity to accommodate crated equipment.
- C. Store laboratory equipment in a ventilated place, protected from the weather, with relative humidity therein of 50% or less at 70 degrees F.
- D. Protect finished surfaces from soiling and damage during handling and installation. Keep covered with polyethylene film or other protective covering.

# 1.7 SEQUENCING

A. Painting and Other Finishing Trades. At no time shall tradesmen use the installed equipment as a workbench, scaffolding, or other uses. Protect installed laboratory equipment from debris, paint and damage during the construction sequence.

# 2.1 MANUFACTURERS

A. STERIS Corporation.

# 2.2 STERILIZER - GENERAL

- A. Features: Provide sterilizer(s) with the following manufacturer's standard features.
  - 1. Non-proprietary Allen Bradley PLC control System: To monitor and control all sterilizer operations and functions.
  - 2. Vertical Sliding Door; Manual, non-lubricated, steam activated door seal. Compressed air backup to door seals provided on double door units.
  - 3. Modularized Vessel and Piping
  - 4. Hinged Front Cabinet Panel: To access sterilizer piping and control board housing
  - 5. Software Calibration: For all temperature and pressure inputs.
  - 6. Optimal Solution Cooling: To safely cool various liquids in vented, borosilicate glass containers with minimum liquid loss due to boil-over, and to keep normal evaporation loss below 5 percent
  - 7. Steam Bleed: Constant steam flow supplied across chamber RTD to assure even temperature distribution and temperature control.
  - 8. Steam Purge: To assist in air removal and to preheat load
  - 9. One-piece Insulation Sleeve: Fitted around exterior of sterilizer vessel. Insulation sleeve consists of 1" thick spin glass temperature rated for 500°F continuous and is covered by an asbestos-free, silicone impregnated, oil and water-resistant outer jacket. Outer jacket rated for 500°F.
  - 10. Lighted DIN Connectors
  - 11. Control Lockout Switch: Limit switch on chamber door to prevent cycle from starting unless door seal is tight against the door.
  - 12. Chamber Float Switch: To activate alarm, abort cycle, and safely vent chamber with a controlled exhaust if excessive condensate is detected in vessel chamber
  - 13. Door Interlocks (Double Door units only): To allow only one door to be opened at a time, and to prevent non-operating end door from being opened until a satisfactory cycle is complete.
  - 14. Pressure Relief Valve: To limit the amount of pressure buildup so that the rated pressure in the vessel is not exceeded
  - 15. Chamber Drain System: To prevent pollutants from entering the water supply system and sterilizer
  - 16. Vacuum System Water ejector to reduce chamber pressure during the conditioning phase and exhaust /post-drying phase. Air to be drawn from the chamber through the vacuum system following the post-conditioning phase, chamber vacuum to be relieved to atmospheric pressure by admitting air through 0.2 micron filter.
  - 17. Electronic water saving control includes a condenser RTD to control the amount of water used in condensing the exhausted chamber steam. Water temperature is set to monitor and reduce drain effluent to < 60°C / 140°F.
  - 18. Connectivity
    - i. Ethernet Port
      - 1. Exporting Cycle Usage, Cycle and Calibration Data, Steam or
      - 2. Remote Monitoring or

- 3. Alarms/alerts sent via e-mail or text messages
- ii. Ethernet Port for Customer provided SCADA Interface
- iii. RS-232 Port for exporting continuous cycle data
- iv. All printer data is saved internally and can be retrieved and viewed on the display screen, exported to a USB drive or emailed to the User.
- 19. Automatic utilities startup/shutdown permits slow cooling of the entire vessel and load. Shutdown may be programmed to activate at the end of any designated cycle or time of day.
- 20. Programmable Green Mode that turns the chamber jacket off after user define idle time
- 21. Thermal Printer for easy to read printed record of cycle data.
- 22. Standard visible pressure gauges for chamber pressure and jacket pressure on both operating and non-operating ends (if double door)
- 23. The control system is provided with features such as audit trail, password management and electronic signatures to facilitate compliance to 21 CFR Part 11 (Code of Federal Regulations Title 21) regulations.
- B. Optional Features: Provide sterilizer(s) with the following manufacturer's optional features.
  - 1. Cabinet Package: 201SS easily removable Stainless Steel panels.
  - 2. Bio-seal (20x20x38" [508 x 508 x 965 mm] double manual door units only) is a 1/4" steel plate which is welded to the chamber and a 1/4" thick silicone gasket that extends between the plate and a carbon steel wall frame which is welded to wall imbeds (by others). No caulking / sealant are used. The bioseal is provided on the non-operating end of the sterilizer, prevents passage of airborne microorganisms from the space between the vessel body and the structural wall opening. All sterilizers with bioseals have air back-up to maintain seal pressure when out of cycle or if the steam source is not available. Compressed air required.
  - 3. Printer on both ends double door units

# C. Construction

- 1. Shell Assembly: Two Type 316L stainless steel shells, welded one within the other, to form the sterilizer vessel.
  - a. End Frame(s): Type 316L stainless steel, welded to door end.
  - b. Single door chamber back: Type 316L stainless steel formed head, welded to back of chamber.
- c. Vessel: ASME rated at 50 psig (3.2 bars). [(16"x16" and 20" x 20" unit only) 1" NPT welded chamber bushing included on the 250LS only.
- Baffle: Shield steam-supply opening inside chamber by a Type 316L stainless steel baffle
- e. Passivated internal chamber and door surfaces to maximize corrosion protection.
- 2. Chamber Door: Type 316L stainless steel; formed from single sheet; insulated.
  - a. Door Seal: Steam activated; construct from long-life rubber compound. Compressed air back up to door seals provided on double door units.
  - b. Manual door operation; cable-supported, counterweight mechanism.

- 3. Insulation: One inch (25 mm) thick, fiberglass insulation sleeve is sealed and held in place with Velcro closures. Insulation is asbestos-free with a silicone impregnated, oil- and water-resistant cover.
- 4. Steam Piping: Constructed of brass; includes steam strainer, shutoff valve, and brass pressure regulator.
- 5. Pipe, valve, and trap sterilizer to receive [building-] [electric steam generator-] [pure steam generator-] supplied steam
- 6. Piping: All piping and electrical connections to terminate within the confines of the sterilizer.
  - a. Solenoid Valves: Located in manifold with DIN Connectors. Pneumatic valves are provided for units with Stainless Piping.
  - b. Manual Shutoff Valves: Pressure rated at 125 psig (862 kPa) for saturated steam. Valve handles to be low-heat conducting.
- 7. Support sterilizer on height-adjustable carbon steel stand, shop-coated for corrosion protection
- 8. Exterior Enclosure: Stainless steel side panels and louvered stainless steel top panel to enclose sterilizer body and piping.

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Repeat the following paragraphs and edit as required for each variation in mounting method, doors, and chamber sizes.

[2. AMSCO 250LS has a 20 x 20 x 38 Chamber Nominal Size:

29-1/2" (747 mm) front panel swing, from face of unit. 27" (686 mm) right side service, from unit centerline.

32" (813 mm) left side service, from unit centerline.

Installation Height: 42-3/4" (1086 mm) H, to centerline of chamber.

[Loading Area: Twice sterilizer length, if loading car & carriage used.]

[Recessed unit: 3-1/8" (79 mm) front of unit to barrier wall.]
[Recessed unit: 20" (508 mm) adjacent wall, from unit centerline.

[Recessed unit: 4" to 8" (102 –203 mm) wall thickness.]

[Recessed unit: 28-1/8" W x 74-1/4" H (714 x 1886 mm) wall opening.]

[Recessed, single door: 9-1/4" D (235 mm) rear service clearance.]

# E. Utility Requirements:

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Repeat the following paragraphs and edit as required for each variation in steam supply method.

- [1. Sterilizer using "House" steam:
  - a. Steam: 1/2" NPT; 30-80 psig (at least 50psig for cycles with

temperatures higher than 125°C) (344.7-551.6 kPa)

dynamic; 97-100 percent vapor quality.

b. Drain: 1-1/2" ODT drain terminal. (Floor drain capacity must

handle peak water consumption.)

c. Electrical - Controls: 120 V, 50/60 Hz, 1-phase, 2.0 A.

d. Feed Water: 1" NPT; 30-50 psig (206.8-344.7 kPa) dynamic; 70°F

(21°C) max.; 171 mg/L max. total hardness (CaCO<sub>3</sub>); 500 mg/L max. total dissolved solids; 180 mg/L max. total alkalinity (CaCO<sub>3</sub>); 6.5-8.5 pH; 2.5 mg/L max. total

silica.]

