

## APPLICATION

AMSCO 600 Series Steam Sterilizers are configured for prevacuum sterilization of heat and moisture-stable medical devices and their accessories used in healthcare facilities.

## DESCRIPTION

AMSCO 600 Series Steam Sterilizers are equipped with the latest features in both state-of-the-art technology and ease of use.

### Primary product features:

Square chamber design with high-quality polished pressure vessel finish.

Interior Chamber Dimensions (W x H x L) and Capacities

- **6 STU** – 675 x 675 x 990 mm; 450L
- **8 STU** – 675 x 675 x 1290 mm; 588L
- **10 STU** – 675 x 675 x 1590 mm; 724L
- **12 STU** – 675 x 675 x 1890 mm; 860L

**Vertical-sliding door(s)** – Pneumatically-driven doors are operated from buttons on the control panel and travel down vertically to open.

**Control system** (with enhanced functionality) – features a Festo Programmable Logic Controller (PLC) and 254 mm HMI (Human Machine Interface) touchscreen display.

## STANDARDS AND DIRECTIVES

**Quality System Standards** – STERIS facilities where AMSCO 600 Series Sterilizers are manufactured and assembled meet applicable requirements of the following standards:

- ISO 9001: Quality Management Systems
- ISO 13485: Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes



AMSCO 600 Series Steam Sterilizer (Typical - details may vary.)

### Product/Performance Standards

- EN 285: 2015 Sterilization. Steam Sterilizers. Large Sterilizers
- EN 61010 Safety Testing
- Compliant with RoHS: restricting the use of hazardous substances in electrical and electronic equipment.

### CE Compliance Directives

- CE marked to Medical Device Directive 93/42/EEC as amended by 2007/47/EC
- Pressure Equipment Directive (PED): 2014/68/EU
- Machinery Directive: 2006/42/EC
- Low Voltage Directive: 2014/35/EU
- Electromagnetic Compatibility Directive: 2014/30/EU

## Selections Checked Below Apply To This Equipment

### SINGLE DOOR UNITS / CAPACITY

- ☐ FAHC7710S - 6 STU
- ☐ FAHC7713S - 8 STU
- ☐ FAHC7716S - 10 STU
- ☐ FAHC7719S - 12 STU

### DOUBLE DOOR UNITS / CAPACITY

- ☐ FAHC7710D - 6 STU
- ☐ FAHC7713D - 8 STU
- ☐ FAHC7716D - 10 STU
- ☐ FAHC7719D - 12 STU

### SINGLE DOOR MOUNTING

- ☐ Recessed
- ☐ Cabinet enclosed/free-standing

### DOUBLE DOOR MOUNTING (Recessed)

- ☐ Through two walls
- ☐ Through one wall

### STEAM SOURCE

- ☐ Facility Steam
- ☐ Steam Generator Bypass Valve
- ☐ Stainless-Steel Integral Electric Steam Generator
- ☐ Stainless-Steel Integral Steam-to-Steam Generator

### STERILIZER ELECTRICAL SERVICE

- ☐ 400V, 50Hz, 3 phase

### WATER CONSERVATION OPTIONS

- ☐ STERI-GREEN Water Savings Package
- ☐ STERI-GREEN Plus Chilled-Water Savings Package

### HTM 01-01 UK OPTIONS

- ☐ Kit #1 – Includes Air Detector and Backflow Preventer
- ☐ Kit #2 – Includes Kit #1 plus Chart Recorder

### OTHER OPTIONS

- ☐ Air Differential Seal
- ☐ Ethernet Connection
- ☐ Steam Quality Measurement Ports (for Steam Generators)

### LOADING ACCESSORIES

**Manual Loading** - refer to Tech Data 10285948

- ☐ Loading cart
- ☐ Transfer carriage
- ☐ Loading cart and transfer carriage
- ☐ Chamber track assembly, single or double door
- ☐ Chamber rack and shelf (6 STU only)

