



cGMP

Steam & Terminal Sterilizers

STERIPRO • VENTIPRO • AQUAPRO • COMBIPRO



cGMP Sterilization
& Laboratory Equipment Solutions

BMT USA

Your partner around the world for sterilization
and laboratory equipment solutions.

BMT USA is a member of the MMM Group, a global supplier of sterilization and life science solutions with offices in over 20 countries and manufacturing facilities in the United States, Germany, and Czech Republic. Since its establishment in 1954, the MMM Group has delivered specialized solutions with industry-leading quality to clients in the Pharmaceutical, Biotech, Healthcare, and Food and Beverage production markets. Special attention is given to the quality, reliability, and serviceability of every unit to ensure complete satisfaction and the integrity of your processes.

cGMP Sterilization

Assuring the quality and safety of your products.

BMT USA understands the critical role of our sterilizers in preventing contamination and ensuring the quality and safety of pharmaceuticals. Our tight adherence to current Good Manufacturing Practices (cGMP), combined with fully sanitary stainless steel construction and high-quality, non-proprietary components, ensures reliable performance with precise process repeatability for optimal outcomes. With a range of fully customizable steam and terminal sterilizer models, BMT USA can deliver a sterilization solution to meet your exact production requirements.

The right sterilization method for your production...



Saturated Steam



Hot Water Cascade



Steam-Air Mixture



3-in-1 Combination



Flexible Solutions

Every BMT USA sterilizer is built to meet your exact requirements. Flexible options for chamber capacity, Allen-Bradley or Siemens PLC-based control systems, integrated pure or clean steam generator systems, and programmable sterilization cycles allow for selection of the right equipment for your specific application.

Quality Built-In

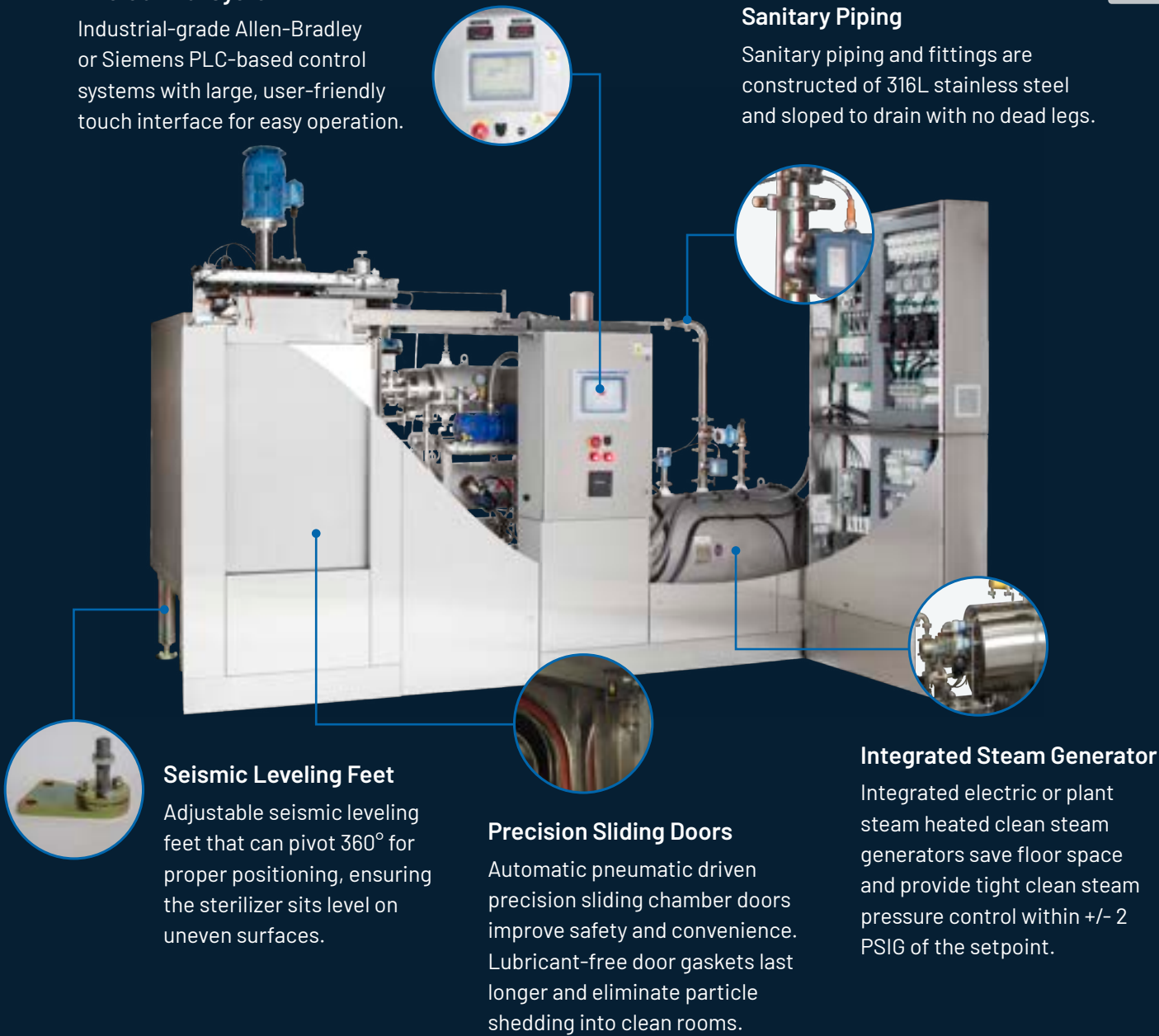
BMT USA sterilizers are designed and built with a focus on providing industry-leading quality in engineering, construction and workmanship. The chamber and jacket are constructed of 100% 316L stainless steel to ensure long life. The sterilizer frame and insulation covers are also stainless steel for greater durability and to prevent rusting. Only the highest quality, industrial-grade, non-proprietary components are used throughout.

