

# PYROPURE® PRODUCTS



**MUELLER**  
BIOPHARM SYSTEMS

# Get to Know Mueller® PyroPure® Products

Since our inception in 1940, Paul Mueller Company has evolved from a small-scale fabricator into a global process solution provider with one million square feet of manufacturing space. Mueller® offers 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; furthermore, Mueller offers integrated systems, modular fabrication, field construction, plant maintenance and repair, and complete turnkey project execution. Our facility is uniquely qualified to handle large and complex fluid handling systems from project concept through installation. Our products are used in over 100 countries in a wide variety of applications. Paul Mueller Company delivers outstanding equipment and unique solutions to the process industries with our technical expertise, innovative engineering, and manufacturing resources.

**We know that building a quality product starts from the ground up.** Our unprecedented purpose is to make your system as valuable and efficient as it can be, and to guarantee that you receive 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 products are made by our highly skilled craftsmen, whose average experience exceeds 15 years.** Our process is well defined and consistently developed. Each Mueller team member fully understands the importance that their individual roles play in producing a quality product. On any given day, their talent and pride of workmanship can be observed in any of our production areas. Our central United States production facility lowers your transportation costs and speeds delivery of product to your location.

**Mueller Transportation, Inc.** allows us to provide you with competitive delivery rates on standard products, as well as dedicated handling for large or critical delivery items. We offer a perfect package by working directly with you to resolve any transportation issues.

**Mueller Field Operations, Inc.** To offer our customers more versatility and flexibility, Mueller's field construction capabilities allows us to install our advanced products at a low cost.

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



## The Mueller Reputation

Every piece of Mueller PyroPure processing equipment is precision engineered for quality form and fit, close tolerances, and high quality finishes. You can depend on Mueller to deliver a product that will perform required functions and offer reliable product protection.





## 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.



# PyroPure Pure Steam Generators

## The Mueller PyroPure P7000 Series Advantage

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. Correspondingly, 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 while filling 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 that 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 the sanitary clamp-type connections and seamless tubes.

**Blowdown Cooler Assembly.** The blowdown cooler assembly serves two functions in making the PyroPure pure steam generator as reliable and efficient as possible: pre-heating the feedwater and cooling blowdown. By transferring heat from blowdown to incoming feedwater, the blowdown cooler serves to preheat the feedwater while 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 constantly 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 potential 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 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 and Mitsubishi. 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 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 mutually with the pure steam condensate sampling system to measure and record the temperature and conductivity of the condensed pure steam. If the conductivity rises above 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 value to any facility. The sturdy Type 304 stainless steel frame enhances the generator's overall appearance, as well as improves the 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 conductivity of the feedwater. If the conductivity rises above 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 feedwater is heated the non-condensable gases are expelled and vented from the equipment.

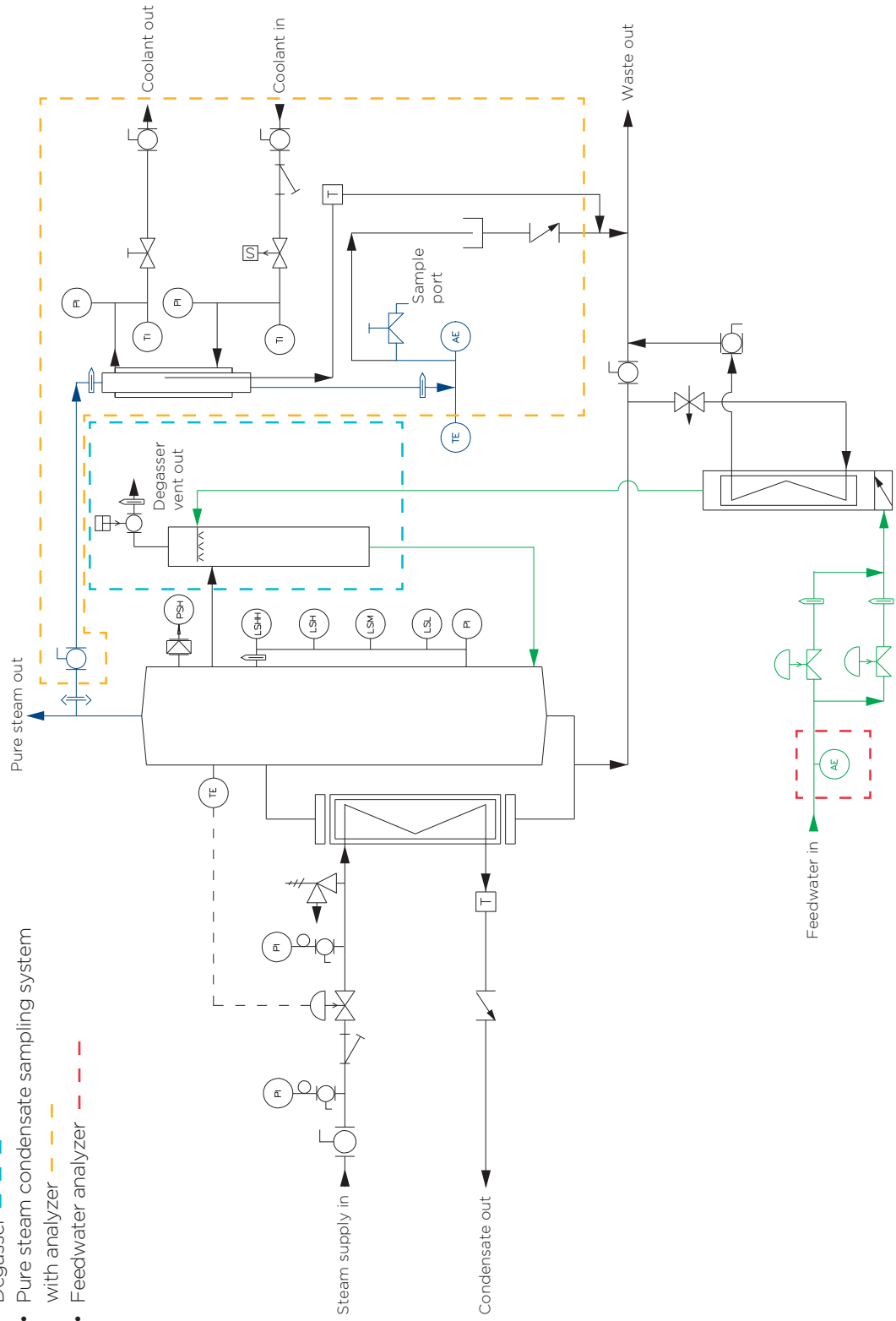
**WFI Production.** A pure steam condenser may be included with the pure steam generator to produce up to 150 gallons per hour (568 LPH) of WFI. The condenser may be provided integral to the pure steam generator skid or as a separate skid.

