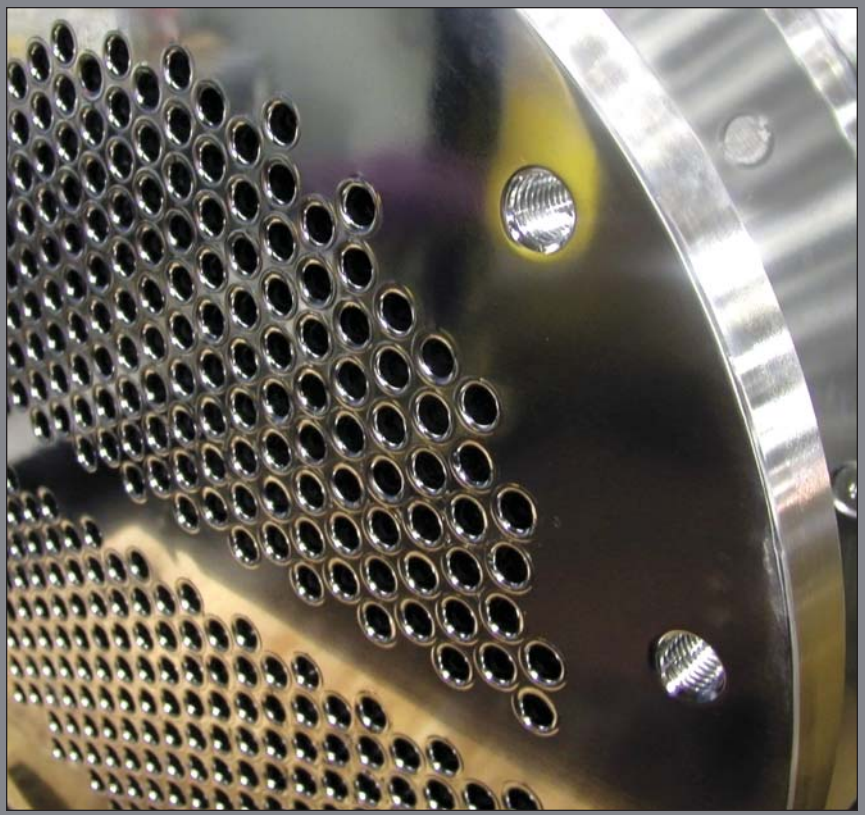
PYROPURE® PRODUCTS



MUELLER®

BIOPHARM SYSTEMS

Why Paul Mueller Company?

Mueller® is Your One-Stop Supplier!

Since our inception in 1940, Mueller® has evolved from a small-scale fabricator into a global process solutions provider with nearly one million square feet of manufacturing space under roof. Our products are used in over 100 countries in a wide variety of applications.We offer a full range of tanks from shop-fabricated alloy vessels up through 20 feet in diameter to field-fabricated vessels up through 2,000,000 gallons, integrated systems, modular fabrication, field construction, plant maintenance and repair, and complete turnkey project execution. We are uniquely qualified to handle large and complex fluid handling systems from project concept through installation. Mueller delivers outstanding equipment and unique solutions to the process industries with our technical expertise, innovative engineering, and manufacturing resources.

Our philosophy is simple: We are committed to meeting and exceeding our customers' expectations of value by providing high quality equipment, excellent service, and complete process solutions.

We know that building a quality product starts from the ground up. Our sole purpose is to make our system as good as it can be to guarantee that you get the highest possible quality in our processes and products. With our skilled craftsmen, quality materials, and one of the best technologically advanced manufacturing facilities in the country, we are able to build exceptional products at a reasonable price.

Mueller PyroPure® products are made in the U.S.A. Highly skilled craftsmen, whose average experience exceeds 20 years, fill our manufacturing ranks. Everyday, their talent and pride of workmanship can be observed in any of our production areas. Our process is well defined, and all Mueller team members fully understand the importance of their individual roles in producing a quality product. Our central U.S. production facility lowers your transportation cost and speeds your product to your location.

Mueller provides a broad range of products. A diverse range of products allows efficient integration of numerous products into custom skid assemblies and provides consistency of documentation as well as superior project delivery. Our product mix includes multiple-effect stills, pure steam generators, bioreactors, vessels, shell-and-tube heat exchangers, plate-and-frame heat exchangers, and sanitary piping assemblies.

Worldwide representation. Mueller PyroPure products are supported by a worldwide network of representatives with thorough, up-to-date product knowledge ensuring rapid response to your inquiries.

Site installation and erection. Mueller Field Operations, Inc. (MFO) offers complete construction services with particular emphasis on large field erected vessels, equipment installation, tank retrofit or repair, and process piping. MFO also provides construction management, site supervision, procurement, and field integration services.

Mueller Transportation, Inc. allows us to provide you with competitive delivery rates on standard products. We are able to offer dedicated handling for large or critical delivery items and are able to work with you directly to resolve any transportation issues.

Factory technicians and field service available. We offer rapid response to your service needs with trained factory personnel knowledgeable in all aspects of PyroPure equipment.


MUELLER

PyroPure® Pure Steam Generators

The Mueller PyroPure® P7000 Series Advantage

Principle of Operation

Mueller PyroPure pure steam generators are capable of producing pyrogen-free pure steam that, when condensed, meets all U.S. Pharmacopoeia (USP) requirements for use in autoclaves, critical area humidification, and routine steam-in-place (SIP) sterilization.

Feedwater enters the system and flows through two level control valves and then into the tube side of the blowdown cooler. In the blowdown cooler, heat is transferred between the feedwater on the tube side and the blowdown exiting the system through the shell side. Consequently, the blowdown exits the system at a lower, safer temperature, and the feedwater enters the system at a higher, more efficient temperature.

The heated feedwater flows into the steam separator and fills the lower part of the steam separator, the tube side of the evaporator, and the level indicator assembly to a factory-determined range controlled by level indicator switches. At the same time, utility steam enters the shell side of the evaporator. Latent heat from steam is rejected to the feedwater through the walls of the evaporator tubes. The feedwater is evaporated, and the resulting vapor is propelled from the evaporator into the steam separator where any impurities are removed from the steam by centrifugal force. Pyrogen-free steam exits from the top center of the separator and feeds the pure steam distribution system.

Simple Design — Reliable Operation

- An external evaporator provides improved access for inspection and preventative maintenance on critical o-rings and gaskets.
- The separation column contains no internal components that require inspection or periodic maintenance.
- All maintenance (including replacement of critical components) can be performed with only 24" of space on all sides (including the top) of the equipment.
- Minimal instrumentation is required for equipment operation. Only one control loop is needed which minimizes the calibration required as well as the potential for downtime.
- All components are fully drainable, including the feedwater pump.
- All elastomers in contact with feedwater and product are provided with USP Class VI certifications.
- ASME-BPE certified fittings are used throughout the design.
- All product contact surfaces are polished to 20 Ra maximum and electropolished. Surfaces in contact with feedwater are polished to 25 Ra maximum. All surfaces in contact with feedwater and product are manufactured from 316/316L stainless steel.

System Components

Evaporator. The natural circulation design of the PyroPure double-tubesheet evaporator ensures maximum surface wetting, eliminating the hot, dry areas that lead to the stress-cracking associated with other designs. The tube bundle creates a large heat transfer surface which vaporizes feedwater almost instantly to allow the unit to respond to large loads. Mueller PyroPure pure steam generators have a fully drainable external evaporator, eliminating the need for the excess headroom required for evaporator removal with other designs. All surfaces that come into contact with pure vapor or distillate are made of type 316L stainless steel, including seamless tubes and sanitary clamp-type connections.

Blowdown Cooler Assembly. The blowdown cooler assembly serves three functions toward making the PyroPure pure steam generator as reliable and efficient as possible: preheating feedwater, cooling blowdown, and preventing the buildup of microbial impurities. By transferring heat from blowdown to incoming feedwater, the blowdown cooler serves to preheat the feedwater while at the same time cooling wastewater and preventing it from flashing into steam as it exits the high-pressure separator. Blowdown temperatures are consistently less than 140˚F (60˚C) when fed with ambient temperature feedwater.

Steam Separator. As the mixture of water and vapor leaves the evaporator at high velocity and enters the steam separator through a tangential port, a natural vortex is formed. The centrifugal force of the vortex separates water droplets and contaminants out of the spiraling vapor. Pure vapor rises up through the steam separator and out of the pure steam outlet at the top of the generator. Because the separator has no baffles or demister, there are no auxiliary surfaces for condensation to accumulate and stagnate. Consequently, concerns over the potential for bacterial growth are eliminated.

Controls. The standard control system is an Allen Bradley PLC with an Allen Bradley operator interface mounted in a NEMA rated panel. Ethernet communication is provided on the standard control system to facilitate communications with adjacent equipment or data archiving systems. Mueller can also provide other Allen Bradley control components, as well as control systems from Siemens, Mitsubishi, and Delta V. Control and electrical panels are supplied with a UL 508a label.

