

# FINN-AQUA® BIO PHARMA SERIES (BPS) GMP STEAM STERILIZERS



## Steam Sterilization

### APPLICATION

Designed for general purpose, sterile room supply, media preparation, or terminal sterilization applications performed in biopharmaceutical and pharmaceutical facilities, and biotech research and development facilities.

### DESCRIPTION

The Finn-Aqua BIO Pharma Series (BPS) GMP Steam Sterilizers provide shortened validation time, increased reliability and flexibility. The sterilizer uses saturated steam for sterilization of hard goods and vented liquids. Optional pressurized air during post-conditioning is available for processing liquids in vented glass containers.

The Finn-Aqua BPS GMP steam sterilizer is designed, manufactured, tested and documented according to the latest global practices and standards to facilitate Customers' compliance with current Good Manufacturing Practices (cGMP) and Good Automated Manufacturing Practices (GAMP). Temperature distribution within the chamber, including drain temperature, is guaranteed to be within  $\pm 0.5^{\circ}\text{C}$  ( $\pm 0.9^{\circ}\text{F}$ ) of the process sterilization temperature (exposure setpoint). This exact temperature distribution verifies the repeatability needed for validation cycles.

The sterilizer is fully tested and prevalidated during factory qualification. Prequalification reports of the installation, operational, and performance qualifications are provided, along with complete documentation on machine design, construction and control software.

The sterilizer can be configured in a number of chamber sizes with either single or double doors.



(Typical - details may vary.)

### STANDARDS

Sterilizer is manufactured in an ISO 9001, ASME Section VIII Division 1, PED Module H/H1 and ISO 3834-2 certified facility and meets applicable requirements of the following listings and standards:

- **GMP**
- **GAMP 5**
- **EU ANNEX 1**
- **EN285**
- **EN ISO 17665-1**
- **Underwriters Laboratory (UL) Standard 508A**
- **ASME Code, Section VIII, Division 1** for unfired pressure vessels
- **CRN (Canada)**
- **European Directives (Europe)**
- **Pressure Equipment 2014/68/EU**
- **Machinery Directive 2006/42/EC**
- **Low Voltage 2014/35/EU**
- **Electromagnetic Compatibility (EMC) 2014/30/EU**
- **FDA 21 CFR Part 11 Compliant/EU Annex 11.** STERIS Finn-Aqua develops, documents, and enforces policies and procedures that ensure security of electronic records and signatures according to 21 CFR Part 11. Together with our Customers, Finn-Aqua will help implement and enforce Part 11-compliant solutions involving validation, audit trails, and security of our computer systems.

### FEATURES

**Control System** can be configured with Allen-Bradley® PLC or Siemens® PLC control. Control system monitors and controls all sterilizer operations and functions. PLC control allows up to 20 sterilizing cycles to be configured to meet specific

processing requirements. All control system components are mounted in an integral cabinet. Control cabinet can be equipped with a 10 m (33') interface cable for optional remote mounting.

**Operator Interface** consists of either a 7" (Allen-Bradley) or a 9" (Siemens) color touch-sensitive screen and panel printer located on non-sterile (operating) end of sterilizer. All sterilizer functions, including cycle initiation and cycle configuration, are performed using touch screen. Displayed messages are complete phrases with no codes that need to be cross-referenced. Screen also displays any abnormal (alarm) conditions that may exist in or out of a cycle.

If sterilizer is equipped with double doors, indicator lights are provided on sterile (non-operating) end.

Panel mounted wide paper printer enables up to 83 characters per row.

**Chamber and Jacket Pressure Gauges** are mounted on non-sterile end. Pressure is displayed in bar/psig and inHg (vacuum). If sterilizer is equipped with double doors, an additional chamber pressure gauge is provided on the sterile end of the sterilizer.

**Horizontal or Vertical (66X Cross Section Only) Sliding Door (s)** are pneumatically operated by buttons on control panel. Each door is equipped with a air-activated, non-lubricated gasket. When cycle completes, gasket retracts under vacuum into machined groove in sterilizer end frame.

