



# cGMP STEAM STERILIZERS



# BMT worldwide

## QUALITY, RELIABILITY, INNOVATION

BMT is a member of the MMM Group, one of the world's leading suppliers of sterilization products with offices in over 20 different countries and manufacturing facilities in the USA, Germany and Czech Republic. Since the beginning in 1954, the group's sterilization products have been placed in Pharmaceutical, Laboratory and Healthcare facilities all over the world. Special attention is given to quality, reliability, innovation and efficiency of every unit. Customer service excellence is our commitment to your organization and the key to our success.

## flexible solutions for your sterilization

### BUILT TO YOUR EXACT NEEDS

Every BMT sterilizer is produced to your exact specifications and needs. Flexible options allow selection of the right equipment for each specific sterilization load and packaging. Control systems are designed to be user friendly, and are easily configured to obtain the exact parameters needed for special products. Built-in steam generation systems are available where pure, clean or building steam is not available. Full cGMP or GMP ready designs are available to meet production needs now and in the future.



# quality built-in

BMT has the right sterilizer for your cGMP production, needs, and you can rest assured that whatever model you choose, the engineering, construction and workmanship of each unit meets our exacting standards. Chambers and jackets are constructed of 100% 316L stainless steel to ensure long life. The frames of the sterilizers and insulation covering are made of stainless steel for durability and to prevent rusting over the life span of the unit. Only the highest quality, industrial-grade, non-proprietary components are used throughout.

## BMT CGMP STEAM STERILIZER MODELS

- Steripro cGMP Vacuum Sterilizers
- Ventipro cGMP Steam-Air Mixture Sterilizers
- Aquapro cGMP Water Cascade Sterilizers

# engineered features

Extensive efforts have been made to offer features that enhance efficiency, reliability and serviceability of the sterilizer. Vertical or horizontal sliding doors that are precision machined operate with exceptional smoothness while providing a safer environment for the operator. Door gaskets operate without the need for lubrication allowing for less maintenance and longer life span. The chamber jacket design utilizes a unique plate and beam construction that provides for a complete envelop around the chamber. PLC-based control systems are intuitive, easily understood and operated, while providing the sophistication for maximum flexibility and ease in validation.

- Complete 316L stainless steel chambers and jackets
- Lubricant-free door gaskets
- Solid precision machined stainless steel door
- Door is secured to the chamber on all four sides
- Stainless steel frames and insulation covering
- Industrial grade, non-proprietary components



# BMT Steripro Steam Sterilizers

Steripro cGMP Steam Sterilizers are designed not only to meet the US FDA cGMP guidelines, but to exceed industry standards. Reliability and serviceability are engineered into every unit. Validation is one of the biggest concerns in purchasing a cGMP sterilizer, so special attention has been given to the documentation and repeatability of each system. Utilizing the latest 3D parametric and MRP software along with BMT's lean manufacturing principles allows for state-of-the-art solutions, which are unsurpassed in quality and reliability yet without sacrificing value.

- Highly polished 316L chambers
- Meets and exceeds US FDA cGMP's
- 316L stainless steel sanitary piping
- Piping sloped to drain with no dead legs
- Sanitary valves and components
- Extensive validation documentation
- 316L stainless steel chamber, jacket and doors
- Lubricant-free door gaskets
- High grade Non-proprietary components and parts



## features

### CHAMBERS

BMT Steripro sterilizers are equipped with highly polished chambers made entirely of 316L stainless steel for superior durability. The chamber door is made from solid plate 316L stainless steel. Precision machined door brackets for retaining the door on four sides ensures smooth door travel and safe, secure doors. All chamber connections are sanitary clamp type and are sloped to drain. Lubricant-free door gaskets last longer and will eliminate particle shedding into clean rooms.

### SANITARY PIPING SYSTEMS

All piping and ports in contact with the chamber are constructed of 316L stainless steel and are sloped to drain. Sanitary clamp fittings are used for ease in removal of components. Non-proprietary sanitary valves and components are selected for their reliability and availability to reduce down time.

