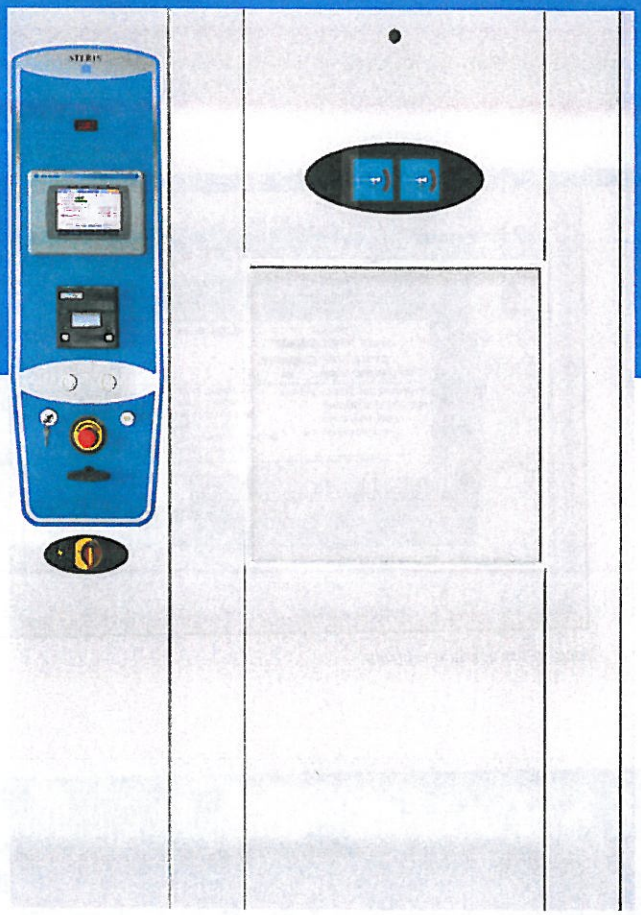
FINN-AQUA® GMP BIO PHARMA STERILIZER (BPS)

Design and precise engineering expertise that address the specific economic and technical challenges of the biotech and biopharmaceutical industries



STERIS®

Life Sciences

STERIS: A Tradition of Excellence

STERIS has the experience and proven reputation as the leader in GMP sterilizers and sterile processing equipment. With the Finn-Aqua BPS series of GMP steam sterilizers, we've used our rigorous design and precise engineering expertise to address the specific economic and technical challenges of the biotech and biopharmaceutical industries.

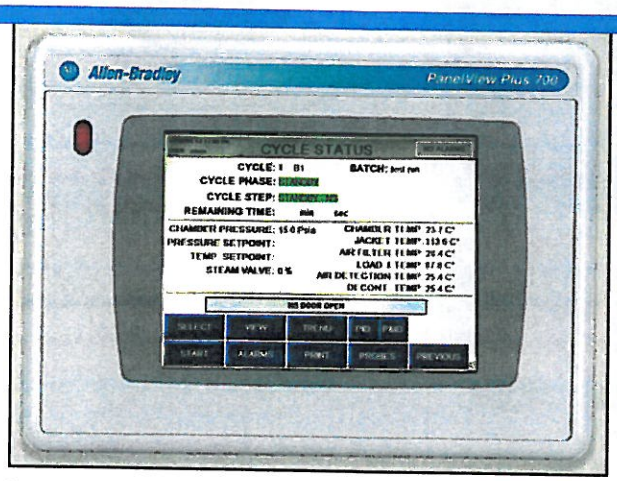
A Full Line of GMP Sterilizers

The Finn-Aqua BPS sterilizers are available with multiple chamber sizes with a choice of various sterilization processes. These sterilizers will satisfy the most basic needs and the specialized requirements of any biotech or biopharmaceutical application.