*NOTE: As an alternative, for GMP sterilizers (models 9, 12 and 15 only) power-assisted hinged doors can be provided for both floor- and pit-mounted versions\**

*For sterilizers installed in a pit, the door is elevated from the pit and locking mechanisms are engaged underneath the door and under each hinge to ensure safe operation.*

*Hinges for door can be mounted on either side of sterilizer, opposite the control. The door is sealed with an active air-backed gasket.*

**\* Refer to table on page 8 in regard to model numbers and associated chamber sizes**

**Equipment Documentation Package** includes three copies of user manual and one copy each of manufacturing, control system, and qualification documentation. Package contains information required to assist in development of validation procedures and final validation of the equipment.

**Calibration** is provided through the control panel to all system temperature and pressure channels. Calibration is performed in Calibration Mode, accessible through touch-screen display, and accomplished using external temperature and pressure sources. Control system provides a printed record of all calibration data for verification of current readings.

**Interface Port** is provided for downloading cycle information to Customer-furnished data acquisition system.

## CYCLE DESCRIPTIONS

### Standard Process Cycles

Depending on cycle options selected, sterilizer is factory-programmed with following process cycles:

- **Cycle B** is a standard high vacuum cycle provided for sterilization of all dry goods and porous loads at 110–

135°C (230–275°F). Preconditioning includes air-removal phase using vacuum and steam pulses. Alternatively, preconditioning could consist of a forced air removal. Forced air removal removes air from chamber by introducing steam to force the air out through drain line system. Vacuum pump is simultaneously operated to assist in evacuating air. Forced air removal is designed for liquid loads in vented containers. Exposure includes timed or optional  $F_0$  based modes. Drying can be accomplished by fast exhaust, deep vacuum or vacuum pulsing. Pre-vacuum and post-vacuum pulses are programmable. Vented Liquid cycles are also possible using slower rated exhaust. Cycle B is primarily used for production, clean room supply and production support.

- **Cycle C** is an optional cycle designed to efficiently process liquid products such as Small and Large Volume Parenteral (SVP and LVP) solutions packaged in vented and non-vented containers that require fast cooling during post-conditioning phase. Cooling phase is designed to cool chamber by flowing cooling water through jacket with simultaneous air over-pressurization in chamber. This process cools the load and prevents the product from boiling. Cycle C sterilization process includes Process B cycle. Cycle C includes compressed air back-up for door gasket(s).
- **Process BX** Process BX is an amplifier-enhanced general-purpose cycle designed for steam sterilization of various types of products such as filter housings and cartridges, equipment parts, baskets, racks, textiles, rubber stoppers, products in pouches, and liquids in vented containers. One load probe is included and it is typically used for big single-packs like rubber stoppers and large textile packs or sterilization of liquids in vented containers.  $F_0$  functionality is included with the load probe. The major benefits of process BX cycle option include faster cycle performance due to faster load pre-heating and cooling, and improved load dryness during post-conditioning, as dry air effectively removes moisture from load surfaces.
- **Process CX** (Ejector-enhanced indirect water cooling) is designed to replace conventional fan assembly in sterilizer chamber. An air ejector cooling process provides air circulation equal to, or more effective than, that which can be provided by a conventional fan. Ejector process is designed to speed up cooling process by generating symmetrical air flow pattern for transferring heat from load to water-cooled chamber walls. Chamber pressure is controlled automatically by bleeding excess air out. There are no moving parts or penetration seals through the chamber to wear. Additional air is required for Process CX. Air consumption is based on size of vessel. See equipment drawing.
- **Steam-Air-Mix (SAMX) Cycle** is designed for moist heat sterilization of various types of non-vented liquid products such as ampoules, vials, bottles, bags, etc. The SAMX process uses one or multiple air ejectors to provide required differential pressure in chamber and to circulate steam and air mix within chamber. Air ejector(s) occupy only 4 inches (102 mm) of space in top of chamber. There are no moving parts or penetration seals through the chamber to wear. Additional air is required for the SAMX cycle. Air consumption is based on size of vessel. See equipment drawing. Ejector-enhanced indirect water cooling is featured with the SAMX cycle.

- **Leak Test Cycle** is a standard cycle provided for verification of chamber integrity. Cycle parameters are user-configurable. Default values for the leak rate test may be used, or specific leak rate test parameters may be configured in accordance with Customer's Standard Operating Procedure (SOP).