PLC Control System

Industrial-grade Allen-Bradley or Siemens PLC-based control systems with large, user-friendly touch interface for easy operation.

Sanitary Piping

Sanitary piping and fittings are constructed of 316L stainless steel and sloped to drain with no dead legs.



Seismic Leveling Feet

Adjustable seismic leveling feet that can pivot 360° for proper positioning, ensuring the sterilizer sits level on uneven surfaces.

Precision Sliding Doors

Automatic pneumatic driven precision sliding chamber doors improve safety and convenience. Lubricant-free door gaskets last longer and eliminate particle shedding into clean rooms.

Integrated Steam Generator

Integrated electric or plant steam heated clean steam generators save floor space and provide tight clean steam pressure control within +/- 2 PSIG of the setpoint.

Engineered Features

BMT USA offers a range of features that enhance the efficiency, reliability, and serviceability of our sterilizers. Vertical and horizontal precision machined sliding doors are exceptionally smooth and provide a safer environment for operators. Door gaskets that reliably operate without the need for lubrication reduce maintenance and prolong life span. PLC-based control systems are intuitive and simple to operate, while providing the necessary sophistication for maximum flexibility and ease of validation.





Setting the standard for sterilizer quality and performance

Chamber Construction

BMT USA cGMP sterilizers are equipped with chambers made entirely of 316L stainless steel for superior durability. The chamber door is also constructed of 316L stainless steel. Precision machined door brackets retain the door on all four sides and ensure smooth travel and improved security throughout the sterilization cycle. All chamber connections are sanitary clamp type and sloped to drain. Lubricant free door gaskets last longer and eliminate particle shedding into clean rooms.

Repeatable Cycle

cGMP sterilizers are designed for use in pharmaceutical and biotech production facilities where repeatability is critical. All BMT USA cGMP sterilizers are equipped with high-performance vacuum pumps, along with high quality instrumentation and PLC-based control systems to ensure repeatable cycles regardless of changing environmental conditions.

