BMT USA

Specialists in cGMP Equipment
For
Pharmaceutical & Biotech
Industries

MMM GROUP WORLD WIDE

MMM GmbH, Planegg
MMM Medcenter Einrichtungen GmbH
Germany

BMT a.s.
Brno
Czech Republic

MMM Krankenhauseinrichtungen GmbH
Austria

BMT USA, LLC
Seattle, USA

MMM Medical Equipment UK Ltd
United Kingdom

BMT Iberia, S.L.
Madrid, Spain

MMM Sterilisatoren AG
Schweiz

BMT s.r.o. Piešťany
Slovakia

MMM Polska Sp.z.o.o.
BMT Sp. z o.o., Krakow
Polen

DP BMT UA, Kiew
Ukraina

OOO MMM Krankenhauseinrichtungen
OOO BMT Moskva
Russland

BMT USA
SEATTLE, WASHINGTON

BMT cGMP Steam Sterilizers

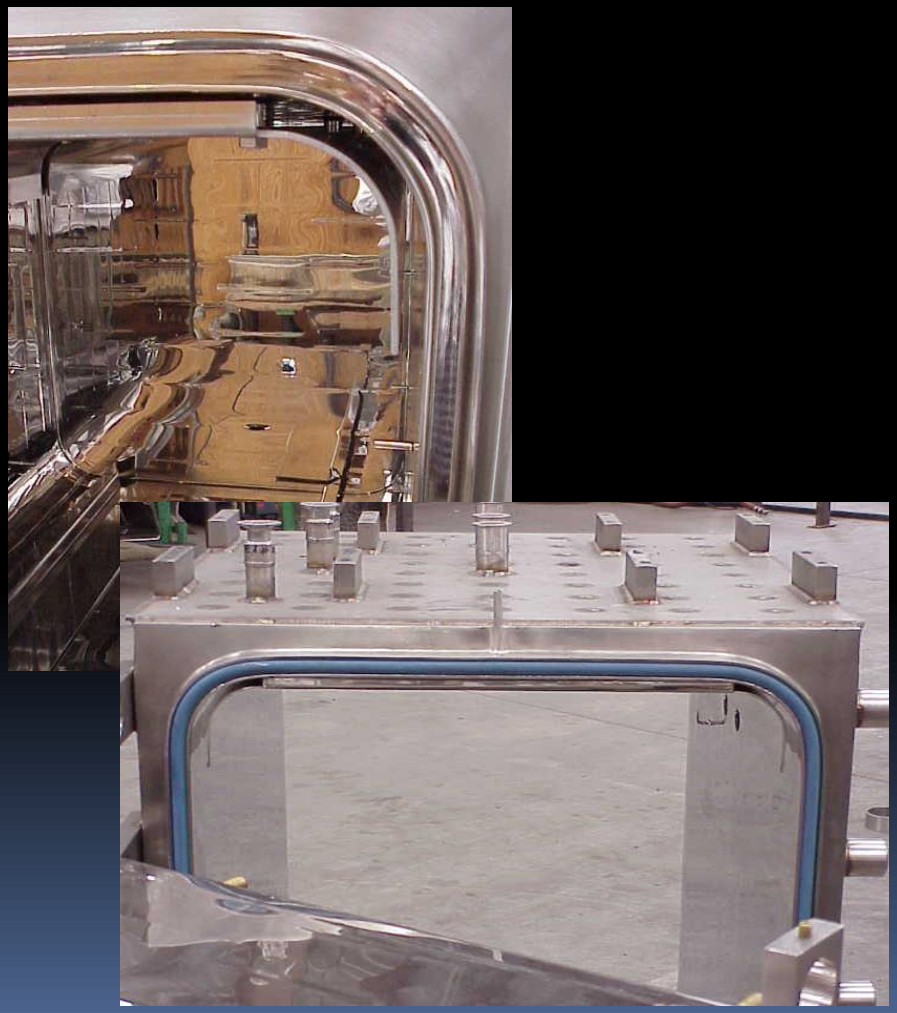
BMT cGMP & cGMP READY STERILIZERS AVAILABLE IN A WIDE RANGE OF CHAMBER SIZES & CONFIGURATIONS

BMT
cGMP Steam Sterilizers

Construction meets or exceeds the requirements or recommendations of:

cGMP	Current Good Manufacturing Practices as per USA FDA
IMHS	Industrial Moist Heat Sterilization: International Standard 11134:1994
EN 285	British Standard for Steam Sterilizers
ASME	American Society of Mechanical Engineers Section VIII, Division 1
CPC	Chinese Pressure Vessel Code
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
GAMP	Good Automated Manufacturing Practice

Chamber Construction



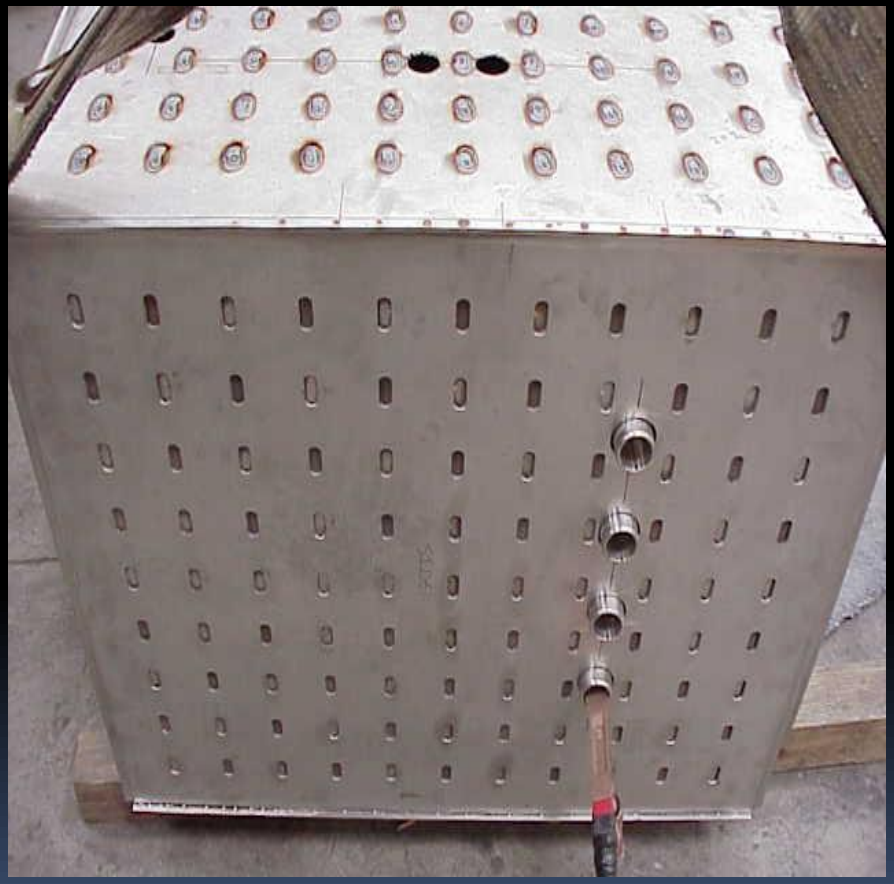
- Chamber is polished to a 25 Ra or a mirror finish with a surface finish of better than 10 Ra
- The gasket head ring is polished a mirror polish .
- This allows for smooth movement of the gasket without the need for any type of lubrication

Chamber Construction

Cut away of chamber corner

- The “U” channels are welded to the four sides of the chamber, with stich welding
- Jacket ports are welded on the inside and outside of the “U” channels

Chamber Construction



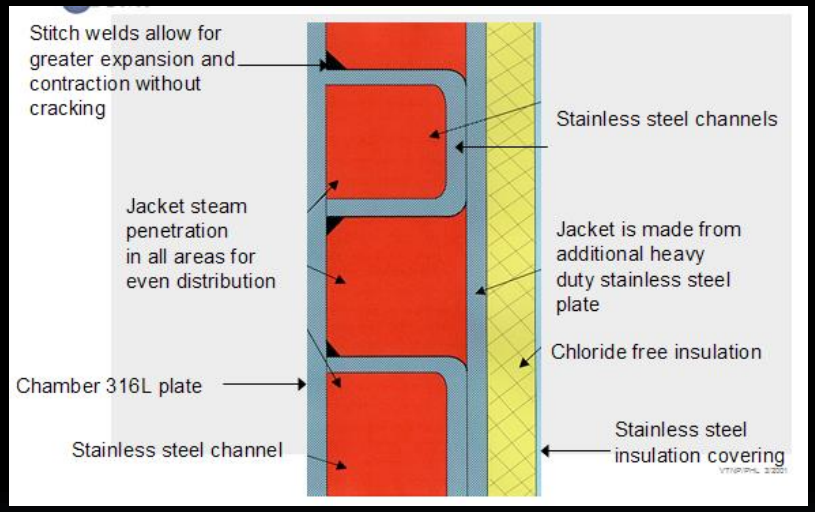
- An additional 316L stainless steel plate is installed over the “U” channels
- The plate is welded on each corner and the plug is welded to each “U” channel
- Forms a complete envelope jacket

Chamber Construction

Chamber ports are welded to inside of chamber, outside of chamber and out side of jacket

Chamber Construction

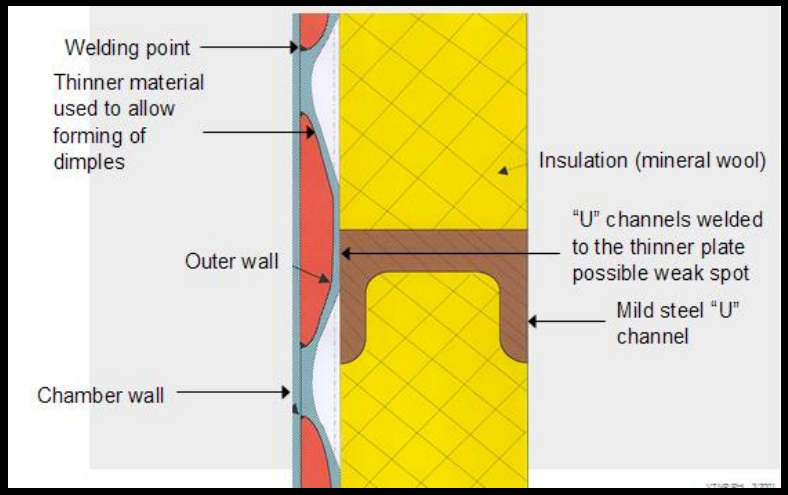
BMT Chamber Construction



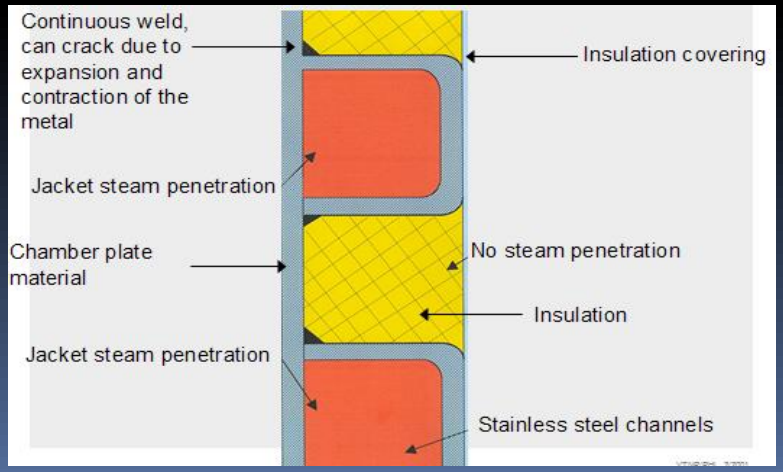
BMT Chamber Features:

- **100% 316L Stainless steel for chamber and jacket**
- **Rigid Stainless Steel insulation covering**
- **Even steam distribution across chamber translates into better temperature distribution in chamber – typical +/- 0.2 C**
- **15-year non-prorated – longest in the industry!**

Typical Dimple Construction



Typical U-Channel Construction



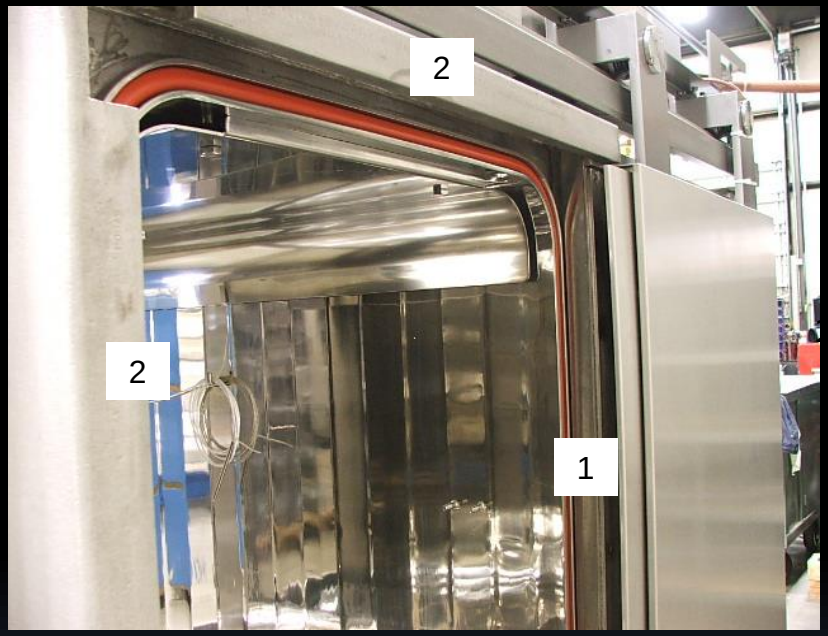
Competitors Pressure Vessel

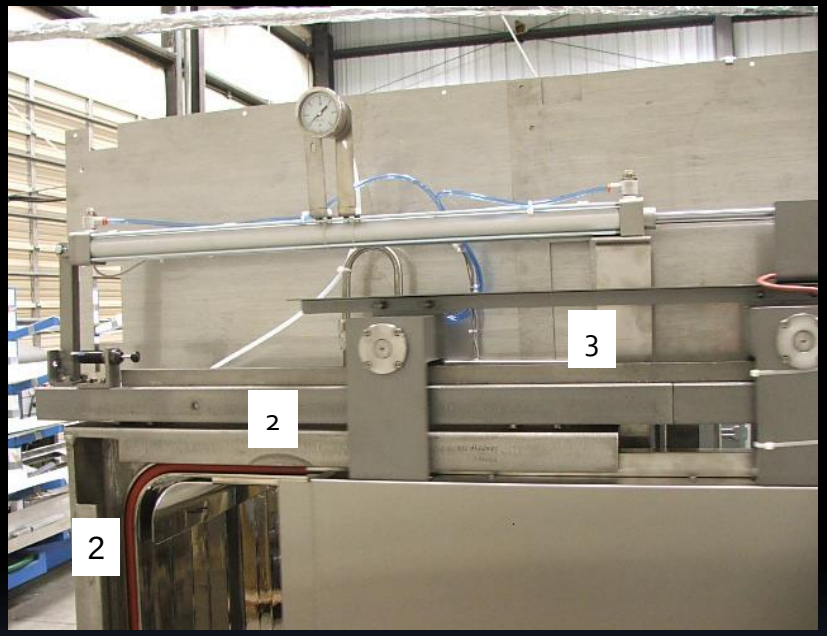
316L stainless steel chamber, dimple jacket, carbon steel support Beams

Door Design

Vertical or Horizontal
Sliding Doors

Door features



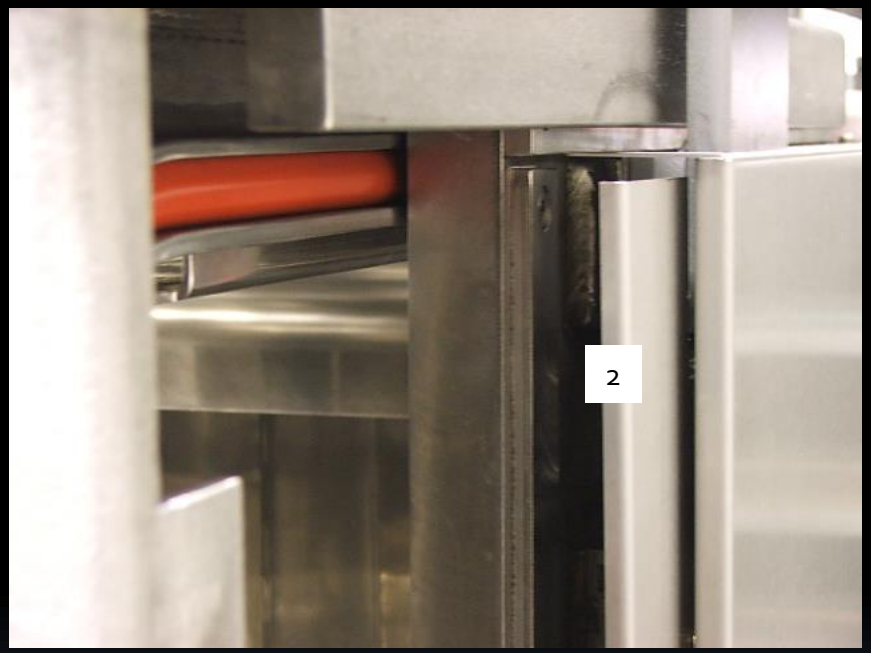


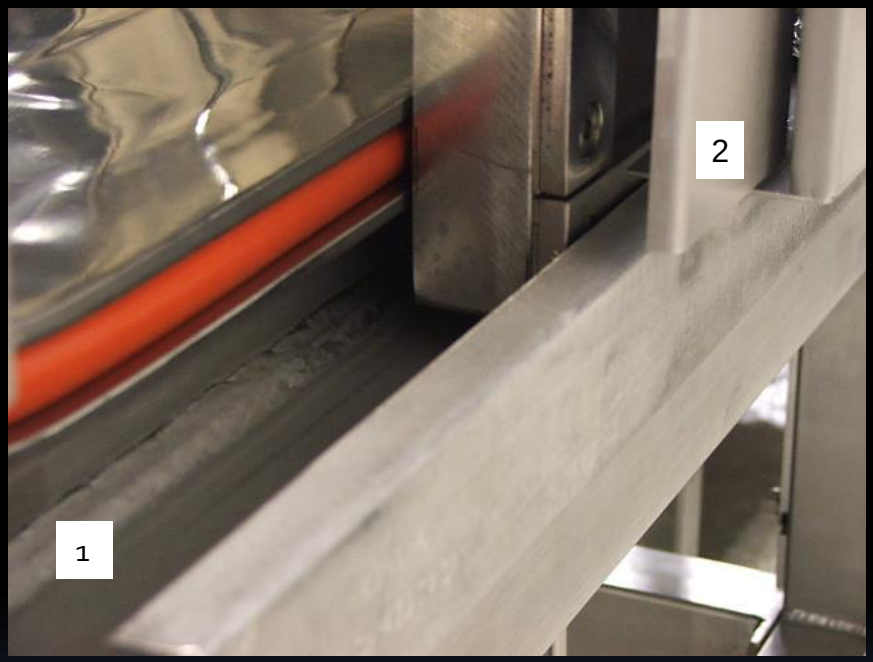
1. 316L solid stainless steel door construction for more reliable precise operation.

2. To close, door slides into 3-sided retaining frame constructed of 316L SS angles (3/4" thick) that are welded to the chamber end plate with full penetration welds. On the trailing end of the door, a C-shaped retainer interlocks with the chamber end plate when fully closed. This design provides full, even restraint of the door on all four sides without the use of locking pins which require frequent readjustment of the door to match the locking restraints.

3. Door wheel assemblies, mounted on top of the door, ride on 400 series SS rail – much harder and more durable than 316SS.