### REPEATABILITY

The primary use of BMT Steripro steam sterilizers is for production in pharmaceutical and biotechnology facilities where repeatability is an important criteria. BMT sterilizers are state-of-the-art in design and utilize high-grade vacuum pumps, the highest quality instrumentation, and industry-standard PLC control systems to ensure repeatable cycles regardless of changing environmental conditions. Temperature distribution within the chamber is better than  $\pm 0.5^{\circ}\text{C}$ .

### VALIDATION

Every Steripro steam sterilizer is subject to rigorous pre-validation testing at the factory and shipped with an extensive documentation package in order to minimize the time required for on-site validation. IQ/OQ protocols as well as on-site execution are available as options.

# Steripro cycles

Regardless of the sterilizer model you choose, BMT has the right sterilization cycle for all your different production needs. Each sterilizer can be equipped with any combination of the cycles described below. Maximum flexibility for each cycle phase is easily programmed into the control system with each individually settable parameter. The programmed recipe is stored in the control system memory and is recalled and started with the touch of a button on the operator interface. Recipes are protected from unauthorized changes via the multi-level password system.

## DRY GOODS CYCLE — VACUUM DRYING

The dry goods cycle provides effective sterilization of hard goods, filters, linens, and other porous materials, wrapped goods, and products that are unaffected by vacuum. The load is preconditioned utilizing vacuum and steam pulses. The cycle then advances to heat-up and continues until it reaches the settable exposure temperature of 110°C up to 135°C. Once the exposure temperature set point is reached, the controller counts down the exposure time. After the exposure time is completed, drying begins and can be accomplished by fast exhaust and pulling a deep vacuum to remove moisture.

## DRY GOODS CYCLE — PULSED AIR / VACUUM DRYING

This cycle provides effective sterilization of rubber stoppers, hoses, and other materials where trapped moisture can be difficult to remove. The load is preconditioned utilizing vacuum and steam pulses. The cycle then advances to heat-up and continues until it reaches the settable exposure temperature of 110°C up to 135°C. Once the exposure temperature set point is reached, the controller counts down the exposure time. After the exposure time is completed, drying begins and is accomplished by fast exhaust and vacuum and air pulses which are highly effective at removing moisture from the load. To aid drying further the air can be heated.

## SOLUTION CYCLE — GRAVITY AIR REMOVAL / RAMPED EXHAUST

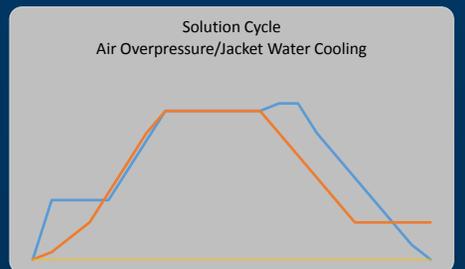
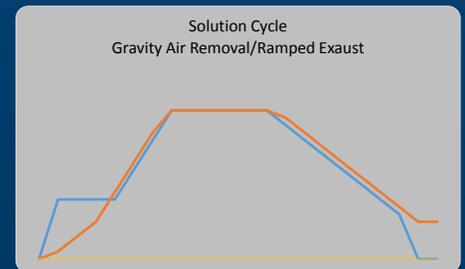
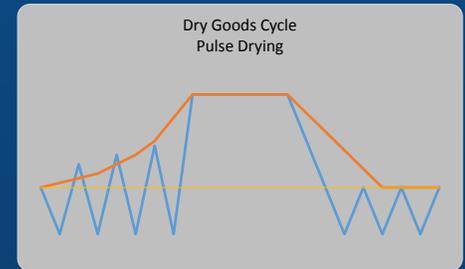
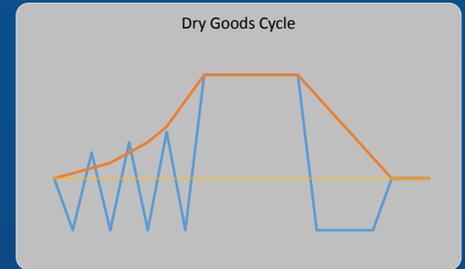
The solution cycle with gravity effectively sterilizes liquid products or items in vented or sealed glass containers. The load is preconditioned utilizing steam pulses. The cycle then advances to heat-up and continues until it reaches the settable exposure temperature of 110°C up to 135°C. Once the exposure temperature set point is reached, the controller counts down the exposure time. After the exposure time is completed, exhaust ramping gradually returns liquids to a temperature below boiling.