### Automatic Loading - refer to Tech Data 10285949

- ☐ Unload only
- ☐ Load and Unload\*

### OTHER ACCESSORIES

- ☐ Spare Parts Kit
- ☐ Stainless-Steel Steam Pressure Regulating Valve (PRV)
- ☐ Feed Water Booster Pump for Integrated Steam Generators

### LANGUAGE PACKAGE

- ☐ English, ☐ French, ☐ Italian, ☐ German,
- ☐ Spanish, ☐ Finnish, ☐ Other \_\_\_\_\_

\*ALUS- Automated Load/Unload System (for Double Door Units Only)

Item \_\_\_\_\_

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

## FEATURES

### Chamber and Jacket

The AMSCO 600 chamber is square in design with 660x660mm cross section and is sized to allow for efficient high-volume processing of sterilization containers, trays and packs.

Fully jacketed chamber construction exhibits superior temperature distribution and reduced internal condensation in comparison with many other designs. The chamber is manufactured from AISI 316L stainless steel, as is the chamber door; and the full structural jacket is manufactured from AISI 304 stainless steel.

### Pressure Vessel

All pressure vessels are designed and manufactured in accordance to the required pressure vessel standards. An identification nameplate is permanently mounted on each pressure vessel. Features include:

- Internal surface of chamber is polished to minimum Ra < 0.6 µm or better. All chamber welds are ground smooth.
- Chamber steam baffle provides uniform steam distribution to the chamber with minimal superheat.
- Chamber and jacket are provided with safety relief devices.
- Chamber bottom is sloped to promote drainage of condensate.
- Chamber includes a 2" sanitary port (≈51 mm) for pressure/temperature validation.
- Pressure vessel and doors are insulated with mineral wool. Jacket is covered with rigid aluminum cladding. Door is covered with stainless-steel cladding.
- Chamber drain port is provided with removable debris screen for easy cleaning.
- Each pressure vessel is hydrostatic pressure tested.
- Chamber is designed to operate from full vacuum to a maximum allowable working pressure of 3.1 bar(g).
- Jacket is designed for a minimal working pressure of 2.5 bar g internal pressure with full vacuum in chamber.
- All pressure vessel fittings are equipped with double bolt hygienic clamps where applicable.
- Units are shipped with removable 316L stainless-steel tracks. The tracks are used to guide the cart during loading and unloading of the sterilizer.

### Door Design

AMSCO 600 Series Steam Sterilizers are available with one or two vertical sliding, pneumatically driven doors. Each door is sealed to chamber by a steam-activated gasket which requires only a one-time lubrication, during initial installation.

- Chamber and jacket pressure gauges are provided on the front face (non-sterile side) of the sterilizer. A chamber pressure gauge is provided on the sterile side of double door units.
- Touch-sensitive safety edge is provided to detect obstructions and stop doors from closing if there is an obstruction.
- Control lock out switch prevents a cycle from starting unless doors are closed.
- Door interlocks, on double door units, ensure only one door can be opened at a time.

### Electrical Design

Electrical design includes the following features:

- Standard configuration requires one 3-phase connection.
- All mechanical limit switches used are designed to be failsafe to ensure deactivation if an abnormal situation occurred during operation.
- Unit is equipped with emergency stop switch (E-Stop) for critical situations. When pushed, the E-Stop activates a safety relay that mechanically deactivates all digital outputs from the PLC and causes an emergency stop alarm. When released, a cycle abort screen displays, prompting operator to abort the cycle.
- Door operation push buttons and emergency stop switch are located on fascia panel at each door.

### Panel and Frame Assembly

The panel and frame assembly supports pressure vessel, piping, electrical construction and fascia panels. Notable points include:

- Frame is a fully welded structure fabricated from carbon steel and painted with corrosion and heat resistance epoxy paint. It includes adjustable stainless-steel legs for leveling the unit.
- Sterilizer is designed and manufactured to allow access for maintenance and service from unsterile end. Certain options may require side access. Refer to applicable equipment drawings for specific requirements.
- Loading and unloading ends of sterilizer are sheeted with AISI 304 stainless steel. Fascia panels are ground finish to No. 3 American Society for Testing and Materials (ASTM) (EN 10088-2: 2G).
- Fascia panels are easy to remove to save time and effort during maintenance.