# The Mueller PyroPure P7000 Series Advantage

## Schematic of Operation

Optional equipment indicated:

- Degasser — — — — —
- Pure steam condensate sampling system with analyzer — — — — —
- Feedwater analyzer - - - - -



# Specifications

Model Nos.	P7060	P7140	P7145	P7310	P7315	P7500	P7505	P7990	P7995
<b>Capacity (lb/hr)<sup>1</sup></b>	600 (272 kg/hr)	1,300 (590)	1,850 (839)	2,300 (1043)	2,900 (1315)	4,000 (1,814)	5,700 (2,586)	7,300 (3,311)	10,500 (4,763)
<b>FW Inlet<sup>2,5</sup></b>	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1.5" TC	1.5" TC
<b>Plant Steam Inlet (150psig max.)<sup>3</sup></b>	1" Flange	1.5" Flange	1.5" Flange	2" Flange	2" Flange	3" Flange	3" Flange	4" Flange	4" Flange
<b>Pure Steam Outlet</b>	1.5" TC	2" TC	2" TC	3" TC	3" TC	4" TC	4" TC	6" TC	6" TC
<b>Condensate Outlet<sup>4</sup></b>	.75" FNPT	1" FNPT	1" FNPT	1.25" FNPT	1.25" FNPT	1.5" NPT	1.5" NPT	2" Flange	2" Flange
<b>Drain</b>	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC	1" TC
<b>Instrument Air</b>	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT
<b>FW Pressure/Quantity Req'd.<sup>5</sup></b>	Maximum of 150 psig/Maximum of 1 ppm silica or total hardness. No chlorine, chlorides, or amines.								
<b>Elec. Srv. (Std.)<sup>6</sup></b>	Without Pump: 115 VAC, 1 phase, 50/60 Hz.; With Pump: 460 VAC, 3 phase, 60 Hz. (Other voltages available upon request.)								
<b>Height<sup>7</sup></b>	94" (239 cm)	107" (272 cm)	107" (272 cm)	115" (292 cm)	115" (292 cm)	126" (320 cm)	126" (320 cm)	143" (363 cm)	167" (424 cm)
<b>Width<sup>7</sup></b>	48" (122 cm)	48" (122 cm)	48" (122 cm)	50" (127 cm)	50" (127 cm)	50" (127 cm)	50" (127 cm)	61" (155 cm)	61" (155 cm)
<b>Depth<sup>7</sup></b>	46.5" (118 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)	63.5" (161 cm)	63" (161 cm)
<b>Operating/Shipping Wt.</b>	1500 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)	8,190 lbs (3,710 kg)	9,200 lbs (3,870 kg)

<sup>1</sup> Capacity is based on a steam supply pressure of 120 psig, a pure steam header pressure of 50 psig, and a feedwater temperature of 70°F.

<sup>2</sup> 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).

<sup>3</sup> 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.

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> Other electrical services must be specified at time of order.

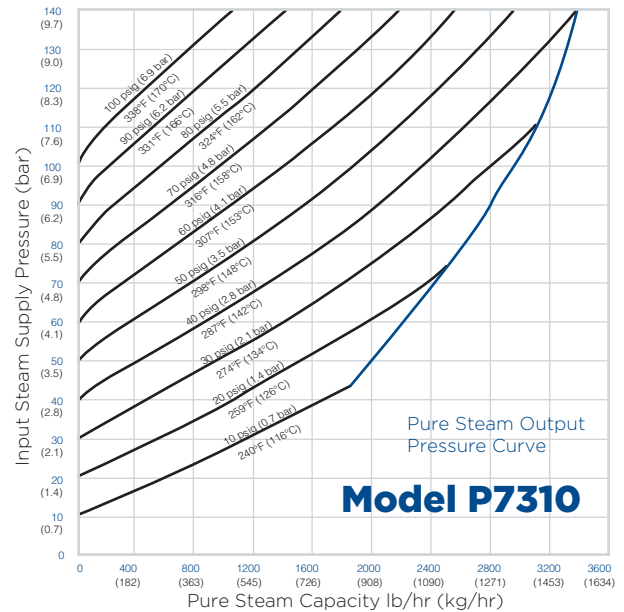
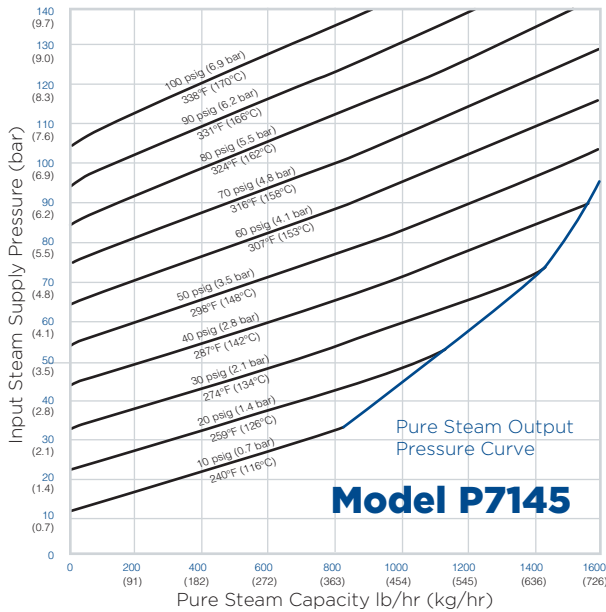
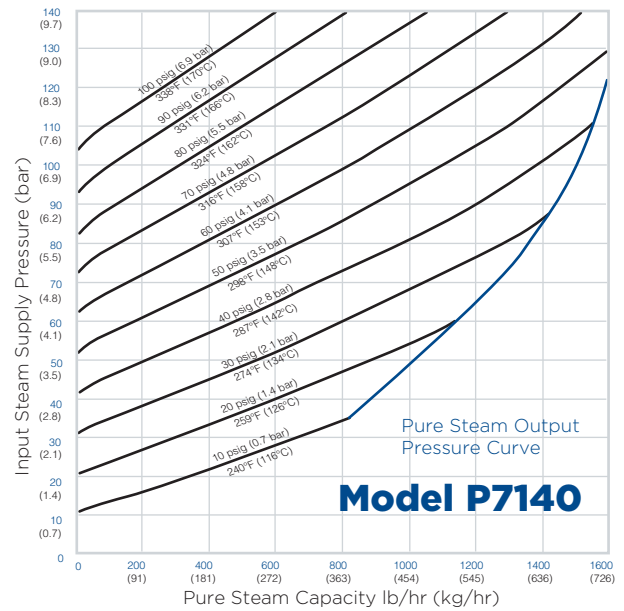
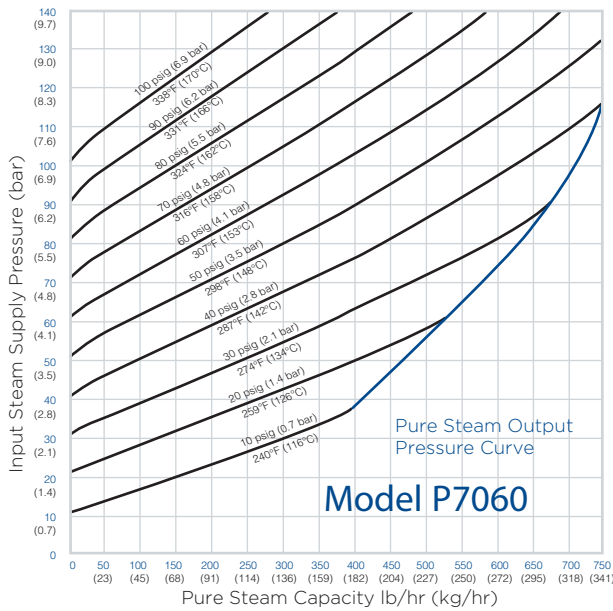
<sup>7</sup> Dimensions and weights do not include options. All specifications subject to change without notice.