## SOLUTION CYCLE — AIR OVER-PRESSURE / JACKET WATER COOLING

This cycle effectively sterilizes liquid products or items in vented or sealed glass containers. The load is preconditioned utilizing steam pulses. The cycle then advances to heat-up and continues until it reaches the settable exposure temperature of 110°C up to 135°C. After the exposure timer is timed out, cooling of the product is started by injecting air at a pressure similar to that of the product to avoid breakage of the container. Cold water is introduced to the jacket of the chamber to help cool the product at a faster rate.



## CYCLE DIAGRAMS



# BMT Ventipro Steam-Air Sterilizers

BMT Ventipro Steam-Air Mixture Sterilizers provide fast, safe and effective terminal sterilization of liquids in open, sealed or heat 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 chamber steam and air to ensure there are no cold pockets inside the chamber and to provide a uniform temperature distribution across the chamber. Rapid heating and cooling is achieved utilizing convection principles. At the end of the cycle, the product comes out dry and ready for labeling.

- Faster heating and cooling times than conventional steam sterilizers
- Ideal for sterilization of liquids in heat-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 fan shaft for ease in inspection and maintenance



## features



### FANS

High performance fans intensify the streaming of the steam-air mixture through the chamber and around the goods. 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.

### CHAMBERS

BMT Ventipro sterilizers are equipped with highly polished rectangular chambers made entirely of 316L stainless steel for superior durability. A full jacket surrounds the chamber for even heat distribution. Precision machined door brackets for retaining the door on four sides ensure smooth door travel and safe, secure doors. All chamber connections are sanitary clamp type and are sloped to drain. Lubricant-free door gaskets will last longer and will reduce particle shedding into clean rooms.

### SANITARY PIPING SYSTEMS

All piping and ports in contact with the chamber are constructed of 316L stainless steel and are sloped for drain-ability. Easily removable sanitary clamp fittings are used for easy removal of components. Non-proprietary sanitary valves and components are selected for their reliability and availability to reduce down time.



# sterilization cycles

## STEAM-AIR MIXTURE CYCLE

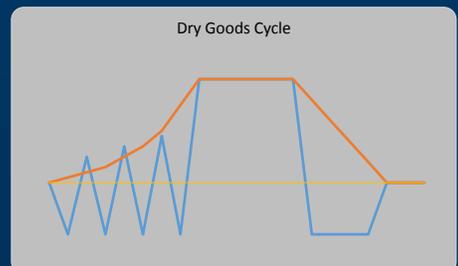
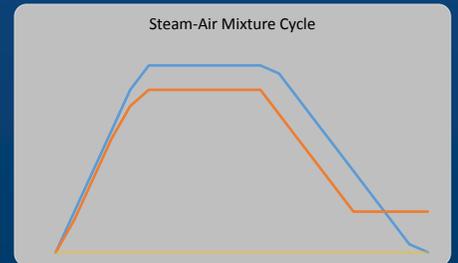
This cycle effectively sterilizes liquid products or items in vented or sealed containers. Heating occurs with steam while injecting compressed air to a preset differential overpressure. The steam and air are circulated and mixed by the internal fans to ensure a rapid heat up to the settable exposure temperature, between 110°C and 135°C. The control of the air overpressure is independent of the saturated steam pressure but corresponds to the temperature and pressure inside the load. Once the exposure temperature set point is reached, the controller counts down the exposure time. After the exposure time is completed the steam is stopped and cool air is blown across the load via the fans. During the cooling step, a preset support pressure is maintained in the chamber to prevent damage of 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.

