



Sterilco Steam Sterilizer

Maximus Bulk Sterilizers Models



| Model | Internal Dimensions w" x h" x d" | External Dimensions w" x h" x d" | Volume (liters) | Capacity (cu. ft.) |
|---------|-------------------------------------|-------------------------------------|--------------------|-----------------------|
| MB-765 | 36" x 36" x 36" | 112" x 81" x 48" | 765 | 27 |
| MB-1812 | 48" x 48" x 48" | 118" x 95" x 60" | 1812 | 64 |
| MB-1925 | 26" x 63" x 76" | 93" x 81" 88" | 1925 | 68 |
| MB-2690 | 48" x 57" x 60" | 144" x 104" x 98" | 2690 | 95 |
| MB-2831 | 37" x 49" x 96" | 118" x 95" x 108" | 2831 | 100 |
| MB-6212 | 48" x 86" x 92" | 144" x 133" x 92" | 6212 | 219.4 |



Standard Features –Exceed Industry Standards:

- Highly polished, 316L stainless steel chambers
- Complete envelope 316L stainless steel jacket
- Industrial based PLC Control Systems
- Lubricant-free door gaskets – less maintenance and longer life
- Extensive validation documentation – reduces on site validation time
- All stainless steel construction – no rusting or rouging
- 15-year pressure vessel warranty
- Modular design – ease in moving into existing buildings, doorways and hallways
- Special attention to validation doumentation and repeatability using the latest 3D paratric and MRP software

TECHNICAL SPECIFICATION

GENERAL

Sterilco cGLP Maximus steam sterilizer fulfills the stringent requirements of the current Good Laboratory Practices (cGLP's).

The is designed for highly effective sterilization of hard goods, pours material and liquid applications in the laboratory field utilizing clean saturated steam as the sterilization medium.

Pursuant to our goal of minimizing equipment downtime, the sterilizer features non-proprietary components. These components are available through multiple commercial outlets as well as from Sterilco.

MOUNTINGS

The sterilizer can be constructed as a single or double-door pass-through. They can be designed to be mounted in one wall or between two walls.

The sterilizer is designed to be mounted in a 24” deep pit, which will allow the chamber floor to be even with the facility floor for ease in loading and unloading. The sterilizer comes with ramps to cover the gap between edge of the pit and the chamber floor. The ramps are designed to be manually raised and lowered according to the door position.

QUALIFICATION

Construction meets or exceeds the requirements or recommendations of:

- cGLP Current Good Laboratory Practices
- IMHS Industrial Moist Heat Sterilization: International Standard 11134:1994
- ASME American Society of Mechanical Engineers
- UL Underwriters Laboratory
- CETL Canadian Testing Laboratories (for conformance to CSA)
- NFPA National Fire Prevention Association
- OSHA Occupational Safety and Health Administration
- NPC National Plumbing Code
- NEC National Electrical Code
- NEMA National Electrical Manufacturers Association



CHAMBER

Constructed in accordance with ASME Section VIII, Division 1, for unfired pressure vessels and so stamped for 45 psig/144° C Design Temperature and Full Vacuum. The chambers are rectangular in design and fully jacketed. The chamber is 316L stainless steel with fully welded construction. Steam baffles are positioned in the chamber to minimize wetting by condensate and ensure proper steam distribution within the chamber.

The chamber is mechanically polished to a mirror finish with a Ra of 10 μ inch or better.

JACKET

The jacket is constructed of 316L stainless steel, is ASME stamped for 45 psig/144° C Design Temperature, and mounted to the chamber with our unique double-plate beam construction. C-channels are stitch welded to the exterior of the chamber to allow for maximum expansion and contraction without the risk of cracking the weld. An additional stainless steel plate is welded over the C-channels to create a complete steam jacket, which allows for jacket steam penetration within and in between the C-channels. This unique jacket construction allows for very tight chamber temperature distribution, decreases the time needed to bring the chamber up to sterilization temperature and prevents the formation of condensate on the chamber walls.