# Pressure and Temperature Charts

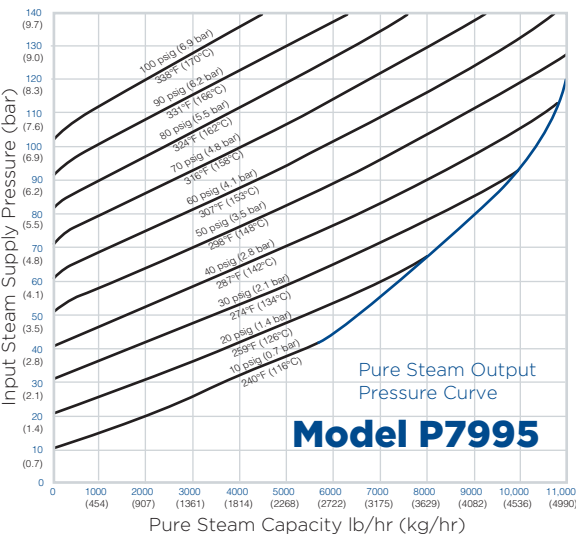
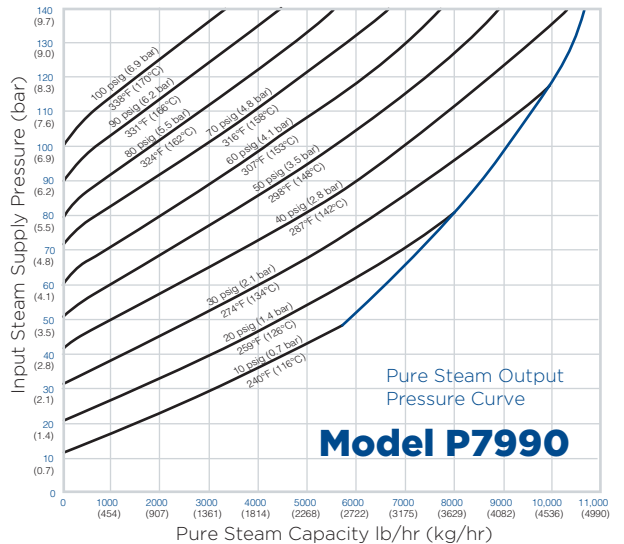
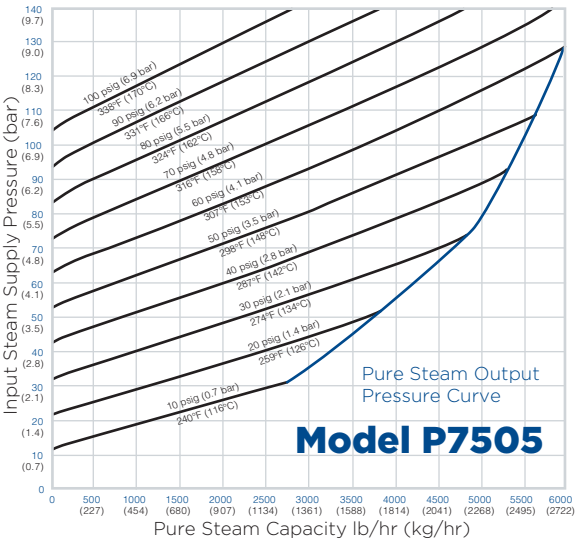
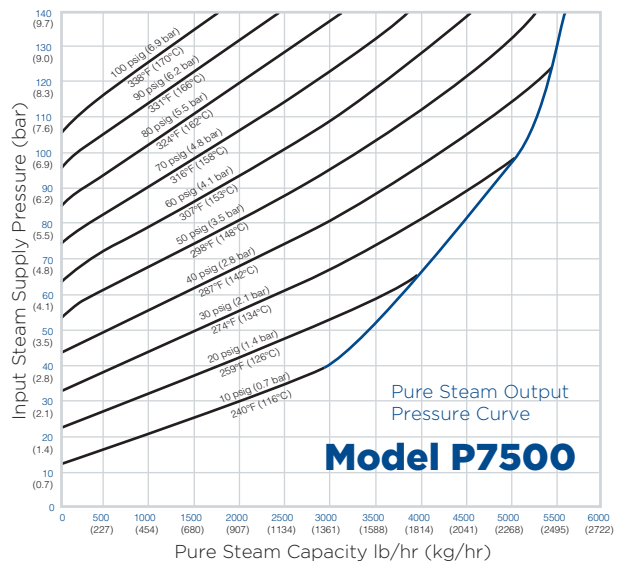
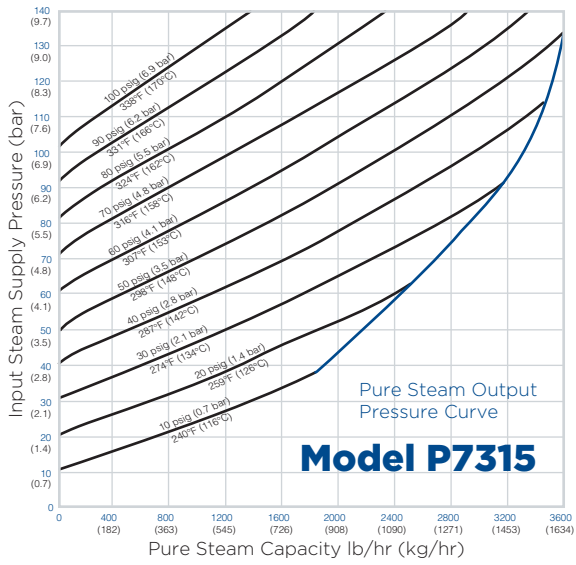
## PyroPure Pure Steam Generator Capacity Curves