## SAFETY FEATURES

**Emergency Stop Button**, located on operating end (and non-operating end if double door unit) of sterilizer, returns valves to safe condition and halts cycle processing when pressed. Once pressed, operator chooses to either abort or continue cycle operation.

**Security Access Codes provide** restricted access of unauthorized users to critical operational modes. Five access levels are available:

1. Operator level password (**level 1**) permits the user to select a cycle, start a cycle, acknowledge alarms, view cycle parameters and manually print reports;
2. Supervisor level password (**level 2**), in addition to level 1, permits the user to edit cycle parameters, edit the Proportional Integral Derivative (PID) parameters, skip the current step of the running cycle and stop the Programmable Logic Controller (PLC) from accumulating exposure time;
3. Calibrator level password (**level 3**), in addition to level 2, permits the user to calibrate instruments;
4. Service level password (**level 4**), in addition to level 3, permits the user to view inputs, view system diagnosis, activate/deactivate outputs, edit common settings and change date/time;
5. Administrator level password (**level 5**), in addition to level 4, permits the user to configure user names and edit passwords.

**Compressed Air Back-up** for door gasket(s) is provided on all double door sterilizers and with C cycle, decontamination cycle, and bioseal installations.

**Door Sensing Device** automatically stops if an obstruction is detected while the door is closing.

**Door Interlock (Double Door Units Only)** allows only one door to be opened at a time, and during processing, prevents either door from being opened until sterilization cycle is complete. Door opening/closing sequencing logic is configurable. Double door not available on 666 (660 x 660 x 660 mm [26 x 26 x 26"]) model.

**Pressure Relief Devices** on chamber and jacket limit the amount of pressure buildup so rated pressure of vessel is not exceeded

**Steam Valve Interlock** prevents steam valve from opening when door is locked

**Pressure Interlock** prevents user from opening door when unit is above/below atmospheric pressure

## CONSTRUCTION

### Pressure Vessel

The standard chamber pressure vessel is a fully jacketed-type vessel that meets ASME and PED pressure vessel codes. Pressure vessel inner shell (chamber) and outer shell (jacket) are designed to withstand operating pressures from full vacuum to 3.1 bar (45 psig). Chamber and jacket are constructed of stainless steel. All process contact surfaces are mechanically polished to a finish of Ra < 0.6 µm (< 25 micro-inch).

Jacket is insulated with 13 mm (1") black foam insulation with aluminum backing.

Steam-supply openings, inside chamber, are shielded by a full-length baffle to evenly distribute clean steam as it enters chamber. A 63 mm (2-1/2") chamber penetration with TRI-CLAMP®<sup>1</sup> connections is provided for validation purposes.

### Chamber Door(s)

Door is constructed of AISI 316L stainless steel and insulated with mineral wool to reduce surface temperature of stainless-steel door cover. Door is equipped with a one-piece, silicone sealing gasket. Gasket is activated by pure steam or compressed air pressure, and retracted by pulling a vacuum.

### Fascia Panel(s)

Sterilizer framework is enclosed by a front fascia panel, located on operating end. If sterilizer is equipped with double doors, a back fascia panel encloses the sterile end. Fascia panels are constructed of stainless steel with No. 3 brush finish.

### Vacuum System

Two-stage, water ring seal-type pump is used for evacuating sterilizer chamber. Pump is sized to create a 7.0 kPa (1.0 psia) vacuum in five minutes utilizing 20°C (68°F) sealing water.

### Air Filter

Air filter, used for chamber pressure equalization, is 0.2 µm hydrophobic bacteria-retentive filter. Filter can be steam-sterilized up to fifty times.

### Piping

Process piping for clean steam and sterile air to chamber, and drain piping up to first valve is constructed of AISI 316L stainless steel. All piping connections terminate within confines of sterilizer and are accessible from right side of sterilizer, when facing non-sterile (operating) end. All sanitary stainless-steel piping utilizes sanitary TRI-CLAMP fittings. Other piping connections are screwed or compression fittings.

## MOUNTING ARRANGEMENT

Sterilizer is designed for freestanding or recessed mounting through one or two walls. All sterilizer components are integrally mounted within sterilizer confines of footprints. Each sterilizer is equipped with adjustable leveling legs.