DOORS

Horizontal Doors

The sterilizer is equipped with horizontally sliding doors. The horizontally sliding doors are pneumatically powered and opened and closed via the OIT. The door is equipped with a leading edge strip that automatically reverses the door should an obstacle be in the door way. In addition, the door cylinder utilizes a low-pressure air system equipped with pressure relief valve to ensure that the pressure cannot build in the system and allows easy override of the door. The door open button is a momentary contact; however, the door close button must be continually depressed during movement. The door will automatically reverse if the door close button is released.

The door is sealed by filtered air pressurizing the continuous O-ring gasket, which is recessed within the chamber head ring against the door. The gasket is retracted by vacuum before the door is opened. Double-door units are safety interlocked so only one door may be opened at one time, which ensures the proper flow from load side to unload side.

INSULATION

The exterior of the jacket is covered with 2" thick chloride-free insulation. The insulation is encased within sturdy stainless steel and sealed for water tightness.

FRAME

The sterilizer chamber is secured to a welded structural frame. The frame is constructed of 304 stainless steel. Adjustable screws at the base of the frame allow for leveling during installation. The sterilizer is constructed in a modular form which allows for easy breakdown of the unit to aid in moving through doors and hallways during installation.



PIPING

Piping on the sterilizer is constructed from brass or copper. All plumbing fixtures and components are readily accessible and removable without requiring major disassembly of the unit.

STEAM TRAPS

The steam traps are thermostatic, non-proprietary, industrial-grade, and are positioned and sized for maximum efficiency for the removal of air and condensate from the system.

VALVES

All control valves are non-proprietary, industrial-grade and pneumatically operated. V Chamber steam control is provided by two on/off control valves to provide chamber temperature control within $\pm 1^{\circ}\text{C}$ or better throughout the chamber during exposure.

OVERPRESSURE RELIEF

The chamber and jacket are protected from over-pressure by ASME stamped safety relief valves. Safety relief devices are factory preset for the vessel design pressure.

STEAM BLEED

The chamber drain is equipped with a bleed valve that enhances the movement of steam within the chamber and through the bleed lines. The constant flow past the drain RTD ensures accurate temperature control.

VALIDATION AND LOAD PORTS

The chamber is equipped with two stainless steel sanitary, 1 1/2" tri-clamp ports for use for validation and one sanitary, clamp-type port for use for a load probe(s) if equipped. Each is constructed of and equipped with blind flanges. They are located in the maintenance space for easy accessibility and are sloped towards the chamber for proper drainage. Additional ports can be ordered as an option.

VACUUM PUMP

The liquid ring vacuum pump efficiently removes air from the chamber prior to the sterilization of wrapped or porous loads. A deep vacuum during the drying step also ensures permeable loads are free of trapped condensate when removed from the chamber.

AIR FILTER

Chamber air routes through a 0.2 micron sanitary hydrophobic filter. .

EXHAUST COOLING SYSTEM

Exhaust cooling protects the facility drainage system by automatically mixing effluent with cooling water to reduce the temperature to an acceptable level. A temperature sensing device located in the exhaust drain opens a mixing valve to introduce cooling water whenever the temperature exceeds the set point. This feature greatly reduces cooling water consumption. Discharge temperature is influenced by the temperature of the cooling water supplied; however, it will typically be 60°C (140°F) or less when cooling water is 21°C (70°F) or less.

CONTROL SYSTEM

Siemens PLC Control System

The Siemens S7-200 PLC provides automatic control of all the sterilizer functions. The PLC is equipped with a central processing unit providing high-level data access through an RS 232 network. The PLC is mounted in a UL Listed NEMA 4/12 panel.



A LCD display with touch screen function is provided for operator control, cycle programming and indicates the sterilizer operating state. Alarms are announced audibly and indicated in clear text. The operator interface is mounted on the front fascia, on the loading side of the sterilizer.