Validation Testing

Validation is a critical concern when purchasing a cGMP sterilizer. Special attention has been given to the documentation and repeatability of each system. Every BMT cGMP sterilizer is subject to rigorous pre-validation testing at the factory and shipped with an extensive documentation package to help minimize the time required for on-site validation. IQ/OQ protocols and on-site execution are also available as options.



cGMP Steam & Terminal Sterilizers

Industrial-Grade PLC Control System

Secure, user-friendly control system for repeatable operation.

BMT USA cGMP sterilizers are equipped with industrial-grade Allen-Bradley or Siemens PLC control systems that provide superior reliability, serviceability, and cycle repeatability. The control systems are developed under the latest Good Automated Manufacturing Practices (GAMP) to ensure reliability and ease in validation. Each system is also supported with a comprehensive documentation package.

The control system can configure and store up to 50 sterilization cycles, which are accessed via a large touch screen operator interface and secured by multi-level user authentication. In pass-through units, an additional operator interface is mounted on the unload side of the sterilizer for cycle accept and pass-back functions as standard, with the option to upgrade to a PVP 1000 operator interface to enable full control on both ends.

If electronic data storage is desired, the control system can be provided with 21 CFR part 11 compliance when connected to a PC or central computer system. The control system can also be equipped with different types of printers and recorders for data storage on paper.



cGMP Steam & Terminal Sterilizers

Saturated Steam Sterilizers

Steripro saturated steam sterilizers are designed for production in pharmaceutical and biotech facilities where repeatability is critical. By utilizing efficient vacuum pumps, high quality instrumentation, and PLC control systems, Steripro sterilizers consistently deliver repeatable cycles with temperature distribution within the chamber better than +/- 0.5°C.

Steripro sterilizers can be customized to meet almost any size and capacity requirements, and can be equipped with a combination of programmable cycles utilizing vacuum or gravity air removal to effectively sterilize a wide range of materials and equipment.



Key Features

- Meets and exceeds US FDA cGMP standards.
- Temperature distribution inside the chamber better than +/- 0.5°C.
- Highly polished 316L stainless steel chamber.
- 316L stainless steel sanitary piping.
- Piping sloped to drain with no dead legs.
- Sanitary valves and components.
- Fully insulated chamber and piping to reduce utility consumption.
- High-grade, non-proprietary components.
- Automatic pneumatic driven precision sliding chamber doors.
- Lubricant-free door gaskets.
- Allen-Bradley or Siemens PLC control system.
- Extensive validation documentation.
- 21 CFR part 11 compliance for secure electronic data storage.

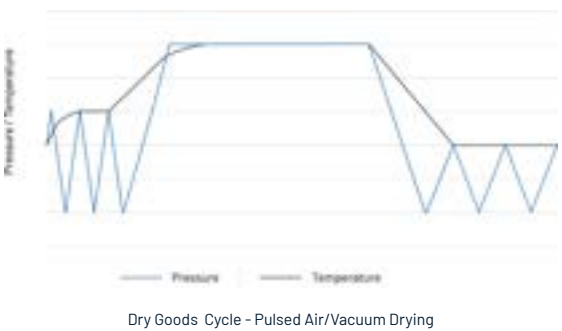
Sterilization Cycles

All BMT USA laboratory sterilizers can be programmed with a combination of sterilization cycles — with configurable parameters for each cycle phase — based on the type of load to be sterilized and the most efficient method of air removal for effective sterilization. The programmed cycle recipes are stored in the control system memory and can easily be recalled and started with the touch of a button on the operator interface. All recipes are protected from unauthorized changes via a multi-level authentication system.

Dry Goods Cycles - Vacuum Air Removal

Saturated steam process sterilizing at temperatures between 110°C up to 135°C provides effective sterilization of hard goods, filters, linens, porous materials, rubber stoppers, hoses, wrapped goods, and materials unaffected by vacuum.