Door features

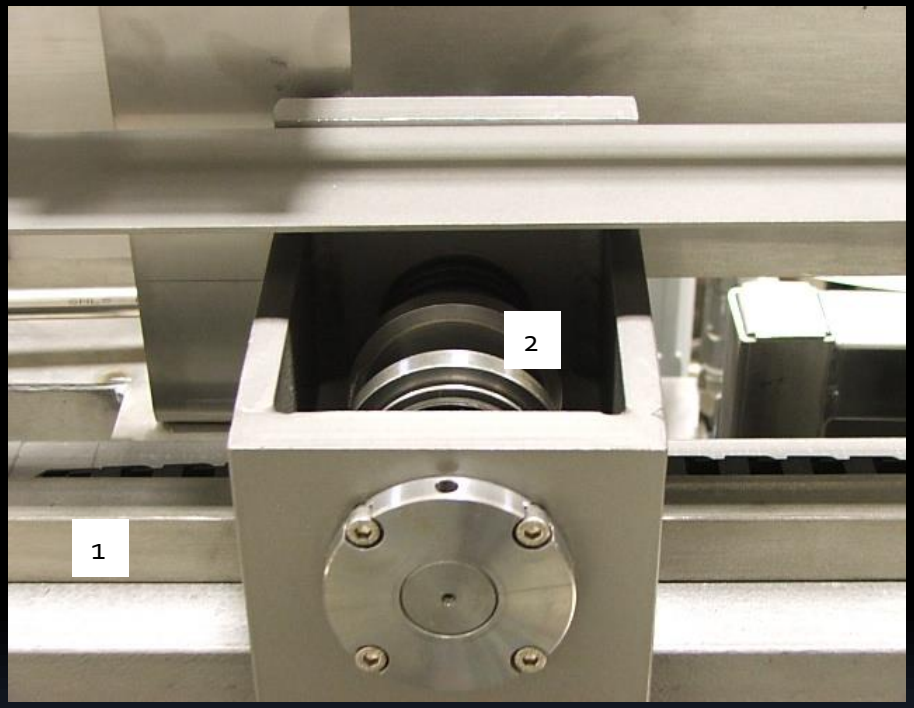


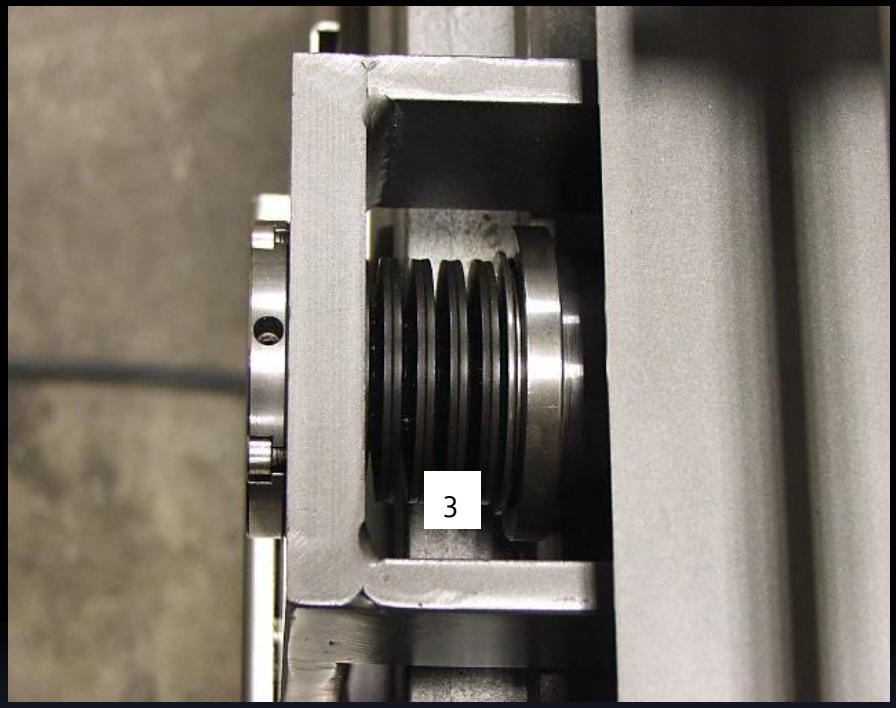


1. Full penetration weld: Door retention angle to chamber end plate.

2. Light curtain will stop door closing and reopen door if obstacle in doorway.

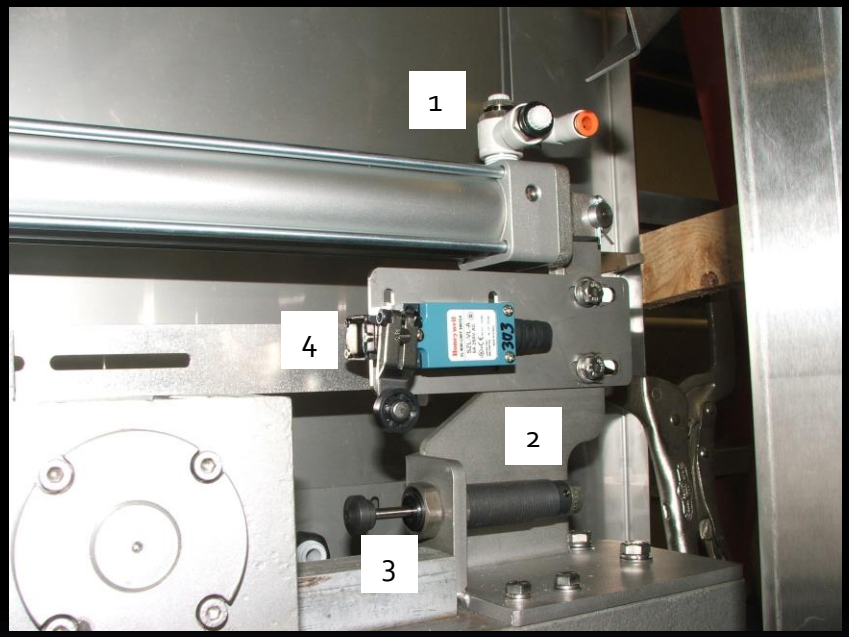
Door Features

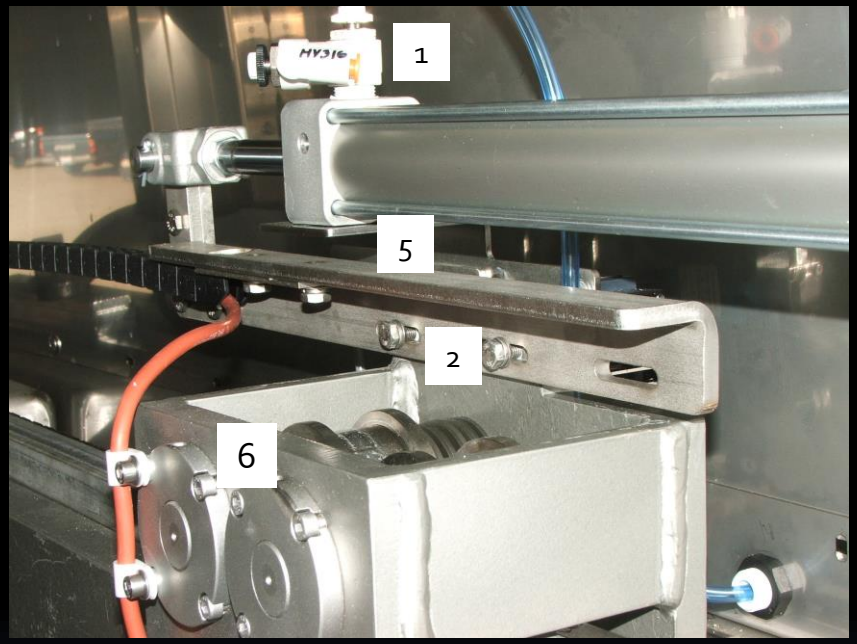




1. 400 Series stainless steel door wheel rail assembly – harder material for maximum durability.
2. Hardened steel door wheel (for larger, heavier doors, dual wheels are used on each end of door)
3. Bi-directional spring washers installed on both sides of the wheel, allows inward movement when chamber is in vacuum, and outward movement when chamber is pressurized. Door returns to neutral starting position at atmospheric pressure, allowing free movement when door seal is retracted.

Door Features





1. Bi-directional flow (speed) adjustment valves allow metering of air flow in and out of the door cylinder. Used on both the fixed end and rod end for fine tuning of door movement speed.
2. Heavy duty 1-piece cylinder mounting bracket made of ¼" SS plate minimizes deflection to keep door movement on track. Used on both ends of the door cylinder.
3. Mechanical damper/shock absorber (1 at each end) prevents door from hard stops at end of travel.
4. Door position switches (both opened/closed) are directly actuated by the door, providing for a higher level of safety than cylinder mounted switches.
5. Cylinder support bracket mounted in center supports door cylinder when rod is extended, preventing binding and damage to the cylinder.
6. Dual wheels provided for larger and heavier doors.

316L Stainless Steel Piping

- All piping in contact with the Chamber is 316L
- Sanitary design
- Sloped to drain
- No dead legs (3x pipe dia.)
- Orbital welded or tri-clamp connections
- Sanitary piston or diaphragm valves

0.2 micron Sanitary Filter

- Filters air for chamber equalization at the end of the cycle
- Can be sterilized in place
- Has ports for water intrusion testing

Vacuum Pump Piping Skid Service Area

The unit is constructed in three separate skids for ease in moving the unit down hallways, doorways and into its final resting place.

- Chamber skid
- Piping Skid
- Control System skid

The piping skid is easily connected by tri-clamp connections. The control system skid is easily connect with quick connectors.

Optional water recirc system for vacuum pump seal water greatly reduces water consumption

All piping is insulated and labeled for hot or cold services.

Optional Pure Steam Sampling System

BIOSEALS

- Typically on double door (pass-through) units, but can be on single door
- Designed to separate load (dirty) & unload (clean) sides
- Constructed of 304 or 316 stainless steel
- Fully welded designs for BSL3/4 area’s

Bioseals on one or both ends of the sterilizer.

Built for standard separation of the clean room from the loading area or BSL3/BSL4 applications

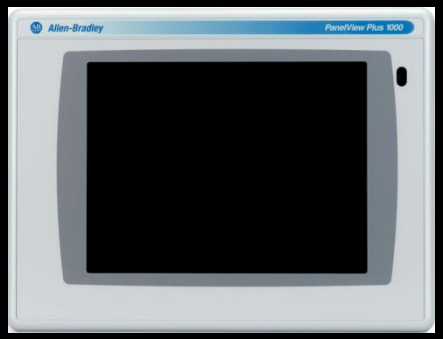

2 TON

Installed Bioseal

Control System Options

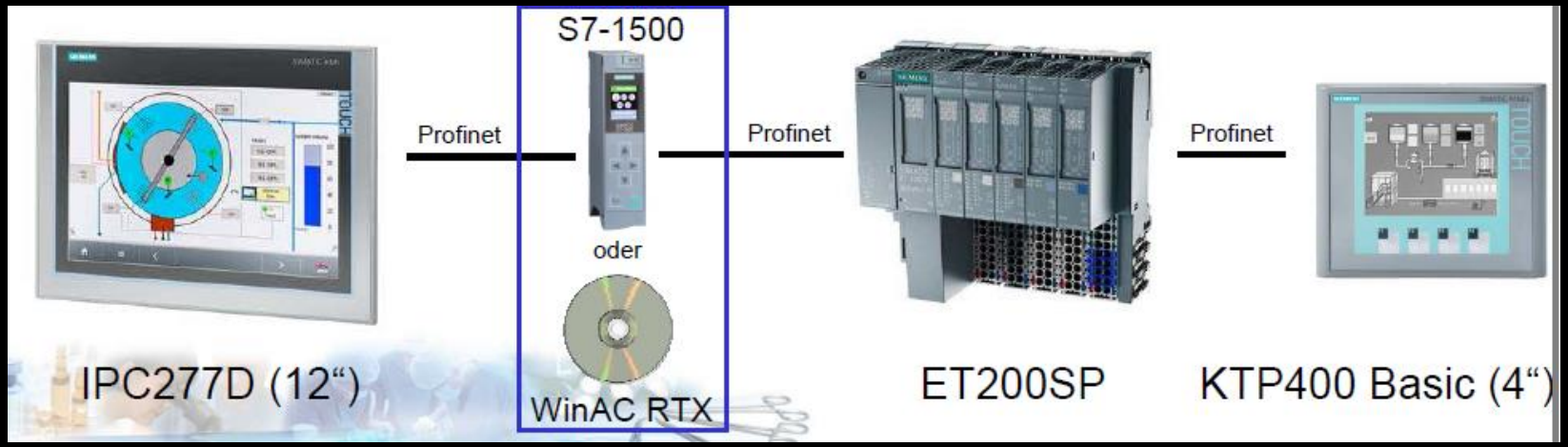
Allen Bradley Compact Logix

- 20 programmable Cycles
- Fo base sterilization
- 21 CFR, Compliant
- Maximum flexibility in setting up cycles
- Over 99 set-able parameters
- Windows CE based system for user friendly navigation
- NEMA 4X Control Box
- UL 508 Listed



PVP 1000

Siemens S7-1500



- PC Based System
- GAMP 5 Documentation Available
- Conformity with 21 CFR Part 11:
  - User management
  - Data archiving with checksum
  - Audit trail (log book for relevant operator actions on load and unload side)
- 50 Programmable Cycles
- Software SiSoft for control panels on loading and unloading side was created with Simatic WinCC flexible (TIA portal) and Step 7.