# 2.3 CONTROL SYSTEM

Allen-Bradley MicroLogix™ Control System\* Programmable Logic Control (PLC) system that monitors and controls all phases of each sterilizing cycle.

- a. Control can be programmed for 20 cycles from three types of cycles (Prevac, gravity, and liquid).
- b. Adjustable cycle values and operating features.
- c. House control system within a sealed compartment to protect components from moisture and heat generated during the sterilization process. Provide cooling fans with filter in the housing compartment to maintain positive pressure within the compartment, keeping components cool and dust-free.
- 2. Operator Interface Control Panel: PanelView Plus™ 7 700 interface screen.\*
  - d. Touch-sensitive screen with 18-bit color graphic display
  - e. Display features 640 x 480 resolution color-active matrix
  - f. Display is designed with emphasis on human factors and user recognizable symbols.
- 3. Thermal Printer: Located on control Panel to provide printed records of all cycle
- 4. Non-operating End Control Panel (double-door units only): To include touch-sensitive screen (to show same messages as operating-end display).
- 5. Alarm tones The end of cycle and alarm tones have adjustable volumes ranging from off, low, medium and high. The alarm tone does not have the selection for off. Touching the display buttons will create an audible beep.
  - \*Allen-Bradley MicroLogixTM and Allen-Bradley PanelView PlusTM are registered trademarks of Rockwell Automation, Inc.
- B. Standard and optional Cycle Descriptions: Each sterilizer factory-programmed with the following cycles:
  - 1. **Gravity Cycle**: Provided on all sterilizers for the sterilization of heat- and moisturestable goods at 212-285°F (100-141°C), and decontamination of bagged laboratory wastes. Gravity cycle utilizes the gravity air-displacement principle.
  - 2. **Liquid Cycle**: Provided on all sterilizers for the sterilization of liquids and media in vented borosilicate glass or metal containers at 212-285°F (100-141°C). Liquid cycle utilizes the optimal solution cooling feature, during exhaust (cooling) phase, to control the exhaust rate.
  - 3. **Prevacuum Cycle**: provided on all sterilizers for efficient, sterilization of porous, heat and moisture stable materials at 212-285°F (100-141°C). Prevacuum cycle uses a mechanical air evacuation system (water ejector as standard, vacuum

- pump as an option).
- 6. **Waste Bags Cycle**: This cycle has been preconfigured with cycle parameters shown to be effective when processing lab waste in autoclavable bags. Through air removal assistance and a controlled exhaust, the internal temperature is increased more effectively and faster, while minimizing boil over of any liquids present. Parameters may need to be adjusted based on specific loads. Bags should not be completely sealed.
- 7. **Leak Test Cycle**: Provided only on prevacuum sterilizers for verification of door seal and piping system integrity. Cycle parameters are preprogrammed and fixed. The acceptable maximum leak rate is 1 mm Hg/min over a 10-minute period following a fixed stabilization time.
- 8. **Daily Air Removal Test (DART)**: Provided only on prevacuum sterilizers for verification of effective removal of residual air in the chamber and load during testing. Test cycle determines if even and rapid steam penetration into test load has occurred. Cycle parameters are preprogrammed and fixed.
- 9. **Effluent Decontamination Cycle (optional)** is used for the processing of contaminated biohazardous laboratory waste (BL-3 and BL-4). The condensate produced during the processing cycle is decontaminated before discharge to the floor drain. The steam is admitted through the bottom of the sterilizer chamber, and the chamber is exhausted out the top side of the vessel. During the purge and vacuum pulses, all purge and exhaust gases are vented through a 0.2 micron bacterial retentive filter. The filter housing is steam jacketed to prevent wetting of the filter membrane. Available with fast exhaust or optimal solution cooling (slow exhaust) exhaust cycles. User is responsible for development of process parameters.

2.3	STERIL	IZER T	YPE(S	6) AND SIZE	(S)
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Repeat the following paragraphs and edit as required for each variation in sterilization method, mounting, doors, and chamber sizes.

- [A. AMSCO 110LS [16" Prevacuum] [16" Isothermal] Scientific Small Sterilizer(s):
  - 1. [Single] [Double] door configuration.
  - 2. [Freestanding] [Recessed through one wall] [Recessed through two walls].
  - 3. Dimensions:
    - a. Nominal Chamber Load Capacity: 16" W x 16" H x 26" D (406 x 406 x 660 mm). 110 Liters
    - b. Overall:

[Single door, Freestanding: 26" W x 74-1/2" H x 35-3/4" D

(660 x 1892 x 908 mm).]

[Single door, Recessed through one wall: (660 x 1892 x 902 mm).]
[Double door, Recessed 26" W x 74-1/2" H x 35-1/2" D 26" W x 74-1/2" H x 34-1/2" D

through one wall: (660 x 1892 x 876 mm).]]

- [B. AMSCO 250LS [20" Prevacuum] Scientific Small Sterilizer(s):
  - 1. [Double] door configuration.
  - 2. [Recessed through one wall]
  - 3. Dimensions:
    - a. Nominal Chamber Load Capacity: 20" W x 20" H x 38" D (508 x 508 x 965 mm), 250 Liters
    - b. Overall:

[Double door, Recessed 30" W x 74-1/2" H x 42-5/8" D through one wall: (762 x 1892 x 1082 mm).]

# 2.4 ENGINEERING DATA

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Select and edit the following paragraphs as required for each variation in steam source, mounting, door configuration and chamber sizes.

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[F. 20 x 20 x 38 Chamber Size, Steam Heated, Double Door:

Shipping Weight: 1470 lbs (667 kg).
 Operating Weight: 1606 lbs (728 kg).
 Heat Loss: (at 70°F (21°C)

[recessed, one wall: 2500 BTU/hr (2638 kJ/h), front of wall. 5300 BTU/hr (5592 kJ/h), back of wall.] [recessed, two walls: 2500 BTU/hr (2638 kJ/h), at each end.

2800 BTU/hr (2954 kJ/h), between walls.]

4. Cold Water Consumption: 4.5 gpm (17 L/min) peak.

~55 gallons (208 L) per cycle.

10 gph (38 L/hr) idle.

5. Hot Water Consumption: N/A.

6. Steam Consumption: 180 lbs/hr (82 kg/hr) peak.

21 lbs/hr (10 kg/hr) per cycle.

7 lbs/hr (3 kg/hr) idle.]

Note: Cold water consumptions are based on Prevac cycle, 3 pulses, 30 min exposure, 5 minute dry

# 2.6 ACCESSORIES

- [A. Loading Rack and Two Shelves for 20x20x38" unit (standard on 16 x 16 x 26" units):
  - 1. Double-Door.
- B. Provide manufacturer's field services to supervise installation.

# 3.5 CLEANING

- A. Follow Section [01700] [01740] [ ].
- B. Prior to final acceptance, clean soiled surfaces and repair or replace items that become damaged.
- C. Remove packaging debris and other waste resulting from installation of equipment.

## 3.6 ADJUSTING

- A. Follow Section [01700] [01750] [ ].
- B. Adjust equipment and apparatus installed to ensure performance meets specified requirements.
- C. Adjust and re-test any units not meeting requirements.

# 3.7 PROTECTION

- A. Follow Section [01700] [01760] [ ].
- B. Protect materials and installed laboratory equipment from damage by work of other trades until final acceptance by the Architect or until beneficial occupancy by the Owner, whichever comes first.

## 3.8 DEMONSTRATION

- A. Follow Section [01800] [01820] [ ].
- B. Demonstrate operation, function and operator performed maintenance of equipment in presence of [Owner] [A/E].
- D. Provide instruction on operation and operator performed maintenance for each type of equipment to Owner's operating personnel.