Options

Feedwater Pump System. The feedwater pump system enhances feedwater pressure and should be installed if feedwater supply pressure does not exceed the desired pure steam operating pressure by 15-30 psig (1-2 bar). When furnished, the feedwater pump system will be installed on the pure steam generator framework.

Pure Steam Condensate Sampling System. Regular product testing is essential for regulatory compliance. The sampling system will simplify your sampling methods and enable you to draw samples for testing. The sample valve is located near the control box for easy access.

Pure Steam Analyzer. This option works in conjunction with the pure steam condensate sampling system to measure and record the resistivity (conductivity) and temperature of the condensed pure steam. If the resistivity falls below the user-selected setpoint, the analyzer will signal an alarm on the operator interface.

Stainless Steel Sheathing and Frame. Sheathing made entirely of Type 304 stainless steel enhances the general appearance of your unit and adds shine to any facility. The sturdy Type 304 stainless steel frame enhances the generator's overall appearance and improves its resistance to corrosion. Standard equipment includes a painted carbon steel frame and embossed aluminum insulation sheathing.

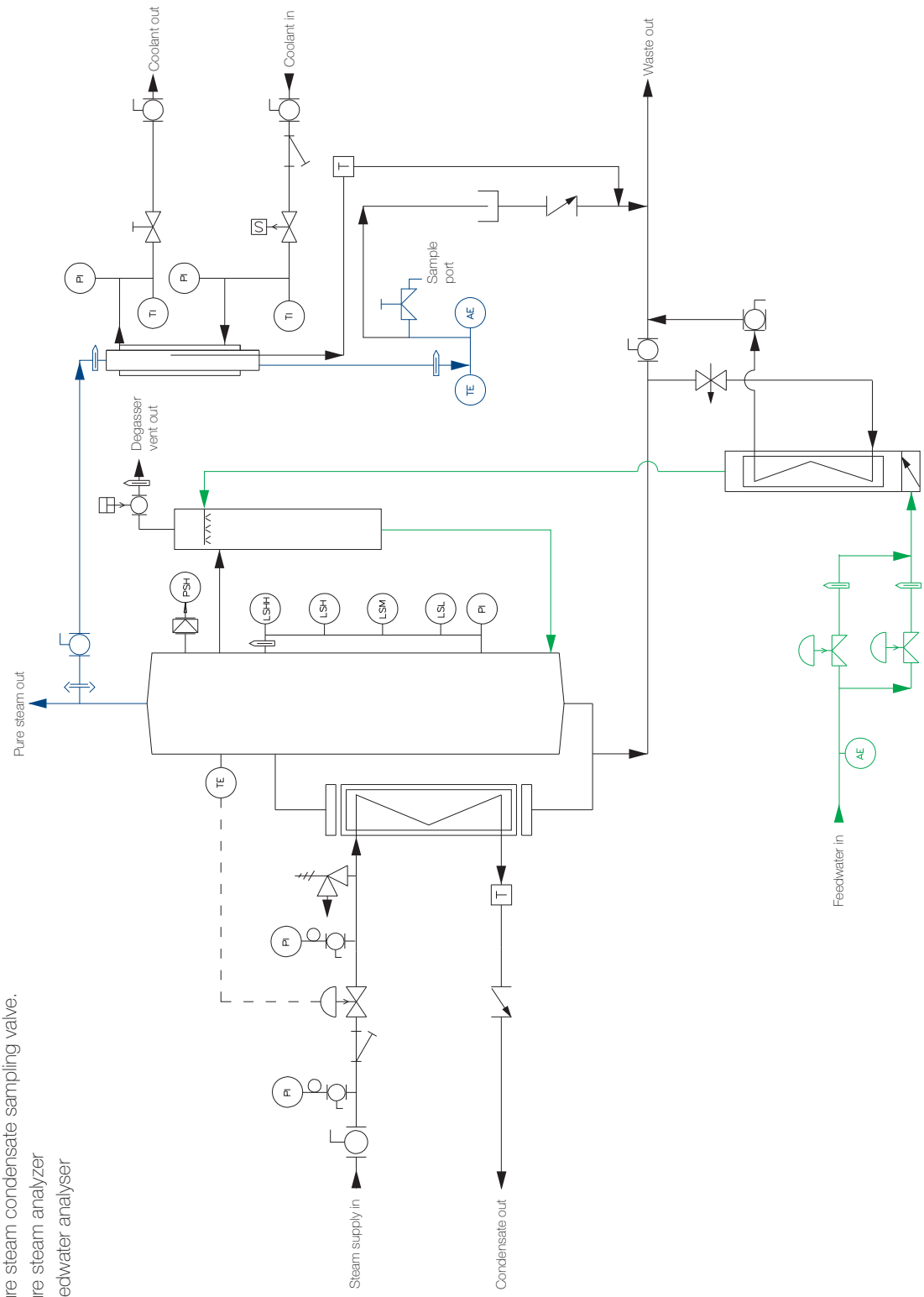
Feedwater Analyzer. The feedwater analyzer option continuously measures and records the resistivity (conductivity) of the feedwater. If the resistivity falls below the user-selected setpoint, the analyzer will signal the operator interface.

Degasser. To ensure compliance with regulations limiting the non-condensable gas content in pure steam the degasser may be desired. The degasser uses steam from the steam separator to heat the feedwater. As the feed-water is heated the non-condensable gases are expelled and vented from the equipment.

WFI Production. A pure steam condenser may be included with the pure steam generator to produce up to 150 gallons per hour (568 LPH) of WFI. The condenser may be provided integral to the pure steam generator skid or as a separate skid.

PyroPure Pure Steam Generators

The Mueller PyroPure P7000 Series Advantage



Schematic of Operation

Optional equipment indicated:

- Degasser
- Pure steam condensate sampling valve.
- Pure steam analyzer
- Feedwater analyser

Specifications

Model Nos.	P7060	P7140	P7145	P7310	P7315	P7500	P7505	P7990	P7995
Capacity (lb./hr.)[1]	600 (270 kg/hr)	1,200 (544)	1,400 (640)	2,300 (1,043)	3,100 (1,400)	4,100 (1,860)	5,000 (2,270)	7,500 (3,400)	10,600 (4,810)
FW Inlet [2,5]	1" TC Sanitary	1" TC Sanitary	1" TC Sanitary	1" TC Sanitary	1" TC Sanitary	1" TC Sanitary	1" TC Sanitary	1.5" TC Sanitary	1.5" TC Sanitary
Plant Steam Inlet (150 psig max.)[3]	1" Flange	1.5" Flange	1.5" Flange	2" Flange	2" Flange	3" Flange	3" Flange	4" Flange	4" Flange
Pure Steam Outlet	1.5" TC Sanitary	2" TC Sanitary	2" TC Sanitary	3" TC Sanitary	3" TC Sanitary	4" TC Sanitary	4" TC Sanitary	6" TC Sanitary	6" TC Sanitary
Condensate Outlet[4]	.75" FNPT	1" FNPT	1" FNPT	1.25" FNPT	1.25" FNPT	1.5" NPT	1.5" NPT	2" Flange	2" Flange
Drain	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC
Instrument Air	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT
FW Pressure/ Quantity Req'd.[5]	150 psig/Maximum of 1 ppm silica or total hardness. No chlorine, chlorides, or amines.								
Elec. Srv. (Std.)[6]	Without Pump: 115 VAC, 1 phase, 50/60 Hz.; With Pump: 460 VAC, 3 phase, 60 Hz. (Other voltages available upon request.)								
Height[7]	94" (240 cm)	107" (270 cm)	107" (270 cm)	115" (290 cm)	115" (290 cm)	126" (320 cm)	126" (320 cm)	143" (363 cm)	167" (423 cm)
Width[7]	47.5" (120.5 cm)	48" (122 cm)	48" (122 cm)	50" (127 cm)	50" (127 cm)	50" (127 cm)	50" (127 cm)	60.5" (154 cm	60.5" (154 cm)
Depth[7]	46" (117 cm)	46.5" (118 cm)	46.5" (118 cm)	54.5" (138 cm)	54.5" (138 cm)	61.5" (156 cm)	61.5" (156 cm)	63" (160 cm)	63" (160 cm)
Operating/ Shipping Wt.	1,500 lbs (680 kg)	2,150 lbs (980 kg)	2,350 lbs (1,070 kg)	2,700 lbs (1,230 kg)	2,800 lbs (1,270 kg)	5,100 lbs (2,313 kg)	5,700 lbs (2,580 kg)	8190 lbs (3710 kg)	9200 lbs (3870 kg)

[1] Capacity is based on a steam supply pressure of 120 psig, a clean steam header pressure of 50 psig, and a feedwater temperature of 70°F.

[2] Feedwater flow rate must be 5 to 10 percent greater than the pure steam volume produced to allow for blowdown (e.g., 100 lb/hr [12 gph] pure steam requires 110 lb/hr [13.8 gph] feedwater).