Cycle Data Printing

Sterilizer printers print data from collected from the PLC during the sterilization cycle such as time, temperature, pressure, cycle steps and alarms is any

- Standard 2.5” strip Chart Printer

- OPTIONAL Laser Printer for 8.5” x 11” paper cycle print reports

OPTIONAL Data Recording

Recording is a secondary verification separate from the PLC

- Strip Chart Recorders
  - 2-Pen
  - 4-Pen
  - 6-Pen

- Circular Chart Recorders

- Paperless Chart Recorders

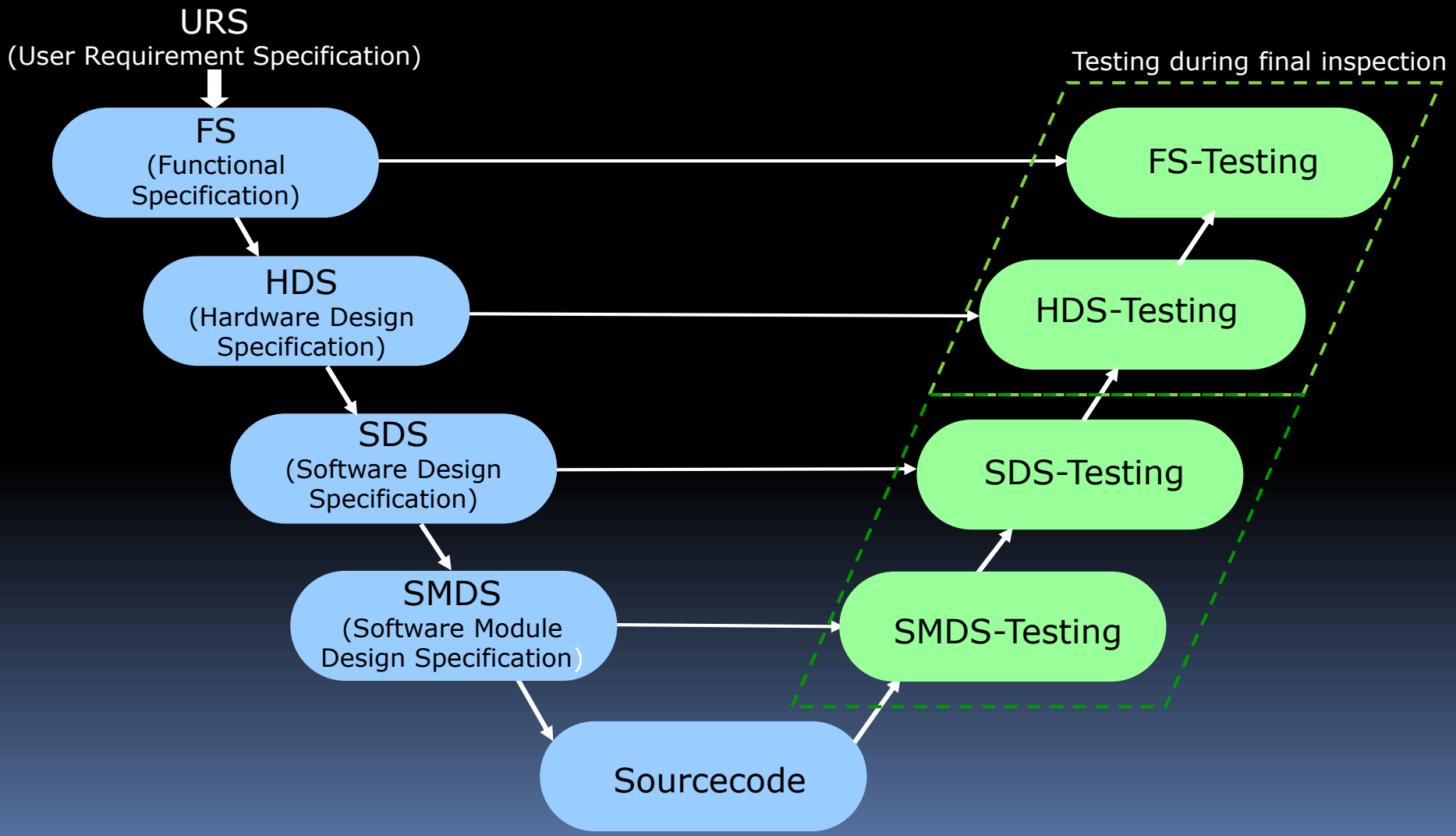
DATA Transfer

DATA on PLC Collected in SCADA DATA File

Common Communication Protocols Available for Transfer of DATA to customer specific sytems ie; Delta V or Pi

- Profibus
- Profinet
- Modbus RTU
- Modbus TCP
- OPC – Common Link to SCADA System utilizing RS Links

V-model for software validation according to BMT "Lifecycle"