## 3.9 WARRANTY

D. Warranty includes 1 year parts and labor, 15 years on chamber, and 2 years on door gasket

# **END OF SECTION**

# **Salient Characteristics**

for

# Replacement Sterilizer for RTP A 580 Decontamination Room July 15, 2024 (updated 8/16/24 for MEP)

- I. **DESCRIPTION:** The U.S. Environmental Protection Agency, Research Triangle Park (RTP) Animal Resources Program Office (ARPO) has a requirement for a replacement sterilizer in the RTP vivarium A580 decontamination room. The A580 sterilizer supports the on-going research performed in the Building A animal laboratories. The current sterilizer is a Steris Amsco Eagle 3000SL, double door, through-wall Steam Sterilizer (A580/A580A). The replacement sterilizer shall fit into the existing footprint, wall opening and bioseal space with no additional construction required for tear out or installation. The replacement sterilizer shall have approximately the same throughput capability as the existing sterilizer. The unit will be used to sterilize dirty cages, dirty bedding, and associated waste from studies using primarily BSL2 pathogens.
- II. Salient Characteristics: The contractor shall provide one (1) sterilizer/autoclave with the following characteristics:
  - Shall be able to fit into existing wall opening and bioseal space without any new construction. Current bioseal measures 42X76 inches, the current bioseal frame measures 44X77 inches.
  - Shall be currently available in the marketplace for the government to buy.
  - Shall fit in existing sterilizer footprint and still be able to receive preventative maintenance and servicing.
  - Double door, through wall construction with either vertical (preferred) or hinged left hand opening. Shall have capability to sterilize both solids and liquids.
  - Capable of operation utilizing building supplied steam. Building pressure set point is 70 psi, but pressure at unit is decreased due to distance from source.
  - Capable of operation utilizing building supplied potable water.
  - Autoclave should include a backflow prevention device.
  - Sterilizer shall use electric power
  - Have an insulated sterilization chamber of sufficient size to sterilize mouse caging (19"L x 10-1/2"W x 6"D) and rat caging (19"L x 10"W x 8 1/2"D).
  - Certified and stamped as meeting Underwriters Laboratories Standard 61010-1, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements
  - Certified and stamped as meeting ASME Boiler and Pressure Code Section VIII Division 1.
  - Shall be provided with preprogrammed cycles meeting sterilization requirements for infectious waste as required State of North Carolina regulations including a gravimetric, prevacuum, and liquid sterilization cycle.
  - Control system permits storage of at least 5 preprogrammed cycles.
  - Controls provide the option of requiring an access code or other identification method to operate the sterilizer or change cycle parameters.
  - Controls shall be located so as not to expose the sensitive components to steam and heat.
  - Controls shall be capable of providing a printed record of all pertinent cycle data including key transition points in the cycle and alarms and deviations that may jeopardize the sterilization process.
  - Pressure gauges displaying the chamber and jacket pressure accessible to the operator.
  - An operators manual.
  - The following safety features and alarms, if possible:
    - o Chamber Emergency Manual Exhaust Valve allows the operator to vent the chamber and save the product in case of power outage.
    - o Chamber door seal interlock and alarm prevent cycle starting until the door is sealed and aborts the cycle and safely exhausts the chamber if door seal is lost during the cycle. Interlock should also prevent the door from being opened until chamber is vented to a safe pressure.
    - Excessive condensate/vessel flooding alarm and interlock to abort the cycle and vent the chamber safely if excessive condensate is sensed within the chamber.

- o Pressure relief valve prevent chamber pressure greater than rated pressure.
- o Under Temperature Alarm informs the operator that the temperature has dropped the sterilization temperature.
- Over Temperature Alarm informs the operator that the chamber temperature has gone above a set point.
- o Waste line alarm informs the operator that drain line temperature is outside the normal range.
- o Pressure/temperature alarm informs the operator that chamber pressure or temperature readings are outside the normal steam range during sterilize phase.
- Quotes shall include:
  - Cost of disconnection of existing Steris Amsco Eagle 3000SL sterilizer.
  - o Discount, if any, provided for trade in of existing Steris Amsco Eagle 3000SL.
  - o Cost of removal of existing Steris Amsco Eagle 3000SL sterilizer remove and transport of equipment to a predetermined location within EPA facility for pickup or disposal.
  - Cost of delivery or specification that delivery is included in the sale price.
  - Cost of professional installation of sterilizer to include all necessary labor and materials required to uncrate, set in place and assemble equipment including all utility connections. Shall fit through existing access doorway of 40" clearance.
  - o Cost of any necessary operational check-out testing following set up including any necessary adjustments
  - Cost of demonstration/training of the equipment for facility personnel.
  - o 1 year of preventative maintenance (including all travel, parts, and labor)
  - 1 year minimum warranty

# III. EPA RESPONSIBILITIES:

EPA will provide:

• Opportunity to view and measure existing sterilizer and A 580 space

## IV. DELIVERABLES:

- One (1) sterilizer meeting the requirements listed in section II
- V. ACCEPTANCE CRITERIA: Providing all the requirements identified in Sections II and IV.
- VI. PERIOD OF PERFORMANCE: 10/02/2024 02/01/2025

VI. EPA POC: Jaimie Graff (Office: 919-541-0690, Cell: 984-484-0332), graff.jaimie@epa.gov

VII: Alternate Invoice Approver: Maria Hoopes (Office: 919-541-0030, Cell: 984-227-3753), hoopes.maria@epa.gov



# AMSCO® 110LS AND AMSCO® 250LS SMALL STERILIZERS – LIFE SCIENCES

## **APPLICATION**

AMSCO 110LS and AMSCO 250LS Small Sterilizers are designed for use in laboratory and industrial applications.

Each is configured with pre-vacuum, liquid, and gravity cycles. A full list of standard and optional cycles begins on page 2.

# **DESCRIPTION**

AMSCO 110LS and AMSCO 250LS Small Sterilizers for life science applications are the next advancement in the STERIS line of steam-jacketed sterilizers. Both sterilizers are equipped with the latest features in state of the art technology and ease of use.

# **Interior Chamber Nominal Dimensions and Capacity**

- AMSCO 110LS 16 x 16 x 26" (406 x 406 x 660 mm), 110L capacity
- AMSCO 250LS 20 x 20 x 38" (508 x 508 x 965 mm),
   250L capacity

Allen-Bradley MicroLogix<sup>™</sup> Control System with enhanced functionality and user-friendly Allen-Bradley PanelView Plus<sup>™</sup> 7 700 interface screen.\*

- Touch-sensitive screen with 18-bit color graphic display
- Display features 640 x 480 resolution color-active matrix



(Typical - details may vary.)