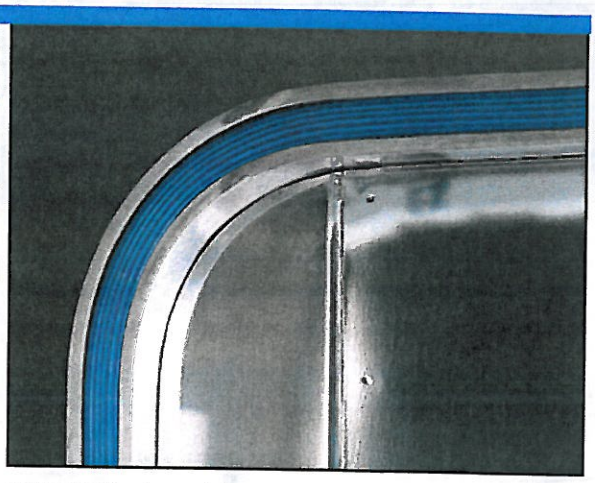
STERIS: An Expert Partner

A partnership with STERIS extends far beyond the delivery of high-quality equipment. Consultation, installation, documentation, service, and application support are essentials of the STERIS tradition. To help you achieve new levels of productivity and profitability from your BPS sterilizer, STERIS offers:

- > Facility design support
- > Installation supervision and start-up services
- > Validation support
- > Preventative maintenance programs
- > 24/7 technical support
- > Comprehensive Factory Acceptance Testing (FAT)
- > Extensive documentation packages
- > On-site qualification and calibration services
- > Cycle development and process selection support



Easy-to-use operator controls



Maintenance free door gaskets

Cycle Versatility For Multiple Applications

Each process type offers a high degree of cycle versatility, providing the flexibility of using the same sterilizer for many types of loads.

Dry Goods and Porous Loads

> Suitable for items such as equipment parts, filters, empty containers, tubing, rubber goods, and textiles.

> Adjustable vacuum and pressure rates, depth, and dwell time in both pre- and post-conditioning phases – for fast and efficient processing.

Media and liquid

> Efficient forced air removal for media and liquids using low pressure, rapid vacuum pulses.

> Forced air removal for liquids in open containers.

> Optional direct air cooling with sterile air overpressure to prevent liquid loss

> Optional indirect water cooling in chamber jacket for reduced cycle times.

Safety Above All

STERIS never compromises on matters of safety. Viewing the requirements of regulatory standards as a first step, STERIS products are designed for maximum user and process safety. The BPS line of sterilizers feature:

> Redundant mechanical and control system interlocks that ensure worker safety and protect product load
> A unique door sensory system that reverses when obstructed to protect against operator injury during loading and unloading
> Ergonomic design for easy loading and unloading of heavy and/or hot materials

Unsurpassed Reliability

STERIS recognizes that reliability is one of the most important requisites for any sterilizer. In the BPS line, STERIS has combined a proven design with precision engineering and durable construction to provide long lasting performance.

> 316L stainless steel chamber construction. Chamber is jacketed for long life and excellent performance.
> Commercially available, reliable components for maximum uptime.
> Commercial, industrial-grade programmable logic controllers (PLC) from Allen Bradley or Siemens provide established reliability and lifetime product support.
> Two-stage vacuum pump for quieter operation and longer intervals between regular maintenance.

Customized To Meet Your Needs

Considering the wide variety of biopharmaceutical applications, the BPS line of sterilizers was designed for flexibility. Customization and function are vital to productivity and profitable performance. These sterilizers help maximize both, in installation and operation.

> Up to 20 individually configured cycles with easy parameter selection for optimized performance.
> Optional decontamination cycle for sterilization of all chamber effluents prior to discharge to the drain.
> Configured with vertical sliding door (66 series) or side-sliding door design (69 series and larger).
> Operator controls can be mounted to either the left or right of the sterilizer door for easy, convenient access. Controls can also be remotely mounted up to 33 feet (10 meters) away if desired.
> All piping and controls are configured within the confines of the installation footprint to conserve space. No separate framework is required.