### Piping

AMSCO 600 series sterilizers contain four categories of piping:

- Steam supply line
- Compressed air supply line
- Water supply line
- Chamber drain line

All piping terminates within the confines of the sterilizer and includes single-point utility connections for easy installation. Manual shutoff ball valves on water, steam and air lines are used to isolate the respective utilities.

Piping and associated valves are made of stainless steel for clean steam.

**Two-stage Vacuum Pump** provides quiet and efficient operation, longer expected life, and deeper vacuum than single stage pumps.

### Double Sensors for Temperature and Pressure Measurements

Independent sensors for controlling and recording of pressure and temperature. Sensors used for controlling are also used for indication. This double-sensor feature fulfills the EN 285 requirement for the independent measuring chains of temperature and pressure.

### Effluent Cooling

Drain effluent discharge is cooled through a water-saving controlled mixing tank.

### Sterile Air Filter

Air entering the chamber is filtered through a 0.2-micron hydrophobic sterilizer air filter.

## MOUNTING ARRANGEMENT

The sterilizer is designed for either freestanding or recessed installation, as specified. Each sterilizer is height adjustable.

## CONTROL SYSTEM

AMSCO 600 Series Steam Sterilizers use a Festo Programmable Logic Controller (PLC) to maximize flexibility and reliability. The control includes a total of 20 programmable cycles for prevacuum and diagnostic cycles. The control system includes a color touch screen with display for operation, maintenance and diagnostic applications.

**Control System Hardware** includes the following main components:

- **Power Supply Enclosure** – houses the main power switch, circuit breakers, control power supply and electrical components for vacuum pump control.
- **Control Panel (non-sterile side)** – includes RS 485 Modbus RTU port (for PLC interface), USB port, and Ethernet interface. In addition, the control panel includes: door open/close buttons, power key switch, emergency stop button and buzzer. Single door unit includes a Festo 254 mm color touchscreen HMI (Human Machine Interface) on the non-sterile side.
- **Control Panel (sterile side)** – double door unit sterile side includes a Festo 254 mm color touchscreen HMI, door open/close button, emergency stop button, cycle control, alarms and pass-through. Double door unit non-sterile side also includes a 254 mm color touch screen HMI.
- **Thermal printer** – panel mounted and included on the unload side of the sterilizer (non-sterile side on single door units, sterile side on double door units). Printer uses 58 mm width paper and exhibits high print quality. The printer includes RS 232/TTL and mini-USB interfaces. Real time process parameters can be printed during each cycle.

**Control System Software** includes the following features as standard:

- PID (*Proportional Gain/Integral/Derivative*) control loop modulates the on-off valve ensuring accurate chamber temperature control.
- System has four user access levels with up to 50 users names.
- Electronic recording of process data (USB port).
- Automatic utilities start up and shut down programmable capability to conserve energy during idle periods.
- Software calibration for all temperature and pressure inputs.

### Ethernet Communication (Option)

Ethernet communication option includes External Communication Specification which documents available data points to read from the PLC and a NAT router for remapping the machine's physical IP address space into another. With this option, the IP addresses can be easily configured to enable communication with external systems.

## HEALTHCARE CYCLES

### Description

AMSCO 600 Series Steam Sterilizers are provided with prevacuum cycles designed for steam sterilization of various types of products such as instruments in trays and rigid containers, textiles, and products in pouches. Twenty individually configurable cycles are provided.

## Pre-Set Processing Cycles

AMSCO 600 is pre-configured with two prevacuum cycles, as indicated in the following table.

**Pre-set Process Cycles**

Cycle Type	Temperature	Sterilize Time (Minutes)	Dy Time (Minutes)
Prevacuum	121°C	16.5	25
Prevacuum	134° C	3.5	25
Pass-Through	Returns loading cart on DD sterilizers that have no separate pass-through hatch available.		