## DRY GOODS CYCLE — VACUUM DRYING

The dry goods cycle provides effective sterilization of hard goods, filters, linens, and other porous materials, wrapped goods, and products that are unaffected by vacuum. The load is preconditioned utilizing vacuum and steam pulses. The cycle then advances to heat-up and continues until it reaches the settable exposure temperature of 110°C up to 135°C. Once the exposure temperature set point is reached, the controller counts down the exposure time. After the exposure time is completed, drying begins and can be accomplished by fast exhaust and pulling a deep vacuum to remove moisture.



## CYCLE DIAGRAMS



# BMT Aquapro Water Cascade Sterilizers

BMT Aquapro Water Cascade Sterilizers provide fast, safe and effective terminal sterilization of liquids in sealed or heat-sensitive containers. Super-heated water is sprayed on the load which enables fast heating and cooling due to the heat transfer properties of water. Over-pressure air is injected into the chamber to compensate for the rising temperature and pressure that builds inside liquid containers when heated.

- Fast heating and cooling enables 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 the recirculating water
- Perforated tray for water distribution with holes on the front back and sides to heat the door and chamber surfaces



## features



### PERFORATED TRAY

The unique perforated tray evenly distributes the recirculating chamber water across the entire load. Additional holes are provided on the front, back and sides of the tray to distribute the water to the chamber and doors to ensure they are heated to the same temperature of the load, allowing for very even heat distribution.

### PROCESS

BMT Aquapro sterilizers utilize 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 exchanger is heated by plant steam and cooled by softened water as it has no direct contact with the chamber recirculating 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.



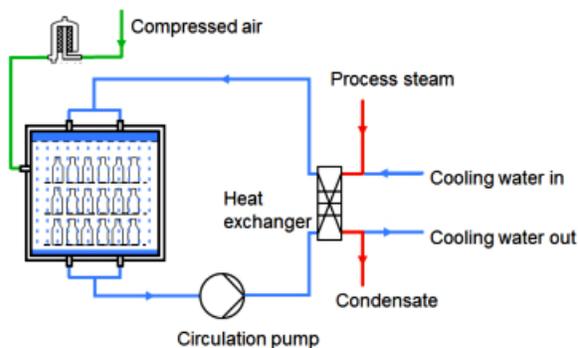
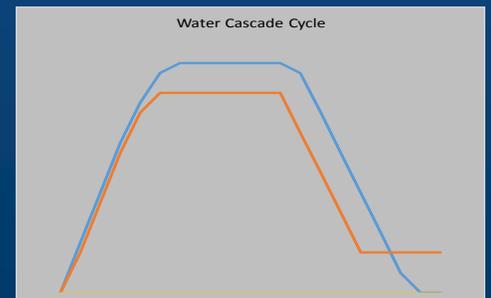


# sterilization cycles

## HOT WATER CASCADE CYCLE

The cycle begins with filling the chamber to a predetermined level with purified water. The water is circulated by a high capacity pump through an external heat exchanger that is heated by plant steam. The water is distributed through a perforation tray onto the product. Due to the efficient heat transfer of the water, the product is heated rapidly. Compressed air at an over-pressure is injected into the chamber to compensate for the rising temperature and pressure that builds inside liquid containers when heated. At the end of the exposure step, cooling begins. The circulating water is cooled by an external heat exchanger that is cooled with cooling or chilled water. The product is quickly cooled to ambient temperature by continuously spraying the circulating water over the load. This method of sterilization is the fastest method for sterilization of liquids in sealed containers.