#### Selections Checked Below Apply To This Equipment **ACCESSORIES (for AMSCO 250LS)** MODEL ☐ Effluent Decontamination Cycle<sup>11</sup> One Intermediate Shelf □ Pure Steam Piping to Chamber<sup>11</sup> ☐ AMSCO 110LS ■ Seismic Tie-Down Kit<sup>7,9</sup> □ Air Detector System ☐ Prevacuum (LV-110) ☐ Isothermal (LI-110) ☐ Air Compressor, Portable, 115 Vac ☐ Printer on Both Ends<sup>8</sup> ■ Loading Rack and Two Shelves ☐ Bioseal 3,11 ☐ AMSCO 250LS □ Single Door Double Door □ RTD Load Probe(s) and F<sub>0</sub> Sterilization □ Prevacuum (LV-250) □ Isothermal (LI-250) Loading Car ☐ One Probe ☐ Two Probes (max. 2) □ Transfer Carriage ☐ Drain Line Reference Probe Chamber Track Assembly **STEAM SOURCE** ☐ Air-Differential Seal (NOE) for Double Door Units<sup>11</sup> □ Single Door □ Double Door ■ Building Steam ☐ Back Panel for Single Door Cabinet Enclosed Unit ☐ Loading Car, Transfer Carriage & Chamber Track ☐ Stand Alone Electric Steam Generator 1" Chamber Penetration, Qty. 1 Assembly □ STERIS Provided □ Customer Provided (AMSCO 110LS only)4 □ Single Door Double Door ☐ Integral Electric Steam Generator<sup>1</sup> One Additional Chamber Penetration ☐ Carbon Steel ☐ Stainless Steel (AMSCO 250LS)4 Notes: Voltage Options □ Vacuum Pump<sup>5</sup> □ 208 Volt, 60 Hz 1. AMSCO 110LS double door sterilizers are not □ 120 V, 1-Ph / 208 / 240 Vac, 3-Ph □ 240 Volt, 60 Hz available with integral electric steam generator. ■ 120 V, 1 Ph / 240 Vac 3-Ph 2. Available for AMSCO 250LS double door □ 400 Volt, 50 Hz □ 120 V, 1-Ph / 480 Vac, 3-Ph □ 480 Volt, 60 Hz sterilizers only. Contact engineering if mounting 120 V, 1-Ph / 600 Vac, 3-Ph through two walls is required for AMSCO 110LS. □ 600 Volt, 60 Hz 230 V, 1 Ph / 400 Vac, 3-Ph (International) 3. Available on AMSCO 250LS double manual door $lue{}$ Integral Indirect Stainless-Steel Clean Steam Other - Specify \_ sterilizers only. Generator (SD589)<sup>10</sup> □ Dry Contacts 4. One chamber penetration is standard on ■ Backflow Preventer AMSCO 250LS. □ SINGLE DOOR Auto Flush for Steam Generator 5. 1-Ph is for control, 3-Ph is for pump motor □ Cabinet Enclosed/Freestanding 0.2 Micron Bacterial Retentive Filter 6. Loading rack & 2 shelves standard on □ Recessed Green Gravity Water Saver System AMSCO 110LS. ☐ STERI-GREEN® Water Conservation System 7. Based on CA requirements. □ DOUBLE DOOR 8. Printer at operating end is standard. Option adds □ STERI-GREEN PLUS® Water Conservation System Recessed through One Wall additional printer to non-operating end. (Chilled water required) ☐ Sterile side ☐ Non-sterile side 9. Units with Bioseal require special seismic kit. □ Recessed through Two Walls<sup>2</sup> 10. Integral indirect clean steam generator requires field certification for UL/CSA **OPTIONS** ACCESSORIES (for AMSCO 110LS)6

One Intermediate Shelf

☐ Air Compressor, Portable, 115 Vac

□ Power Door(s)

☐ Liquid Air Cool (w/vacuum)

11. Compressed air is required for these options.

Item \_\_\_\_\_ Location(s)\_\_\_

<sup>\*</sup> Allen-Bradley MicroLogix<sup>TM</sup> and Allen-Bradley PanelView Plus<sup>TM</sup> are registered trademarks of Rockwell Automation, Inc.

- Display is designed with emphasis on human factors and user recognizable symbols.
- Noise level for units with water ejector 68Dba, units with vacuum pump 74Dba.

# **Cycle Programming and Flash Memory**

- 20 cycles may be individually selected and programmed
- Help screens for control operation
- Program permanently stored in flash memory
- · Variables permanently stored in flash memory

# **Vertical Sliding Door(s)**

AMSCO LS configurations include choice of single or double door sterilizers and open or recessed mounting. The doors are manually operated. Door seals (1 per door) are non-lubricated, steam activated.

NOTE: Recess two wall mounting is not available for AMSCO 110LS double door sterilizers.

# **Modularized Vessel And Piping**

Vessel and piping are designed for increased dependability and reduced service time.

- Reduced piping components increase reliability
- Vessel design allows higher operating temperature of 141°C (285°F)
- Non-clogging chamber drain line prevents media from plugging drain line
- Emergency manual exhaust valve

## **STANDARDS**

Each sterilizer meets applicable requirements of the following listings and standards, and carries the appropriate symbols.

- Governing Directives for Affixing the CE Mark:
- » Low-Voltage Directive (2014/35/EU)
- » EMC Directive (2014/30/EU)
- » Machinery Directive (2006/42/EEC)
- Pressure Equipment Directive (PED): 97/23/EC.
- **UL/EN/CSA 61010-1:** Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use

Part 1: General Requirements

- **UL/EN/CSA 61010-2-040:** Safety Requirements For Electrical Equipment For Measurement, Control, And Laboratory Use, Part 2-040: Particular Requirements For Sterilizers And Washer-Disinfectors Used To Treat Medical Materials
- ASME Code, Section VIII, Division 1 for unfired pressure vessels. The pressure vessel is so stamped; ASME Form U-1 is furnished. The shell and door are constructed to withstand a working pressure of 45 psig (3.1 bar).

# **CYCLE DESCRIPTIONS**

Standard and optional cycles are as follows:

**Gravity Cycle (standard)** provided on prevacuum, and isothermal sterilizers, for sterilization of heat- and moisture-stable goods at 100°C to 141°C (212°F to 285°F), and decontamination of bagged non bio-hazardous laboratory wastes. Gravity cycle utilizes gravity air-displacement principle. However, the gravity cycle has a standard drying phase which uses a vacuum. The drying phase can be disabled.

**Liquid Cycle (standard)** provided on prevacuum, and isothermal sterilizers, for sterilization of liquids and media in vented borosilicate glass or metal containers at 100°C to 141°C (212°F to 285°F). Liquid cycle uses optimal solution cooling feature, during exhaust (cooling) phase, to control exhaust rate.

**Prevacuum Cycle (standard)** provided only on prevacuum sterilizer, for efficient, high-volume sterilization of porous, heat-and moisture-stable materials at 100°C to 141°C (212°F to 285°F). Prevacuum cycle utilizes a mechanical air-evacuation system.

**USP 660 Cycle (standard)** developed to assist meeting the requirements of USP 660 sterilization test cycle for glassware. Load probe option is recommended when using this USP cycle.

**Continuous Cycle (standard)** This cycle allows for up to 9,999 cycles to be run consecutively without the need of an operator. Cycle parameters can be set, along with the amount of time to lapse in between cycles. For this cycle to function, a power door is required to facilitate automatic opening and closing.

Waste Bag Cycle (standard) This cycle has been preconfigured with cycle parameters shown to be effective when processing lab waste in autoclavable bags. Through air removal assistance and a controlled exhaust, the internal temperature is increased more effectively and faster, while minimizing boil over of any liquids present. Parameters may need to be adjusted based on specific loads. Bags should not be completely sealed.

**Isothermal Cycle (optional)** provided only on isothermal sterilizer, for processing of heat-sensitive and heat-coagulable solutions in vented borosilicate glass or metal containers at 78°C to 110°C (170°F to 230°F). Isothermal cycle utilizes steam to enhance temperature control and prevent layering of steam and air within the chamber. Process maintains positive pressure in chamber to inhibit media boiling.

NOTE: Temperature control spread is greater on Isothermal units  $\pm 6^{\circ}C$ .

**Liquid Air Cool (Optional)** provides water to jacket, and air pressure to chamber to improve exhaust time for liquid loads, and to reduce boil-over. Compressed air is required for this cycle.

**ATF 1 and ATF 2 Cycles (Alternating Tangential Flow)** are designed to sterilize the XCell™ ATF system. These can be used for other purposes that require rates and hold times in the pre-conditioning pulses and a cool down in exhaust by temperature.

Effluent Decontamination Cycle (Optional) is used for processing contaminated laboratory waste (BL-3 and BL-4). Condensate produced during processing cycle is decontaminated before discharge to floor drain. Steam is admitted through bottom of sterilizer chamber, and chamber is exhausted out top side of vessel. During purge and vacuum pulses, all purge and exhaust gases are vented through a 0.2 micron bacterial retentive filter. Filter housing is steam jacketed to prevent wetting of filter membrane. Available with fast exhaust or optimal solution cooling (slow exhaust) exhaust types. User is responsible for development of process parameters. Compressed air is required for this cycle.

**Leak Test Cycle,** for verification of door seal and piping system integrity. Cycle parameters are pre-programmed and fixed. Acceptable maximum leak rate is 1.0 mm Hg/minute over a 10-minute period following a fixed stabilization time.

**Daily Air Removal Test (Dart) Cycle,** provided only on prevacuum sterilizer, for verification of effective removal of residual air in chamber and load during testing. Test cycle determines if even and rapid steam penetration into test load occurred. Cycle parameters are preprogrammed and fixed.