Drying of the load is accomplished by fast exhaust and pulling a deep vacuum to remove moisture. Optionally, pressure pulses can be added to the end of the cycle, improving steam penetration for loads where trapped moisture can be difficult to remove. The air can also be heated to further aid in drying.

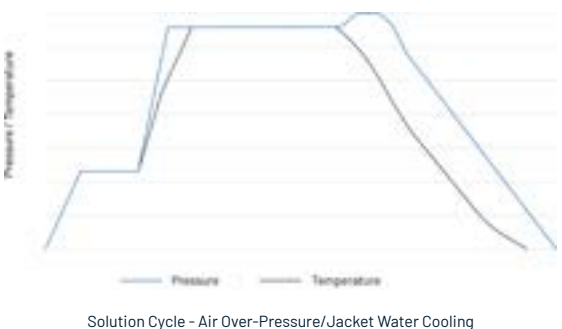
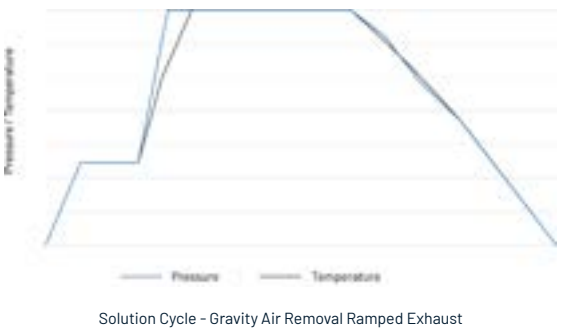


Solution Cycles - Gravity Air Removal & Air Overpressure/Jacket Water Cooling

Solution cycles are used for effectively sterilizing liquids in sealed, open or vented containers.

For open liquids, the load is preconditioned utilizing steam pulses. The cycle then heats to an exposure temperature of 110°C up to 135°C. After the exposure time is completed, exhaust ramping gradually cools the load.

For sealed liquids, cooling begins by injecting air at a pressure similar to that of the load to avoid breakage of the container. Cold water is then added to the chamber jacket to cool the load at a faster rate.



Aquapro

Hot Water Cascade Terminal Sterilizers

Aquapro hot water cascade sterilizers use the efficient heat transfer properties of recirculating water to deliver rapid terminal sterilization cycles, while being gentle enough to prevent damaging products and packaging that may be heat or pressure sensitive, including syringes, IV bags, BFS containers and ampoules.



Key Features

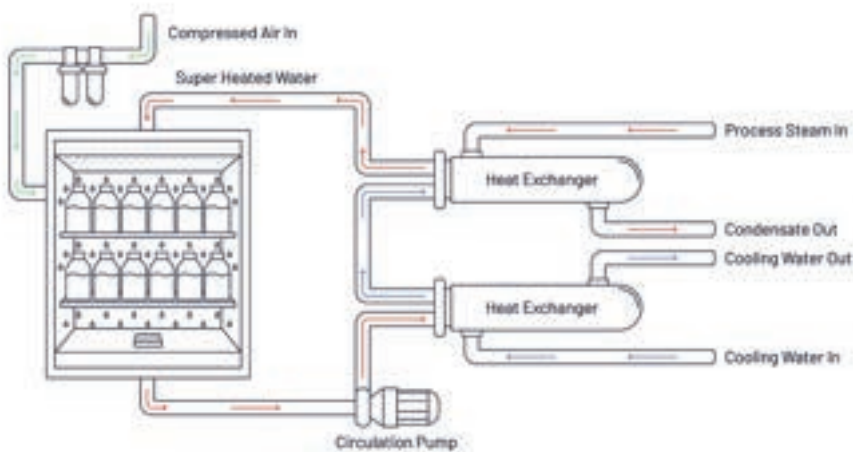
- Fast heating and cooling for gentle sterilization of heat-sensitive loads.
- Ideal for sterilization of liquids in sealed containers.
- No pure steam required as water is heated indirectly by plant steam.
- Allen-Bradley or Siemens PLC control systems.
- High capacity recirculation pump for even temperature distribution.
- External heat exchangers for heating and cooling of the recirculation water.
- Perforated tray for water distribution with holes on the front, back and sides to evenly heat the door and chamber surfaces.
- 316L stainless steel chamber and sanitary piping – piping sloped to drain with no dead legs.