[3] If feedwater temperature is at least 160°F (71°C) then plant steam must be 20 percent greater than pure steam capacity (e.g., 100 lb/hr pure steam requires 120 lb/hr plant steam). If feedwater temperature is approximately 70°F, then plant steam must be 30 percent greater than pure steam capacity.

[4] Generator performance curves assume no back pressure on the condensate outlet. Any back pressure must be subtracted from the inlet supply steam pressure to figure the net effective inlet steam pressure and actual unit performance.

[5] If a feedwater pump is used, feedwater must be supplied at a minimum pressure of 10 psig and connection size may be larger than indicated.

[6] Other electrical services must be specified at time of order.

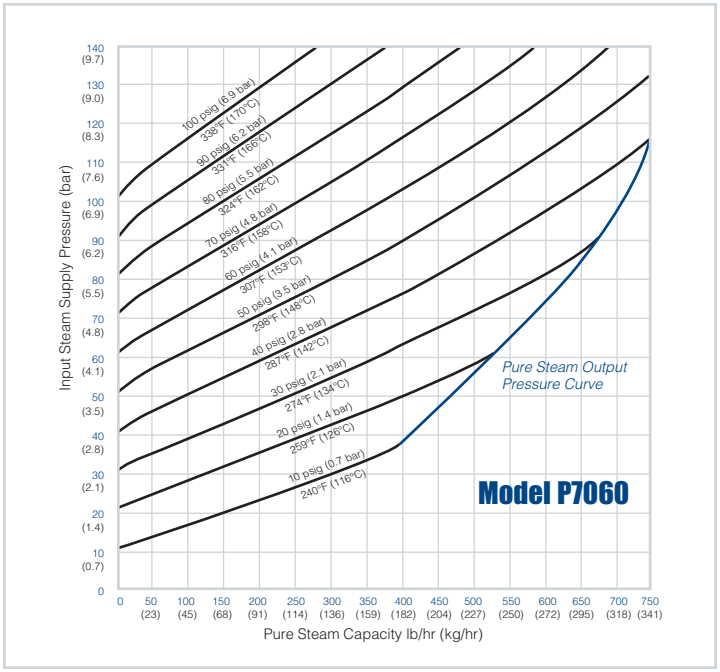
[7] Dimensions and weights do not include options. All specifications subject to change without notice.

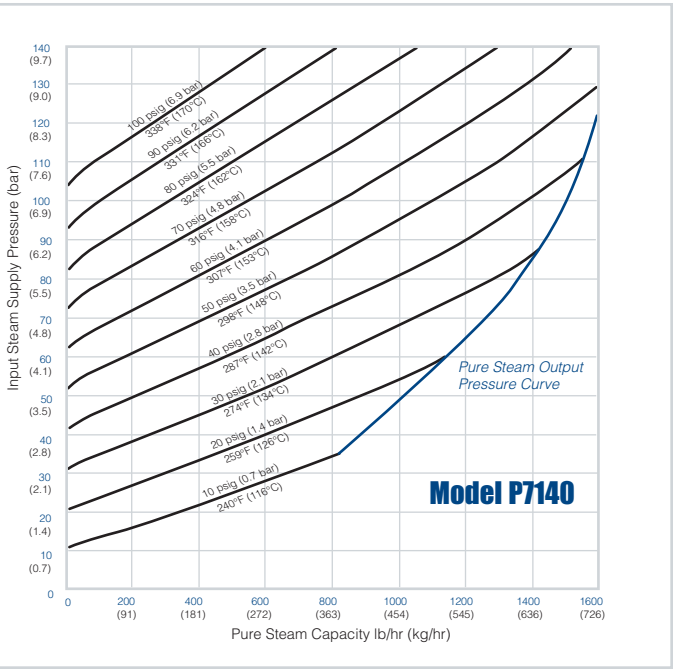
PyroPure Pure Steam Generators

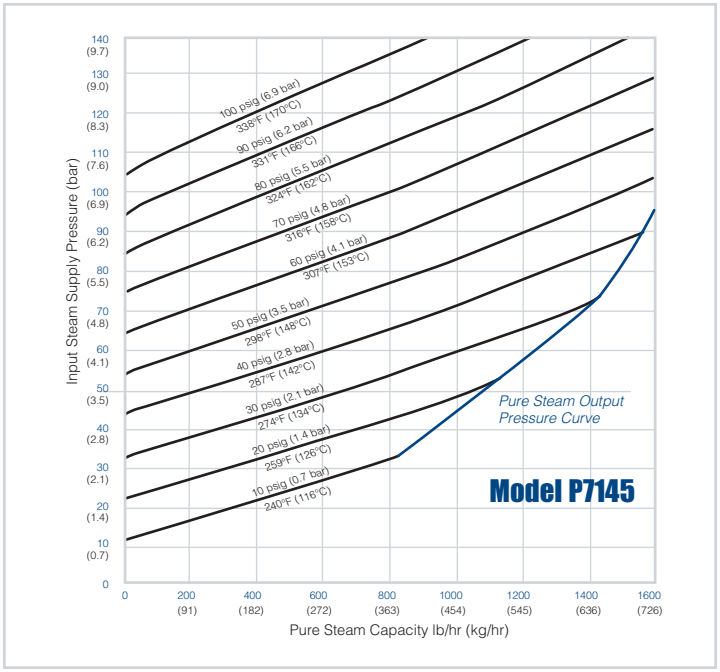
The Mueller PyroPure P7000 Series Advantage

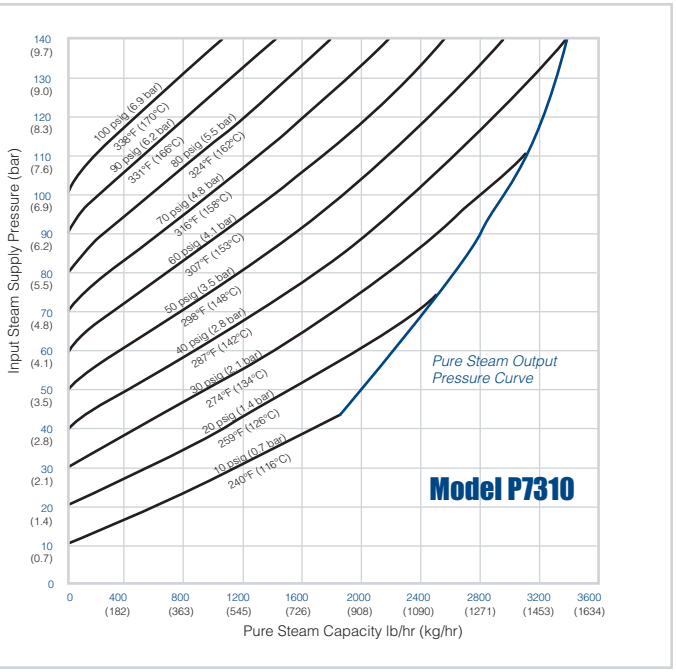
Pressure and Temperature Charts — Capacity Curves

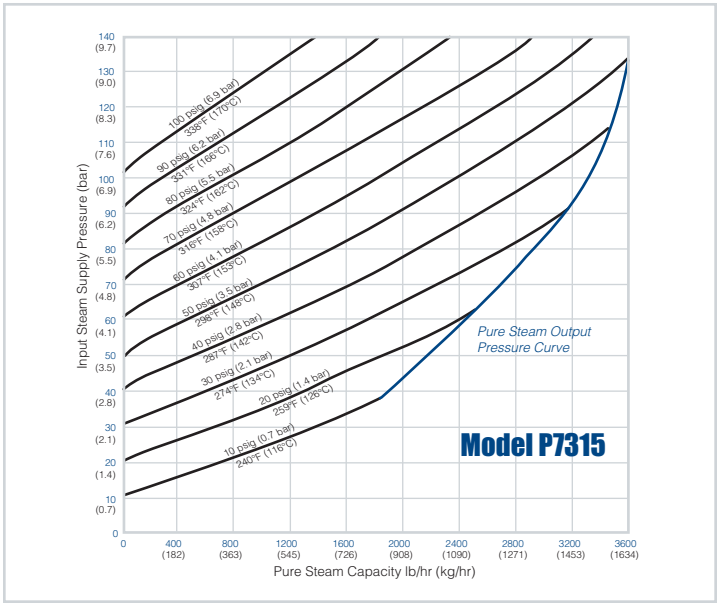
1. Select the chart(s) with pure steam capacities closest to the one you need.
2. Locate your supply steam pressure on the vertical axis.
3. Follow that line across to the point where it intersects with the curve representing your required pure steam pressure.
4. Drop down from this point to the horizontal axis to determine the model's pure steam capacity.
5. Select the model which most closely fits your capacity needs given your pressure requirements.