**Bowie-Dick Test** is available for 121°C (250°F) and 132°C (270°F) prevacuum cycles.

**Healthcare Cycles** - The LS Series sterilizers can be programmed to reproduce cycles that are used for healthcare applications, however, these sterilizers do not have FDA clearance and cannot be used for patient treatment applications

## **ENVIRONMENTAL SUSTAINABILITY**

# **Automatic Utilities Startup/Shutdown**

This feature permits slow cooling of the entire vessel and load. Shutdown may be programmed to activate at the end of any designated cycle or time of day. When activated, control system automatically shuts off all utility valves, conserving steam and water usage. Sterilizer utilities can be restarted either by programmed time or manual operation. A different shutdown and restart time can be programmed for each day.

#### **Green Mode**

The Green Mode is a standard feature on the control that will shut off the steam to the jacket after the unit has sat idle for a specified period of time. The specific time frame is determined by the user and entered into the control during set up; it can be changed at any time.

# **Green Gravity Water Saver System**

The Green Gravity Water Saver System provides additional water savings by collecting steam effluent and holding it in a cooling tank, reducing the amount of water required to cool the effluent.

# STERI-GREEN® Water Conservation System

This system significantly reduces the consumption of potable water. The STERI-GREEN system utilizes a mixing tank and an air-cooled heat exchanger to cool and recycle vacuum pump water and steam effluent. Water temperature is constantly monitored to minimize the need to add fresh cool water to the mixing tank. The system can provide up to 79% water savings over the vacuum pump alone, or up to 87% over a water ejector. When ordered, system includes a vacuum pump (3-phase power required).

# STERI-GREEN PLUS® Water Conservation System

The STERI-GREEN PLUS system utilizes facility chilled water supply. The system utilizes a mixing tank and a series of heat exchangers, integrated with the a chilled water loop, to cool and recycle vacuum pump water and effluent. Water temperature is constantly monitored to minimize the need to add fresh cool water to the mixing tank. This system provides up to 99% water savings over water ejector or vacuum pump upgrade alone. When ordered, system includes a vacuum pump (3-phase power required).

# STANDARD FEATURES

**Hinged front cabinet panel** opens for convenient access to sterilizer piping and control system.

Resistance Temperature Detectors (RTDs) are installed for sterilizer temperature control. The chamber drain line RTD senses and controls temperature variations within the sterilizer chamber. A jacket RTD provides temperature control within the jacket space. These RTD signals, converted into electrical impulses, provide accurate control inputs and readouts throughout entire cycle.

**Software calibration** is provided for all temperature and pressure inputs. Calibration is performed in the service mode, accessible through the touch screen displays, and accomplished using external or internal temperature and pressure sources. Control system provides a printed record of all calibration data for verification to current readings.

**Cycle Data Records,** recorded on the printer tape. They can also be retrieved for on-screen review, through the USB port located on the front fascia panel, or sent via e-mail if the system is enabled. The e-mail feature requires a network connection.

**Optimal solution cooling** is designed to safely cool various liquids in vented, borosilicate glass containers with minimum liquid loss due to boil-over, and to keep normal evaporation loss below 5%. Optimal solution cooling is an integral part of the factory-programmed liquid cycle. During the exhaust (cooling) phase, the control utilizes this feature to optimize the exhaust rate regardless of load size or container fill volume, up to one liter. During cooling, the initial rate, initial rate transition point, as well as the second rate and final vacuum level are adjustable.

**Steam purge** feature is provided to assist in air removal and preheat the load.

**Automatic steam shutoff to jacket** is provided for isothermal and liquid cycles. When activated for isothermal cycles, the jacket control conducts a timed jacket drain, automatically allowing for the operation of cycles at lower temperatures. When activated for liquid cycles, steam supply to the jacket is turned off during exhaust phase, allowing load to cool more efficiently.

**Insulation,** one-inch thick, asbestos-free spin-glass (rated at 1000 °F [538 °C] continuous) encompasses the exterior of the sterilizer vessel and is sealed in an oil and water resistant outer jacket.

**Lighted DIN connectors** are installed on all steam, water, and exhaust valves for reliability and ease of maintenance.

**Air Backup** to seals is provided on all double door sterilizers, with either bioseal or air differential seals.

**Visible Gauges** are standard. Chamber and jacket pressure gauges are standard on the operating end and non-operating end.

# **CONTROL SYSTEM**

# **Design Features**

Together, the Allen-Bradley MicroLogix<sup>™</sup> PLC control and PanelView Plus<sup>™</sup> 7700 display, monitor and control all sterilizer operations and functions. Control system is factory-programmed with standard sterilizing cycles, each adjustable to meet specific processing requirements. All control configuring is performed through touch screen displays.

Cycle values and operating features may be adjusted and verified prior to cycle operation. Once cycle is started, cycles and cycle values cannot be changed until cycle is complete. On completion of cycle, timers reset to the previously selected values, eliminating the need to reset values between repeated

cycles. If chamber temperature drops below the under temperature setting during the exposure phase, timer can be set to stop and automatically reset or resume once normal operating temperature is reached.

Critical control system components are housed within a sealed compartment to protect components from moisture and heat generated during sterilization process.

The control system is provided with features such as audit trail, password management and electronic signatures, which can



Typical Cycle Menu Display

facilitate compliance to 21 CFR Part 11 (Code of Federal Regulations Title 21)

**Operator interface control panel,** consisting of touch screen and thermal printer, is located on operating (load or nonsterile) end of sterilizer. If the sterilizer is equipped with double doors, an additional touch screen is provided on the non-operating (unload or sterile) end.

- Touch-Sensitive Screen features a color active matrix 18-bit graphics display. All sterilizer functions, including cycle initiation and cycle configuration, are operated by pressing the touch-sensitive areas on the display, referred to as buttons. Display indicates appropriate control buttons, operator prompts and status messages necessary to assist in sterilizer operation. All displayed messages are complete phrases with no codes to be cross-referenced. Display also indicates any abnormal conditions that may exist either in or out of a cycle.
- Thermal printer is a high resolution (8 dots per mm) printer. It is fast and quiet, printing at 25 lines per minute on industrial grade thermal paper. The device provides an easy-to-read printed record of all pertinent cycle data on 2.25" (57 mm) wide paper. Data is automatically printed at the beginning and end of each cycle and at transition points during the cycle. Three paper tape rolls are furnished with each unit. Printouts have a guaranteed lifetime of 25 years and are resistant from exposure to steam, alcohol, UV and visible light, oil, heat and water.
- Non-operating end (NOE) control panel (equipped on double-door sterilizers only) includes a touch-sensitive screen similar to the operating end screen. Preprogrammed cycles can be started from the NOE control panel. Display concurrently shows the same information as the operating end screen display.
- Cycle configuration is performed by accessing the change values menu on either end of a double door sterilizer. Utility shutdown parameters can only be changed on the OE

display. In addition to adjustment of cycle values, the following operating parameters can also be changed through the change values menu:

- » Time Display and Printout Units in standard AM/PM or 24-hour military (MIL) time.
- » Selectable Cycle Name permits user to name each cycle with any combination of letters, numbers, blank spaces, and underscores, up to eight characters long.
- » Print Interval permits adjustment of the time period between cycle-status printouts generated during the sterilize phase.
- » Security access code is required to enter the operating mode (running cycles), supervisor mode (changing values), and service mode. Operating the sterilizer or accessing change values menu causes display to request the entry of an access code. If access code is not properly entered, display returns to the standby screen, denying user access to the sterilizer or programming. Access to the sterilizer can be limited to 12 operators, each with a different access code.
- » Alarm tones The end of cycle and alarm tones are adjustable from low, medium and high. The end of cycle tone can also be set off.
- » Temperature Display and Printout Units in Celsius (°C) or Fahrenheit (°F). Temperature is set, displayed, controlled, and printed to the nearest 0.1°. Recalibration is not required when changing temperature units from °C to °F and vice versa.
- » Pressure/Vacuum Display and Printout Units in psi/In/Hg, Bar (Gauge and Absolute). Recalibration is not required when changing pressure units.

# Mobile and PC Messaging (Standard)

This is a standard feature on the control that allows the user to receive text messages or emails alerts regarding the status of the autoclave. The operator can choose from a list of # possible alerts from which to be notified.

# SCADA Ready Control Interface (Standard)

If requested, STERIS can provide the user the information to allow communication between the autoclave and the Building Management System. An ethernet connection is required.