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.

Note: Capacities shown are approximate and do not include an allowance for pure steam sampling.







# PyroPure Pure Steam Condensing System

## The Mueller PyroPure P4000 Series Advantage

The Mueller PyroPure pure steam condensing systems are designed for use by companies in the pharmaceutical and biotechnological industries who want to use their pure steam generating systems for the production of WFI quality distillate as well as WFI quality pure steam. When used with a Mueller PyroPure pure steam generator or when fed WFI quality pure steam from another source, the water produced will be pyrogen free and will meet or exceed the latest specifications of the USP for water-for-injection (WFI). The condensing system may be provided integral to a Mueller PyroPure pure steam generator skid or as a separate stand-alone skid. The stand-alone design for the condensing system allows it to be installed adjacent to a pure steam generator or located remotely at the point of use.

Pure steam enters the system and flows into the shell side of the condenser for the condensation and subcooling to the required product temperature. Coolant such as chilled water or a glycol solution is used on the tube side of the condenser for cooling. The final product is measured for conductivity to ensure compliance with specifications.

Control of the condensing system is accomplished by a single control loop. The loop monitors the product temperature and manipulates a coolant control valve to maintain the specified product temperature.

## Simple Design, Reliable Operation

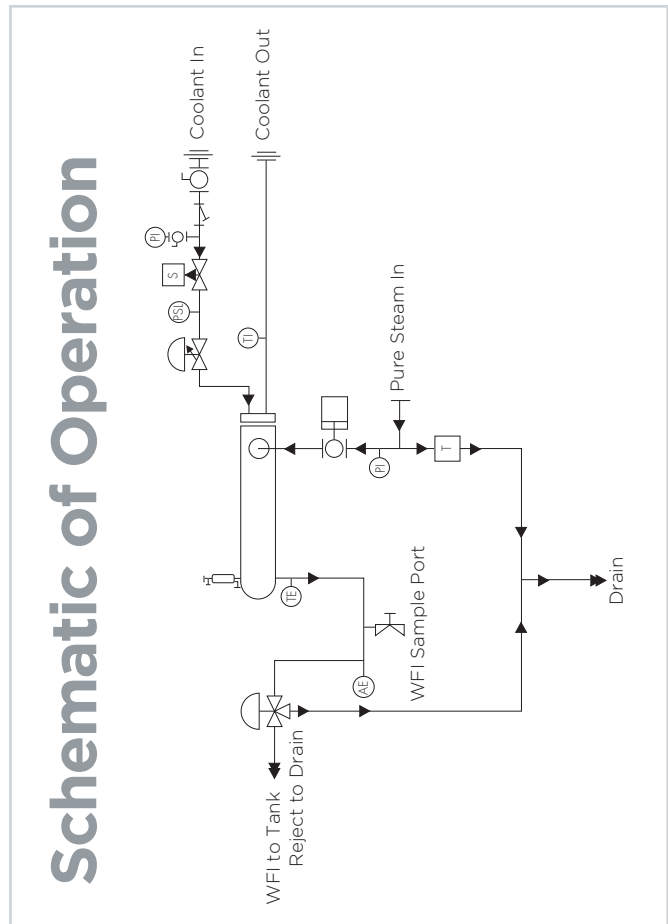
- WFI condensers have removable tube bundles for easy cleaning and inspection of product contact surfaces.
- All maintenance, including replacement of critical components, can be performed with only 24" of space on all sides (including the top) of the equipment.
- All components are fully drainable.
- Minimal instrumentation is required for operation of the equipment. Only one control loop is needed which minimizes the calibration required as well as the potential for downtime.
- All elastomers in contact with pure steam and product are provided with USP Class VI certifications.
- ASME-BPE certified fittings are used throughout.
- All product contact surfaces are manufactured from 316/316L stainless steel polished to 20 Ra maximum and electropolished.



## System Components

**Condenser.** Mueller PyroPure condensers have a double-tubesheet design, providing users with efficient heat exchange while ensuring pure vapor and distillate 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 vessel's lowest point. The condenser is designed to allow the removal of the U-tube bundle for easier inspection of critical pure distillate contact surfaces.