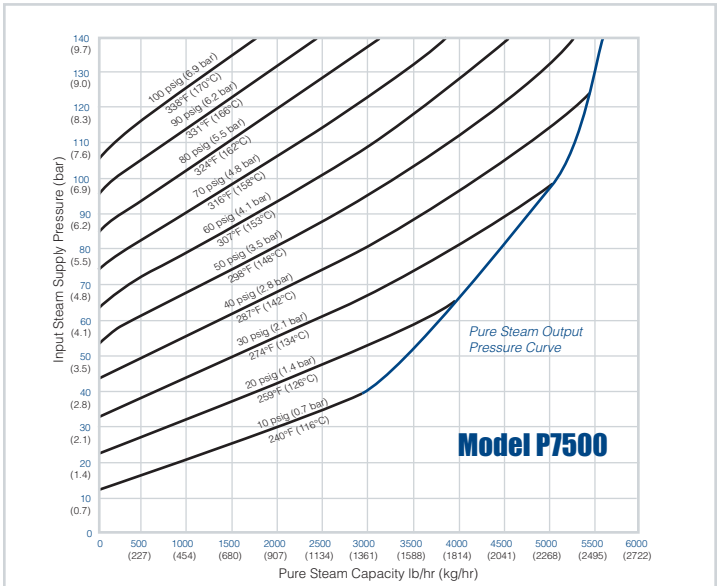









Input Steam Supply Pressure (bar)
Pure Steam Capacity lb/hr (kg/hr)
100 psig (6.9 bar) 338°F (170°C)
90 psig (6.2 bar) 331°F (166°C)
80 psig (5.5 bar) 324°F (162°C)
70 psig (4.8 bar) 316°F (158°C)
60 psig (4.1 bar) 307°F (153°C)
50 psig (3.5 bar) 298°F (148°C)
40 psig (2.8 bar) 287°F (142°C)
30 psig (2.1 bar) 274°F (134°C)
20 psig (1.4 bar) 259°F (126°C)
10 psig (0.7 bar) 240°F (116°C)
Pure Steam Output Pressure Curve
Model P7315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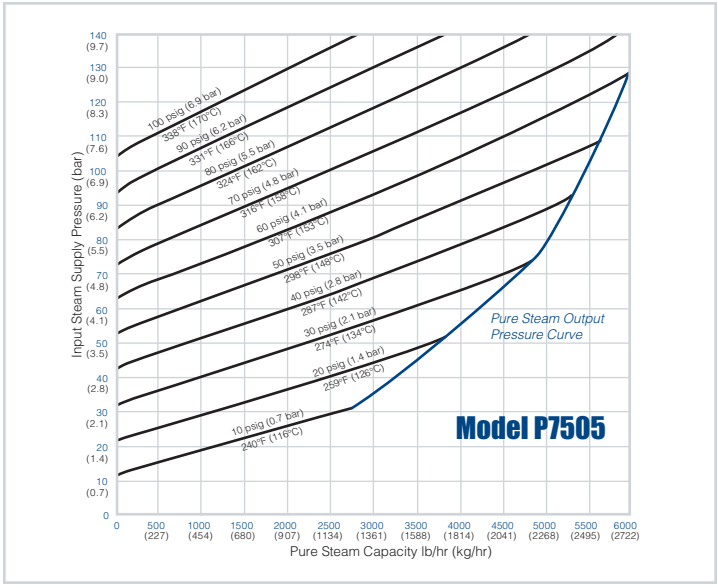
30 psig (2.1 bar) 274°F (134°C)
20 psig (1.4 bar) 259°F (126°C)
10 psig (0.7 bar) 240°F (116°C)
Pure Steam Output Pressure Curve
Model P7500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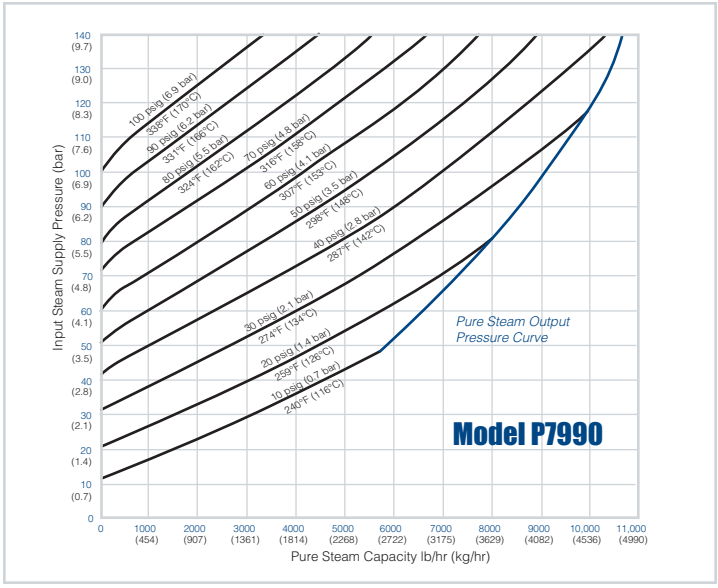
20 psig (1.4 bar) 259°F (126°C)
10 psig (0.7 bar) 240°F (116°C)
Pure Steam Output Pressure Curve
Model P7505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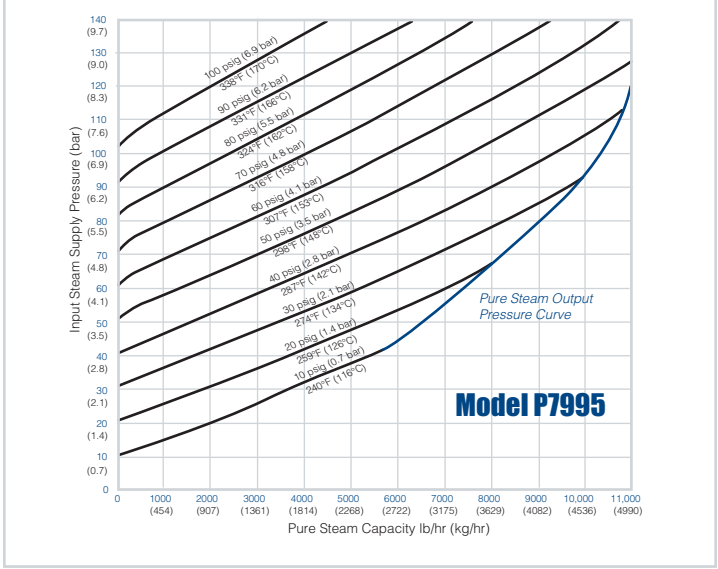
20 psig (1.4 bar) 259°F (126°C)
10 psig (0.7 bar) 240°F (116°C)
Pure Steam Output Pressure Curve
Model P7990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30 psig (2.1 bar) 274°F (134°C)
20 psig (1.4 bar) 259°F (126°C)
10 psig (0.7 bar) 240°F (116°C)
Pure Steam Output Pressure Curve
Model P7995

PyroPure Multiple-Effect Stills

The Mueller PyroPure P6000 Series is Built to Last

Principle of Operation

Mueller PyroPure multiple-effect stills (MES) are the simplest, most reliable means of producing pyrogen-free water-for-injection (WFI) that meets all U.S. Pharmacopoeia requirements. The MES is designed with efficiency in mind. Because the system recovers the latent heat of vaporization occurring within its own process to heat feedwater and uses feedwater as its primary source of cooling, the MES is an energy and money-saving model of ingenuity. Due to the absence of moving parts, the PyroPure MES requires less maintenance and is much quieter than mechanical compression stills. Multiple-effect stills also lack the seal and associated oil supply required by mechanical compression stills; consequently, there is no danger of contamination due to seal breakdown associated with mechanical compression. The PyroPure MES is manufactured according to FDA current Good Manufacturing Practices (cGMPs) and ASME-BPE requirements.

Each PyroPure MES is designed to minimize operating costs associated with production of WFI by minimizing the required utility steam and coolant consumption. This is accomplished by utilizing sources of energy within the various process streams to preheat the feedwater and thus use the feedwater as a cooling source. Using the feedwater as a coolant source also reduces the utility steam consumed to elevate the temperature of the feedwater. The feedwater ultimately enters the tubes of the first effect evaporator where utility steam is applied to the shell to evaporate the feedwater. The resulting steam produced is then directed to the separation column where a tangential inlet produces centrifugal force that separates the entrained water droplets away from the clean steam. This clean steam is then used as the heating source for the subsequent effect.

As the clean steam is condensed in the shell side of the subsequent evaporator, the resulting WFI flows through feedwater preheating devices and to the WFI condenser for subcooling to the required product temperature. Only pure steam discharged from the last effect of the still is condensed in the product condenser. The final product as well as the feedwater supplied to the still is measured for conductivity to ensure compliance with specifications.

Control of the multiple-effect still is accomplished by two control loops. The first control loop monitors the first effect temperature and manipulates the plant steam valve as needed to maintain the specified temperature. The second control loop monitors the product temperature and manipulates a coolant control valve to maintain the specified product temperature. Level switches in the separation columns provide control for the feedwater supply and provide alarm capabilities to ensure that all effects are operating correctly. The control and operational simplicity results in a design that requires no rotating equipment, flow measurement devices or pressure transmitters.