Sterilization Cycle

Hot Water Cascade

The cycle begins by filling the chamber with purified water to a predetermined level. The water is circulated by a high-capacity pump through an external heat exchanger until reaching a set temperature between 110°C and 125°C. The heated water is then distributed through a perforated tray onto the load. The load is rapidly heated due to the efficient heat transfer properties of water. At the same time, compressed air is injected into the chamber at an over-pressure to compensate for the rising pressure that builds inside liquid containers when heated, protecting the integrity and shape of products and packaging.

After the exposure phase is complete, the circulating water is cooled by an external heat exchanger using chilled softened water, which has no direct contact with the circulating chamber water. The circulating water is then continuously sprayed over the load until cooled to ambient temperature. The hot water cascade cycle is the fastest and most gentle method of terminal sterilization.



Sterilization Process Overview

The Aquapro utilizes a high capacity water pump and large diameter piping to ensure high water flow rates. The recirculating water is heated and cooled by external heat exchangers. The heat exchangers are heated by plant steam and cooled by softened water as there is no direct contact with the recirculating chamber water. The recirculating water is directed to a perforated tray which evenly distributes the cascading water over the product. Due to the high flow rate of the cascading water, very even heat distribution is realized.

Ventipro

Steam-Air Mixture Terminal Sterilizers

Ventipro steam-air mixture sterilizers provide rapid and gentle terminal sterilization of liquids in heat or pressure-sensitive containers. Pure steam is utilized inside the chamber for heating the liquids and over-pressure filtered air is injected into the chamber to compensate for the rising temperature and pressure that builds inside the liquid container.

Internal fans mix the steam and air inside the chamber to ensure there are no cold pockets and provide uniform temperature distribution. Fast heating and cooling is achieved utilizing convection principles. At the end of the cycle, the product leaves the chamber dry and ready for labeling or additional handling.



Key Features

- Faster heating and cooling times than conventional steam sterilizers.
- Ideal for sterilization of liquids in pressure-sensitive containers such as PVC bags, plastic bottles, syringes, blister packs and glass.
- Product containers leave the chamber dry and ready for labeling.
- Allen-Bradley or Siemens PLC control systems.
- Unique sealing of the fan shaft for ease in inspection and maintenance.
- 316L stainless steel chamber and sanitary piping - piping sloped to drain with no dead legs.

Sterilization Cycles

Steam-Air Mixture Cycle

Effective sterilization of pressure sensitive products and packaging, including syringes, flexible plastic and sealed or vented glass containers.

Pure steam is pumped into the chamber while being injected with compressed air at a preset differential over-pressure. The steam and air are circulated and mixed by internal fans to ensure rapid heating to the user-configured exposure temperature, between 110°C and 135°C. The air over-pressure and saturated steam pressure are each independently controlled; however, both correspond to the temperature and pressure inside the load.

Once reached, the exposure temperature is maintained for a duration specified by the controller or a manually entered time period. After the exposure countdown completes, the pure steam is stopped and the fans begin blowing cool air across the load.

During the cooling step, a preset support pressure is maintained in the chamber to prevent damaging the product containers. The load is cooled to a safe temperature and the pressure in the chamber is vented to atmosphere before the door can be opened.