## CYCLE DIAGRAMS



# loading equipment

## STANDARD OR CUSTOM DESIGNS

BMT manufactures stainless steel loading equipment in standard or custom designs to meet the needs of any type of load. Smaller chamber sizes can be equipped with wire or perforated chamber shelves or loading racks. Larger chambers can be equipped with loading carts and transfer trolleys. Large pit-mounted chambers can come equipped with tracks and/or rub rails for almost any type of wheel configuration on existing equipment. Carts with drop down wheels are available for rooms with limited space.



# control systems

## INDUSTRIAL GRADE PLC'S

BMT steam sterilizers are equipped with industrial- grade, Allen Bradley or Siemens PLC based control systems for superior reliability, repeatability of cycles, and serviceability. The programming was developed utilizing the latest GAMP (Good Automated Manufacturing Practices) guidelines for ease in validation and to ensure reliability while allowing maximum flexibility for the owner. The system allows for 20 sterilizing cycles to be configured and stored. The operator interface terminal is a large touch screen that is user-friendly and intuitive. Double door units have an operator interface touch screen on both the load and unload sides of the sterilizer. All sterilizer functions are accessed through these touch screens. Displayed messages are in clear text. Multi-level passwords protect from unauthorized access. Each system is supported with a very comprehensive documentation package. The control system can be equipped with different types of printers and/or recorders for data storage on paper. If electronic data storage is desired the control system can be provided with 21 CFR, Part 11 compliancy when connected to a PC or central computer system.



# examples of Chamber sizes

BMT steam sterilizers are available in a wide range of chamber sizes. The examples below are only a sample of the models that we offer.

Please contact BMT for further details on standard or custom chamber sizes and standard or custom exterior dimensions.

Models	Internal Chamber Dimensions w x h x d	Overall Dimensions w x h x d	Chamber Volume	Door Slide Direction	Mountings	Weight lbs.\kg
measurement	inch	inch	ft3	Vertical or Horizontal	Floor or Pit	lbs
	mm	mm	M3			kg
P202038	20 x 20 x 38	60 x 74 x 50	8.8	Vertical	Floor	1485
	508 x 508 x 965	1270 x 1880 x 1270	0.24			674