# **Printer Data Storage (Standard)**

All printer data is saved internally and can be retrieved and viewed on the display screen, exported to a USB drive (port located on the front fascia panel) or emailed to the User.

# Cycle usage (Standard)

Utilization of the sterilizer can be monitored for each User, data can be exported via an Ethernet or USB port located on the front fascia panel.

# **SAFETY FEATURES**

**Control lockout switch** (equipped on chamber door) senses when door seal is energized and tight against the door. Control prevents cycle from starting until the limit switch signal is received. If control loses appropriate signal during cycle, alarm activates, cycle aborts, and chamber safely vents with a controlled exhaust.

**Chamber float switch** activates alarm, aborts cycle, and safely vents chamber with a controlled exhaust if excessive condensate is detected in the vessel chamber.

**Door interlocks (double door units only)** allow only one door to be opened at a time and, during processing, prevent the non-operating end (NOE) door from being opened until a satisfactory cycle is complete. If a cycle is aborted, the NOE door cannot be opened. The use of this feature may affect the door gaskets life expectancy unless an air differential or bio seal is provided.

**Pressure relief valve** limits the amount of pressure buildup so that the rated pressure in the vessel is not exceeded.

**Emergency stop button** (located on front of the sterilizer) is included on all sterilizers. A key is required to release the emergency stop (once pushed) before the unit can return to normal operation.

# CONSTRUCTION

# **Shell Assembly**

Two fabricated Type 316L stainless-steel shells, welded one within the other, form the sterilizer vessel. Type 316L stainless-steel end frame(s) is welded to door end. On single door units, back of chamber is fitted with welded, 316L stainless-steel formed head.

Sterilizer vessel is ASME rated at 50 psig (3.2 Bar) and insulated. The Vessel (for AMSCO 250LS only) includes one 1.0" (25 mm) NPT welded chamber bushing for Customer use.

Steam-supply opening inside the chamber is shielded by a Type 316L stainless-steel baffle.

# **Chamber Door(s)**

Door is constructed of a single formed piece of Type 316L stainless steel. Door is insulated to reduce the surface temperature of the stainless-steel door cover.

During cycle operation, door is sealed by a **steam-activated door seal**. Door seal is constructed of a special long-life rubber compound. When sterilizer cycle is complete, the seal retracts under vacuum into a machined groove in sterilizer end frame. Door seal can be manually retracted to open the door and remove critical load in an emergency situation (if loss of vacuum or loss of power occurs).

A handle is used to manually open (by lowering) and manually close (by raising) the door which is suspended by cables attached to a counterweight.

A long-life proximity switch is used, by the control, to determine if the door is closed. An additional seal pressure switch prevents inadvertent cycle initiation if door is not sealed.

The door assembly is equipped with a mechanical locking mechanism that ensures the door cannot be opened, as long as the seal is intact and energized, and more than 2.0 psi pressure is in the chamber. Door interlocks on double door sterilizers can be programmed to prevent inadvertent opening of door(s). Access code is required to override door interlocks.

NOTE: Bio-Seal option is available for AMSCO 250LS, double manual door sterilizers, as discussed on page 5.

# **Chamber Drain System**

Drain system is designed to prevent pollutants from entering into the water-supply system and sterilizer. An optional backflow preventer is available. Water supply shutoff valve is located behind the front cabinet service panel under the chamber.

# **Automatic Drain Effluent Cooling**

The piping system to the drain provides automatic condensing of chamber steam and disposal of condensate to waste. Cooling water is added to ensure discharge temperature is discharged at or below 60°C (140°F). A separate resistance temperature detector (RTD) is included to limit the volume of water to only the amount required to achieve target temperature, thus conserving water.

# **Vacuum System**

Chamber pressure is reduced during the conditioning phase and drying phase through the means of either a standard water ejector or an optional vacuum pump upgrade. Subsequent to the drying phase, the chamber is returned to atmospheric pressure by admitting air through a bacteria-retentive filter.

#### **Steam Source**

Sterilizers are piped valved, and trapped to receive building-supplied steam delivered at 50 to 80 psig (344.7 to 551.6 kPa) dynamic. If building steam source is not available, an electric carbon-steel steam generator or electric stainless-steel steam generator may be provided to supply steam to the sterilizer. Steam piping is constructed of brass and includes a shutoff valve, steam strainer and a brass pressure regulator.

Optional stainless-steel indirect-type steam generator can be installed as a pure steam source. Pure steam reduces the probability of contamination which could adversely affect research, such as tissue culture and trace metals studies.

Steam feeds from the jacket to the chamber. A check valve is added between the jacket and chamber on sterilizers with decontamination cycle option.

# **Piping**

All piping connections terminate within the confines of the sterilizer and are accessible from the front and side of sterilizer.

- Solenoid Valves in manifold with DIN connectors simplify sterilizer piping and can be serviced individually.
- Manual Shutoff Valves are pressure rated at 125 psig (862 kPa) for saturated steam. Valve handles are low-heat conducting.

# **MOUNTING ARRANGEMENT**

Sterilizers are arranged for either freestanding or recessed installation, as specified. Each sterilizer is equipped with a height-adjustable, steel floor stand. Sterilizer subframe is equipped with a synthetic rubber gasket to ensure tight fit between the cabinet panels on freestanding units or between the front cabinet panel and wall partition on recessed units.

On freestanding units, stainless-steel side panels enclose the sterilizer body and piping.

Each AMSCO 110LS and AMSCO 250LS sterilizer has a lockable front service panel.

## **OPTIONS**

**Stainless-steel piping to chamber** delivers steam generated from Customer purified water source to the chamber and its contents. All steam-to-chamber piping components are constructed of 300 series stainless steel. Option is provided with Pressure Reducing Valve. Compressed air required for pneumatic valves.

**Integral indirect stainless-steel clean steam generator** automatically produces clean steam using Customer-supplied steam and purified water. Generator is integrally connected to the clean steam-to-chamber piping system.

**30 kW carbon-steel electric steam generator** typically fed by a potable water source with hardness not to exceed 171 mg/L. The generator is available for both single and double door sterilizers. The generator is mounted underneath both single and double door units. The generator option is not available for AMSCO 110LS double door units.

**30 kW electric stainless-steel steam generator** is electrically powered, automatically filled with water having 1 M $\Omega$ ·cm resistivity, and operates whenever the sterilizer power is on. Generator is integrally connected to the clean steam-to-chamber piping system. The generator option is not available for AMSCO 110LS double door units.

**Auto Flush for Steam Generator** provides automatic flush of steam generator upon startup of sterilizer. Not required for SS generators.

**RTD load probes and F\_0 sterilization** (maximum of 2) automatically sense the load temperature during cycle operation. A single thermal load probe is sealed through the sterilizer vessel and manually placed in the product container within the chamber prior to cycle operation.

In conjunction with the load probe option, individual cycles can be set to start exposure phase according to chamber drain temperature or according to load temperature. Also,  $F_{\rm 0}$  set points are available for each cycle, allowing for exposure phase termination based on the calculated  $F_{\rm 0}$  value.

Bioseal (for AMSCO 250LS double manual door units only) is a 1/4" steel plate which is welded to the chamber and a 1/4" thick silicone gasket that extends between the plate and a carbon steel wall frame which is welded to wall imbeds. The bioseal is provided on the non-operating end of the sterilizer, prevents passage of airborne microorganisms from the space between the vessel body and the structural wall opening. Steam is the primary source of pressure behind the door seal. All sterilizers with bioseals have air back-up to maintain seal pressure when out of cycle or if the steam source is not available.

**Air-differential seal (double door units only)**, provided on the non-operating end of the sterilizer, minimizes airflow between the dirty and clean sides of the barrier.

**Back cabinet panel** is provided on single door, freestanding units where the unit is accessible on all sides.

**Air detector** (integral factory piping option) is used to determine whether any air or non-condensible gas present in the chamber is sufficient to impair the sterilizing process.

**Backflow preventer** option can be installed on sterilizer piping to prevent the unwanted reverse flow of water or other substances into the potable water supply.

**Power door** provides automatic opening and closing by depressing a foot pedal. (Not available for sterilizers with Bio-Seal option).