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



## Specifications

Model Numbers	P4001	P4002	P4003	P4004
Capacity, gph (lph) <sup>2</sup>	25 (95)	50 (189)	100 (379)	150 (568)
Pure Steam Inlet	1.5" TC	1.5" TC	1.5" TC	2" TC
Coolant Inlet/Outlet	.75" FNPT	.75" FNPT	1" FNPT	1" FNPT
Distillate Outlet	1.5" TC	1.5" TC	1.5" TC	1.5" TC
Instrument Air	.25" FNPT	.25" FNPT	.25" FNPT	.25" FNPT
Pure Steam, lb/hr (kg/hr)	202 (92)	403 (183)	807 (366)	1,210 (549)
Coolant, gph (lph) <sup>2</sup>	241 (912)	486 (1,840)	978 (3,702)	1,470 (5,565)
Electrical Service (Standard) <sup>3</sup>	115 VAC, 1phase, 50/60 Hz. (Other voltages available upon request)			
Height <sup>4</sup>	106" (269 cm)	108" (274 cm)	111" (282 cm)	111" (282 cm)
Width <sup>4</sup>	55" (140 cm)	55" (140 cm)	55" (140 cm)	55" (140 cm)
Depth <sup>4</sup>	37.5" (95 cm)	37.5" (95 cm)	37.5" (95 cm)	37.5" (95 cm)
Distillate Outlet Height <sup>4</sup>	85" (216 cm)	85" (216 cm)	85" (216 cm)	85" (216 cm)

<sup>1</sup> Pure Steam 15–90 psig (1.0–6.2 barg) dry and saturated (capacity based on 45 psig, 3.1 barg).

<sup>2</sup> Coolant water at 32°F to 100°F (0°C to 38°C) at 40 psig (2.8 barg) (flow rates based upon a distillate outlet temperature of 190°F [88°C] and cooling water inlet temperature of 60°F [16°C]).

<sup>3</sup> Other electrical services must be specified at time of order.

<sup>4</sup> Dimensions for stand-alone system only. For systems integral to a pre steam generator, dimensions will vary based on the model of pure steam generator used. Approximate operating/shipping weight is 2,500lb (1,134 kg).



# PyroPure Single-Effect Stills

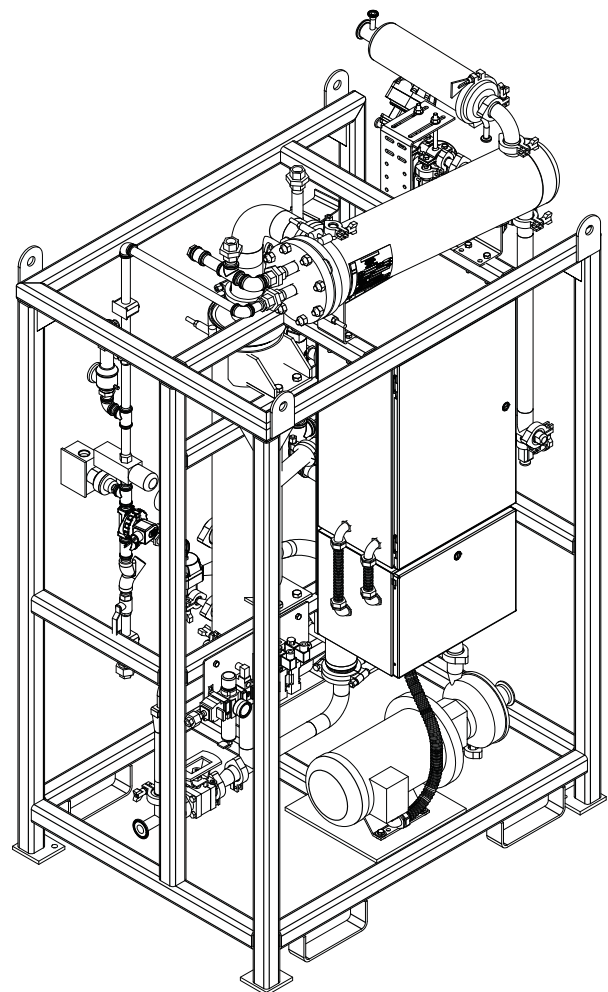
## The Efficient Mueller PyroPure Single-Effect Still

Mueller PyroPure single-effect stills (SES) are a smaller distillation units 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 (cGMPs). It features a pharmaceutical vent filter, double-tube-sheet condenser, and evaporator, including stainless steel seamless evaporator and condenser tubing, and stainless steel steam separator. 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.

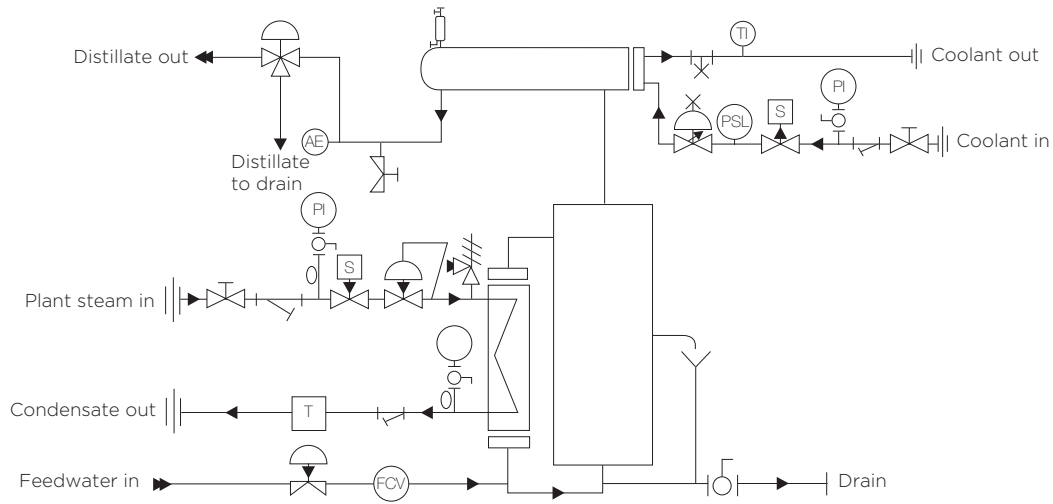
Feedwater enters the system and fills the steam separator, the tube side of the evaporator, and the level indicator assembly. At the same time, supply steam enters the shell side of the evaporator where it yields its latent heat to the feedwater through the walls of the evaporator tubes. The feedwater 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.

## Simple Design, Reliable Operation

- External evaporators access for inspection and 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.
- ASME-BPE certified fittings are used throughout.
- WFI condensers have removable tube bundles for easy cleaning and inspection of product contact surfaces.
- All product contact surfaces are manufactured from 316/316L stainless steel polished to 20 Ra maximum and electropolished.
- All elastomers in contact with feedwater and product are provided with USP Class VI certifications.
- All components are fully drainable including the optional feedwater pump.