Models are available with 3 to 6 effects to provide the best solution for your application. Additional effects will result in further reduced utility consumption while a minimum of effects will provide the lowest capital cost solution and occupy the smallest footprint.

All product contact surfaces are polished to 20 Ra maximum and electropolished. Surfaces in contact with feedwater are polished to 25 Ra maximum. All surfaces in contact with feedwater and product are manufactured from 316/316L stainless steel.

Simple Design — Reliable Operation

- External evaporators provide improved access for inspection/preventative maintenance on critical o-rings and gaskets.
- The separation columns contain no internal components that require inspection or periodic maintenance.
- All maintenance, including replacement of critical components, can be performed with only 24" of space on all sides (including the top) of the equipment.
- All components are fully drainable including the feedwater pump.
- WFI condensers are designed with removable tube bundles for easier cleaning and inspection of product contact surfaces.
- Minimal instrumentation is required for operation of the equipment. Only two control loops are needed which minimizes the calibration required as well as the potential for downtime.
- All elastomers in contact with feedwater and product are provided with USP Class VI certifications.
- ASME-BPE certified fittings are used throughout.

System Components

Condenser. PyroPure condensers have a double-tubesheet design that provides users with the efficiency of heat exchange and at the same time ensures that pure vapor and distillate will never come into contact with feedwater and coolant. To facilitate maintenance, all PyroPure condensers are mounted at an angle to allow full drainage of the pure distillate through the distillate outlet port installed at the lowest point of the vessel. The condenser is designed to allow the removal of the U-tube bundle, making it easy for the user to inspect the critical pure distillate contact surfaces.

Controls. The standard control system is an Allen Bradley PLC with an Allen Bradley operator interface mounted in a NEMA rated panel. Ethernet communication is provided on the standard control system to facilitate communications with adjacent equipment or data archiving systems. Mueller can also provide other Allen Bradley control components, as well as control systems from Siemens, Mitsubishi, and Delta V. Control and electrical panels are supplied with a UL 508a label.

Evaporator. The natural circulation design of the PyroPure evaporator ensures maximum surface wetting, eliminating the hot, dry areas that lead to the stress-cracking associated with other designs. The tube bundle creates a large heat transfer surface which vaporizes feedwater on contact. The PyroPure multiple-effect still has fully drainable external evaporators, eliminating the need for the excess headroom required for evaporator removal with other designs. The evaporator on the single-effect still and the first effect of the multiple-effect still are double tube-sheet to prevent cross-contamination. All other effects have single-tubesheet evaporators.

Preheaters. Each still is equipped with a preheater for each effect to provide for maximum energy recovery and efficiency. As the water flows under pressure from each effect to the next the pressure of the water is reduced which will result in “flashing” of the water into steam. The preheater recovers this energy into the feedwater to reduce the overall plant steam consumption.

Steam Separator. As the mixture of water and vapor leaves the evaporator at high velocity and enters the separator through a tangential port, a natural vortex is formed. The centrifugal force of the vortex separates water droplets and contaminants out of the spiraling vapor. Pure vapor rises up through the steam separator and out of the port at the top of the separator. Because the steam separator has no baffles or demister, there are no auxiliary surfaces for condensation to collect and stagnate. Consequently, concerns over the potential for bacterial growth are eliminated.

Options

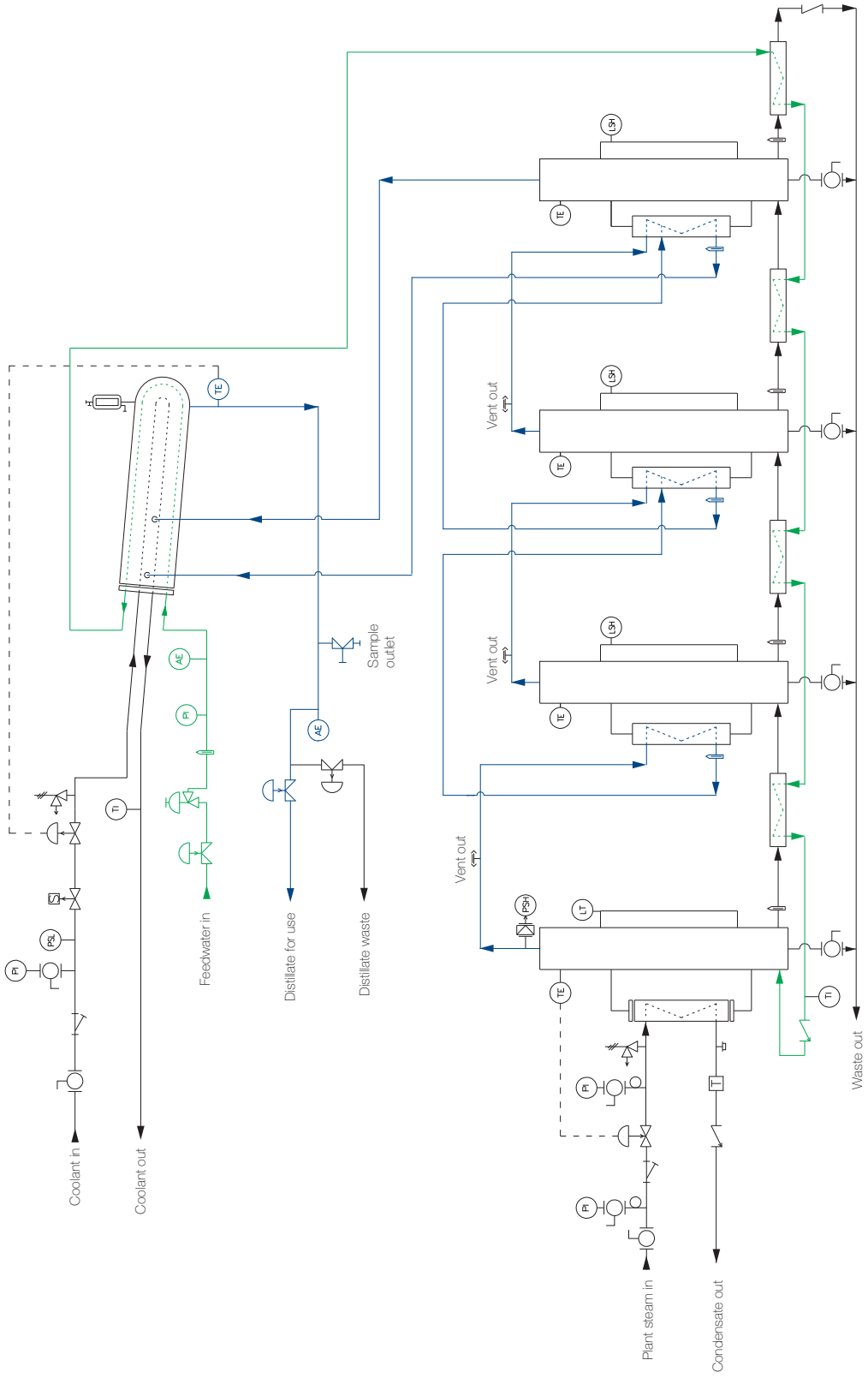
Feedwater Pump System. The feedwater pump system enhances feedwater pressure and is required if feedwater supply pressure is not equivalent to the plant steam pressure. When purchased, the feedwater pump system will be installed on the MES framework.

Pure Steam Option. The multiple-effect still can be configured to produce pure steam from the first effect. Simultaneous WFI and pure steam production is also available.