P262639	26 x 26 x 39	66 x 80 x 51	15.8	Vertical	Floor	2600
	660 x 660 x 990	1423 x 2032 x 1296	0.44			1179
P262649	26 x 26 x 49	66 x 80 x 61	19	Vertical	Floor	2985
	660 x 660 x 1245	1320 x 2032 x 1541	0.54			1354
P263639	26 x 36 x 39	100 x 80 x 60	21	Vertical or Horizontal	Floor	3400
	660 x 915 x 990	2540 x 2032 x 1524	0.59			1542
P263648	26 x 36 x 48	100 x 80 x 60	25.9	Vertical or Horizontal	Floor	4500
	660 x 915 x 1220	2540 x 2032 x 1524	0.73			2041
P263660	26 x 36 x 60	100 x 96 x 72	32.5	Vertical or Horizontal	Floor	5200
	100 x 80 x 1524	2540 x 2438 x 1829	0.92			2360
P363648	36 x 36 x 48	128 x 96 x 60	36	Horizontal	Floor	6500
	914 x 914 x 1220	3251 x 2438 x 1524	1.02			2950
P363660	36 x 36 x 60	128 x 96 x 72	45	Horizontal	Floor	6900
	914 x 914 x 1524	3251 x 2438 x 1829	1.27			3130
P375760	37 x 57 x 60	129 x 114 x 72	73.2	Horizontal	Floor or Pit	7200
	940 x 1448 x 1524	3277 x 2896 x 1829	2.07			3260
P375786	37 x 57 x 86	129 x 114 x 98	102.4	Horizontal	Floor or Pit	8700
	940 x 1448 x 2184	3276 x 2896 x 2489	2.9			3950
P484860	48 x 48 x 60	148 x 96 x 72	80	Horizontal	Floor or Pit	10,500
	1219 x 1219 x 1524	3759 x 2438 x 1829	2.26			4760
P484872	48 x 48 x 72	148 x 96 x 84	96	Horizontal	Floor or Pit	11,500
	1219 x 1219 x 1829	3759 x 2438 x 2133	2.72			5220
P484886	48 x 48 x 86	148 x 96 x 98	114.5	Horizontal	Floor or Pit	12,500
	1219 x 1219 x 2184	3759 x 96 x 2489	3.24			5670
P495748	49 x 57 x 48	148 x 114 x 60	77.5	Horizontal	Floor or Pit	9500
	1219 x 1448 x 1219	3759 x 2896 x 1524	2.19			4300
P495760	49 x 57 x 60	148 x 114 x 72	96.9	Horizontal	Floor or Pit	10,500
	1219 x 1448 x 1524	3759 x 2896 x 1829	2.74			4760
P495772	49 x 57 x 72	148 x 114 x 84	116.3	Horizontal	Floor or Pit	12,000
	1219 x 1448 x 1829	3759 x 2896 x 2133	3.29			5443
P495786	49 x 57 x 86	148 x 114 x 98	138.8	Horizontal	Floor or Pit	13,000
	1219 x 1448 x 2184	3759 x 2896 x 2489	3.84			5897
P495796	49 x 57 x 96	148 x 114 x 110	155	Horizontal	Floor or Pit	14,000
	1219 x 1448 x 2438	3759 x 2896 x 2794	4.39			6350
P488660	48 x 86 x 60	148 x 133 x 72	143	Horizontal	Floor or Pit	15,000
	1219 x 2184 x 1524	3759 x 3378 x 1829	4.05			6804
P488686	48 x 86 x 86	148 x 133 x 98	205	Horizontal	Floor or Pit	16,000
	1219 x 2184 x 1524	3759 x 3378 x 2489	5.8			7258
P548686	54 x 86 x 86	166 x 133 x 98	230.7	Horizontal	Floor or Pit	17,000
	1371 x 2184 x 2184	4217 x 3378 x 2489	6.5			7711