# Schematic of Operation



## Specifications

Model Numbers	SES-15	SES-30	SES-50
Capacity, gph (lph) <sup>2</sup>	15	30	50
Feedwater Inlet	.5" TC	.5" TC	1" TC
Plant Steam Inlet	.75" FNPT	1" FNPT	1" FNPT
Coolant Inlet/Outlet	.5" FNPT	.75" FNPT	.75" FNPT
Distillate Outlet	.75" TC	1" TC	1.5" TC
Instrument Air	.25" FNPT	.25" FNPT	.25" FNPT
Feedwater, gph (lph)	17	33	55
Pure Steam, lb/hr (kg/hr) <sup>1</sup>	155	308	501
Coolant, ghp (lph) <sup>2</sup>	138	280	473
Electrical Srv. (Std.) <sup>3</sup>	115 VAC, 1phase, 50/60 Hz. (Other voltages available upon request)		
Height	94" (cm)	103"(cm)	122" (cm)
Width	45" (cm)	45" (cm)	56.5" (cm)
Depth	33.5" (cm)	33.5" (cm)	33.5" (cm)
Distillate Outlet Height	68" (cm)	82" (cm)	97" (cm)

<sup>1</sup> Plant Steam 60 psig (4.1 barg) dry and saturated.

<sup>2</sup> Coolant water at 32°F to 80°F (0°C to 26°C) at 40 psig (2.8 barg). (Flow rates based upon a distillate outlet temperature of 190°F [88°C] and cooling water inlet temperature of 60°F [16°C]).

<sup>3</sup> Other electrical services must be specified at time of order.

# PyroPure Multiple-Effect Stills

## The Mueller PyroPure P6000 Series is Built to Last

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; therefore, 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 pure steam. This pure steam is then used as the heating source for the subsequent effect.

## Simple Design, Reliable Operation

- External evaporators access for inspection and 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.
- ASME-BPE certified fittings are used throughout.
- WFI condensers have removable tube bundles for easy cleaning and inspection of product contact surfaces.
- Minimal instrumentation is required upon 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.
- All components are fully drainable including the optional feedwater pump.





As the pure 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 control 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.

## System Components

**Condenser.** PyroPure condensers have a double-tube-sheet 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 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 and Mitsubishi. Control and electrical panels are supplied with a UL 508a label.

**Steam Separator.** 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. The steam separator has no baffles or demister, there are no auxiliary surfaces for condensation to collect and stagnate. Concerns over the potential for bacterial growth are eliminated.

**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.

**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 first effect of the multiple-effect still is double tube-sheet to prevent cross-contamination. All other effects have single-tubesheet evaporators.

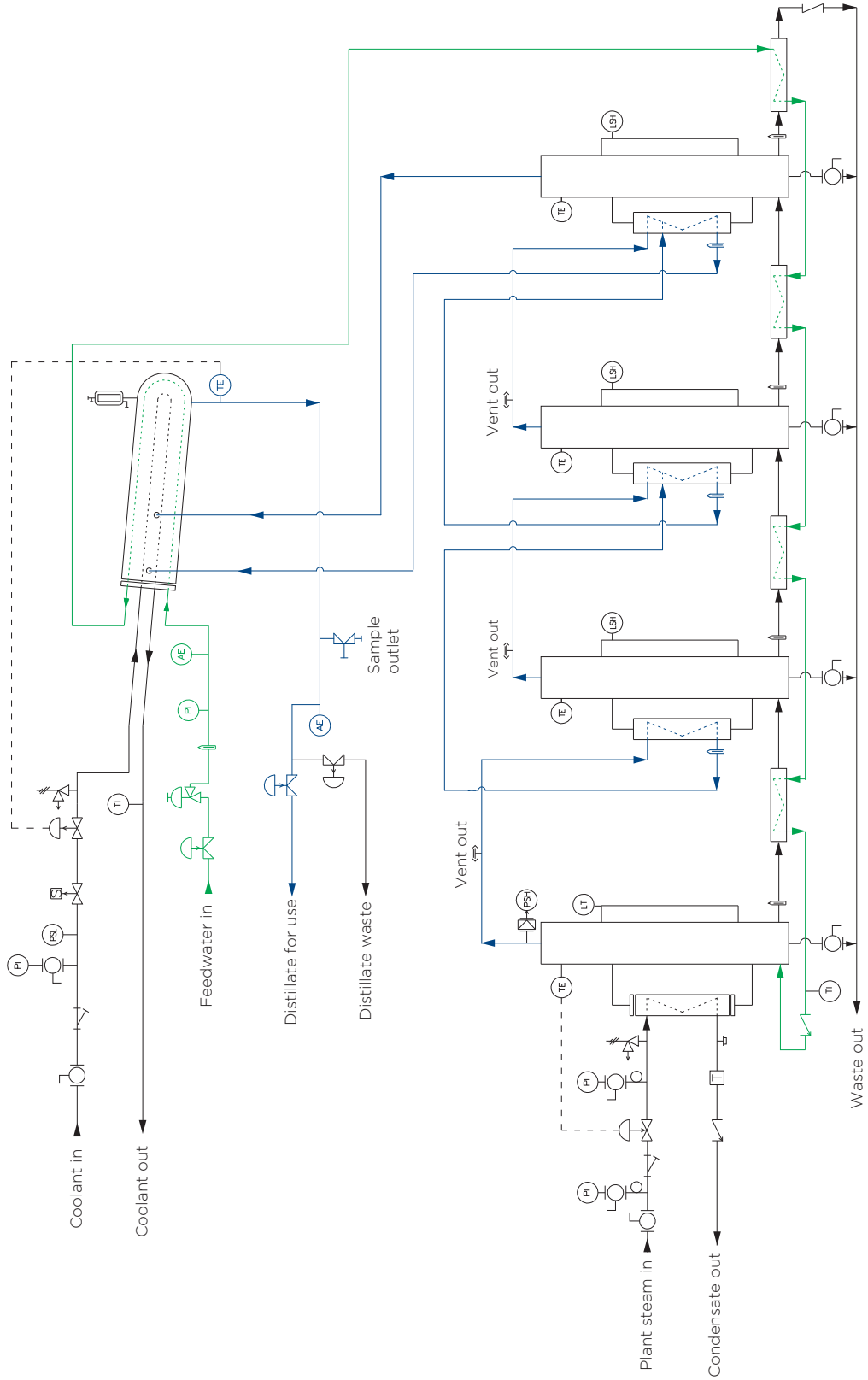
## Options

**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.** Multiple-effect stills can be configured to produce pure steam from the first effect. Simultaneous WFI and pure steam production is also available.