## OPTIONAL FEATURES

**GMP or NON-GMP applications** The BPS sterilizer platform extensively covers both GMP manufacturing and research applications by selecting the applicable configuration - e.g., supplying the sterilizer with pure steam or plant steam.

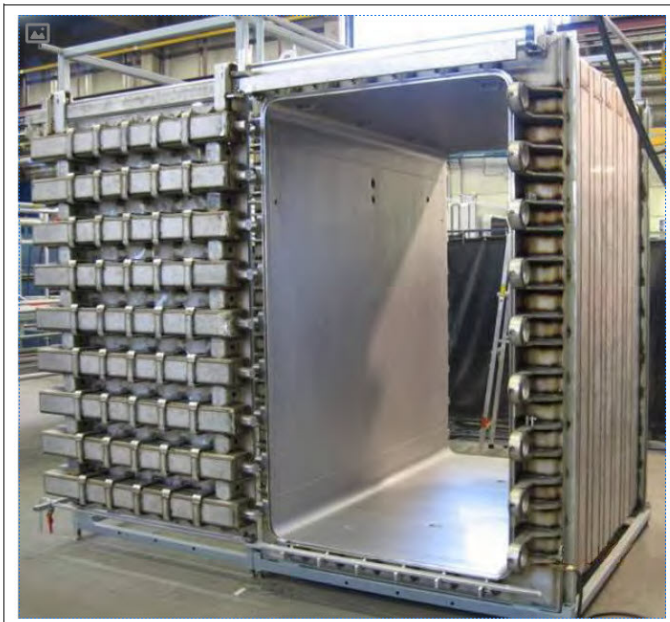
1. TRI-CLAMP is a registered trademark of ALFA LAVAL INC.

**Automatic Air Filter Sterilization** cycle used for sterilization of the 0.2 mm sterile air filter, filter housing and piping (from filter housing to chamber air shut-off valve) either prior to or after cycle processing.

**Air Filter Test Ports** add valves and ports to perform integrity test in-place.

**Decontamination Cycle** is used in situations where chamber condensate may be contaminated and cannot be drained before sterilization. During this cycle, steam is introduced into chamber through drain line, and all effluent is sterilized before discharge. Decontamination cycle includes process B cycle. Decontamination cycle includes compressed air back-up.

**Decontamination Cycle with VIRASURE™ Air Decontamination System.** A fixed decontamination pre-conditioning phase is added to pre-conditioning menu selection. The pre-conditioning phase uses one vacuum pulse that is pulled through a dedicated heated stainless steel coil followed by an in-line 0.1 µm stainless steel strainer. Air exiting the chamber through the element is forced to contact the stainless steel coil and then pulled through the heated stainless steel strainer. The assembly can be set to heat up within a temperature range of 350° C [662 °F] as standard. The entire element is welded together and monitored for temperature at the beginning of the system and end to ensure consistent temperature and consistency of air flow. For more information please request a copy of THE VIRASURE TECHNICAL MONOGRAPH.



**Full Jacket Chamber**

**Operator Interface Control Function (Double Door Units Only)** permits operator to select and initiate cycles from operator interface panel located on sterile (non-operating) end of sterilizer.

**Cascade Jacket Cooling** enables cycle operation with zero cooling water consumption. This is achieved by using the vacuum pump to flow water through a jacket manifold/cascade system that absorbs heat from the load in the chamber. The heated water passes through a heat exchanger to cool it before returning to a supply tank. The system operates in a closed loop so that water is not sent to drain during the cooling process. Jacket steam condensate is also

used to create the cooling media so no supplemental domestic water is required for cooling. The system requires attachment to the facility's closed loop chilled/tower water cooling system. This option can be selected with cycles C, CX and SAMX.

**Six-Channel Paperless Recorder** records chamber pressure and temperature in electronic format. Data is stored in 21 CFR Part 11 compliant system. An additional RTD is installed for load temperature recording.

**Mirror Construction** reverses standard positioning of sterilizer chamber and service area. In mirror construction, as viewed from operating end, sterilizer chamber is relocated to right side and service side is relocated to left side. Standard configuration is chamber on left and service on right side (as viewed from operating side).