Ready For Fast Validation

STERIS offers a lifecycle approach to ongoing regulatory compliance – for speed and efficiency that can deliver significant cost savings.

Prospective Validation Before Delivery

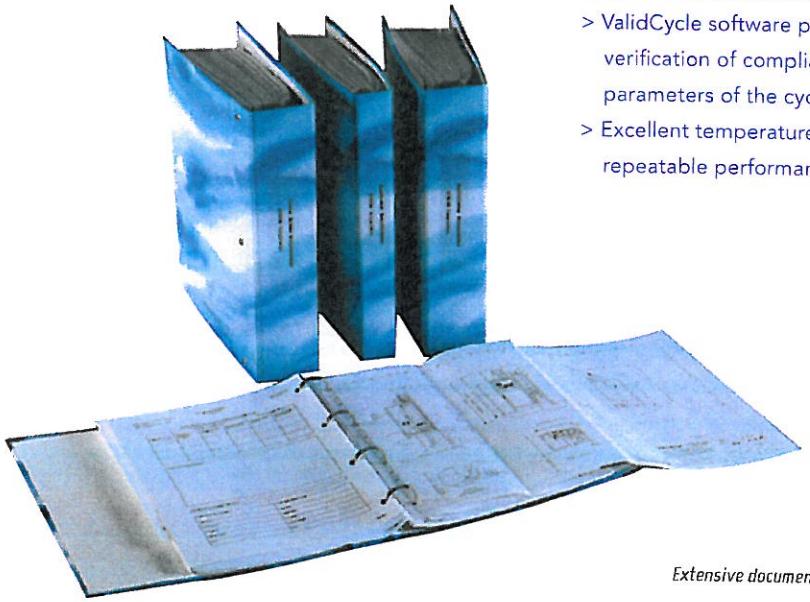
> Extensive FAT Testing Procedures and Results
> Complete Factory Acceptance Testing to simulate the IQ/OQ process

On-site Qualification

> Optional site acceptance and IQ/OQ performance testing

Repeatable, Documented Evidence

> ValidCycle software provides automated and documented verification of compliance for every cycle by comparing the parameters of the cycle in process to a pre-validated cycle.
> Excellent temperature control and distribution provide repeatable performance.



Extensive documentation packages

Cost Efficiency For Today's Biopharmaceutical Industry

The BPS line of sterilizers are designed with cost efficiency as a priority.

> User-friendly controls that reduce training time and the likelihood of costly operator errors.
> Readily accessible, industry-standard components for easy maintenance and minimal downtime.
> Designed for fast and simple installation with no subassemblies or field wiring required.

STERIS: Technological Innovations with Proven Worldwide Applications

STERIS Life Sciences is the recognized expert in preventing contamination by providing superior products and services throughout the world. Our unique integrated offering of validated capital equipment, cleaning chemistries, and services allows STERIS to support the pharmaceutical process from research and discovery to manufacturing.

At STERIS Life Sciences, we help customers achieve business-critical goals – such as streamlining operations through automation, enhancing cost-efficiencies through centralization, and improving time-to-market through faster validation – with our comprehensive family of leading technologies.

Our commitment to furthering the science of contamination control is stronger today than ever. In fact our product offerings are recognized worldwide as industry standards.

STERIS offers a wide range of innovative, high quality solutions for contamination control throughout your research and production areas.

> Finn-Aqua® GMP Steam Sterilizers
> Finn-Aqua® WFI Water Stills
> Finn-Aqua® Pure Steam Generators
> VHP® Biodecontamination Systems
> (CED) Continuous Effluent Decontaminators
> Reliance® and Hamo® Washing Systems

We provide a host of solutions expressly developed for particular market sectors. For example we offer an extensive line of aqueous-based cleaning agents and microbiological control products specifically formulated to address the unique challenges of the biotech and biopharmaceutical industries.