# 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

Model	Capacity <sup>1</sup>		Supply Steam <sup>2</sup>		Coolant Supply <sup>3</sup>		Approximate Dimensions		Distillate Outlet Ht		Est. Weight	
	gph	lph	lb/hr	kg/hr	gph	lph	HxWxD (in)	HxWxD (cm)	in	cm	lb	kg
MES 6009-3	90	341	345	156	214	810	113x62x40	287x157x102	90	229	2,500	1,135
MES 6015-3	165	625	625	283	424	1,604	114x62x40	290x157x102	89	226	3,050	1,385
MES 6015-4	150	568	467	212	267	1,011	114x75x40	290x191x102	89	226	3,200	1,453
MES 6015-5	140	530	382	173	185	702	114x88x40	290x224x102	89	226	3,350	1,521
MES 6032-4	305	1,154	958	435	569	2,155	112x80x45	284x203x114	85	216	3,600	1,635
MES 6032-5	275	1,041	753	342	382	1,447	112x94x45	284x239x114	85	216	4,100	1,861
MES 6032-6	240	908	593	269	256	969	112x108x45	284x274x114	85	216	4,600	2,088
MES 6040-5	400	1,514	1,060	481	544	2,059	112x94x45	284x239x114	85	216	4,400	1,998
MES 6040-6	390	1,476	922	418	408	1,544	112x108x45	284x274x114	85	216	4,800	2,542
MES 6064-4	630	2,385	1,926	874	1,169	4,425	128x100x52	325x254x132	102	259	4,900	2,225
MES 6064-5	600	2,271	1,554	705	811	3,070	128x119x52	325x302x132	102	259	5,600	2,543
MES 6064-6	500	1,893	1,198	543	542	2,052	128x138x52	325x351x132	102	259	6,300	2,860
MES 6076-5	690	2,612	1,811	822	945	3,578	131x119x52	333x302x132	102	259	6,800	3,087
MES 6076-6	660	2,498	1,557	706	706	2,671	131x138x52	333x351x132	102	259	7,500	3,405
MES 6110-5	1,100	4,163	2,393	1,085	1,896	7,176	136x147x53	345x373x135	107	272	12,100	5,494
MES 6110-6	1,070	4,050	2,055	932	1,558	5,897	136x168x53	345x423x135	107	272	15,000	6,810
MES 6140-6	1,300	4,921	2,467	1,119	1,877	7,105	151x184x58	384x467x147	117	297	16,400	7,446
MES 6175-6	1,810	6,852	3,423	1,553	2,642	10,001	180x184x58	457x467x147	145	368	16,800	7,620
MES 6200-6	3,200	12,112	6,126	2,779	4,797	18,157	155x209x64	394x531x163	113	287	34,500	15,649
MES 6300-6	3,700	14,004	7,060	3,202	5,547	20,994	188x192x64	478x488x163	87	221	56,500	25,628

<sup>1</sup> Distillate 170°F (77°C) to 190°F (88°C) (customer determined). Gravity flow.

<sup>2</sup> Plant steam 110 to 125 psig (7.6 to 8.6 bar) dry and saturated (capacity based on 110 psig).

<sup>3</sup> 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 cooling water inlet temperature of 60°F [16°C] and cooling water outlet temperature of 160°F [71°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.)
- Electrical Service (Standard): Without pump: 115 VAC, single phase, 60/50 Hz; with pump 460 VAC, 3 phase, 60Hz.



# 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 partnered with a variety of end users to provide an integrated system approach to their water system including the multiple-effect stills, WFI storage tanks, 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.



## Custom Skidded Systems

Paul Mueller Company custom skidded systems are designed to meet the specific requirements of your application. These systems can incorporate all of the monitoring equipment and control devices for the system into a compact skid which is assembled, integrated into a single PLC system, and tested at the Springfield, Missouri, factory. Documentation for all components are also incorporated into a comprehensive turnover package.

### Additional Skids Offered

- Custom Process Skids
- Alternative Fuel Skids
- Filter Carts
- Purewater Distiller
- Hotwater
- Pump Skids
- Pretreatment



## 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 periodic sterilization cycle with temperature monitoring at all low point drains.

## 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.

# Documentation and Validation

## Documentation

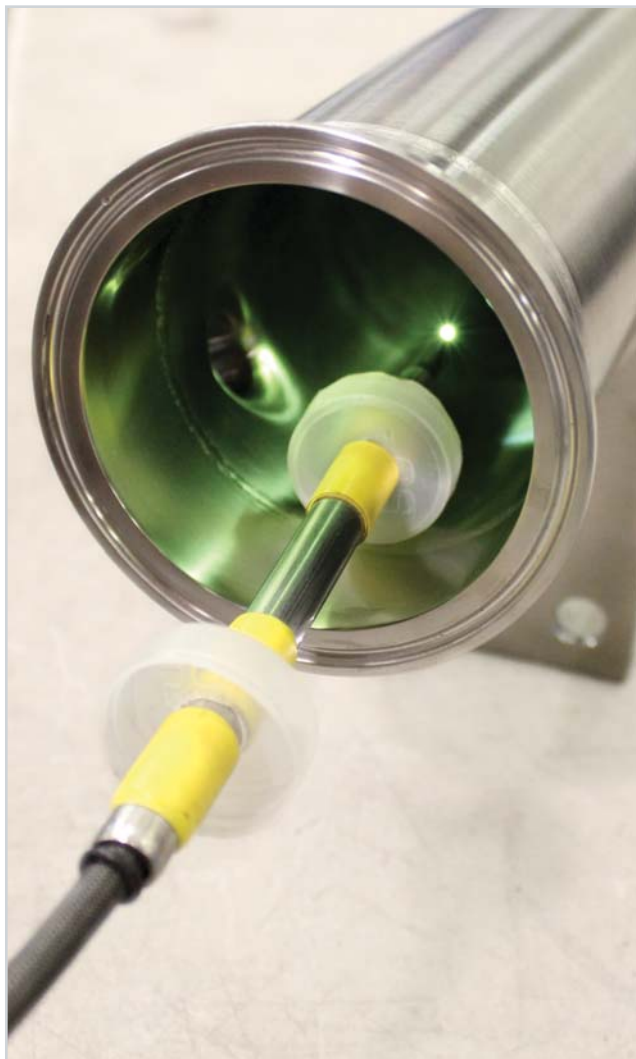
### Material Traceability

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 fabrication 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 design specification (as required).
- Master inspection traveler.
- Weld records.