**Air Differential Seal (Non-Operating Side)** is fabricated from stainless steel, and is affixed to sterile end. Adjustable interface panels are provided at top, bottom, and sides, with a silicone gasket to seal unit system to facility structure. This seal is used to help maintain room air pressure

**Bioseal (BL3/BL4 Environment)** is located on sterile end of sterilizer to prevent passage of airborne microorganisms from one classified area to another. The seal is used most often in Biolevel 3 (BL3) and Biolevel 4 (BL4) applications. The bioseal includes compressed air back-up on the door seal.

**Side Enclosure Panels** are installed on the right and/or left side of the sterilizer framework as specified. Side panels are constructed of stainless steel.

**Seismic Restraints** provided, along with an anchoring report in conformance with latest seismic Zone 4 requirements

**Modular Electric Steam Generator (ESG)** Produces steam of a quality equal to the feed water that is introduced into the system. The modular electric steam generator has 1–3 equal power rating steam generator elements depending on electric power and steam generation capacity required. Depending on sterilizer chamber size and number of generator elements, the Modular ESG may be installed on top of the sterilizer unit (chamber door sizes 66 range only), within the equipment mechanical area or independently beside the sterilizer equipment (other chamber door sizes range). The modular ESG does not include any entrainment device to remove pyrogens. The modular ESG vessel is 316/316L SS and is ASME or PED rated. Applicable connection voltage is provided within the main equipment configuration selection. The BPS control system provides start/stop handshake signal to the modular ESG. Electric power and capacity range is 35/70/105 kW.

**Feed water booster pump for Modular ESG** This option provides a feed water booster pump for the modular ESG option. This option is required if the facility feed water pressure is below 4 bar [58 psig].

**EN285 Independent Monitoring** Designed to enable meeting applicable EN 285 equipment and performance requirements for porous load BPS sterilizer cycles B and BX. This option provides accessories for meeting the EN 285 standard requirements for independent recording and monitoring of critical process sensors for a sterilization cycle (temperature and pressure). Independent indication sensors for drain line temperature and pressure are added. The dedicated process control sensors for temperature and pressure are connected to the PLC. The independent indication sensors for

temperature and pressure are connected directly to an electronic chart recorder for recording the independent indication sensor values and comparison of these to the process control sensors values.

**EN 285 Compliance Accessories** These accessories are designed to meet requirements for a porous load sterilizer and have ability to demonstrate performance requirements of EN 285 according to test clauses 15–22. System includes sample ports to facilitate testing in regard to non-condensable gases, superheat, and dryness fraction. The option includes an air detection system which uses an additional temperature probe located in the drain line.

**Additional Temperature Probes** One product load probe is provided. The probe can be placed in product during a sterilization cycle for controlling and monitoring purposes. The “Additional Temperature Probes” option provides three additional probes, bringing the total to four.

**Extended Documents** In addition to standard validation document package, extended document packages are available to assist IQ/OQ and validation. Packages include:

- Extended pressure vessel
- Extended piping
- Extended control system
- FAT procedures and results
- Manufacturing procedures
- Surface finish reports chamber and piping
- Loop diagrams
- Component data sheets

**Cooling Water Savings Package** utilizes the facility’s closed loop water supply and heat exchanger system (not provided by STERIS) to cool the vacuum pump and effluent.

**Heated Pressurized Pulsed Air Drying** uses steam heated heat exchanger to provide hot pressurized air during post conditioning phase. This method is recommended for porous rubber loads, e.g., stoppers.

**Pure Steam PRV** includes stainless steel PRV to reduce steam pressure coming into the unit that is > 3 bar (45 psig).

**Utility Supervision and Monitoring** includes pressure gauges and switches to monitor incoming steam, air and water pressure. Alarm is included to indicate if pressure is below requirements.

**Spare Parts Kit** A spare parts kit containing selected mechanical and electrical components is provided. The kit includes a two year supply (with normal maintenance and operation of the sterilizer) of these selected items.

**36–Thermocouple Feed-Through Assembly** is provided for use with 38 mm (1–1/2”) TRI-CLAMP chamber penetration to simplify the validation process.