**Vacuum Pump Upgrade**: Water ejector is replaced with a water ring vacuum pump.

**Drain line reference probe** automatically senses the drain line temperature during cycle operation. During the Sterilize phase, the chamber and reference probes are compared and if the difference is outside the allowable range, an alarm will occur. This option replaces the standard drain RTD probe with a dual element RTD probe, in the same sheathing.

**0.2 micron bacterial retentive filter** provides sterile air during airbreak at end of cycle.

**Additional chamber penetration:** One 1" NPT capped chamber penetration port is located at the side of the vessel so as not interfere with other piping. The port provides for up to twelve (12) owner provided thermocouple probes or other test instrumentation.

One port is provided as standard on AMSCO 250LS.

**Printer on both ends.** An additional printer is provided on the non-operating end of the sterilizer.

**Dry Contacts** provide four (4) relays to communicate the following equipment status: door open, door closed, alarm, and unit on.

## **ACCESSORIES**

**Air Compressor, Portable, 115 Vac.** This accessory is intended for pneumatic valves on sterilizers when an air utility is not provided by the facility. It may also be used for back-up pressure source for the door seal in bioseal applications.

This is a portable 1.5 Gallon compressor tank that delivers 48 LPM @ 689 KPa (1.7CFM @ 100 PSI). Refer to STERIS drawing no. 755718-038 for complete specifications.

NOTE: UL/CSA certified only.

**Seismic tie-down kit** conforms to current California Code of Regulations.

# 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 agreements.

# **NOTES**

- The sterilizer is not supplied with a vacuum breaker or backflow preventer and, where required by local codes, installation of such a device in water line is not provided by STERIS.
- Pipe sizes shown indicate terminal outlets only. Building service lines, not provided by STERIS, must supply the specified pressures and flow rates.
- Disconnect switches (with OFF position lockout only; not provided by STERIS) should be installed in electric supply lines near the equipment.
- Access to the recessing area from the control end of the sterilizer is recommended.
- Clearances shown are minimal for installing and servicing the equipment.
- If loading car and carriage are to be used with a AMSCO 250LS sterilizer, front clearance should equal twice the length of the sterilizer. This will permit complete withdrawal of the loading car from the chamber and allow convenient maneuverability of the transfer assembly to and from the sterilizer.
- Floor drain should be provided within confines of sterilizer framework.

# **UTILITY REQUIREMENTS**

Refer to Equipment Drawing for complete information.

# Sterilizer Using Facility Steam<sup>1</sup>

# Steam

1/2" NPT, 50 to 80 psig (344.7 to 551.6 kPa) dynamic, 97 to 100% vapor quality

#### Drain

1-1/2" ODT drain terminal. (Floor drain capacity must handle peak water consumption; refer to engineering data.)

# **Electrical - Controls**

120 Volt, 50/60 Hz, 1-phase, 3.0 Amp

# International:

230 Volt, 50/60 Hz, 1-Ph, 1.5 Amp

## Sterilizer Feed Water

1.0" NPT, 30 to 50 psig (206.8 to 344.7 kPa) dynamic. Water is used for ejectors, vacuum pumps, exhaust condensers, and trap cooling. Refer to **Table 1** for recommended water quality. Use of feed water within the nominal conditions will optimize equipment performance and reduce maintenance.

NOTE: Backflow prevention is not standard on the unit, but a backflow preventer option can be ordered.

# Sterilizer Equipped With Integral Carbon Steel Steam Generator

#### Drain

1-1/2" ODT drain terminal. (Floor drain capacity must handle peak water consumption; refer to engineering data.)

# **Generator Drain**

1/2" ODT

#### **Electrical - Controls**

120 Volt, 50/60 Hz, 1-phase, 9.5 Amp

## International:

230 Volt, 50/60 Hz, 1-Ph, 1.5 Amp

#### **Electrical - Generator**

208 Volt, 50/60 Hz, 3-phase

240 Volt, 50/60 Hz, 3-phase

480 Volt, 50/60 Hz, 3-phase

600 Volt, 60 Hz, 3-phase

# International:

380/415 Volt, 50/60 Hz, 3-Ph, (Prevacuum Units)

## Sterilizer Feed Water

1.0" NPT, 30 to 50 psig (206.8 to 344.7 kPa) dynamic. Refer to **Table 1** for water specification guidelines.

# **Steam Generator Feed Water**

1/2" NPT, 20 to 50 psig (137.9 to 344.7 kPa) dynamic. Refer to **Table 2** for required water quality. Use of feed water within the nominal conditions will optimize equipment performance and reduce maintenance.

NOTE: Backflow prevention is not standard on the unit, but a backflow preventer option can be ordered.

# Sterilizer Equipped With Integral Stainless-steel Steam Generator

## Sterilizer Feed Water

1.0" NPT, 30 to 50 psig (206.8 to 344.7 kPa) dynamic. Refer to **Table 1** for required water quality.

## **Steam Generator Feed Water**

1/2" NPT, 20 to 50 psig (137.9 to 344.7 kPa) Refer to **Table 3** for required water quality.

#### Drain

1-1/2" ODT generator drain terminal. (Floor drain capacity must handle peak water consumption; refer to engineering data).

## **Generator Drain**

1/2" ODT

## **Electrical - Controls**

120 Volt, 50/60 Hz, 1-phase, 9.5 Amp

## International:

230 Volt, 50/60 Hz, 1-Ph, 1.5 Amp

## **Electrical - Generator**

208 Volt, 50/60 Hz, 3-phase

240 Volt, 50/60 Hz, 3-phase

480 Volt, 50/60 Hz, 3-phase

600 Volt, 60 Hz, 3-phase

#### International:

380/415 Volt, 50/60 Hz, 3-Ph, (Prevacuum Units)

Refer to the Following Equipment Drawings for Installation Details		
Equipment Drawing Number	Equipment Drawing Title	
AMSCO 110LS		
387362-169	110LS, SINGLE DOOR, RECESSED, STEAM HEAT	
387362-170	110LS, SINGLE DOOR, CABINET, STEAM HEAT	
387362-171	110LS, SINGLE DOOR, RECESSED, ELECTRIC STEAM	
387362-172	110LS, SINGLE DOOR, CABINET, ELECTRIC STEAM	
387362-173	110LS, DOUBLE DOOR, RECESSED 1 WALL, STEAM HEAT	
AMSCO 250LS		
387362-159	250LS, SINGLE DOOR, RECESSED, STEAM HEAT	
387362-160	250LS, SINGLE DOOR, CABINET, STEAM HEAT	
387362-161	250LS, SINGLE DOOR, RECESSED, ELECTRIC STEAM	
387362-162	250LS SINGLE DOOR, CABINET, ELECTRIC STEAM	
387362-163	250LS, DOUBLE DOOR, RECESSED 1 WALL, STEAM HEAT	
387362-164	250LS, DOUBLE DOOR, RECESSED 2 WALLS, STEAM HEAT	
387362-165	250LS, DOUBLE DOOR, RECESSED 1 WALL, ELECTRIC STEAM	
387362-166	250LS, DOUBLE DOOR, RECESSED 2 WALLS, ELECTRIC STEAM	

<sup>1.</sup> External Supplied Steam (Facility Steam/Stand-Alone Steam Generator)

**Table 1. Recommended Feed Water Quality for Sterilizers** 

Condition	Nominal Conditions	Maximum Conditions	
Temperature	40°-60°F (4°-16°C)	70°F (21°C)	
Total Hardness as CaCO <sub>3</sub> *	50-120 mg/L	171 mg/L	
Total Dissolved Solids	100-200 mg/L	500 mg/L	
Total Alkalinity as CaCO <sub>3</sub>	70-120 mg/L	180 mg/L	
рН	6.8-7.5	6.5-8.5	
Total Silica	0.1 - 1.0 mg/L	2.5 mg/L	

<sup>\* 17.1</sup> mg/L = 1.0 grain hardness

Table 2. Required Feed Water Quality for Carbon-Steel Steam Generators

Condition	Nominal Conditions	Maximum Conditions	
Temperature	70-140°F (21-60°C)	140°F (60°C)	
Total Hardness as CaCO <sub>3</sub> *	0-17 mg/L	130 mg/L	
Total Dissolved Solids	50-150 mg/L	250 mg/L	
Total Alkalinity as CaCO <sub>3</sub>	50-100 mg/L	180 mg/L	
рН	6.8-7.5	6.5-8.5	
Total Silica	0.1 - 1.0 mg/L	2.5 mg/L	
Resistivity <sup>†</sup>	2 - 6 kΩ⋅cm	26 kΩ⋅cm	

<sup>\* 17.1</sup> mg/L = 1.0 grain hardness

**Table 3. Required Feed Water Quality Stainless Steel Generators** 

Type of Water	Deionized Water, Distilled or Reverse Osmosis
Temperature	70-140°F (21-60°C)
Minimum Specific Resistivity	1.0 MΩ·cm

NOTE: Do not connect tap water to stainless-steel steam generator. Use of water not meeting the required feed water quality will invalidate the warranty and is a violation of ASME Boiler Codes.