PyroPure Multiple-Effect Stills

The Mueller PyroPure P6000 Series is Built to Last

Schematic of Operation



Specifications

Plant Steam (psig): 110 • Distillate (°F): 190 • Feedwater (°F): 75 • Coolant Inlet (°F): 60

	Capacity[1]		Supply Steam[2]		Coolant Supply[3]		Approximate Dimensions		Distillate Outlet Ht		Est. Weight	
Model	gph	lph	lb/hr	kg/hr	gph	lph	HxWxD (in)	HxWxD (cm)	in	cm	lb	kg
MES 6009-3	90	340	350	160	200	760	111x62x40	280x158x102	90	229	2,500	1,135
MES 6015-3	150	570	550	250	360	1,360	112x62x40	285x158x102	89	226	3,050	1,385
MES 6015-4	140	530	450	200	230	870	112x75x40	285x191x102	89	226	3,200	1,453
MES 6015-5	130	490	430	200	200	760	112x88x40	285x224x102	89	226	3,350	1,521
MES 6032-4	300	1,140	900	410	520	1,970	110x80x45	279x204x115	86	219	3,600	1,635
MES 6032-5	280	1,060	730	330	350	1,320	110x94x45	279x239x115	86	219	4,100	1,861
MES 6032-6	260	980	610	280	250	950	111x108x45	280x274x115	87	221	4,600	2,088
MES 6040-5	370	1,400	950	430	460	1,740	110x94x45	279x239x115	86	219	4,400	1,998
MES 6040-6	350	1,320	800	360	330	1,250	111x108x45	280x274x115	87	221	4,800	2,542
MES 6064-4	610	2,310	1,800	820	1,060	4,010	128x100x52	325x254x132	102	259	4,900	2,225
MES 6064-5	570	2,160	1,450	660	740	2,800	128x119x52	325x302x132	102	259	5,600	2,543
MES 6064-6	540	2,040	1,230	560	525	1,990	128x138x52	325x351x132	102	259	6,300	2,860
MES 6076-5	700	2,650	1,760	800	880	3,330	128x119x52	325x302x132	102	259	6,800	3,087
MES 6076-6	670	2,540	1,500	680	640	2,420	128x138x52	325x351x132	102	259	7,500	3,405
MES 6110-5	1,125	4,260	2,460	1,120	1,710	6,470	137x148x53	348x376x135	107	272	12,100	5,494
MES 6110-6	1,080	4,090	2,060	930	1,350	5,110	137x168x53	348x423x135	107	272	15,000	6,810
MES 6140-6	1,400	5,300	2,700	1,220	1,760	6,660	149x184x58	379x468x148	117	346	16,400	7,446
MES 6200-6	2,000	7,570	3,700	1,680	2,450	9,270	171x204x64	434x518x163	141	358	19,800	8,989
MES 6300-6	3,000	11,360	5,500	2,490	3,750	14,190	181x232x78	460x590x198	150	381	26,500	12,031

[1] Distillate 170°F (77°C) to 190°F (88°C) (customer determined). Gravity flow.
[2] Plant steam 110 to 125 psig (7.6 to 8.6 bar) dry and saturated (capacity based on 110 psig).
[3] Coolant water at 32°F to 100°F (0°C to 38°C) at 40 psig (2.8 bar) (flow rates based upon a distillate outlet temperature of 190°F [88°C] and feedwater/cooling water inlet temperature of 60°F [16°C]).
ADDITIONAL REQUIREMENTS:
Feedwater: Feedwater supply 10 percent over distillate capacity. If feedwater pressure is less than plant steam pressure, a feedwater booster pump may be required. (Max. of 1 ppm silica or total hardness. No chlorine, chlorides, or amines.)
Elec. service (Std.): Without pump: 115 VAC, single phase, 60/50 Hz; with pump 460 VAC, 3 phase, 60Hz.

PyroPure Single-Effect Stills

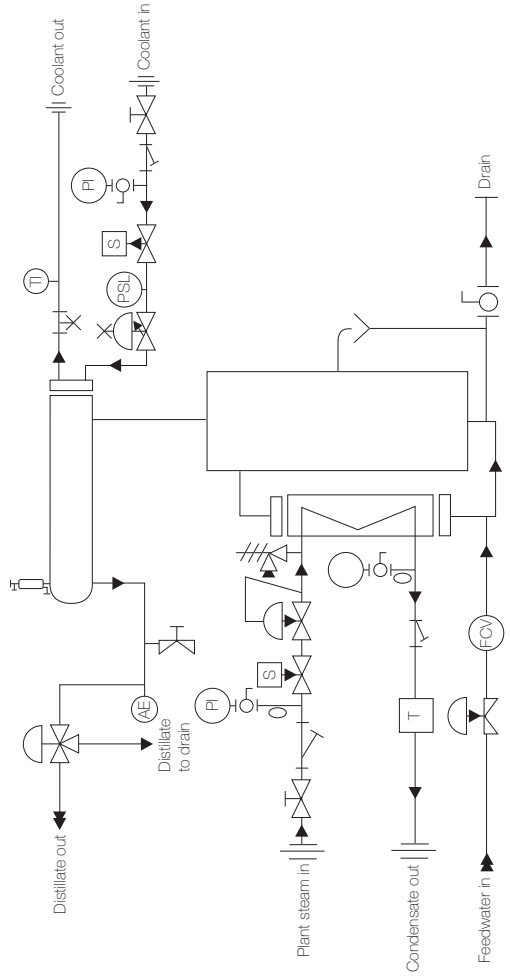
The Mueller PyroPure Single-Effect Still is Designed with Efficiency in Mind

Principle of Operation

The PyroPure single-effect still (SES) is a smaller distillation unit designed to meet the needs and budgets of growing organizations interested in developing new products. The SES is capable of producing up to 50 gallons of WFI per hour. The SES is manufactured according to FDA current Good Manufacturing Practices (GMPs). It features a pharmaceutical vent filter, double-tube-sheet condensers, and ASME-rated vessels — including stainless steel seamless evaporators and condenser tubing, and stainless steel steam separators. All components coming into contact with feedwater, pure vapor, or distillate are made of Type 316 stainless steel, and all welded parts are made of Type 316L stainless steel.

Feedwater enters the system and fills the steam separator, the tube side of the evaporator, and the level indicator assembly. At the same time, supply steam enters the shell side of the evaporator where it yields its latent heat to the feedwater through the walls of the evaporator tubes. The feedwater is evaporated, and the resulting vapor is propelled from the evaporator and into the steam separator where any impurities are centrifuged out. Pyrogen-free steam rises up through the steam separator and flows into the condenser. The pure steam is condensed by rejecting heat into cooling water circulating through the tubes of the condenser. The resulting distillate is then drained into a suitable storage vessel.

Schematic of Operation



Required Service Connection at Still

Name/Connection	Size	Pressure	Flow Rate
Steam Supply	1" FNPT	50–125 psig (3.5–8.6 bar)	513 lb/hr (233 kg/hr)
Condensate Return	¾" FNPT	Atmospheric 5 psig max (.3 bar)	513¼" (233¼")
Distillate Outlet	1½" TC	Atmospheric vented	52 Gph (197 lph) at 180°F (82°C)
Drain/Waste	1" TC	Atmospheric vented	8 gph (30 lph)
Cooling-Water Inlet	¾" FNPT	40 psig (2.8 bar) greater than CW Outlet pressure, 125 psig max (8.6 bar)	460 gph (1,741 lph) at 60°F (16°C)
Feedwater Inlet	1" TC	10–55 psig (.7–3.8 bar)	60 gph (227 lph)
Air-Supply Inlet	¼" FNPT	50–125 psig (3.5–8.6 bar)	2 cfm max
Cooling-Water Outlet	¾" FNPT	85 psig max (5.8 bar)	472 gph (1,786 lph) at 170°F (77°C)
Distillate-Divert Drain	1½" TC	Atmospheric	52 gph max (197 lph)
Sample Port	½" TC	Atmospheric	52 gph max (197 lph)
Steam-Relief Outlet	1¼" FNPT	125 psig max (8.6 bar)	355°F max (179°C)

Controls: 115 vac, 50/60 Hz, single phase, 5 amp max (Other voltages available upon request.)
Radiant Heat Loss: 11,000 Btu/hr (2,772 Kcal/hr)
Operating Weight: 2,000 lb (908 kg)
H x W x D (in): 112 x 57 x 34
Distillate Outlet Height (in): 91
H x W x D (cm): 285 x 145 x 87
Distillate Outlet Height (cm): 231
Plant Steam: 40–125 psig (2.8–8.6 bar), dry and saturated (Capacity based on 40 psig.)

Sanitary Shell-and-Tube Heat Exchangers

Custom Sanitary Heat Exchangers for the Pharmaceutical Industry

Mueller has extensive sanitary heat exchanger manufacturing experience with the production of PyroPure multiple-effect stills and pure steam generators. Each still and generator produced contains numerous sanitary heat exchangers consisting of single-tubesheet and double-tubesheet designs. We have established a long-standing reputation of providing reliable project execution and delivery as well as thorough documentation to meet the needs of the pharmaceutical and biotech industries.

Applications

Typical applications for the shell-and-tube heat exchanger include the most demanding sanitary applications in the pharmaceutical and biotech industries.