Sterile/Unload Side

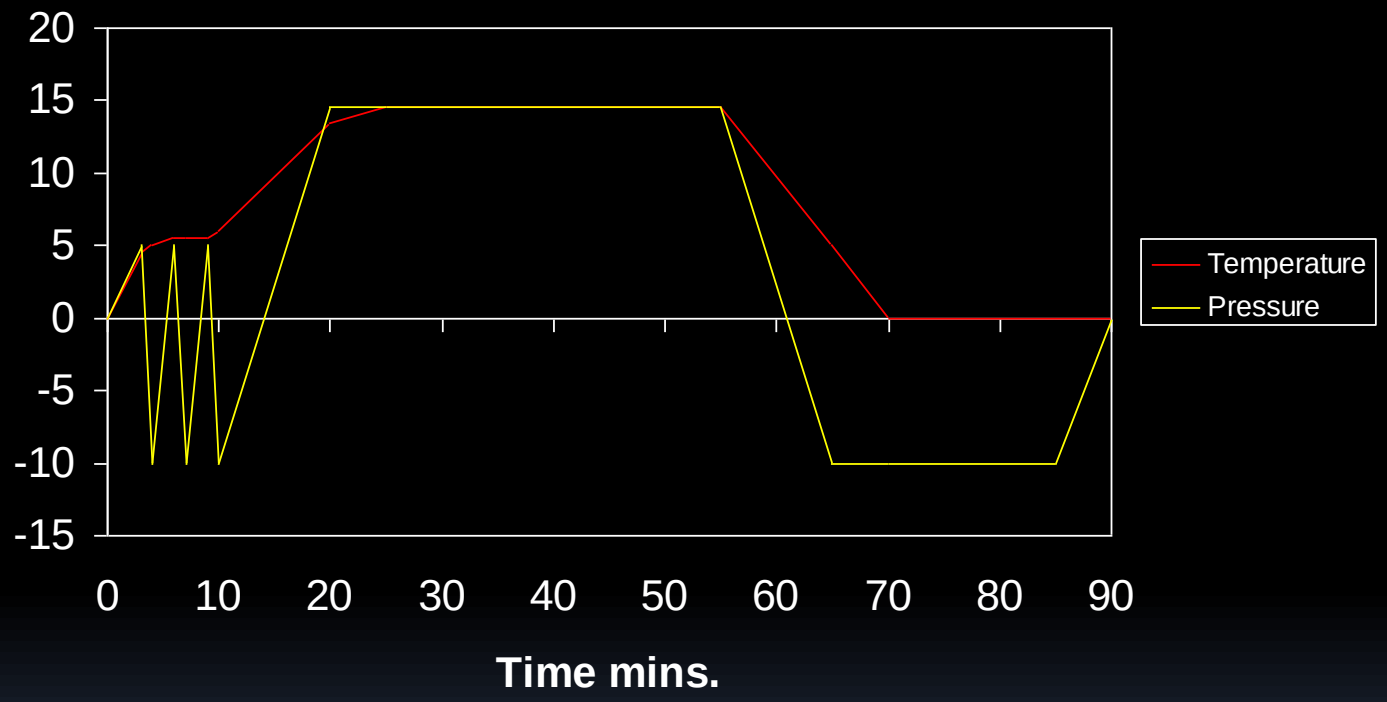
Pit-Mounted Sterilizer

Floor Mounted

Vacuum Steam Sterilizer

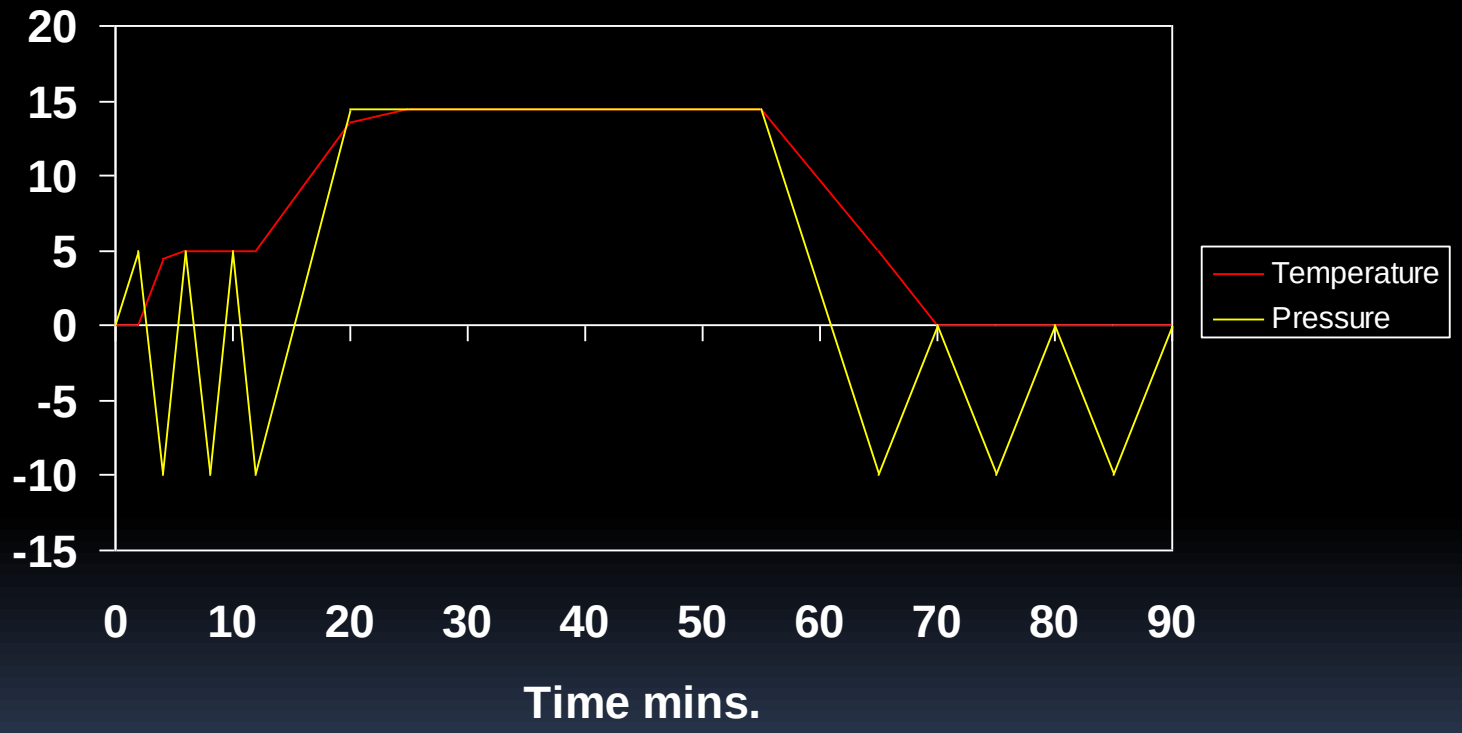
- Pre and Post vacuum pulses for air removal and drying purposes
- Ideal for sterilization of porous loads, textiles, glass or metal containers, machine parts, rubber stoppers and infectious waste as well as liquid loads in open or vented containers
- Loads leave the chamber dry and ready for use or disposal

General Purpose Cycle – Vacuum

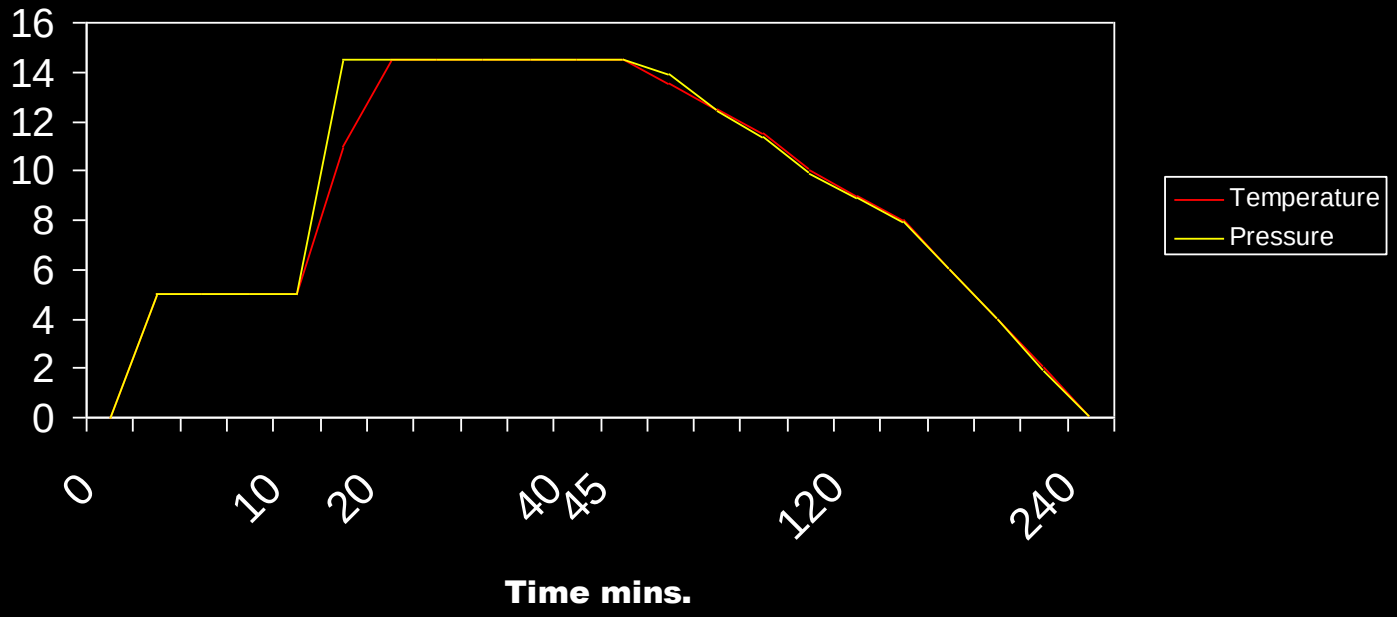


Effective for sterilization of hard goods, filters, linens and other porous materials, wrapped goods and product that is unaffected by vacuum. Very effective at removing moisture from load during drying.

Rubber Stopper Cycle – Optional heated air drying

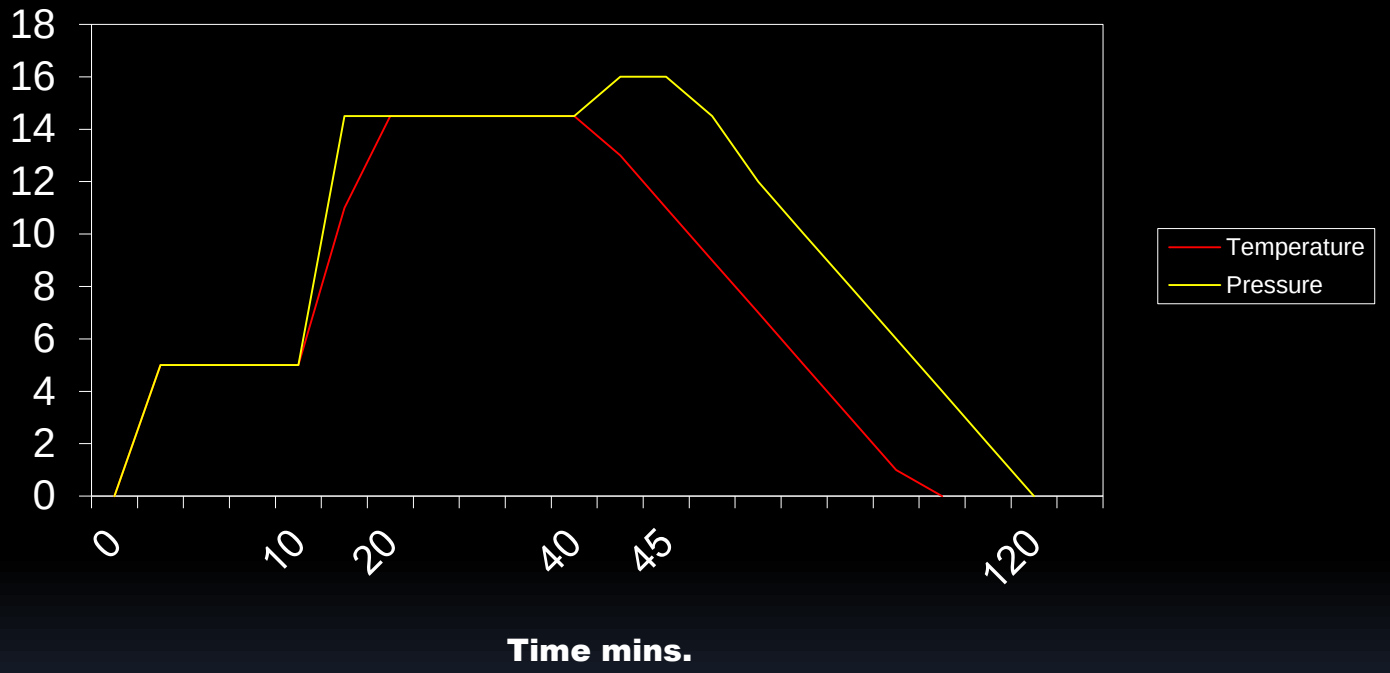


Solution Cycle with slow exhaust



Effective for sterilizing liquid products or items in vented glass containers. Load is pre-conditioned by steam pulses, then heat-up to set point. Cooling by slow exhaust ramping until liquids reach a temperature below boiling.

Solution Cycle – Air overpressure and water in jacket cooling (optional)



Allows faster sterilization of liquids in sealed containers than a solution cycle with slow exhaust by providing an over-pressure of air after exposure and replacing the steam in the jacket with cooling water.

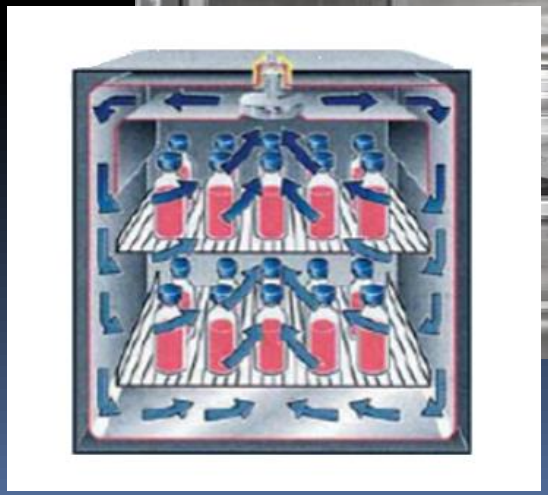
Terminal Sterilizers

Ventipro Steam-Air Sterilizer

- 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 liquid in semi sealed or sealed glass containers
- Product containers leave the chamber dry and ready for labeling