High Performance Fans

Ventipro sterilizers are equipped with high performance fans that intensify the streaming of the steam-air mixture through the chamber and around the load. The fan wheel and all parts mounted inside the chamber are made of 316L stainless steel. The motor is installed outside the chamber and connected to the fan wheel with a unique sealing system that allows for ease in inspection and maintenance.

Combipro

3-in-1 Combination Sterilizers

Combipro sterilizers are equipped with a vacuum pump for effective sterilization of dry goods, a fan system for steam-air-mixture sterilization, and water recirculation pipework for hot water cascade sterilization, allowing contract manufacturers or process development centers to utilize the necessary sterilization process for any given product or container. Combipro sterilizers can also be equipped with the necessary ports and controls to utilize gas such as H₂O₂ for the sterilization of heat sensitive containers.



Key Features

- Combination saturated steam, steam-air mixture, and hot water cascade process built into one sterilizer.
- Allows for programming any type of cycle or any combination of cycles.
- Allen-Bradley or Siemens PLC control systems.
- Options for adding the necessary ports and controls to utilize gas, including H₂O₂ for the sterilization of heat sensitive containers.
- 316L stainless steel chamber and sanitary piping - piping sloped to drain with no dead legs.

Examples of Sterilizer Chamber Sizes

BMT USA sterilizers are offered in almost any chamber size and volume. The table below contains examples of our standard sizes; however, **custom sizes are available upon request to meet your exact requirements.**