**NOTE:** *Separate, additional cycles (with sterilization and drying parameters same as those listed in the table) have been designed specifically for use with the optional air detector and are provided standard with the sterilizer.*

### Configurable Cycles

In addition to 121°C and 134°C pre-set prevacuum cycles, configurable operating parameters enable the Customer to develop and optimize cycles for a variety of applications. All cycles consist of three separate phases as follows:

- **Pre-conditioning phase:** this phase removes air from the chamber prior to the exposure phase. *Pulsed Air Removal* and *Forced Air Removal* cycles are available. After air removal, the chamber heats up to reach the defined exposure temperature.
- **Exposure phase:** The standard process operates with time based exposure. The timer runs only when the chamber reaches and maintains the pre-selected exposure temperature.
- **Post-Conditioning drying phase:** The post-conditioning drying phase uses vacuum to evaporate moisture from the chamber and load.

### Test Cycles

AMSCO 600 sterilizers are pre-programmed with the following three test cycles.

- **Warm Up Cycle** is run to heat the sterilizer chamber and jacket to set temperature. The operator typically runs a 5 minute warm up cycle prior to running a Bowie-Dick Cycle.
- **Bowie-Dick Test Cycle** is used to test 121°C and 134°C prevacuum cycles for verification of effective air removal in chamber and load. The Bowie-Dick test cycle also functions as a Helix steam penetration test. Test packs should be placed in an empty chamber directly over the drain on the bottom rack or shelf. The test cycle determines if even and rapid steam penetration into test load has occurred. The cycle is pre-programmed per parameters set by the Bowie-Dick Test.
- **Leak Test** is a standard test provided for verification of chamber and piping integrity. Test parameters are user-configurable; but standard durations are: 10-minute evacuation, 5-minute stabilization and 10-minute leak test.

## STEAM SOURCE OPTIONS

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### Integral Steam to Clean Steam Generator (CSG)

CSG 100 is an Integral Shell-and-Tube Steam Generator designed to produce steam of a quality equal to that of the feed water introduced into CSG.

Plant steam is supplied to the shell, while process quality water is fed to the inner tubes according to the *falling film principle*. Plant steam vaporizes the feed water to produce clean process steam. Feed water that is not vaporized in the process is removed from a column as blowdown.

The feed water for the integral steam generator system should be either deionized or RO quality water.

As standard, the CSG 100 unit is built on the right-hand side of the sterilizer (when facing the non-sterile end). An additional 300 mm is required for the installation footprint and side service access is necessary. One CSG 100 unit can feed one sterilizer. Sterilizer control system is used to control the CSG 100 unit.

#### Steam generator features:

- CSG is controlled by the sterilizer through a pneumatic feed water valve.
- The pressure vessel is designed in accordance with ASME or PED standards.
- All piping and components in contact with the feed water or clean steam are constructed of AISI 316 or 316L stainless steel.
- Steam generation unit includes stainless-steel (AISI 316L) shell and tube (double tube sheet) vertical heat exchanger. Interior tube surface finish has an Ra of 0.6 µm.
- Some components for use with facility steam and sterilizer discharge are constructed of bronze or cast iron.
- Required plant steam pressure is 5-8 bar(g).
- Clean steam pressure is controlled by a pressure reducing valve.
- The unit is equipped with a pressure gauge to indicate the steam pressure inside the generator.

### Integral Electrical Steam Generator

The Integral Electrical Steam Generator is designed to produce steam of a quality equal to the feed water that is introduced into the system.

The feed water for Electrical Generator system should be either deionized or RO. The Integral Electrical Steam Generator does not include any entrainment device to remove pyrogens.

The system is built under the sterilizer chamber and includes the feed water system, steam generation system and the controls. The Integral Electrical Steam Generator is provided with the following features:

- The pressure vessel meets ASME or PED pressure vessel codes.
- The AISI 316L stainless-steel vessel is rated for 3.1 bar(g) per code requirements and stamped.
- The heating element contains stainless-steel AISI 316L tubular elements.
- The unit is equipped with three water level sensors.

### Steam Generator Bypass Valve

The addition of a 2-way ball valve permits the quick exchange of steam source from the integral generator to a stand-alone generator or facility steam source.