**Electronic Data Security** Upgraded Siemens control package provides 21 CFR Part 11 and EU Annex 11 capability. System includes electronic batch report data, audit trail and batch cycle data that is viewable from the HMI screen via appropriate password setting, E-signature for final batch verification/acceptance, local removable memory for temporary data storage of audit trail and batch cycle data, and data export capability.

**Electronic Data Security with Data Archiving and Enhanced Batch Reporting** Upgraded Siemens control package provides 21 CFR Part 11 and EU Annex 11 capability. System includes electronic batch report data, audit trail, and batch cycle data (formatted into a PDF file) that is viewable from the PC screen via appropriate password setting, E-signature for final batch verification/acceptance, local hard drive for data storage of audit trail and batch cycle data, and data export capabilities.

**Electronic Data Security With Data Archiving and Enhanced Batch Reporting ñ Allen-Bradley.** This option provides 21 CFR Part 11 and EU Annex 11 capability upgrade to the Allen-Bradley control system. The features provided with this option are audit trail, local hard drive for storage of audit trail and batch cycle data, predefined batch report in PDF format that can be exported or printed, password protection features and E-signature for final batch verification/acceptance.

**Enhanced Dual Doors Unloading Side Controls for Electronic Data Security ñ Allen-Bradley.** This enhancement option provides an HMI panel for sterilizer unloading side to operate, verify and record cycle data within Electronic Data Security option for Allen-Bradley control system.

**VHP Ready System (see Note 5).** The VHP Ready System allows the use of a portable VHP Biodecontamination System such as VHP 1000ED or VHP ARD Biodecontamination Systems\* (sold separately). The unit is used for biodecontamination of heat sensitive products when the sterilizer chamber is not being used for steam sterilization. Ports are welded into sterilizer. Hoses are extended to front fascia of sterilizer and fitted with automated valves. The portable unit is manually connected to the sterilizer automated valves and a cable to sterilizer control. Operator selects the VHP cycle from the portable VHP Biodecontamination System and the steam sterilizer operator interface.

**Self-Cleaning Drain Strainer** With this option the drain line is fitted with a drain strainer with valve control on the strainer clean-out screen. During cycle the strainer is automatically cleaned of debris using water flush.

**\* See tech data SD840, SD716 and SD776 for information on these systems**

## NOTES

1. The drain line should have a 51 mm (2”) air-gap to prevent backflow.
2. The pipe sizes shown indicate terminal outlets only. Building service lines, provided by others, must supply the specified dynamic pressures and flow rates.
3. A non-fused, pad-lockable disconnect switch is provided with the sterilizer.
4. The clearances shown are the minimum clearances for installing and servicing the equipment.
5. The VHP options are to be used by trained and certified Applicators who have successfully completed both the STERIS Training and Certification Course for applicators of Vaprox Hydrogen Peroxide Sterilant and the VHP pertinent Biodecontamination System Operator Course. Certification must be active and in force for all Applicators of Vaprox Hydrogen Peroxide Sterilant.

## UTILITY REQUIREMENTS\*

\* See drawings for specific quantities and additional notes.  
Utility connection sizes and flow rates are dependent on the

chamber size selected. Refer to STERIS equipment drawing for details.

Refer to the Following Equipment Drawing for Installation Details	
Equipment Drawing Number	Equipment Drawing Title
329343	Finn-Aqua BPS GMP Steam Sterilizer 66X
329341	Finn-Aqua BPS GMP Steam Sterilizer Pit Mounting