Double door sterilizers are equipped with a digital operator interface panel for door operation and cycle progress monitoring

The software is configured to GAMP 4 regulations as follows:

- Up to 20 programmable cycles are available with a wide range of settable parameters, which provides for a high degree of functionality and allows great freedom in designing cycles for various products.
- Cycles 21 and 22 are reserved for a Vacuum Leak Test and the optional Filter Sterilization Cycle
- Three Level Pass code protection
 - Level 3 – Operator level: Allows access to the operation screens to select a cycle and run the selected cycle
 - Level 2 – Supervisor level: Allows access to the operation and the cycle management screens
 - The cycle management screens allow setting and storing program parameters.
 - Level 1 - Engineer Level: Allows access to the operation and service screens for calibration of RTD's, control analog inputs, discrete inputs and discrete outputs, management of date and time, and password management.
- All messages, alarms and interlocks are expressed in user friendly full text
- System home screen enables quick user navigation between all displays
- Operation
 - Operation features are governed by the pass code level assigned
 - System information: System mode, active alarm status, current user and date/time.
 - Loaded recipe information: Recipe, phase and step.
 - Step messages
 - Interlock messages
 - Process variables with set-points
 - Door and gasket status
 - Interlock prevents door operation if the chamber is not sterile.
 - Powered door safety bar – reverses door if an obstruction is detected.
 - Chamber steam is interlocked with the door position switches. If an open door is detected than chamber steam is not allowed to activate.
 - Chamber pressure interlock prevents door operation if there is pressure inside the chamber.
 - Programmable temperature interlock prevents door operation if the temperature exceeds the set point.
 - Annunciator silence
 - PID control of temperature
 - Single display for ease of viewing and controlling
 - Process setup provision for modifying global process settings (requires authorization by administrator)
- Real time active alarm status
- Active interlock status
- Date\time editor



- System I/O status and in the service mode, control of outputs and system functions
- Reports:
 - Full report time stamped logging that includes recipe information, phase sequence, step sequence, data capture and alarms.
 - Fast printing by directly utilizing the PLC onboard serial port.
 - Recipe parameter report
- Electrical
 - Emergency Stop button located on the loading side and if a double door unit on the unloading side
 - The PLC is enclosed in a UL 508, NEMA 4 box.
 - Ethernet port built-in
 - Inputs, Outputs and HMI's and pushbuttons are low voltage 24VDC.
 - Control valves feature low power wattage consumption
 - Control panels feature finger safe design
 - All outputs are fully fused in order to provide operator safety, equipment safety and simplified trouble shooting

Data Logger (Sterilizer Report Printer)

The data logger provides digital printout of cycle progression and information including any fault statements during the entire cycle. The following process parameters are recorded on the 24-character 2¼" impact printer with take-up reel.

- Date
- Sterilizer identification
- Load identification
- Operator identification
- Cycle parameters
- Cycle start time (real time)
- Initiation of steam charging
- Chamber pressure
- Chamber temperature
- Exposure start time
- Exposure end time
- Cooling time/final temperature
- Alarms if any (real time)

Temperature Control

A Resistance Temperature Device (RTD) is placed in the drain line (coldest spot of the chamber) to sense and control temperature within the chamber. The RTD emits a signal to the PLC which in turn controls the chamber steam valve.

Temperature Distribution

The temperature distribution is within $\pm 0.1^{\circ}\text{C}$ of set point throughout the chamber during sterilization. Temperature readout and printout are provided in 0.1°C increments.

Chamber and Jacket Pressure Displays

The chamber pressure and temperature and jacket pressure is displayed on pressure gauges mounted above the chamber.



Pressure / Temperature Sensors

An analog pressure transducer senses chamber and jacket pressure. Chamber and jacket temperatures are sensed by platinum RTD's.

STANDARD CYCLE DESCRIPTIONS

Dry Goods - Vacuum Cycle (Standard)

This cycle provides effective sterilization of hard goods, rubber stoppers, filters, linens, and other porous materials, wrapped goods, and product that is unaffected by vacuum. The load is preconditioned utilizing vacuum and steam pulses. The cycle then advances to heat-up and continues till 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, deep vacuum or vacuum pulses which is highly effective at removing moisture from the load.

Solution Cycle - Gravity Air Removal / Ramped Exhaust (Standard)

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 till 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.

STANDARD DOCUMENTATION PACKAGE

Design Qualification

- Piping and Instrumentation Diagram
- Installation Drawings
- Electrical Diagrams
- Control System Documentation
- Software Source Code Listing
- Installation Manual
- Operational Manual
- Mechanical Component Parts List s
- Electrical Component Parts List
- Mechanical Component Catalog Cut Sheets
- Electrical Component Catalog Cut Sheets
- Factory test results

FACTORY TESTING

The sterilizer is extensively tested at our factory prior to shipment to ensure a trouble free start-up of the sterilizer once it arrives at the purchaser's facility. Tests include mechanical check out, electrical check out, control system check out, input/output testing, alarm initiation testing, operational check out.