In addition, we provide on-site training, educational seminars, and technical service and support to keep employees up-to-date on regulatory compliance issues, product safety, new technologies, and protocols.

STERIS support is available whenever and wherever you need it through our worldwide manufacturing and distribution network.

STERIS®

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Document # M2995EN.2006-04, Rev. A
GPSI Printed 04/2006. 2500

STERIS®

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

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 ±0.5°C (±0.9°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 only - some details may vary.)

The Selections Checked Below Apply To This Equipment

MODEL/CHAMBER DEPTH
See chart on last page for most commonly available model sizes and chamber depths

DOORS
- ☐ Single
- ☑ Double

MOUNTING CONFIGURATION
- ☑ Floor
- ☐ Pit

CYCLE OPTIONS
- ☐ Cycle CA
- ☐ Cycle C
- ☐ Cycle CX
- ☐ Cycle SAMX
- ☐ Decontamination Cycle

CONTROL SYSTEM
- ☑ Allen-Bradley PLC Control
- ☐ Siemens PLC Control

OPTIONS
- ☑ Heated Pressurized Pulsed Air Drying
- ☐ Cooling Water Savings Package
- ☐ 21 CFR Part II Compliant Control System
- ☐ Automatic Sterilization of Air Filter
- ☐ Operator Interface Control Function (Sterile Side)
- ☐ Control System, Remote Mounted
- ☐ Three-Channel Pen Chart Recorder
- ☐ Mirror Construction, Chamber Right Side
- Air Differential Seal
  - ☑ Sterile Side
- BioSeal (BL3/BL4 Environment)
  - ☐ Sterile Side
- ☐ Seismic Anchorage Restraints and Calculations
- ☐ Enclosure Side Panels
  - ☐ Right
  - ☐ Left
  - ☐ Back
- ☐ 36-Thermocouple Feed-Through Assembly
- ☑ Process Contact Chamber Surface Finish <0.6 µ meters Ra
- ☐ Electric Steam Generator (for units with door size 66 only)

OPTIONS (Cont'd)
- ☐ HTM 2010 Compliance Accessories
- ☐ Probe for Load Temperature
- ☐ VHP® Ports
- ☐ VHP® Ready
- ☐ VHP® Combination
- ☐ Spare Parts Kit
- ☐ Extended Manufacturing Procedure Documentation
- ☐ Extended Pressure Vessel Documentation
- ☐ Pure Steam PRV
- ☐ Air Filter Test Ports
- ☐ Utility Supervision and Monitoring
- ☐ Six-Channel Paperless Recorder
- ☐ ValidCycle Software

ACCESSORIES
- ☑ Loading Equipment

See separate product literature.

Item _____

Location(s)_____

_____

STANDARDS

The sterilizer is manufactured in an ISO 9001, ASME Section VIII Division 1, PED Module H/H1 and EN729-2 certified facility and meets applicable requirements of the following listings and standards:

- **GMP**
- **GAMP 4**
- **EN285**
- **EN554**
- **Underwriters Laboratory (UL) Standard 508**
- **Canadian Standards Association (CSA) Standard C22.2 No. 125**
- **ASME Code, Section VIII, Division 1** for unfired pressure vessels.
- **CRN (Canada)**
- **European Directives (Europe) Pressure Equipment 97/23/EC**
  Machinery 98/37/EC
  Low Voltage 73/23/EEC, 93/68/EEC Electromagnetic Compatibility (EMC) 89/336/EC, 93/68/EEC, 92/31/EC

FEATURES

Control System can be configured with an Allen-Bradley PLC control or a Siemens PLC control. Control system monitors and controls all sterilizer operations and functions. The PLC control allows up to 20 sterilizing cycles to be configured to meet the specific processing requirements. All control system components are mounted in an integral cabinet. The control cabinet can be equipped with a 10 m (33') interface cable for optional remote mounting. The Finn-Aqua batch process is not permanently saved on any magnetic media during operation and therefore does not fall within the scope of 21 CFR Part 11. Compliance of optional data storage equipment with 21 CFR Part 11 is available as an option, if required.