<sup>†</sup> WARNING-BURN HAZARD: Never use supply water with resistivity exceeding  $26~\mathrm{k}\Omega$ -cm, as doing so may cause malfunction of steam generator level control, resulting in <u>sterilizer operator being severely burned by scalding water</u>. If supply water resistivity exceeds  $26~\mathrm{k}\Omega$ -cm immediately contact STERIS Service Engineering.

# **ENGINEERING DATA**

Model	Heating	MAXIMUM OPERATING WEIGHT <sup>a</sup> Ibs (kg)		HEAT LOSS <sup>b</sup> BTU/hr at 70°F (21°C) Single Door Double Door							
		Single Door	(1.9)	Oak A Fina		Recessed		Recessed	Two Walls		
			Double Door	To Room	Front of Wall	Back of Wall	Front of Wall	Back of Wall	At Each End	Between Walls	
AMSCO 110LS	Steam	750 (340)	989 (449)	4300	1600	2700	1600	3500	N/A	N/A	
	Electric	890 (404)	N/A	6050	2300	3750	N/A	N/A	N/A	N/A	
AMSCO 250LS	Steam	1231 (558)	1606 (728)	7000	2500	4500	2500	5300	2500	2800	
	Electric	1371 (622)	1726 (782)	8750	3300	5450	3300	6250	3300	2950	

Model	Heating	UTILITIES CONSUMPTION									
		Water <sup>c</sup>							Steam		
		Cold			Hot <sup>d</sup>			Steam			
		Peak gpm (lpm)	Per Cycle <sup>e</sup> gal/cycle (l/cycle)	ldle gph (lph)	Peak gpm (lpm)	Per Cycle <sup>e</sup> gal/cycle (l/cycle)	ldle gph (lph)	Peak <sup>f</sup> lb/hr (kg/hr)	Per Cycle <sup>e</sup> lb/cycle (kg/cycle)	ldle lb/hr (kg/h)	
AMSCO 110LS	Steam	4.5 (17)	24 (91)	7 (27)	N/A	N/A	N/A	180 (81)	18 (8)	7 (3)	
	Electric	4.5 (17)	24 (91)	7 (27)	1 (4)	3 (11)	1 (4)	N/A	N/A	N/A	
AMSCO 250LS	Steam	4.5 (17)	55 (208)	10 (38)	N/A	N/A	N/A	180 (81)	21 (10)	7 (3)	
	Electric	4.5 (17)	55 (208)	10 (38)	1 (4)	4 (15)	1 (4)	N/A	N/A	N/A	

<sup>&</sup>lt;sup>a</sup> Based on chamber fully loaded with water flasks. Noise level is based on the vacuum pump, 74 dB at 24"Hg vacuum. Estimated noise level of 68dB for units with water ejector.

Additional utilities are required for units with the following options:

- Liquid Air Cool (Compressed Air)
- Decontamination Cycle (Compressed Air)
- Bio-Seal and Air Differential Seal (Optional Compressed Air Backup)
- Vacuum Pump (3-Phase Voltage)
- Stainless-Steel Piped Units (Treated Water and Compressed Air)
- Steam Source (one of the following):
  - >> Integral Steam Generator Carbon Steel or Stainless Steel (3 Phase Voltage)
  - >> Indirect Steam Generator; Minimum 75 psig Steam Required

Consult Customer service for specially configured equipment drawings.

MODEL	NOMINAL CHAMBER	DIMENSIONS - inches (mm)									
	SIZE in. (mm)	Aa	Ba	С	F	Ha	Ja	Ka	Гр		
110LS	16 x 16 x 26	25 <sup>c</sup>	30	35-3/4	26	25-1/2	18	40	24-1/8 ± 1/4		
	(406 x 406 x 660)	(635)	(762)	(908)	(660)	(641)	(457)	(1016)	(613 ± 6)		
250LS	20 x 20 x 38	27 <sup>c</sup>	32	45-1/8	30	29-1/2	20	52	28-1/8 ± 1/4		
	(508 x 508 x 965)	(686)	(813)	(1146)	(762)	(749)	(508)	(1321)	(714 ± 6)		

<sup>&</sup>lt;sup>a</sup> Minimum Service Clearance

b At 70°F (21°C).

<sup>&</sup>lt;sup>c</sup> Backflow preventer device in water line, when required by local codes, is not provided by STERIS.

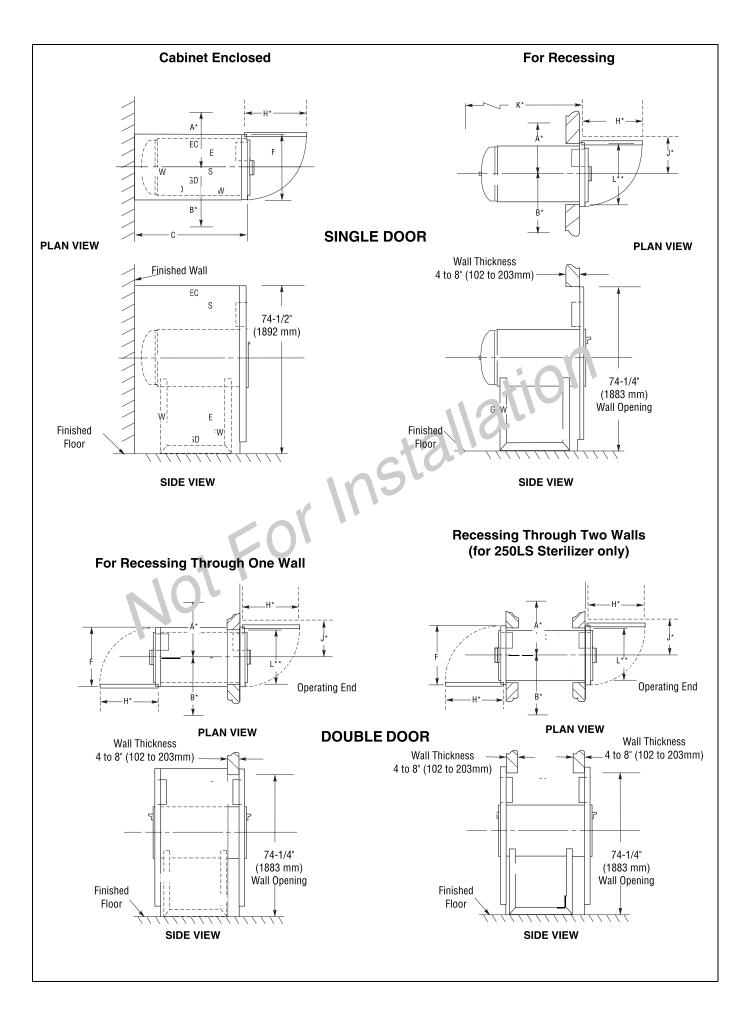
<sup>&</sup>lt;sup>d</sup> Hot water recommended for units equipped with electric steam heat.

e Based on Prevac cycle, 3 pulses, 30 minute exposure time and 5 minute dry time. Tested with empty chamber and Water Ejector.

f Peak steam demand (lbs/hr) may vary depending on operating conditions.

b Wall Opening

<sup>&</sup>lt;sup>c</sup> If recessed through one wall and using facility steam: 18" (457 mm) for 110LS; 20" (508 mm) for 250LS.



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

The base language of this document is ENGLISH.

Any translations must be made from the base language document.

# For further information, contact:



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