Models	Internal Chamber Dimensions (w x h x d)	Overall Unit Dimensions (w x h x d)	Chamber Volume	Door Slide Direction	Unit Mounting	Weight
202038	20" x 20" x 38" 508 x 508 x 965 mm	60" x 74" x 50" 1270 x 1880 x 1270 mm	8.8 ft ³ 0.24 m ³	Vertical or Horizontal	Floor or Pit	1,485 lbs 674 kg
262639	26" x 26" x 39" 660 x 660 x 990 mm	66" X 80" X 51" 1423 x 2032 x 1296 mm	15.8 ft ³ 0.44 m ³	Vertical	Floor	2,600 lbs 1,179 kg
262649	26" x 26" x 49" 660 x 660 x 1245 mm	66" x 80" x 61" 1320 x 2032 x 1541 mm	19 ft ³ 0.54 m ³	Vertical	Floor	2,985 lbs 1,354 kg
263639	26" x 36" x 39" 660 x 915 x 990 mm	100" x 80" x 51" 2540 x 2032 x 1296 mm	21 ft ³ 0.59 m ³	Vertical	Floor	3,400 lbs 1,542 kg
263648	26" x 36" x 48" 660 x 915 x 1220 mm	100" x 80" x 60" 2540 x 2032 x 1524 mm	25.9 ft ³ 0.73 m ³	Vertical or Horizontal	Floor	4,500 lbs 2,041 kg
263660	26" x 36" x 60" 660 x 915 x 1524 mm	100" x 96" x 72" 2540 x 2438 x 1829 mm	32.5 ft ³ 0.92 m ³	Vertical or Horizontal	Floor	5,200 lbs 2,360 kg
363648	36" x 36" x 48" 915 x 915 x 1220 mm	128" x 96" x 60" 3251 x 2438 x 1524 mm	36 ft ³ 1.02 m ³	Vertical or Horizontal	Floor	6,500 lbs 2,950 kg
363660	36" x 36" x 60" 915 x 915 x 1524 mm	128" x 96" x 72" 3251 x 2438 x 1829 mm	45 ft ³ 1.27 m ³	Horizontal	Floor	6,900 lbs 3,130 kg
375760	37" x 57" x 60" 940 x 1448 x 1524 mm	129" x 114" x 72" 3277 x 2896 x 1829 mm	73.2 ft ³ 2.07 m ³	Horizontal	Floor	7,200 lbs 3,260 kg
375786	37" x 57" x 86" 940 x 1448 x 2184 mm	129" x 114" x 98" 3276 x 2896 x 2489 mm	102.4 ft ³ 2.9 m ³	Horizontal	Floor or Pit	8,700 lbs 3,950 kg
484860	48" x 48" x 60" 1219 x 1219 x 1524 mm	148" x 96" x 72" 3759 x 2438 x 1829 mm	80 ft ³ 2.26 m ³	Horizontal	Floor or Pit	10,500 lbs 4,760 kg
484872	48" x 48" x 72" 1219 x 1219 x 1829 mm	148" x 96" x 84" 3759 x 2438 x 2133 mm	96 ft ³ 2.72 m ³	Horizontal	Floor or Pit	11,500 lbs 5,220 kg
484886	48" x 48" x 86" 1219 x 1219 x 2184 mm	148" x 96" x 98" 3759 x 96 x 2489 mm	114.5 ft ³ 3.24 m ³	Horizontal	Floor or Pit	12,500 lbs 5,670 kg
495748	49" x 57" x 48" 1219 x 1448 x 1219 mm	148" x 114" x 60" 3759 x 2896 x 1524 mm	77.5 ft ³ 2.19 m ³	Horizontal	Floor or Pit	9,500 lbs 4,300 kg
495760	49" x 57" x 60" 1219 x 1448 x 1524 mm	148" x 114" x 72" 3759 x 2896 x 1829 mm	96.9 ft ³ 2.74 m ³	Horizontal	Floor or Pit	10,500 lbs 4,760 kg
495772	49" x 57" x 72" 1219 x 1448 x 1829 mm	148" x 114" x 84" 3759 x 2896 x 2133 mm	116.3 ft ³ 3.29 m ³	Horizontal	Floor or Pit	12,000 lbs 5,443 kg
495786	49" x 57" x 86" 1219 x 1448 x 2184 mm	148" x 114" x 98" 3759 x 2896 x 2489 mm	138.8 ft ³ 3.84 m ³	Horizontal	Floor or Pit	13,000 lbs 5,897 kg
495796	49" x 57" x 96" 1219 x 1448 x 2438 mm	148" x 114" x 110" 3759 x 2896 x 2794 mm	155 ft ³ 4.39 m ³	Horizontal	Floor or Pit	14,000 lbs 6,350 kg
488660	48" x 86" x 60" 1219 x 2184 x 1524 mm	148" x 133" x 72" 3759 x 3378 x 1829 mm	143 ft ³ 4.05 m ³	Horizontal	Floor or Pit	15,000 lbs 6,804 kg
488686	48" x 86" x 86" 1219 x 2184 x 2184 mm	148" x 133" x 98" 3759 x 3378 x 2489 mm	205 ft ³ 5.8 m ³	Horizontal	Floor or Pit	16,000 lbs 7,258 kg
548686	54" x 86" x 86" 1371 x 2184 x 2184 mm	166" x 133" x 98" 4217 x 3378 x 2489 mm	230.7 ft ³ 6.5 m ³	Horizontal	Floor or Pit	17,000 lbs 7,711 kg



Pure & Clean Steam Generators

Fully integrated or stand-alone steam source for safe and effective steam sterilization.

BMT USA clean steam generators produce steam that is free of additives, impurities and other substances. When equipped with an optional steam separator, the generators produce pure steam that satisfies the requirements of U.S. Pharmacopoeia (USP), and, when condensed and tested, will also meet water for injection (WFI) standards.



Electric Vertically Integrated

BMT USA is one of the only manufacturers offering both horizontal or **vertical** electric steam generators integrated directly into a sterilizer for a reduced the overall footprint.

Plant Steam Heated

Steam-to-steam generators utilize plant steam as the heat source to produce pure or clean steam. The shell and tube heat exchanger is made from 316L stainless steel with either single or double-tube-sheet construction. The evaporator utilizes a wetted design to minimize the temperature difference between the feed water and the heating steam, resulting in less stress on the evaporator tube sheet. Available in capacities up to 5000 lbs/hr.