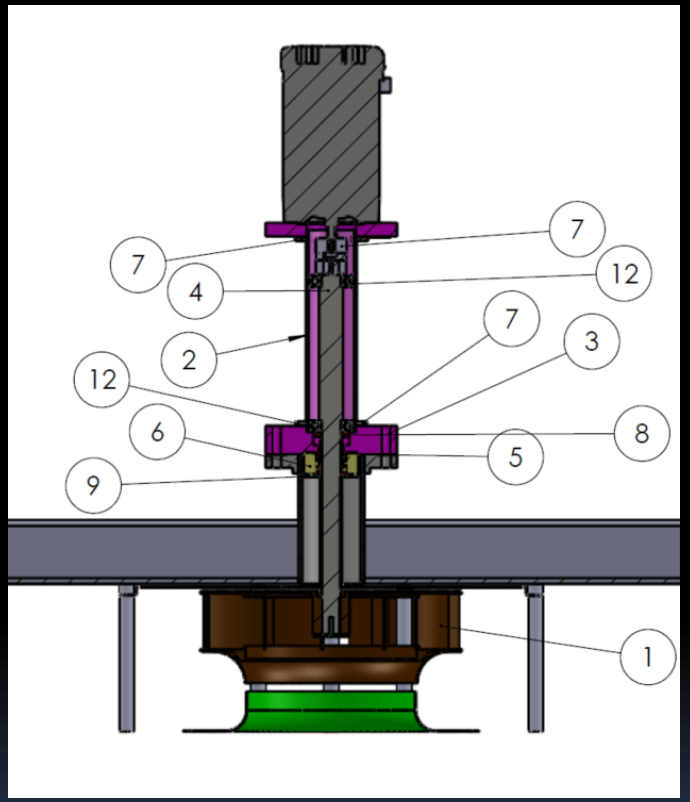
Ventipro Steam-Air Sterilizer

- 316L SS Chamber
- Creation of steam and air mixture with air above saturated steam pressure for cool down
- Fan in chamber ceiling for mixing and recirculating steam-air mixture
- Heat exchangers on chamber wall for rapid cooling



Ventipro Steam-Air Sterilizer

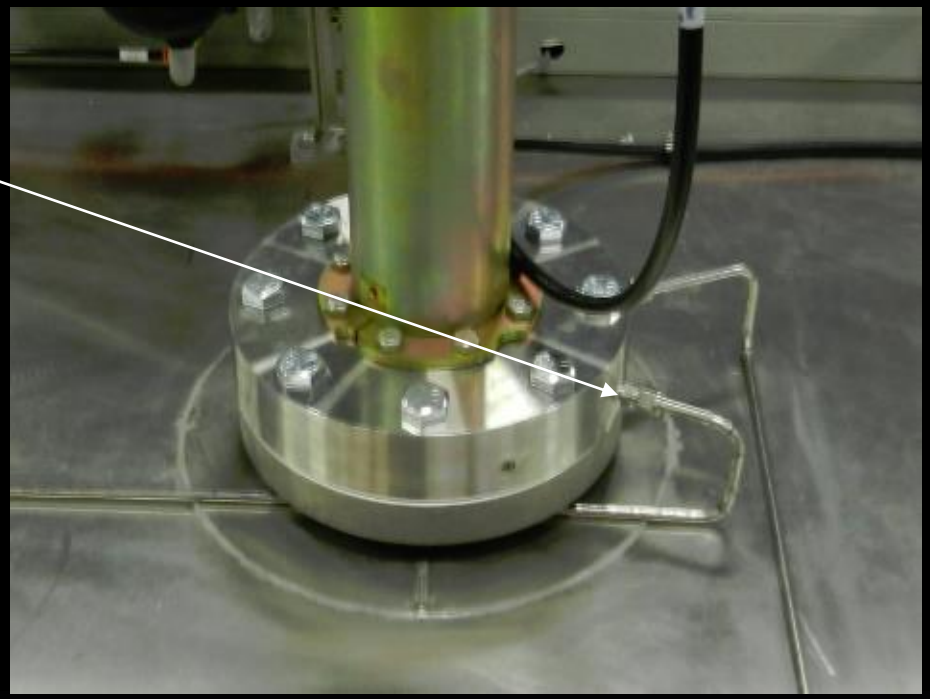
ITEM NO.	PART NUMBER	DESCRIPTION	Default/ QTY.
1	121-30129-1	3-1/2" custom pipe flange	1
2	121-30129-2	3" Outer Pipe machined	1
3	121-30129-3	Lower 3-1/2" Pipe flange 316SS Custom	1
4	121-30129-4	SAM Shaft	1
5	121-30129-5	Chromed Sleeve	1
6	121-30129-6	Seal Cartridge	1
7	121-30129-7	Retaining flange, half	4
8	121-30129-8	safety washer	1
9	121-30129-9	seal cartridge cover	1
10	121-30129-10	Shaft End Washer Chamber side	1
11	121-30129-11	3-1/2" custom pipe flange small motor	1
12	6661K128	bearing	2

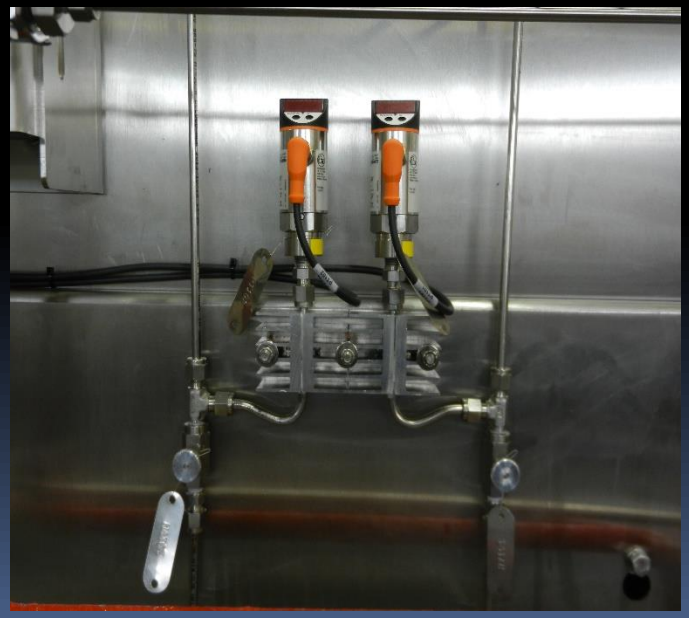


- Fan shaft assembly allows for easy removal and replacement of seals

Ventipro Steam-Air Sterilizer

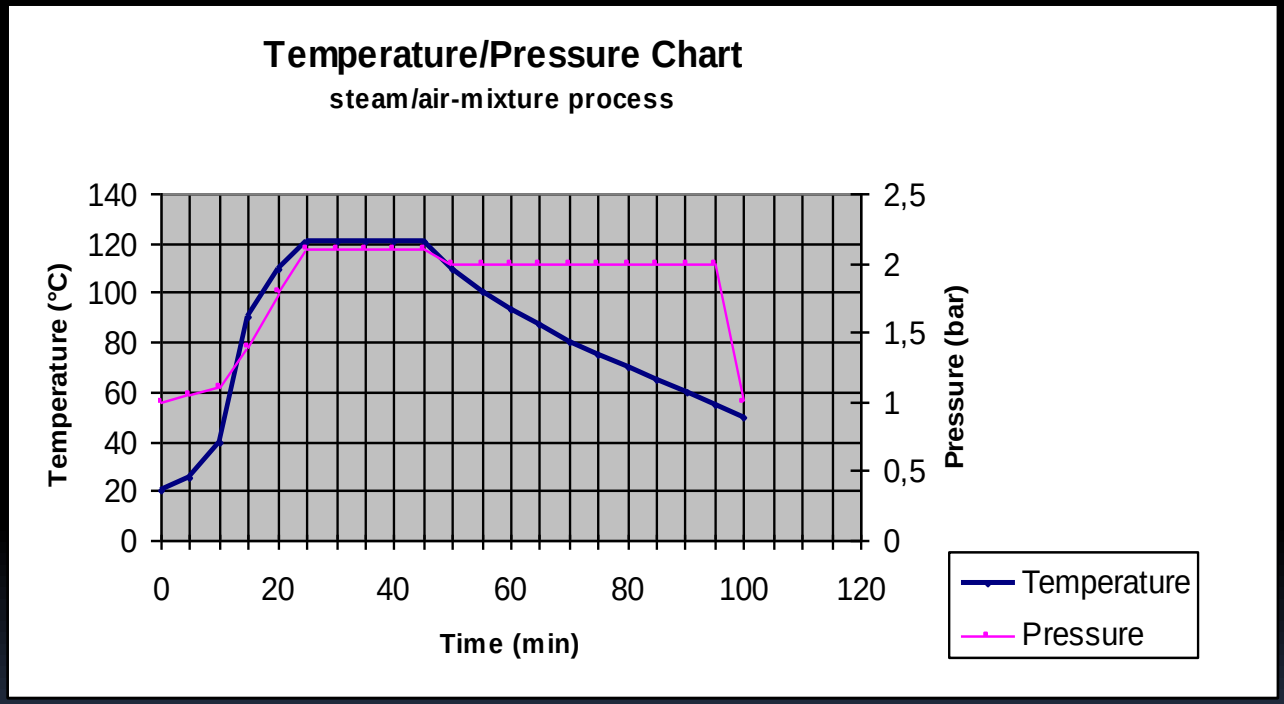
- Vacuum and Pressure Leak Test system for chamber fan seal
- Allowable leakage from seals to pressure transmitters





- Informational alarm for seal replacement is produced when pressure exceeds set-point