## Steam Quality Measurement Ports for Steam Generators

Quality Test ports for the measurement of steam dryness values, superheat and amount of non-condensable gases.

### Feed Water Booster Pump for Integrated Steam Generators

Feed water booster pump is needed when the available feed water pressure is too low, less than 4 bar(g), for integrated electrical or clean steam generators. This option includes pressure switch for the pump protection and water request and available signals for control of the purified water loop valve.

## WATER CONSERVATION OPTIONS

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### STERI-GREEN Water Savings Package

With the STERI-GREEN option, cooling water is supplied only when vacuum pump seal water temperature is insufficient to draw to the necessary vacuum level. A small, non-pressurized recirculation tank supplies most of the vacuum pump seal water during the cycle. The control system monitors and determines when to add supplemental water to maintain vacuum pump efficiency at approximately 90%, resulting in a significant reduction in the use of domestic water.

Water saving efficiency depends highly on pre-and post-conditioning parameters, for example, the required vacuum level and amount of pulses. A separate chilled water supply is not required with this option.

The following components are added to the system:

- Monitoring instruments - for vacuum seal water temperature
- Recirculation tank - for vacuum pump water

**NOTE:** *Water saving options are assembled on the right-hand side of the unit (looking from non-sterile side) increasing the total width of the unit by 300 mm.*

### STERI-GREEN Plus Water Saving Package

The STERI-GREEN Plus is designed to utilize a Customer-supplied closed loop water (tower or chilled) utility to minimize the consumption of water. This is accomplished by cooling and recirculating the initial charge of vacuum pump seal water back to a break tank with a heat exchanger. The following components are added to the system:

- 316 SS plate heat exchanger – for vacuum pump
- Recirculation tank – for vacuum pump water
- Closed loop cooling water supply and return piping – for savings in water use

## HTM 01-01 UK OPTIONS

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HTM 01-01 UK options satisfy requirements stated in Health Technical Memorandum (HTM) 01-01: Management and decontamination of surgical instruments (medical devices) used in acute care.

### HTM 01-01 Kit # 1

Includes Air Detector and Backflow Preventer.

### HTM 01-01 Kit # 2

Includes Kit # 1 plus additional Chart Recorder.

### Air Detector

The air detector system is designed to automatically detect the presence of air in the chamber during the sterilization cycle.

## Backflow Prevention Kit

This RoHS compliant and lead-free check-valve backflow preventer isolates the water source from backflow contamination.

The sterilizer is a Water Regulations Advisory Scheme (UK) [WRAS] category 4 waste water source and does not require an air gap.

## Additional Chart Recorder

An independent chart recorder can be added to the sterilizer if desired.

## OTHER OPTIONS

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### Air-differential Seal

#### (Non-sterile side, double-door units only)

The sterilizer is provided with an air-differential seal at the non-sterile end of the sterilizer to maintain pressure difference between the sterilizer service area and classified area.

### Cabinet Enclosure

AISI 304 stainless-steel side and back panels are designed to enclose both sides (and back of a single door unit) of a sterilizer to conceal sterilizer internal piping, mechanical and electrical components.

## ACCESSORIES

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### Manual Loading Accessories

Manual loading accessories for AMSCO 600 series sterilizers include the following:

- Racks and Shelves (6 STU)
- Wire Baskets
- Loading Carts
- Loading Cart Shelves
- Transfer Carriages
- PouchCare (Rack for peel pouches)

Refer to tech data 10285948 for details pertaining to the above items. For details pertaining specifically to PouchCare, refer to marketing document M3557EN.

### Automatic Loading Accessories

Automatic loading accessories for AMSCO 600 series sterilizers include the following:

- Automated Unloading Table
- Automated Loading Table
- Bar Code Scanner Kit
- Bar Code Tag Kits
- Pass-Through Hatch

Refer to tech data 10285949 for details pertaining to the above items.