OPTIONAL ITEMS

KW Electric Steam Generator

A electric steam generator provides heating steam for the chamber and jacket when steam is not available from a central source. Components and fittings in contact with feed water and steam is constructed of brass or copper. The steam generator is made from mild steel. Softened feed water is recommended to prolong the life of the boiler and reduce scale up of the heating elements. The electric steam generator is designed and constructed for constant and continuous use using industrial grade components throughout. The boiler is built in accordance to ASME pressure vessel codes and complies with Part PEB of section 1. The pressure vessel bears the ASME "M" stamp. The boiler operates on 480v/3p/60Hz. A six step solid state progressive sequencer with proportionate pressure control is included. Feed water to the boiler must be at least 60 psig or an optional feed water booster pump should be purchased. See Option 8.1.1 below.

CHAMBER CONFIGURATIONS

Bioseal – Cross Contamination Seal for Loading Side or Unloading Side

The bioseal provides a cross-contamination barrier to isolate the mechanical room from a clean room on either the unload or load side of the sterilizer. The bioseal is constructed with a stainless steel flange welded to the sterilizer chamber. Stainless steel panels are then fitted to the flange to provide a complete wall. The bioseal wall is secured to the facility wall and sealed with silicone to provide an air tight seal.

LOADING EQUIPMENT

Loading Cart

The loading cart is designed for use with a transfer carriage to allow the cart to be moved on tracks from the carriage into the chamber. (Pit-mounted sterilizers do not require a transfer carriage). The loading cart is fabricated of 316L stainless steel and has wheels for ease of insertion and removal from the chamber of the sterilizer. The loading cart has all-welded construction. The bottom shelf is stationary; other shelves are height adjustable. The cart comes equipped with one bottom shelf and one adjustable shelf. Includes removable tracks installed in the chamber to guide the loading cart. Units with chamber depths greater than 60" may utilize two half size carts for ease in loading and unloading the chamber.

Additional Loading Cart Shelves

The 316L stainless steel wire shelves are designed for use in conjunction with the loading cart and are height adjustable.

Transfer Carriage

The transfer carriage provides a stable platform for moving the loading cart within the work area. A locking mechanism holds the loading cart securely to the carriage. Two transfer carriages are recommended on pass-through models. Transfer carriages are constructed of 304 stainless steel.



CONTROL SYSTEM OPTIONS

Allen Bradley Compact Logix PLC Control System

The Allen-Bradley PLC provides automatic control of all the sterilizer functions. The PLC is a Compact Logix central processing unit providing high-level data access. The PLC is mounted in a UL listed NEMA 4 panel.

A Panelview Plus 1000 operator interface is provided for operator control and cycle programming. A color LCD alphanumeric display indicates the sterilizer operating state. Alarms are announced audibly and indicated in clear text. The Panelview Plus 1000 is mounted on the front fascia on the loading side of the sterilizer.

Double door units come equipped with a Panelview Plus 600 operator interface and allows the user to open and close the unload door and view the cycle progress as well as temperature, pressure and alarms. When enabled by an administrator, an operator can select a cycle and start a cycle.

The software is fully developed according to GAMP 4 regulations. Contact Sterilco for full configuration cycles.

RECORD KEEPING

Two-Pen Recorder

A two-pen strip chart recorder documents chamber temperature and pressure.

Six-Pen Recorder

A six-pen strip chart recorder (dot printer) documents chamber pressure and temperature as well as four load temperatures (optional, see item 4.6 below).

Paperless Video graphic Recorder

A six-channel panel mounted paperless recorder is available to store cycle date electronically. The recorder has a color LCD screen and records data on 3.5" floppy disk, zip disk or PCMCIA flash card. The Video graphic recorder is Ethernet ready for network communications. 21 CFR, Part 11 Software for data storage on a PC is provided with the recorder as standard.

8.5" x 11" Dot Matrix Printer

In place of the 2.5" strip chart printer, this larger printer allows for digital recording of multiple product probe temperatures (optional, see item 4.6 below) and Fo, as well as the standard data as listed in 1.18.2.