Operator Interface consists of either a 7" (Allen-Bradley) or an 8" (Siemens) color touch-sensitive screen and integral impact printer located on the non-sterile (operating) end of the sterilizer. All sterilizer functions, including cycle initiation and cycle configuration, are performed using the touch screen. Displayed messages are complete phrases with no codes that need to be cross-referenced. The screen also displays any abnormal (alarm) conditions that may exist in or out of a cycle.

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

A 42-column impact printer provides real-time process data and alarms in a comprehensive batch report.

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

Horizontal or Vertical (66 only) Sliding Door(s) are pneumatically operated using buttons located on the control panel. Each door is equipped with a steam-activated, non-lubricated gasket. When the cycle is complete, the gasket retracts under vacuum into a machined groove in the sterilizer's end frame.

Equipment Documentation Package includes three copies of the user manual and one copy each of the manufacturing documentation, control system documentation, and qualification documentation. The package contains information required to assist in the 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 the Calibration Mode, accessible through the touch-screen display, and accomplished using external temperature and pressure sources. The 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 DESCRIPTION

Standard Process Cycles

Depending on the cycle options selected, the sterilizer is factory-programmed with the 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 an air-removal phase using vacuum and steam pulses. Alternatively, preconditioning could consist of a forced air removal. Forced air removal removes air from the chamber by introducing steam to force the air out through the drain line system. The vacuum pump is simultaneously operated to assist in evacuating the 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 CA** is an optional cycle designed to process liquid products in vented vials that require cooling after sterilization. Sterile air over-pressure prevents liquid from boiling during the cooling phase. Jacket steam is vented. Cooling water is not circulated in the jacket. The sterilization process CA includes the process B cycle. CA process cooling may precede or follow a vacuum drying or pulse drying phase. Cycle CA includes compressed air back-up for the door gasket(s).
- **Cycle C** is an optional cycle designed to efficiently process liquid products such as SVP's and LVP's packaged in vented containers that require fast cooling during the post-conditioning phase. The cooling phase is designed to cool

the chamber by flowing cooling water through the jacket with simultaneous air over-pressurization in the chamber. The process cools the load and prevents the product from boiling. Cycle C sterilization process includes the Process B cycle. Cycle C includes compressed air back-up for the door gasket(s).

- **Process CX** (Ejector-enhanced indirect water cooling) is designed to replace the conventional fan assembly in sterilizer chamber. An air ejector cooling process provides similar or higher air circulation efficacy than a conventional fan. The ejector process is designed to speed up the cooling process by generating a symmetrical air flow pattern for transferring heat from the load to the water-cooled chamber walls. Chamber pressure is controlled automatically by bleeding the excess air out. There are no moving parts or penetration seals through the chamber to wear. Additional air is required for this option. 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, backs, etc. The SAMX process uses one or multiple air ejectors to provide the required differential pressure in the chamber and to circulate the steam and air mix within the chamber. The air ejector(s) occupy only 4 inches (102 mm) of space in the top of the chamber. There are no moving parts or penetration seals through the chamber to wear. Additional air is required for this option. Air consumption is based on size of vessel. See equipment drawing.
- **Leak Test Cycle** is a standard cycle provided for verification of the chamber's 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 the 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, the 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 the door gasket(s) is provided on all double door sterilizers and with C cycle, CA 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 the sterilization cycle is complete. The 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 the chamber and jacket limit the amount of pressure buildup so the rated pressure of the vessel is not exceeded.

Steam Valve Interlock prevents the steam valve from opening when the door is open.

Pressure Interlock prevents the user from opening the door when the 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. The pressure vessel inner shell (chamber) and outer shell (jacket) are designed to withstand operating pressures from full vacuum to 3.1 bar (45 psig). The chamber and jacket are constructed of stainless steel. The chamber interior is glass-beaded to a fine finish.