Typical Steam-Air Cycle



Aquapro Water Shower Sterilizer

Aquapro Water Shower Sterilizer

Fast heating and cooling enables gentle sterilization of heat-sensitive loads

Ideal for sterilization of liquid in sealed containers

No pure steam required as water is heated indirectly by plant steam

Load will be wet when unloaded from the chamber

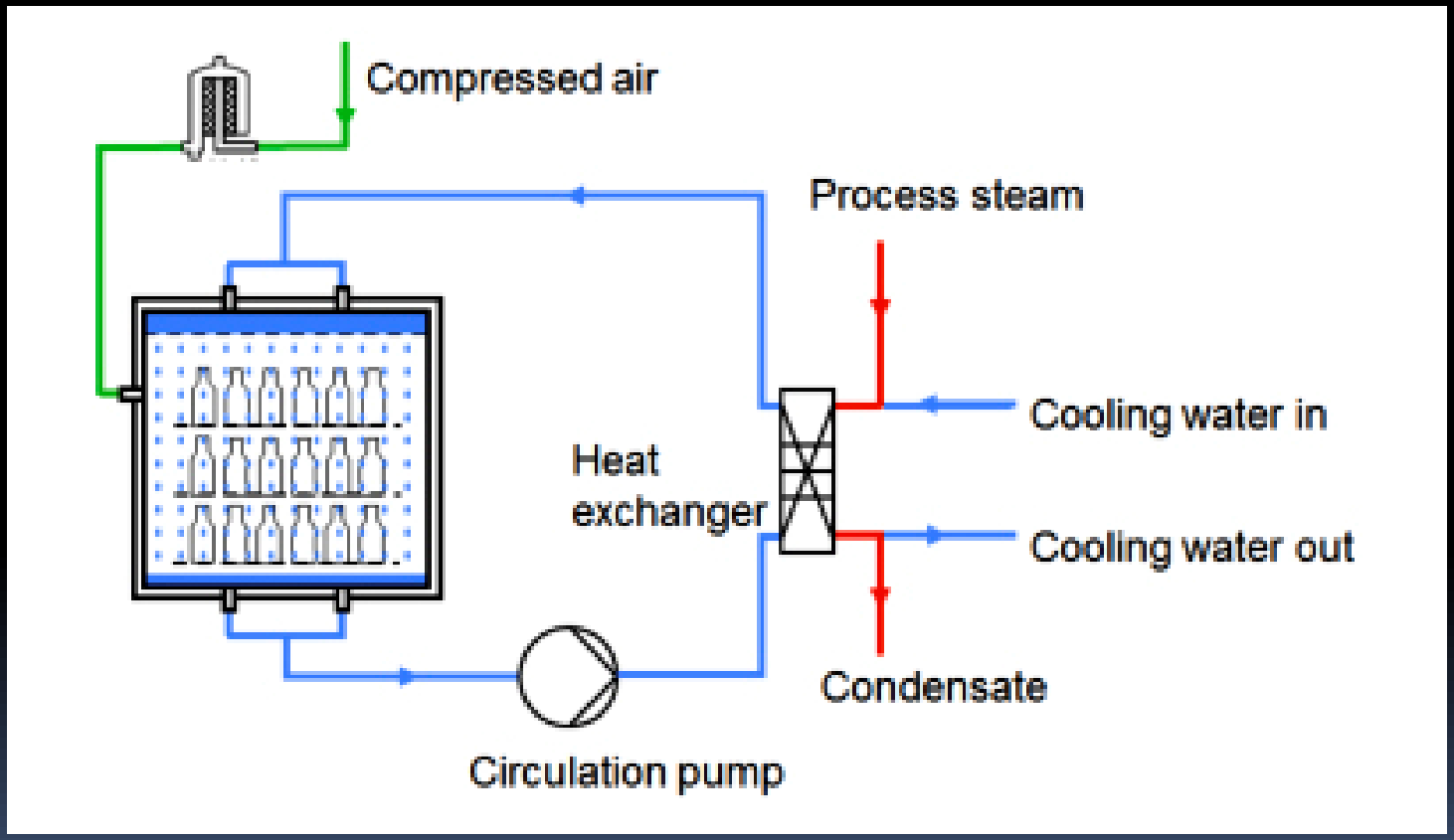
Aquapro Water Cascade Sterilizer

Perforated tray for water distribution with holes on front, sides, back and bottom for heating chamber

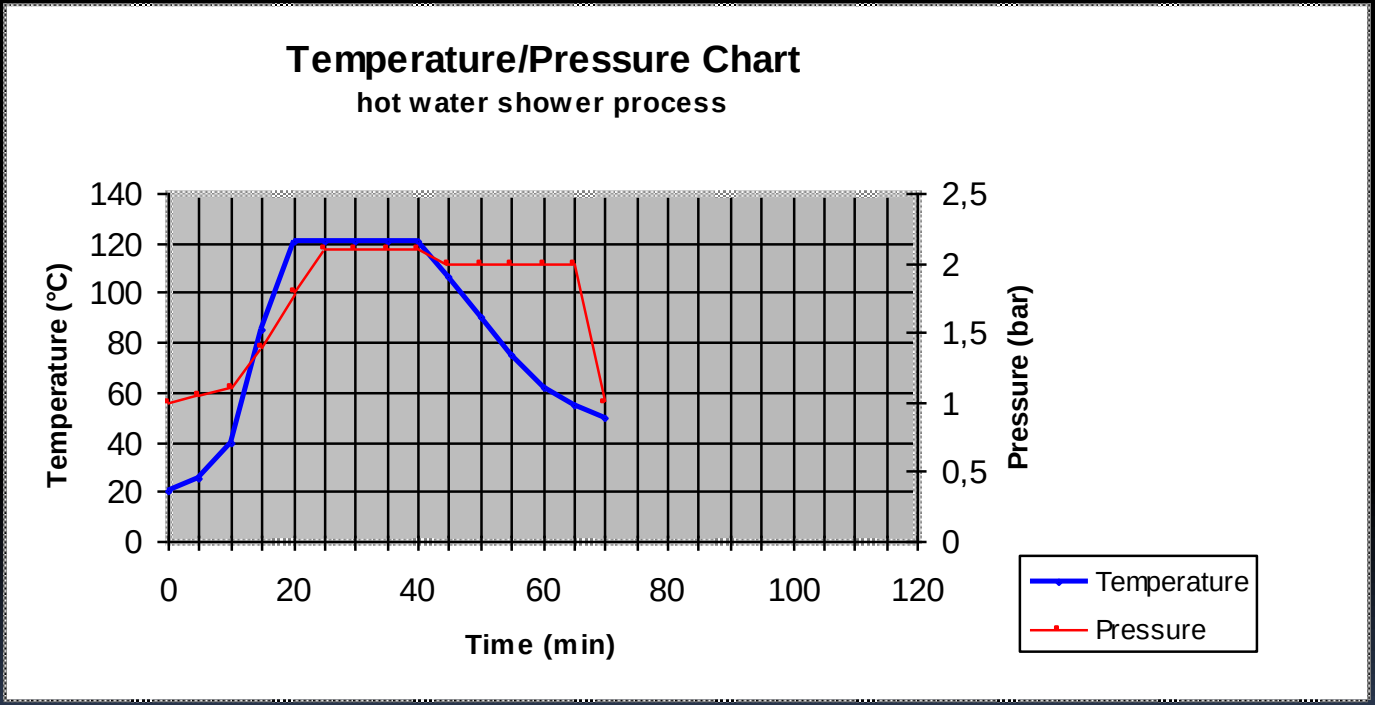
High capacity recirculation pumps for even temperature distribution over the load

External heat exchangers for heating and cooling the recirculating water

Aquapro Water Cascade Sterilizer

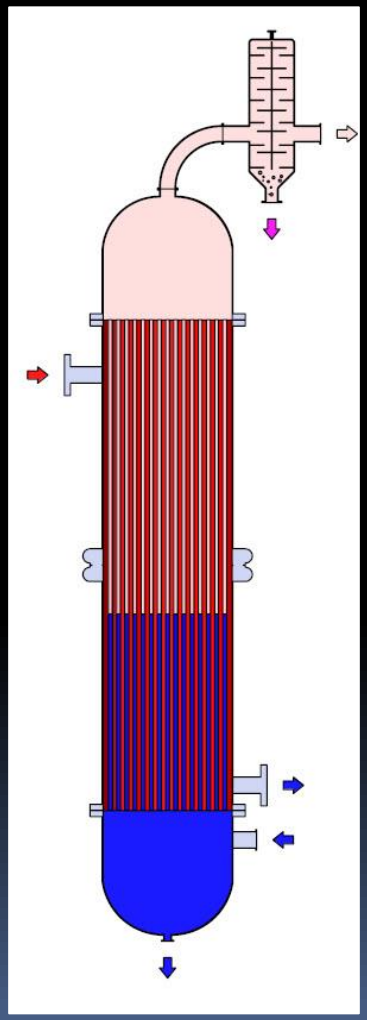


Aquapro Water Cascae Sterilizer Typical Cycle



BMT Steam-to-Steam Generators

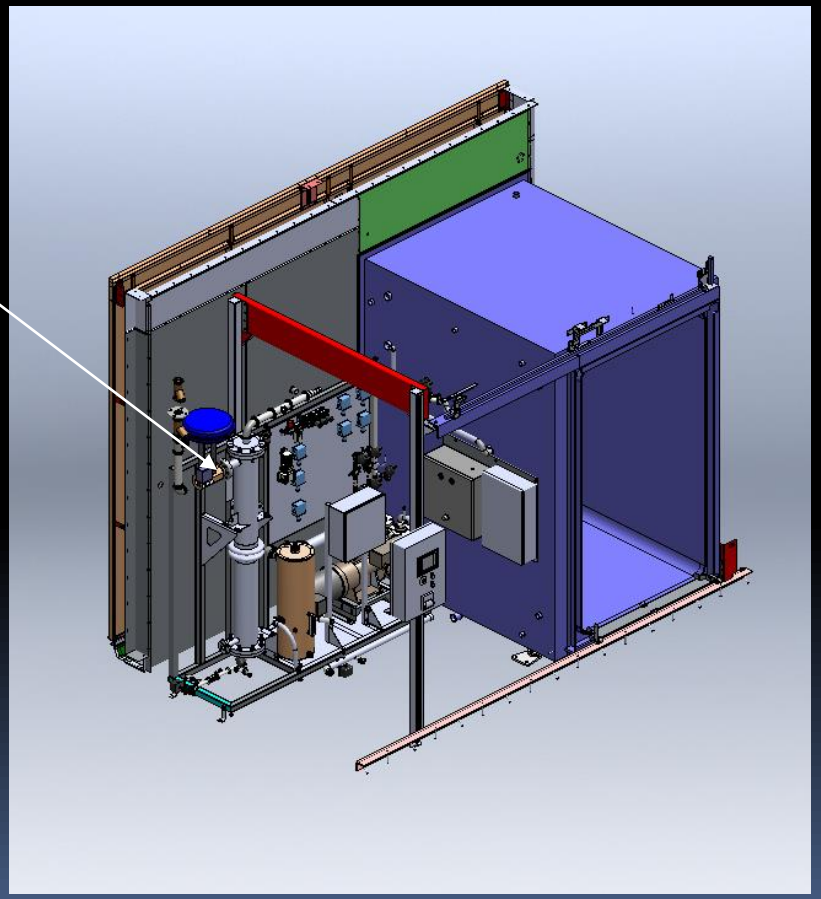
BMT Steam Generator Column



- Full sanitary design for cGMP Operations
- Construction in 316L SS on product side
- 25Ra µinch internal finish standard
- Built as double tube sheet design to prevent accidental contamination of plant steam from entering clean steam

Integrated Steam-to-Steam Generator

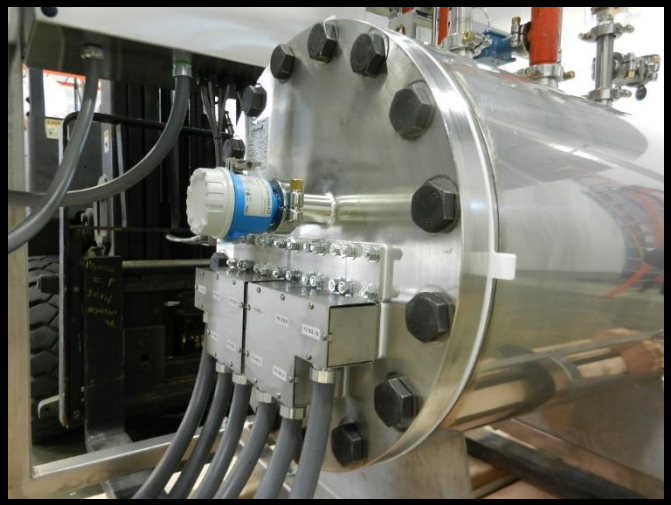
- Steam Generator integrated into the steam sterilizer mechanical space.
- Control of the steam generator via the sterilizer Allen Bradley control system.
- Location of steam generator within the mechanical space will be determined based on customer space availability