### Submittals

Once your order is received, Mueller will send you drawings for final 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 as required. 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 provides a well organized and comprehensive validation reference that parallels customer protocols. In addition to the standard three-ring binders, packages are also provided in CD/DVD formats.

### IQ/OQ Capabilities

Paul Mueller Company offers installation qualification (IQ) and operational qualification (OQ) documents to support our products. These are prepared concurrently with the turnover package and provided for review at the time of factory acceptance testing. 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. We 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, Paul Mueller Company has extensive industry experience preparing comprehensive turnover documentation and validation packages. Our various completed projects have withstood scrutiny by numerous customers, independent validation companies, numerous customers, 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 as well as broad educational backgrounds in quality, technical services, engineering, chemistry, and microbiology to name a few. Since our validation and quality systems are integrated within the company infrastructure, there are substantial benefits realized from shared databases along with our comprehensive 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's Product Support Team

## 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 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. 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 department 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 factory acceptance test (FAT). Basic operation and maintenance training will be provided to any available personnel.

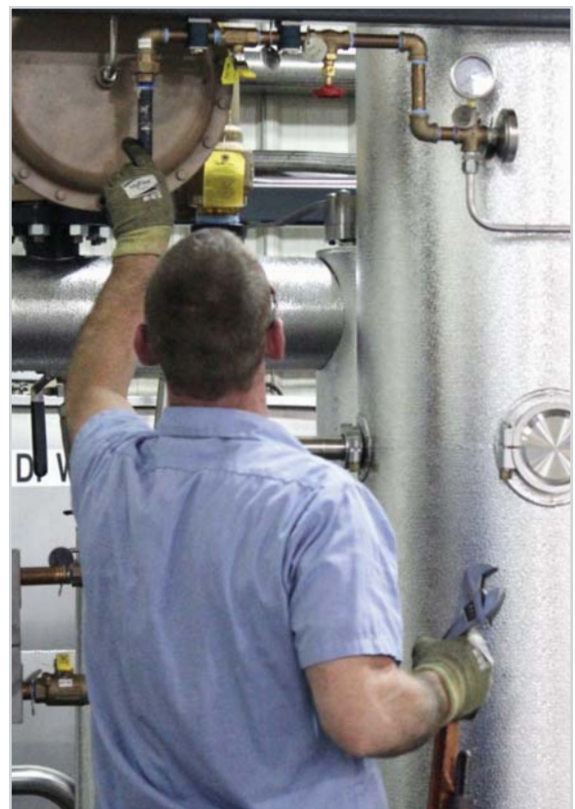
### Factory Training Seminars

Operation and maintenance training seminars can be held at your facility as needed. These seminars include both classroom as well as hands-on training. During classroom discussions, participants are able to learn from the experience of the factory technicians. Many who have attended past seminars have commented that this is the most valuable training they have ever invested in.

### On-Site Troubleshooting and Repair

Mueller factory technicians are available for scheduled or unexpected maintenance repairs. Our technicians have years of experience working with all types of Mueller equipment. Their understanding of the control logic for the equipment allows them to troubleshoot nearly any situation promptly. Many situations can be resolved over the phone; however, some situations may require an experienced eye on-site to resolve the problem without delay.

When the need arises, you can depend on the knowledge and experience of Mueller product support technicians to get your equipment back in operation as soon as possible.



## Replacement Parts

Each documentation package includes a list of recommended replacement parts that will minimize downtime in the event of a failure. Mueller stocks the most critical replacement parts for your equipment. Our parts specialists literally provide replacement parts to you as quickly as possible when your machine is down.

## Technical Support Via Phone, Fax, or Email

There is never a charge for technical support from the factory via telephone, fax, or email. 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, send a facsimile to 417-575-9662, or email us at [biopharm@paulmueller.com](mailto:biopharm@paulmueller.com).

## Technical Support Agreements

A Mueller technical support agreement (TSA) establishes a preventative maintenance plan that can be customized to meet your specific operational and equipment needs. The goal is to minimize downtime caused by mechanical failure. The TSA allows a factory technician to visit your facility periodically throughout the year to thoroughly inspect your equipment. During a TSA visit, the technician will verify all operational parameters and challenge each alarm in accordance with the original FAT to verify your equipment is in good working order. The technician will provide a detailed service report that documents the operational condition of your equipment during each visit, explains all work performed, and identifies any defects which could not be repaired during the allotted time. The service report becomes an on-going document for your equipment's permanent records. During the TSA visit, the technician can also provide basic training to new employees or advanced training to more experienced employees.

We are pleased to offer you this enhanced service, and we look forward to helping you minimize unnecessary downtime. For more detailed information or a quote for a Mueller technical support agreement based on your specific needs, contact Mueller's Product Support Team at 1-888-281-5800 or email us at [biopharm@paulmueller.com](mailto:biopharm@paulmueller.com).

## Technical Support Agreement Services

Mueller technical support agreements can be set up to provide quarterly, semi-annual, or annual service calls. The contract period begins when you sign, and it includes the following:

- Visual and operational inspection of all major components and assemblies.
- Visual and operational inspection of select accessory components.
- Visual and operational testing of all safety devices.
- Performance testing with a complete service report for your records.
- Factory training for equipment operators and your service personnel.
- Recommendations for preventative repairs.

“It has been our privilege to place the skills and techniques of Paul Mueller Company at the service of many of the nation's leading companies. It would be a further privilege to serve your company.”

**PyroPure Equipment — Proudly built in the heartland of America and shipped worldwide for over 30 years.**

**MUELLER**

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