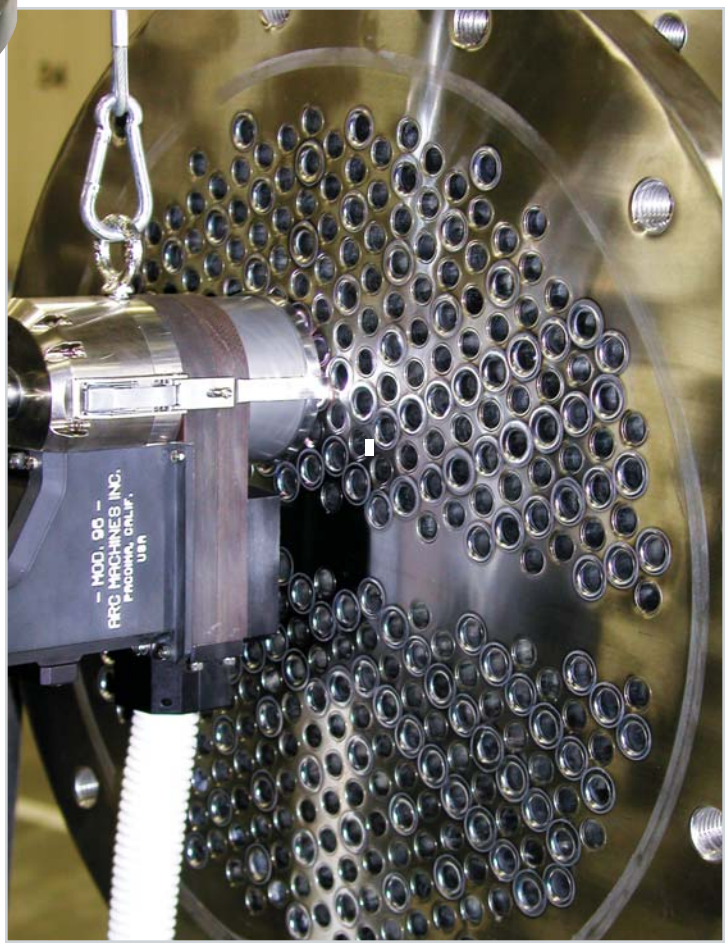
- Point of use heating and cooling of water-for-injection and purified water.
- Loop heating and cooling of water-for-injection and purified water.
- Pure steam condensing.
- CIP solution heating or cooling.

Design Standards

Familiarity with industry design expectations can only come from experience. Mueller is constantly working to develop the latest design standards via active participation in various industry groups including ASME-BPE. In addition, each of the hundreds of successful projects for the pharmaceutical industry have provided an understanding of the general industry requirements.

Examples of the detailed heat exchanger design standards that we have established include:

- Double-tubesheet construction with open gap provides access for inspection per ASME-BPE requirements.
- Tube spacing designed to prevent weld area overlap on tubesheet.
- Tubesheet-to-head o-ring joint configuration based on the latest ASME-BPE requirements.
- Full drainability of each heat exchanger.
- Detailed vibration analysis is performed on each unit to prevent premature failure.
- Compliance with ASME, TEMA, and cGMP standards.



Water-for-Injection Systems

Mueller WFI Systems — Your Integrated Process Solution

When upgrading your water systems, consider the full range of products available from Mueller. We have worked with a variety of end users to provide an integrated system approach to their water system including the multiple-effect stills, WFI storage tanks, sanitary heat exchangers, closed loop cooling systems, and integrated control systems.

Advantages

- Complete testing of all system components ensures system performance when the equipment arrives at site.
- An integrated control system reduces the number and complexity of control systems needed to operate your water systems.
- Equipment documentation is consistent and presented as an integrated system. All test documentation, including the Functional Requirements Specification, Software Design Specification, and Factory Acceptance Test documents are written with a system approach.
- Control of schedule is improved since all major components are manufactured at Mueller.
- Reduced labor and site construction required at your site.
- In many instances facility construction can proceed simultaneously with the water system construction.

Manufacturing and Test Facility Capabilities

- Seven test bays equipped with coolant, utility steam, DI water, compressed air, and ability to accommodate a variety of electrical configurations.
- Final assembly and test areas are climate controlled and isolated from welding and grinding areas.
- Carbon steel processing is not permitted in final assembly and test areas.
- An area dedicated for orbital welding is used for all sanitary connections.

Typical WFI Distribution System Components and Instrumentation

- WFI pump(s)
- Sanitary heat exchangers for trim heating or cooling as well as periodic sanitization.
- Conductivity analyzer for monitoring WFI quality.
- TOC analyzer for monitoring WFI quality.
- Level transmitters to monitor WFI tank level and activate still.
- Interconnecting piping valves and tubing between still, tank and WFI distribution skid
- Flow and pressure instruments to monitor spray ball conditions and/or loop pressure.
- Steam in place (SIP) equipment to allow periodic sterilization cycle with temperature monitoring at all low point drains.

WFI Storage Tanks

Mueller WFI Tanks — An Affordable Way to Store High-Purity Water

Mueller WFI tanks are engineered specifically for the special needs of the pharmaceutical and biotech industry. They consist of a Type 316L stainless steel vessel and utilize sanitary clamp-style connections, an aseptic manway, and a spray ball for interior sanitization. Chloride-free insulation surrounds the tank's sides and bottom, which is covered with Type 304 stainless steel outer sheathing. The vessel and all components are fabricated to the requirements of ASME Section VIII, Division 1. Standard tank sizes range from 250- to 10,000-gallons (945- to 37,800-liters) to satisfy a broad spectrum of capacity requirements. Custom fabrication is also available.

Components

Vessel. The ASME code-stamped WFI vessel has a rating of 40 psig and full vacuum at 300°F. Interior surfaces are mechanically polished to 25 Ra maximum (BPE SFVV6) and then electropolished to maintain optimum sanitary conditions. Exterior surfaces are 2B or mill finish with welds buffed. Mechanically polished material and/or flush ground weld finishes to 32 Ra maximum (BPE SFVV6) are available options.

Aseptic Manway. The 18" hinged opening meets cGMPs standards for validation ease. It has an EPDM o-ring seal and is made of Type 316L stainless steel to match the vessel. It may be centered on top of the vessel or located off-center, depending upon installation requirements. Silicone and Viton o-rings are available options.

Connections. Standard sanitary clamp-type connections include an outlet connection, inlet connection, CIP/SIP connection, vent connection, rupture disc connection, pressure gauge connection, upper and lower level connection, temperature thermowell connection, and a spare connection.

Insulation. A 2" chloride-free insulation surrounds the sides and bottom of each WFI vessel. A 12-gauge, Type 304 stainless steel sheathing is welded around the insulation to seal it from moisture.

Sanitary Spray Ball. When connected to a CIP or SIP system, the spray ball will rinse the vessel interior and top head with hot water to keep the tank environment sanitary. The spray ball and its components are removable for cleaning and inspection. The ball is constructed of electropolished Type 316L stainless steel. CIP coverage testing is available.

Options

Heat Transfer Surface. Dimpled heat transfer surface can be included on the bottom of the vessel to keep WFI at a constant temperature using plant steam. The surface is ASME-rated at 125 psig at 360°F and is constructed of 14-gauge Type 316L stainless steel. Additional heat transfer surface on the sidewall is also available.

Rupture Disc. Protects the vessel from excessive pressure buildup when combined with a sanitary port.

Temperature Indicator. Provides a digital readout of WFI temperatures via an RTD probe.

Pharmaceutical Vent Filter. Allows air in while protecting stored water from airborne contaminants with a 0.2 micron hydrophobic, steam-sterilizable filter element. Both the filter and the element comply with requirements for LVP cGMPs.

Pressure/Vacuum Gauge. Stainless steel casing encloses a sanitary diaphragm pressure sensor. Gauge attaches to the vessel.

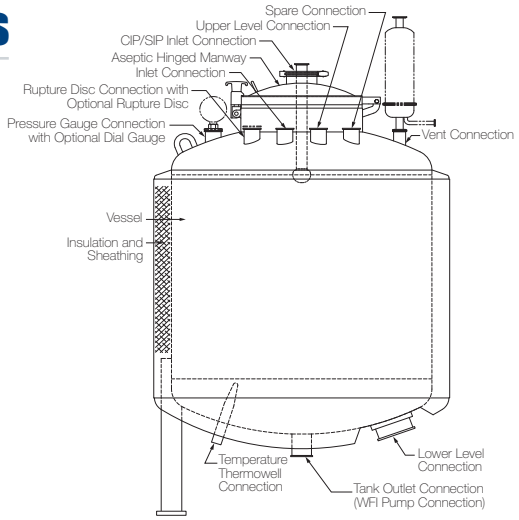
Sanitary Level Controller. Monitors tank level and can be set to activate a level alarm while starting/stopping the connected still.

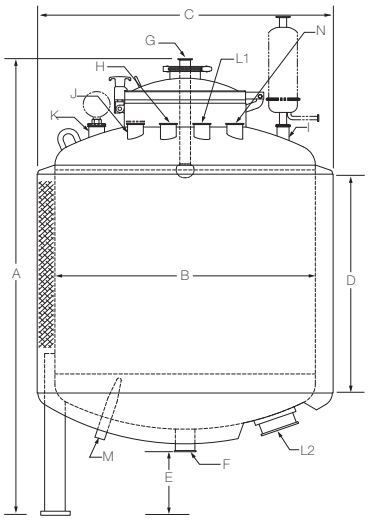
Vortex Breaker. Prevents problems caused by high draw-off rates.