### Steam Pressure Regulating Valve (PRV)

The PRV option involves fitting the plant steam line with a 316 stainless-steel pressure regulating valve to limit incoming steam pressure to that of pressure vessel design requirements. The option includes a pressure gauge and is recommended for systems where steam pressure is higher than 3.1 bar(g).

## Spare Parts Kit

The Spare Parts Kit contains selected mechanical and electrical components to fulfill the need for two years of normal sterilizer maintenance and operation. Components typically provided are steam trap, solenoid valve, temperature sensor, door gasket, strainer screen, printer paper. Additional parts may be required for other sterilizer processes or options.

## EQUIPMENT DOCUMENTATION

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A User's Manual is provided to the Customer after the equipment is manufactured. The document typically includes the following sections:

1. General Regulations
2. General Safety Instructions
3. Transportation, Uncrating and Installation Instructions
4. Operational Manual
5. Maintenance Manual
6. Equipment Drawings and Parts Lists
7. Manufacturer's Component Data Sheets
8. Unit Test Results

*NOTE: The drawings in electronic format are provided in PDF and ACAD formats. Additional copies of the User's Manual can be provided at extra cost. The base language is English. The operator manual and HMI screens are provided in one of the official languages used in CE countries, if applicable.*

## PREVENTIVE MAINTENANCE

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Preventive Maintenance programs designed to maximize equipment uptime can be tailored to meet Customer's requirements. A typical contract provides preventive maintenance site visits twice per year. This maintenance is performed by factory trained STERIS Technicians following documented preventive maintenance procedures to inspect and adjust the equipment. The exact Customer requirements can be determined by a visit with the STERIS District Service Manager before the equipment arrives.

A maintenance-training program can be designed to provide training on preventive maintenance and first response troubleshooting. This training takes place at the Customer site on their equipment and is customized to address specific training needs. The Service Engineering department at a daily rate provides STERIS Maintenance Training. A typical maintenance-training program is performed for two (2) days. Maintenance Training, provided by the Service Engineering Department, can be scheduled by contacting the STERIS District Service Manager three weeks prior to the requested training to allow scheduling of personnel.

## UTILITY REQUIREMENTS

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Refer to the following table for basic information pertaining to required utilities and connection types.

*NOTE: For detailed information always refer to associated equipment drawings.*

UTILITY PARAMETERS AND CONNECTIONS			
UTILITY	PRESSURE	TEMPERATURE	CONNECTION
STEAM (Dry Saturated) <sup>1</sup>	2.5 +0.0 / -2.0 bar(g)	125 - 128°C	G 3/4 BSP Female
WATER <sup>2,3</sup>	1 - 3 bar(g)	10 - 15°C	G 1/2 BSP Female
RO/DI WATER	3 - 6 bar(g)	15 - 80°C	G 1/2 BSP Female
COMPRESSED AIR <sup>4</sup>	5.3 - 8.3 bar(g)	N/A	G 1/2 BSP Female
DRAIN	Gravity	60°C	1-1/2" (38.1 mm) Open
SAFETY RELIEF DEVICE - CHAMBER	3.1 bar(g) max	145°C	G 1-1/4 BSP Female
SAFETY RELIEF DEVICE - JACKET	2.5 bar(g) max	145°C	G 1-1/4 BSP Female
SAFETY RELIEF DEVICE - ESG	3.1 bar(g) max	145°C	G 1 BSP Female
ELECTRICAL CONNECTION	N/A	N/A	Terminal

Notes:

1. Dry saturated steam is required with a dryness value of 0.95 or higher.
2. Maximum recommended water temperature is 20 °C. Efficiency and the depth of vacuum reached with the liquid ring vacuum pump is reduced as water temperature increases. Contact STERIS for temperatures above 20 °C.
3. Conductivity of supplied water shall not exceed 500 micro-Siemens/cm.
4. Dry, oil free, compressed air is required.