Steam Generators
Electric Heated or Steam-to-Steam

Electric heated model

Electric Clean Steam Generator Pressure Vessel



- 316L stainless steel vessel with sanitary fittings for feed water & clean steam.
- All piping in contact with feed water and clean steam is 316L stainless steel, sanitary connections with sanitary components.
- The pressure vessel bears the ASME code stamp

- The heating elements are fully immersed in water.
- Heating Elements are 316L stainless steel with sanitary connections on the vessel

Siemens LOGO PLC

- Automatic Control of all Steam Generator Functions
- Industrial Grade PLC
- UL508 Enclosure

Optional AB Micrologix or Compact Logix PLC Systems

Optional Stainless Steel Feed water Pump System with Variable Frequency Drive

Optional Clean Steam Cooler with Sample port

Custom Made Loading Equipment

Every Sterilizer is Factory Acceptance Tested

Purified Water and Clean Steam is utilized for testing

Standard Documentation

Design Qualification

- Piping and Instrument Diagram
- Installation Drawings
- Electrical Drawings
- Software Design Document
- Functional Specification
- Software Source Code Listing
- Control System Documentation
- Installation Manual
- Operation Manual
- Mechanical Component Parts List
- Electrical Component Parts List
- Mechanical Component Cut Sheets
- Electrical Component Parts List

Installation Qualification

- Material Certificates
- Welding logs
- Pressure Vessel Certificates
- Calibration Certificates
- Factory Acceptance Test Protocols
- Site Acceptance Test Protocols
- IQ/OQ Protocols (optional)

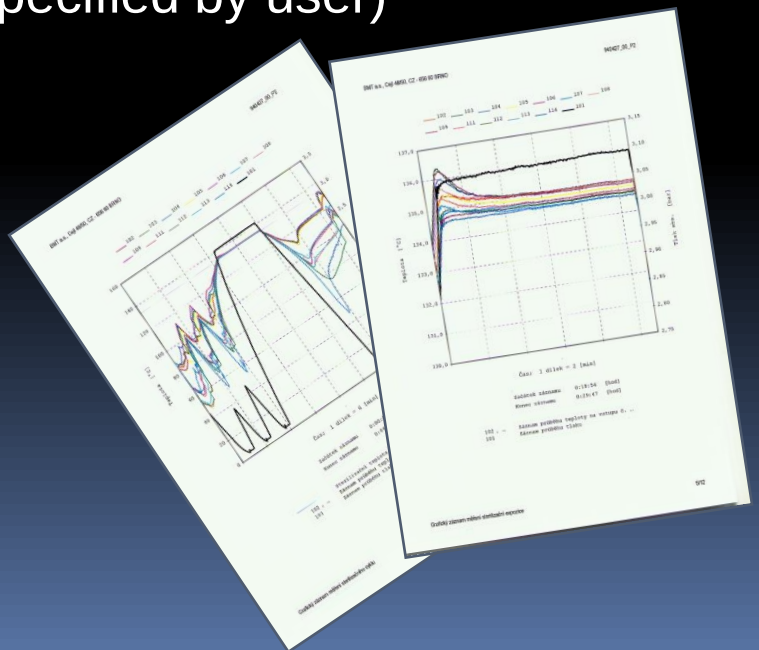
Bill of Material Sample

Material list comes complete with manufacturer and manufacturers part no. so parts can be located locally or purchased from BMT USA

TAG NUMBER	FUNCTION/SERVICE	BMT P/N	DESCRIPTION	MANUFACTURER	MANUFACTURER PART NUMBER
Steam Inlet to Chamber & Jacket Assemblies					
ASY-A1	Air inlet - orbital weld	135-10194	Sanitary orbital welded manifold, 15 ra min. ID finish	CSI	
ASY-A2	Air inlet elbows - orbital weld	135-10193	Sanitary orbital welded manifold, 15 ra min. ID finish	CSI	
ASY-C1	Chamber inlet - orbital weld	135-10191	Sanitary orbital welded manifold, 15 ra min. ID finish	CSI	
ASY-S1	Clean steam inlet manifold - orbital weld	135-10192	Sanitary orbital welded manifold, 15 ra min. ID finish	CSI	
CV107.1	Filter drain check valve	131-10295	VLV\CHECK\T\.5 \SS\1/3PS	Hylok	CV3-H-8T-1/3-S316
CV107.2	Filter drain check valve	131-10295	VLV\CHECK\T\.5 \SS\1/3PS	Hylok	CV3-H-8T-1/3-S316
CV200	Clean Steam to Jacket check Valve	131-10465	1" SAN. CHECK VALVE, SILICONE SEAL, 15 RA EP	Check All Valve	3SHSS-3S-.550-SS-EC
CV202	Jacket Steam Check Valve	131-10507	VLV\CHK\SS\.75\NPT\SWING	Sharpe	.75" 20276 200# 316SS Swing Check Valve
CV207	Jacket drain air check valve	131-10512	VLV\CHK\SS\.375\NPT\POPPET	Hylok	CV2-M-6N-1-S316
F100	Chamber Air Filter	131-10003	FILTER\VENT\SS\1\ TC	Pall	ALT105G23DDH4
	Filter element for F100	131-10315	FILTER\ELEMENT5 IN\.2 MICRON \CART\ CODE 7	Pall	AB05PFR2PVH4
HV100	Clean steam sample condenser shutoff	131-10463	VLV\BALL\SS\.5\15RA\SANITARY\CAVFIL	STERIFLOW	9020-050-6L/CDHL
HV101	Chamber fan shaft seal sensor flow adj.	4995K41	VLV\NEEDLE\SS\1/8"NPT	McMaster Carr\Deltrol	4995K41
HV102	Chamber fan shaft seal sensor flow adj.	4995K41	VLV\NEEDLE\SS\1/8"NPT	McMaster Carr\Deltrol	4995K41
HV103	Clean steam sample condenser drain vent	131-10463	VLV\BALL\SS\.5\15RA\SANITARY\CAVFIL	STERIFLOW	9020-050-6L/CDHL
HV110	Filter Integrity Test Isolation	131-10463	VLV\BALL\SS\.5\15RA\SANITARY\CAVFIL	STERIFLOW	9020-050-6L/CDHL
HV205	Jacket pressure gauge isolation	4073T11	VALVE\BALL\1/4"\NPT\BR-NCKL PLT	McMaster Carr	4073T11
LV207.2	Jacket drain valve	130-10398	VLV\ANG\SS\.5\NPT\PA\NC\FL.BLW.	Burkert	463613
MTR101	Chamber fan motor	130-10566	MTR\1.5HP\1140RPM\TEFC\56C\208-230/460V\5-4.9/2.45 AMPS	Baldor	VM3557
MTR102	Chamber fan motor	130-10566	MTR\1.5HP\1140RPM\TEFC\56C\208-230/460V\5-4.9/2.45 AMPS	Baldor	VM3557
PI100	Clean steam pressure gauge	131-10524	GAUGE\PR\SS\1.5 \BOTTOM MOUNT\-30-100PSI	Anderson Instruments	EM032010041211A
PI103	Chamber pressure gauge	131-10015	GAUGE\PR\SS\1.5\TC\30-60PSI	Anderson Instruments	EM031010041021A
PI205	Jacket pressure gauge - service area	131-10640	GAUGE\PR\2.5 DIAL\.25\NPT\0-100PSI\SS CASE\GYL.FILLED	McDaniels	J6D
PS100	Clean Steam pressure OK switch	130-10104	SWITCH\PR\SS\1.5\TC\10-100PSI\ADJ RANGE	United Electric	H100 566
PSV100	Chamber Safety Relief Valve	131-10654	VLV\SAFETY RELIEF\SECTION VIII\316SS WETTED\TEFLON SEAT\STEAM 45 P	Aquatrol	AQV573FET-1
PSV200	Jacket Safety Relief Valve	131-10326	VLV\SAFETY RELIEF\BRASS\.75 IN-1OUT\45PSI	Aquatrol	Series 571-EC, Teflon seats
PT101	Seal pressure transmitter	130-10552	SENSOR\PRESSURE\W-SWITCH\4-20MA\-14.5-145 RANGE	IFM EFECTOR	PN2224
PT102	Seal pressure transmitter	130-10552	SENSOR\PRESSURE\W-SWITCH\4-20MA\-14.5-145 RANGE	IFM EFECTOR	PN2224
PT112	Chamber pressure transmitter	130-10373	Transmitter, Pressure, 0-60 psia, 4-20 mA, 2" Tri-clamp	Endress Hauser	PMP75-ABC2M61TDABP
PV102	Chamber filter air valve	130-10559	VLV\ANG\SS\.75\NPT\PA\NC\FL.BLW.	Burkert	463 615
PV109	Chamber Filter Isolation valve	130-10368	VLV\DIA\SS\1\TC\NC\PPS\15RA	Burkert	445252
PV202.2	Jacket vent valve	130-10390	VLV\ANG\SS\.75\NPT\PPS\NC	Burkert	463637
SC100	Clean steam sample condenser	131-10114	Heat Exchanger, sanitary, tube-in-tube spiral	Exergy	00459-01
TE114	Filter temperature RTD	142-10001-RA15	RTD\PT100\.01%\SINGLE ELEM.\RA15	Pyromation	R5T185L483Z-006-00-18-T-3288-2 (Z627)
TE115.1	Chamber RTD	142-10056	RTD\PT 100\.25 DIA X 4 PROBE\RA15 - 40ft. Lead wire	Pyromation	R5T185L483ZZ-004-00-18-T3288-2 (Z459,858)
TE115.2	Chamber RTD	142-10056	RTD\PT 100\.25 DIA X 4 PROBE\RA15 - 40ft. Lead wire	Pyromation	R5T185L483ZZ-004-00-18-T3288-2 (Z459,858)
TE115.3	Chamber RTD	142-10056	RTD\PT 100\.25 DIA X 4 PROBE\RA15 - 40ft. Lead wire	Pyromation	R5T185L483ZZ-004-00-18-T3288-2 (Z459,858)
TE205	Jacket RTD	142-10001-40	RTD\PT100\.01%\SINGLE ELEM.\316SS\40ft. LEAD	Pyromation	R5T185L483-006-00-13-T3480-2
TT114	Filter RTD transmitter		See electrical BOM		
TT115.1	Chamber RTD transmitter		See electrical BOM		
TT115.2	Chamber RTD transmitter		See electrical BOM		
TT115.3	Chamber RTD transmitter		See electrical BOM		

Validation
IQ/OQ Protocals and Execution

Documents for validation of sterilization processes incl. certificates of materials, calibration certificates of components, etc. (special requirements should be specified by user)



BMT WARRANTY

One-Year Full Parts & Labor Warranty

15-year non-prorated warranty on the Chamber and Jacket

Extended Warranties and Preventative Maintenance Contracts Available

Questions?

Thank you
for
Attending