The generators feature an all 316L stainless steel construction and are fully built with non-proprietary components, including industrial-grade PLC control systems. Each generator can be configured as a central steam source for multiple sterilizers or directly built-in to a sterilizer for a fully integrated solution.

Electrically Heated

BMT USA electric pure and clean steam generators utilize 316L stainless steel heating elements with 3-phase voltage to heat and evaporate purified water, resulting in clean steam that is dry and free of pyrogens. Electric steam generators are ideal for facilities without access to utility steam and are available in capacities ranging from 50 lbs/hr up to 900 lbs/hr,



Steam Generator Features & Options



Double-Tube-Sheet Construction
Heat Exchanger



Steam Sample
System



Feed Water Booster
Pump System

Standard Features

With a focus on providing exceptional quality and value, BMT USA steam generators are engineered to include a range of standard features that improve performance, increase functionality and prolong unit life.

- All stainless-steel construction ensures no rusting or roughing.
- Fast response times and tight steam pressure control without the need of a pressure regulator.
- Industrial-grade Allen-Bradley or Siemens PLC-based control system.
- Non-proprietary components are readily available and easier to maintain.
- 100% drainable design ensures there is no standing water.
- Extensive validation documentation to reduce on-site validation time.

Additional Options

- Double-tube-sheet construction.
- Sanitary feed water piping with sanitary components and connections.
- Automatic drain valve for prolong shut down.
- Stainless steel and/or sanitary feed water booster pump system.
- Electropolishing of the vessel and piping.
- Steam separator for pure steam demands.
- Steam conductivity monitoring and recording.
- Feed water conductivity monitoring and recording.
- Steam quality sample system.
- Block and bleed valve arrangement to drain feed line when fed with USP or WFI feed water.

Loading & Testing Equipment

Optimize space, improve ergonomics, streamline validation.

Loading Carts & Trolleys

Loading carts designed for loading materials, containers and equipment into the sterilizer chamber by means of either a transfer trolley for floor mounted sterilizers or directly from the facility floor for pit mounted sterilizers.

The loading carts are constructed from 316L stainless steel with height adjustable shelves and 304 stainless steel transfer trolleys. For pit-mounted units, non-marking wheels are used and tracks or rub rails for almost any type of wheel arrangement can be installed inside the sterilizer chamber. Carts with drop down wheels are available for rooms with limited space.



Validation Flange

BMT USA's validation flange allows for individually sealing each thermocouple lead wire. By individually sealing the wires, significantly less time is required to replace installed wires in the event of a single thermocouple failure. The seals of surrounding thermocouples are also undisturbed during wire replacement. BMT USA's validation flange is available for 16 or 24 load probes and can be attached to 1½" or 2" tri-clamp validation ports. Custom sizes available upon request.



Sterilizer Trays

For the sterilization of vials and other materials that require special handling, BMT USA can design and manufacture custom trays and boxes in a configuration that best suits the load to be sterilized and maximizes the capacity of your sterilizer. Our trays and boxes are constructed from 316L stainless steel and finished to your requirements.



Committed to supporting our clients at every stage

We recognize the important role our equipment plays in your process. Therefore we are committed to providing the highest quality equipment that is backed up with excellent customer service and support. Our team of highly experienced field-service technicians provide the following expert services:

Installation Supervision—Eliminates installation errors.

Start-up—For optimization of equipment on-site.

Training—For ease in operation.

Calibration—Accurate and reliable instrumentation.

Validation—Expert knowledge for ease in validating.

Preventative Maintenance—Reduced downtime.

Emergency Service—On-site or remote service to restart your operations as quickly as possible.

BMT USA Equipment:

cGMP Steam Sterilizers

cGMP Washers

Pure & Clean Steam Generators

Depyrogenation Ovens

Laboratory Steam Sterilizers

Laboratory Washers

Laboratory Drying Ovens

Laboratory Incubators

Climate & Stability Test Chambers



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