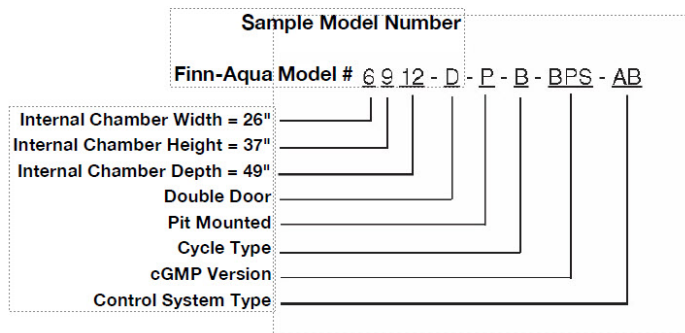
Common Finn-Aqua BIO Pharma Series (BPS) Sterilizer Models		
Typical Sizes*	Nominal Chamber† Size - W x H mm (inches)	Internal Chamber Depth - mm (inches)
666, 669, 6612, 6615	650 x 650 (26 x 26)	650, 950, 1250, 1550 (26, 37, 49, 61)
699, 6912, 6915	650 x 950 (26 x 37)	950, 1250, 1550 (37, 49, 61)
61212, 61215	650 x 1250 (26 x 49)	950, 1250, 1550 (37, 49, 61)
999, 9912, 9915	950 x 950 (37 x 37)	950, 1250, 1550, 1854 (37, 49, 61, 73)
91212, 91215, 91218	950 x 1250 (37 x 49)	1250, 1550, 1850 (49, 61, 73)
121212, 121215	1250 x 1250 (49 x 49)	1250, 1550, 2150 (49, 61, 85)
121521	1250 x 1550 (49 x 61)	2150, 2450, (85, 96)
122121	1250 x 2150 (49 x 85)	2150 (85)

\* Additional sizes are available; please consult your STERIS sales representative for further details

†. See detailed drawing for external dimensions. Actual load dimensions may differ.

Chamber Size Key to Model Numbers*	
Number	Size: mm (inches)
6	650 (26)
9	950 (37)
12	1250 (49)
15	1550 (61)
18	1850 (73)
21	2150 (85)

\* Additional product key characters may apply- see technical specification



## Selections Checked Below Apply To This Equipment

### DOORS

- Single
- Double

### MOUNTING CONFIGURATION

- Floor
- Pit

### CYCLE OPTIONS

- Cycle C
- Cycle BX
- Cycle CX
- Cycle SAMX
- Decontamination Cycle
- Decontamination Cycle with VIRASURE™ Air Decon System

### TERMINAL CYCLE OPTIONS

- Cycle AC (on special request)
- Cycle RP (on special request)

### CONTROL SYSTEM

- Allen-Bradley PLC Control
- Siemens PLC Control

### OPTIONS

- Heated Pressurized Pulsed Air Drying
- Pure Steam Supply
- Plant Steam Supply
- Cooling Water Savings Package
- Cascade Jacket Cooling
- Automatic Sterilization of Air Filter
- Operator Interface Control Function (Sterile Side)
- Control System, Remote Mounted
- Two-piece construction
- Mirror Construction, Chamber Right Side
- Bioseal (BL3/BL4 Environment) (Sterile Side)
- Seismic Anchorage Restraints and Calculations
- Enclosure Side Panels
  - Right
  - Left
- 36– Thermocouple Feed-Through Assembly
- Modular Electric Steam Generator (35/70/105 kW)
- Electronic Data Security – Siemens
- Electronic Data Security with Data Archiving and Enhanced Batch Reporting – Siemens
- EN285 Compliance Accessories
- VHP Ready
- Self Cleaning Drain Strainer
- Separate 3-phase and 1-phase connections
- Air Differential Seal (Sterile Side)
- Air Differential Seal (Non-sterile Side)

### OPTIONS (CONT'D)

- Feed Water Booster Pump for Modular ESG
- Extended Manufacturing Procedure Documentation
- Extended Pressure Vessel Documentation
- Pure Steam PRV
- Air Filter Test Ports
- Utility Supervision and Monitoring
- Six-Channel Paperless Recorder
- Electronic Data Security With Data Archiving and Enhanced Batch Reporting – Allen-Bradley
- Enhanced Dual Doors Unloading Side Controls for Electronic Data Security – Allen-Bradley
- EN285 Independent Monitoring

### ACCESSORIES

- Loading Equipment
- Loading Cart (incl one wire shelf)
- Wire Shelf for Loading Cart
- Perforated shelf for loading cart
- Transfer Trolley

Item:	
Locations:	

**For Further Information, contact:**



STERIS Corporation  
5960 Heisley Rd.  
Mentor, OH 44060-1834 ■ USA  
440-354-2600 ■ 800-548-4873  
[www.steris.com](http://www.steris.com)

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

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

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