Pull-Out Drawer for Printer Mounting

A totally enclosed pullout drawer is mounted on the front fascia below the Panelview interface for easy access to the 8.5" x 11" printer. A clear Lexan cover allows viewing of the printer without pulling open the drawer. The printer rests on a wire rack within the drawer to allow for continuous paper feed and storage.

Three Additional Load Probes

In addition to the standard load probe, three additional load probes can be added for a total of four, for continuous monitoring of multiple locations.



OPTIONAL CYCLES

Solution Cycle with Air Over-pressure and 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 till 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, cooling of the product is started by injecting air at a pressure similar to that of the product to avoid breakage of the container. Fresh air is introduced in pulses to cool the product while cold water is introduced to the jacket of the chamber to further cool the product at a faster rate.

Elastomer Stopper Cycle with Heated Air Drying

This cycle provides effective sterilization of rubber stoppers. The load is preconditioned utilizing vacuum and steam pulses. The cycle then advances to heat-up and continues till 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 with heated air and vacuum pulses. This cycle is highly effective at removing moisture from the load.

Automatic Documented Filter Sterilization

Filter sterilization as a separate selectable cycle is provided via the control panel. Exposure time and temperature are settable parameters. Temperature and time are documented automatically via the data logger. Includes all necessary piping and instrumentation.

Effluent Sterilization Cycle

The chamber steam condensate is held inside the chamber throughout the sterilization cycle. Steam enters the chamber from the bottom of the chamber to ensure that the condensate is kept at the sterilization temperature throughout the cycle. Vacuum is pulled from the top of the chamber through the 0.2 micron filter to ensure adequate filtration before the drain.

STEAM GENERATOR OPTIONS

Feed Water Booster Pump System

Boosts the feed water pressure to 100 psig. The steam generator requires feed water at 10 psig higher pressure than the desired clean steam output pressure. The Feed Water Booster Pump System comes complete with piping, pump, wiring and necessary components.

Automatic Blow Down System w/Tank

The automatic blow down system allows 24 hour operation, with programmable single or multiple blow downs to occur daily with an adjustable time delay for precise control of the blow down period. During the blow down period, the control system shall de-energize the clean steam generator heaters and will not re-energize the heaters until the blow down cycle is complete. The blow down effluent is lead into a ASME tank to relieve the pressure, prior to drain.

ADDITIONAL SERVICES

IQ/OQ Protocols

Complete executable IQ/OQ protocols are provided for use by the purchaser for execution by others. Travel costs, living expenses and local transportation billed at actual +15%.



On-Site IQ/OQ Validation

Complete on-site Installation Qualification (IQ) and Operational Qualification (OQ) is performed at the purchaser's site. Deliverables will include completed IQ and OQ package with a summary report. Travel costs, living expenses and local transportation billed at actual +15%.

MAINTENANCE

Spare Parts Kit

The kit includes replacement items needed in extended use such as: chart paper, gaskets, valve repair kits, fuses, lamps, stainless steel cleaner, strainers, etc. See attached list for details.

Preventative Maintenance Contract

The sterilizer is maintained under a preventative maintenance contract, which includes one visit per year. Wear parts are changed, strainers and traps are cleaned, the sterilizer is completely checked over, and the

INSTALLATION AND START-UP SERVICES OPTIONS

Installation Supervision

A Sterilco Service Engineer will supervise the installation of the sterilizer to ensure it is placed level and all utilities are correctly connected to the sterilizer.

Installation Service

Complete installation can be provided upon request. Please contact Sterilco with your complete installation needs in order to provide a quote. A sample installation package may include: Off-load the sterilizer from the delivery truck, move the unit into place, reassemble any components, final connections by others. Pricing assumes that a normal loading dock height is available for off loading the unit and moving into the building, the sterilizer will be installed on a ground floor. Free and clear access through hallways and doorways without the need for dismantling. Utilities will be brought up to the connection points indicated on the submittal drawings by the owner of the facility.

Start-up Service

After the equipment has been installed and connected to utilities, a Sterilco service engineer will perform start-up of the equipment at the purchaser's site. Start-up services include inspection of the equipment and installation, operating and adjustment of the sterilizer, testing the operation and training of the purchaser's operating and maintenance personnel.