Features and Benefits

- Seismic design means strength enough to withstand earthquakes up to and including zone-four conditions.
- With over 60 years experience in stainless steel fabrication and finishing, quality and reliability in design and construction are assured.
- We manufacture a broad range of standard sizes to meet your specific storage needs. We also offer custom sizes and dimensions for special requirements.
- Insulated sides and bottom of vessel helps maintain WFI temperature.
- Can be integrated with Mueller PyroPure® stills or pure steam generators and tested as a system prior to shipment. Speeds installation by pre-assembly and shop fit-up.
- CIP coverage/FAT testing available. Each tank comes with a complete documentation package that speeds validation of your system.

Specifications





Model No.		WFIT-1	WFIT-2	WFIT-3	WFIT-4	WFIT-5	WFIT-6	WFIT-7
Nominal Capacity	(gal)	250	500	1,000	1,500	2,500	5,000	10,000
	(liter)	943	1,887	3,774	5,660	9,434	18,868	37,736
Shipping Weight	(lb)	1,100	1,800	3,100	4,000	6,250	9,000	17,000
A - Height	(in)	71	83	104	109	132	173	256
B - Inside diameter	(in)	42	54	68	79	96	114	124
C - Outside diameter	(in)	46 3/4	59 3/16	73 1/4	84 1/4	101 5/16	119 1/2	129 1/2
D - Straight side (T/L)	(in)	39	45 1/2	57	63	68	97	176
E - Outlet height	(in)	18	18	18	18	18	18	18
F - Outlet connection	(in)	2	2	2	2	2	3	3
G - CIP/SIP Inlet connection	(in)	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2
H - Inlet connection	(in)	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	2	2
I - Vent connection	(in)	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	2	2
J - Rupture disc connection	(in)	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	2	2
K - Pressure gauge connection	(in)	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2
L1 - Upper level connection	(in)	2	2	2	2	2	2	2
L2 - Lower level connection	(in)	Spud	Spud	Spud	Spud	Spud	Spud	Spud
M - Temperature thermowell	(in)	.5 NPT	.5 NPT	.5 NPT	.5 NPT	.5 NPT	.5 NPT	.5 NPT
N - Spare connection	(in)	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2	1 1/2
Optional Heat Transfer Surface	(ft^2)	7	12	19	25	38	54	64
Number of Legs		4	4	4	4	4	4	6

Documentation and Validation

Documentation and Validation — Mueller Has Your Complete Solution

Documentation

Material Traceability

The documentation for your system begins before the first drawing is generated or the first welding arc is struck. Material traceability is established with the purchase and receipt inspection of materials and is systematically maintained throughout the manufacturing and assembly processes.

Process Traceability

Many different processes take place during the manufacture of BioPharm equipment. Several methods are used to document that the equipment has been designed, fabricated, assembled, and tested appropriately. These include:

- Borescope inspection and video capabilities.
- Factory testing procedures.
- Inspection records.
- Software and functional design specifications.
- Master inspection traveler and inspection records.
- Weld records.

Submittals

Once your order is received, Mueller will send you drawings, functional specifications, and instrument details for approval. These documents define the mechanical scope of supply and allow procurement and fabrication of key components to proceed so the schedule is minimized while ensuring the proper equipment will be supplied. Subsequent submittals are provided for software and functional testing details. These submittals include the detailed design specification and factory acceptance test procedure. We encourage your comments and feedback on these documents to ensure compliance with your project requirements.

Turnover Packages — Per BPE Requirements

The resulting turnover package (TOP) provides a well organized and comprehensive validation reference that satisfies customer protocols. In addition to standard three-ring binders, packages are also available in CD/DVD formats.

IQ/OQ Capabilities

Paul Mueller Company now offers installation qualification (IQ) and operational qualification (OQ) documents to support our products. The execution of these protocols can be performed by Mueller service technicians at the time of start-up and commissioning.

Factory Acceptance Testing

Mueller factory acceptance testing starts prior to your arrival on site with your review and approval of the test documents. Mueller will also pre-test the equipment prior to your arrival. Any project specific requirements outlined in the functional specification and design specification documents will be checked and tested as needed.

Validation

As a world leader in water and processing systems for the finished pharmaceutical, bulk API, biotechnology, medical device, and medical diagnostic industries, Mueller has extensive industry experience preparing comprehensive turnover documentation and validation packages. The many projects that we have completed have withstood scrutiny by numerous customers, independent validation companies, and the Food and Drug Administration (FDA).

As the pharmaceutical industry has evolved, so has our approach to validation. We are qualified to provide documentation and validation compliance due to our extensive experience within the industry, our attention to regulatory changes, and our capability to adapt to each of our customers' specific needs. The completed installation qualification (IQ) and operational qualification (OQ) documentation and validation packages provide documented evidence that our systems are built and commissioned in accordance with user requirements specifications (URS), functional requirements specifications (FRS) and detail design specifications (DDS), as well as FDA and cGMP standards.

Paul Mueller Company maintains a staff of professionals with considerable experience within the pharmaceutical industries and broad educational backgrounds in quality, engineering, chemistry, microbiology, and technical services. Since our validation and quality systems are integrated within the company structure, there are substantial benefits realized from shared databases as well as our detailed understanding of the equipment.

Industry Experience

Mueller has successfully provided documentation and validation assistance for large and small pharmaceutical and biotech projects, including:

- Hundreds of multiple-effect stills and pure steam generators.
- Seed train and production bioreactors, including controls and related process equipment.
- Process equipment for numerous buffer hold and preparation facilities consisting of as many as 40 vessels, as well as the associated controls, electrical equipment, structure, utility piping, and process piping.
- Hundreds of vessels used in pharmaceutical and biotech service.

Mueller Services

Mueller Field Operations, Inc. — We Install What We Sell

We're with you from the ground up. Mueller Field Operations, Inc., a wholly owned subsidiary of Paul Mueller Company, offers complete construction services with particular emphasis on expanded scope projects utilizing our construction management, engineering, procurement, equipment installation, and field integration capabilities. We provide specialized labor for on-site field erected tanks/vessels, equipment installation, vessel retrofit or repair, and process piping that allows us to go beyond the capabilities of our manufacturing facility.

Services offered in the clean utility area of your facility include:

- Engineering site assessments.
- Utility consumption surveys.
- Process design and equipment selection.
- Procurement of ancillary equipment such as boiler, chiller, cooling tower, and pretreatment system.
- Installation of Mueller equipment.
- On-site project management.
- System integration.
- Process and utility piping, including sanitary loop piping and drops.
- Startup.
- Operator training.
- IQ/OQ services.
- Preventative maintenance and system monitoring.

Mueller Transportation, Inc. — Mueller Quality Delivered Right to Your Door

Mueller Transportation, Inc. has the capability to deliver by rail or on our own fleet of trucks. Use of our trucks, and our central location, enables us to provide quick delivery throughout the U.S.A. and Canada.

Mueller Product Support Team — At Your Service

Our Mission

The mission of Paul Mueller Company's Product Support Team is to meet and exceed our customers' expectations of value by setting the industry standard for exceptional service to our customers. In support of this mission, we maintain a technical staff of specialized technicians highly trained on our products, vendor software, controls, and the various trade disciplines. Mueller equipment is serving our customers worldwide. Factory trained technicians are available to meet the needs of our customers and can normally be on-site within 24 to 48 hours of notification.

Paul Mueller Company makes some of the most reliable equipment in service today. However, regardless of how well- built a product is, continuous use without periodic inspection and maintenance can result in mechanical failure and costly downtime. When you purchase Mueller equipment, you aren't just buying a machine, you are investing in a partnership — a partnership in which we work together to assure that your equipment continues to perform at its best for years to come.

Our Services

Start-Up / Commissioning

When your new Mueller equipment is fully installed, our Service Coordinator will assist you with scheduling a start-up by a factory technician. The technician will inspect the equipment for any damage which may have occurred during shipping or installation. The technician will then inspect the installation and make certain that the utilities meet the minimum requirements, and make recommendations to assure you have the most efficient installation. The equipment will then be operated to challenge all of the alarm conditions and operational parameters according to the site acceptance test (SAT). Basic operation and maintenance training will be provided to any available personnel.

Technical Support Via Phone, Fax, or E-mail

There is never a charge for technical support from the factory via telephone, fax, or e-mail. Your experienced operators and our factory technicians are able to resolve most issues over the phone, which saves you time and money. Please call 1-888-281-5800, fax us at (417) 575-9662, or e-mail us at biopharm@muel.com.

Factory Training Seminars

Operation and maintenance training seminars are scheduled four times a year for your convenience. These seminars are held at the factory and include both classroom as well as hands-on training. You will be able to witness the fabrication and testing of new equipment as you tour the Mueller facility. During the classroom discussions, participants are able to learn from the experience of other operators and maintenance mechanics, as well as the factory technicians. Many who have attended past seminars have commented that this is the most valuable training they have ever invested in.

Replacement Parts

Each TOP includes a list of recommended spare parts that will minimize downtime in the event of a failure. Mueller warehouses the most critical replacement parts for your equipment. Our parts personnel literally go out of their way to get replacement parts to you as quickly as possible when your machine is down.

MUELLER®

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