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

The steam-supply openings, inside the chamber, are shielded by a full-length baffle to evenly distribute the clean steam as it enters the chamber. A 63 mm (2-1/2") chamber penetration with tri-clamp connections is provided for validation purposes.

Chamber Door(s)

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

Facia Panel(s)

The sterilizer's framework is enclosed by a front facia panel, located on the operating end. If the sterilizer is equipped with double doors, a back facia panel encloses the sterile end. Facia panel(s) is constructed of stainless steel with No. 3 brush finish.

Vacuum System

A two-stage, water ring seal-type pump is used for evacuating the sterilizer chamber. The pump is sized to create a 0.2 bar (3 psia) vacuum in five minutes utilizing 20°C (68°F) sealing water.

Air Filter

An air filter, used for chamber pressure equalization, is a 0.2 µm hydrophobic bacteria-retentive filter. The filter is steam sterilizable up to fifty times.

Piping

The process piping for clean steam and sterile air to chamber, and drain piping up to the first valve is constructed of AISI 316L stainless steel. All piping connections terminate within the confines of the sterilizer and are accessible from the right side of the 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

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

OPTIONAL FEATURES

Automatic Air Filter Sterilization cycle is used for sterilization of the 0.2 µm 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.

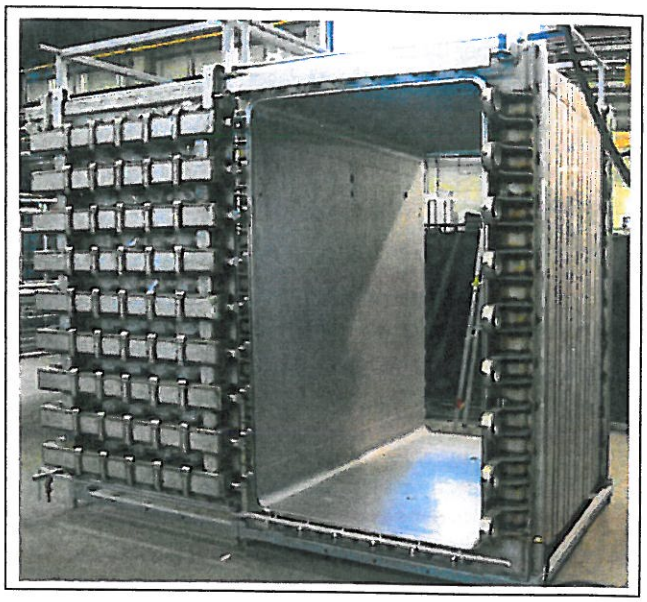
ValidCycle™ software provides automated and documented verification of compliance for each cycle by comparing the parameters of the cycle in process to a pre-validated cycle.

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

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

Three-Channel Pen Chart Recorder records chamber pressure and temperature for each channel in a different color. An additional RTD is added in the drain for independent recording. The recorder is integrally mounted in the cabinet.

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



Full Jacket Chamber

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

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

BioSeal (BL3/BL4 Environment) is located on the sterilizer's sterile end 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. Bioseal includes compressed air back-up on the door seal.

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

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

Integral Electrical Steam Generator. The Integral Electrical Steam Generator is designed to produce steam of a quality equal to the feed water. The Integral Electrical Steam Generator does not include any entrainment device to remove pyrogens. The feed water for the Integral Electrical Steam Generator system should be either Deionized (DI), Reverse Osmosis (RO) or Water for Injection (WFI) quality water. GMP requirements dictate that steam must not contain any boiler additives. The system is built into the sterilizer service area and includes the feed water pump, steam generator and associated controls. This option increases the height or width (depending on installation) of the unit by 800 mm (31"). Electrical steam generator is available for sterilizers with door size 66. For specific capacities, connections and utility consumption values, please refer to the dimensional drawing.