Note: Dimensions and weights are approximate and are subject to change without notice.

# service for our clients

## COMMITMENT TO EXCELLENCE

We recognize the important role our equipment plays in your research. Therefore we are committed to provide 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 Services**—reduces time and effort

**Start-up**—for optimization of equipment on-site

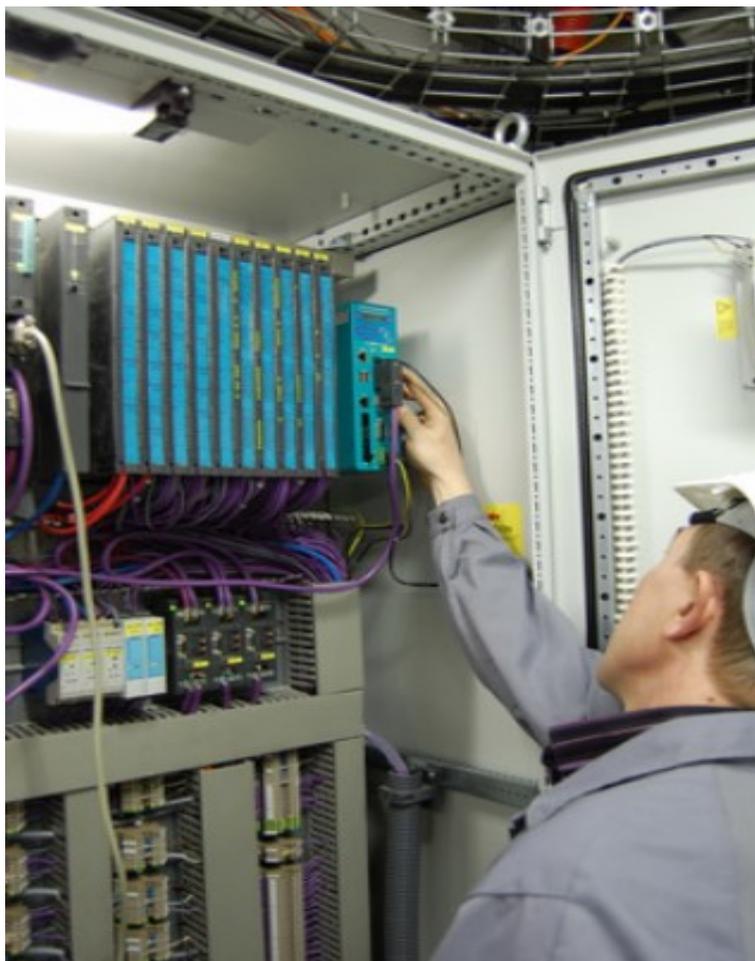
**Training**—for ease in operation

**Calibration**—accurate reliable instrumentation

**Validation**—expert knowledge for ease in validating

**Preventative Maintenance**—reduced downtime

**Emergency Service**—24 hours, 7-days a week



# other sterilizers available from BMT

## STERIVAP LABORATORY STEAM STERILIZERS

Sterivap steam sterilizers are designed specifically for the high demands of today's research facilities. The sterilizers are available with small to medium size 316L stainless steel chambers and incorporate industry leading features:

- Engineered for energy efficiency
- Stainless steel piping
- Dual microprocessor controls
- Large, color touch-screen operator interface
- Highly insulated chamber and piping
- Two-stage vacuum pump
- Water recirculation for less waste
- Integrated stainless steel steam generator



## STERILAB LABORATORY STEAM STERILIZERS

Sterilab steam sterilizers are designed specifically for the exacting needs of today's animal laboratories and research facilities. The sterilizers are available with medium to large size 316L stainless steel chambers and are custom designed to meet almost any demand. The units are available as "GMP ready" with many GMP features available as options to be added at the time of order or later in the field should requirements change.

- 316L stainless steel chamber
- Sanitary chamber fittings
- Effluent sterilization cycles available
- BSL3 & 4 Bioseal available
- cGMP ready design
- Non-proprietary components
- Industry-standard PLC control systems
- Lubricant-free door gasket
- Highly customizable to meet specific needs
- Modular design for ease in installation



# Steam Generators

## PURE AND CLEAN STEAM GENERATORS

BMT Steam Generators are designed to provide Pure or Clean Steam for all your sterilization needs. These units can be purchased as stand-alone units to be used as a central source for multiple units or built into a BMT sterilizer for a fully integrated solution. BMT steam generators can be electrically heated or heated by plant steam.



## ELECTRIC HEATED STEAM GENERATORS

BMT Electric Clean Steam Generators are equipped with an ASME pressure vessel constructed from 316L stainless steel. The heating elements require three-phase voltage that can be specified at time of order. The units are equipped with an automatic timed blow-down system that carries impurities to drain. Feed water booster pumps are available when feed water pressure is not available at required pressures. Available in many different configurations and capacities.

## STEAM HEATED STEAM GENERATORS

BMT Steam-to-Steam Clean Steam Generators utilize plant steam as the heating source to produce clean steam. The tube and shell heat exchanger is made from 316L stainless steel and can be built in single-tube or double-tube construction. The evaporator utilizes a wetted design that minimizes the temperature difference between the feed water and the heating steam which results in less stress on the evaporator tube sheet. Available in almost any capacity and need.

- 316L stainless steel pressure vessels
- 316L stainless steel piping
- Sanitary piping, connections and components
- cGMP design and constructed
- High-grade, non-proprietary components
- All stainless steel frames and control boxes
- Single or double tube-sheet construction
- Industrial-grade PLC controls

## STEAM TO STEAM GENERATOR



# BMT USA Products

- Water Stills
- Pure Steam Generators
- Clean Steam Generators
- cGMP Steam Sterilizers
- Laboratory Sterilizers
- Glass & Parts Washers
- Animal Cage Washers
- Depyrogenation Ovens
- Dry Heat Sterilizers
- Laboratory Ovens & Incubators



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