

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.

Expanded options to allow you to customize the sterilizer to meet your processing needs.



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.



Easy-to-use operator controls



Air ejectors in chamber for SAMX cycle

Wide Selection of Features and Options

We offer a selection of standard features and options on the BPS GMP sterilizer to provide the user with a wide variety of upgrades to the basic sterilizer. From the expansive list, one can configure a sterilizer to process anything from the most basic product to those that require specialized parameters and control. Components and processes such as a stainless steel filter housing, automatic sterilization of air filters, and sterile air integrity test ports and valves are some of the features that are standard options on the BPS.

The SAMX (steam-air mix) cycle option is a terminal process cycle designed to sterilize liquid products in flexible containers such as IV bags, liquids in sealed plastic bottles, filled syringes, blister packs and the like.



The space-saving air ejector pressurizes the chamber at a controlled rate and circulates the air and steam to provide an even distribution of heat and steam throughout the entire cycle. This design, which replaces a conventional fan, requires significantly less space, eliminates a rotating shaft and seal into the chamber, and has no moving parts to wear down over time. You can rely on fast, effective processing of flexible containers time after time. Optional VHP applications are available on the BPS sterilizer for those wishing to optimize their throughput by using the same chamber for both steam and VHP processing.

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.

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

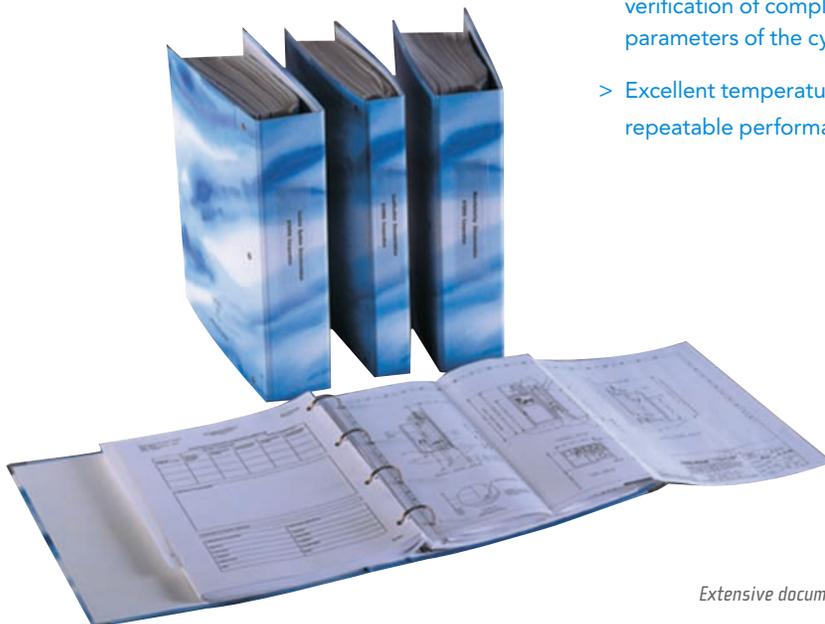
- > Extensive FAT Testing Procedures and Results.
- > Complete Factory Acceptance Testing to simulate the IQ/OQ process.

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

Operating Efficiency For Today's Biopharmaceutical Industry

The base BPS 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.
- > Selectable options to build a sterilizer to meet your needs.

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 Still.
- > 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 Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.steris.com

STERIS OFFICES WORLDWIDE

Belgium	32 2 523 2488	Italy	39 022 130341
Brazil	5511 5053 9823	Japan	81 78 321 2271
Canada	800 661 3937	Latin America	800 884 9550
China	86 21 6137 1166	Nordic	358 9 25851
France	33 2 38 70 83 50	Singapore	65 68 41 7677
Germany	49 2203 890 6969	Spain	34 916 585 920
Greece	30 210 6800848	Switzerland	41 32 376 0200
		United Kingdom	44 1256 840400

Document # M2995EN.2009-03, Rev. C
Printed 03/2009, 3000

©2009 STERIS Corporation.
All rights reserved. Printed in USA.