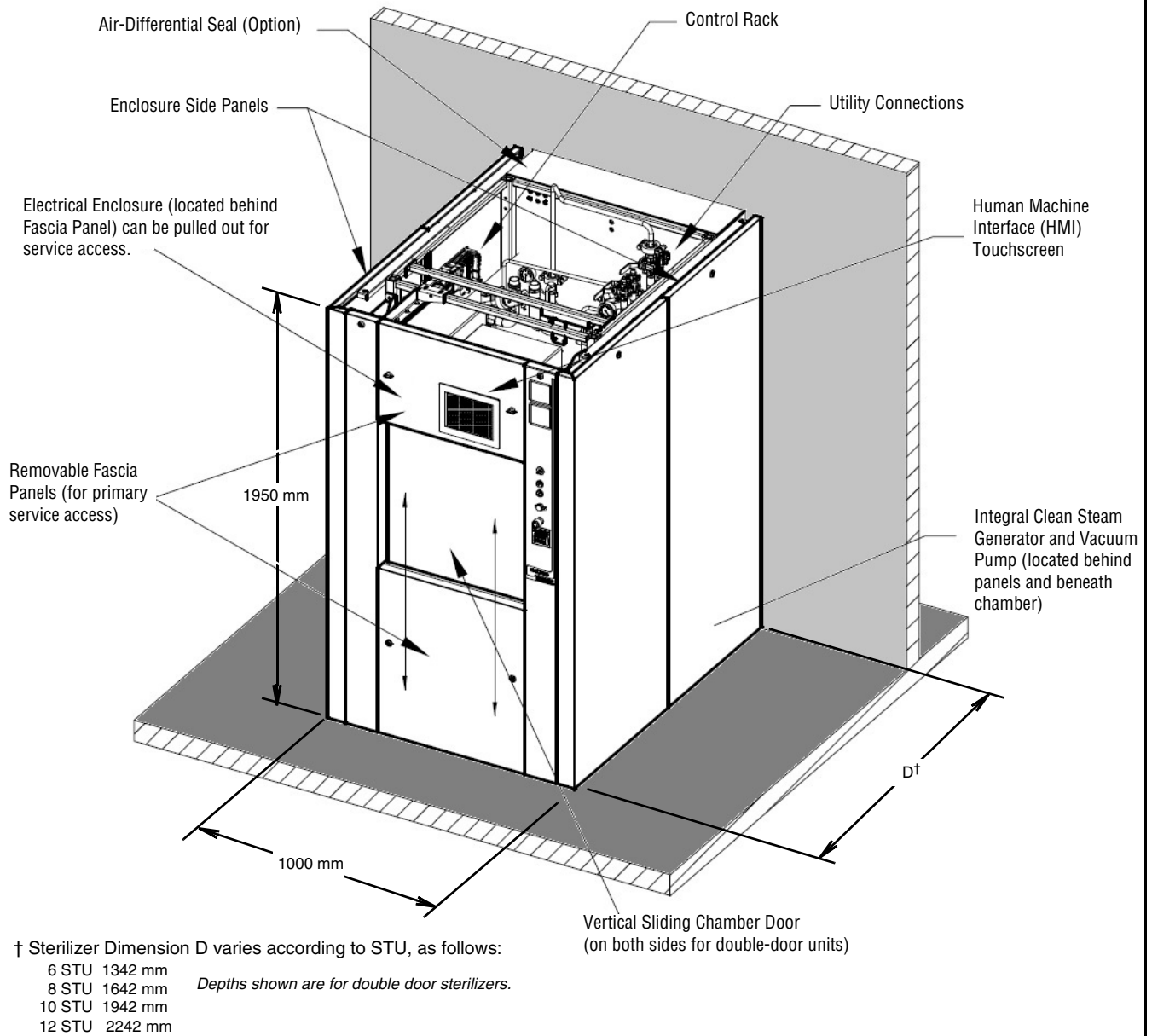
Refer to equipment drawings for additional notes concerning utilities and installation.

## ADDITIONAL SPECIFICATION

**Sound Power:** 70dB

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

# NOT FOR INSTALLATION\*



## AMSCO 600 Series Sterilizer

\*Refer to applicable equipment drawings for installation details.

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**The base language of this document is ENGLISH.  
Any translations must be made from the base  
language document.**