



Cert. No. LRQ 0963008

ISO 9001

# spirax/sarco

**TI-P478-01**  
CH Issue 3

## PSG Pure Steam Generator

### Description

The PSG - Pure Steam Generator is a packaged skid mounted unit incorporating all necessary controls and function to produce pure steam. The product steam is dry saturated which when condensed exceeds quality requirements for USP Water For Injection. The PSG is 'pre-piped' and 'pre-wired' to form a complete, functional and integrated system. The unit is provided with a PLC and HMI for the full automation of system operations. The pure steam is generated via an external double tube-sheet evaporator and a vertical separation column. Plant steam is utilised as the heating media with electrical heat source as an option for low production loads.

### Key features:

- Capacity range 50 to 3000 kg/h.
- External evaporator, ease of maintenance.
- Unique optimised separation method.
- Full PID level control for safe consistent performance.
- In-house design and manufacture, cGMP double tube sheet heat exchanger, ensuring high quality control and consistency.
- cGMP design and regulatory compliance.
- Degasser option to reduce non-condensable gases.

### Limiting conditions

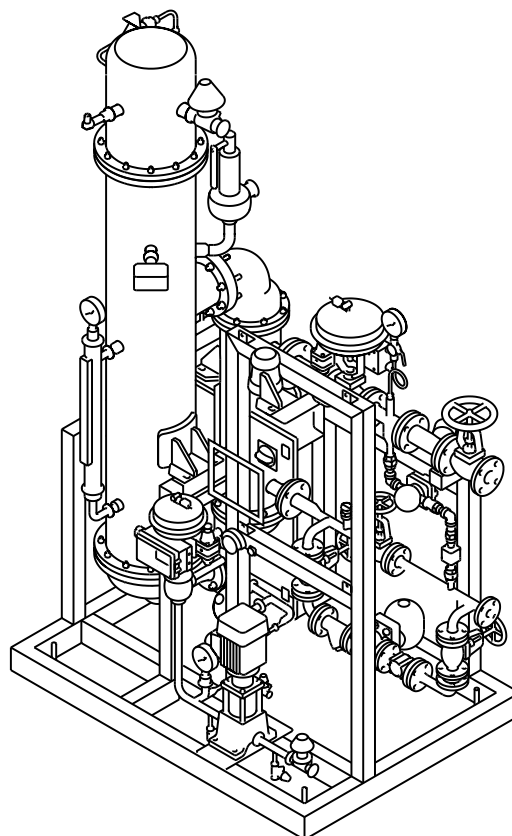
PMO	Maximum operating pressure	8 bar g
TMO	Maximum operating temperature	175°C
PMA	Maximum allowable pressure	12 bar g
TMA	Maximum allowable temperature	191.7°C
	Hydrostatic test pressure	18 bar g

### Manufacturing and design standards:

- UNI EN 285.
- HTM 2031.
- HTM 2010.
- FDA - Guide to inspection of high purity water systems.
- Guide for Validation of Automated Systems in Pharmaceutical Manufacture.
- European Commission - Good Manufacturing Practices.
- ASME BPE - 2007 Bioprocessing Equipment.
- European Pressure Equipment Directive 97/23/EEC.
- Option for compliance with CFR 21 Part 11.

### Feedwater requirements

The Spirax Sarco Pure Steam Generators are capable of producing pure steam meeting USP criteria for Water For Injection when the feedwater is demineralised/reverse osmosis water free of silica, chlorine, amine and volatile substances.



### Distillate quality

pH	5.0 – 7.0
Conductivity	≤ 1.3 µSiemens @ 25°C
Chlorides	Absent
Sulphates	Absent
Calcium	Absent
Metals	Absent
Nitrates	Absent
Micro-organisms	Absent
Total bacteria count	≤ 10 cfu/100 ml
Total organic carbon	< 0.5 ppm
Endotoxin	< 0.25 EU/ml

### Utility requirements

Electrical feed	400 V / 3 ph / 50 Hz
Pneumatic feed	7 - 15 bar g

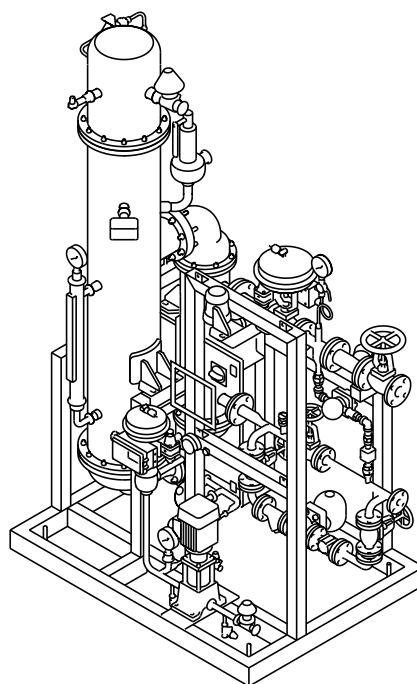
**Note:** 460 V / 3 ph / 60 Hz is available on request.

## Materials of construction

Product contact components	Stainless steel 316L
Frame	Carbon steel (standard)
	Stainless steel 304
Control panel	Carbon steel (standard)
	Stainless steel 304
Insulation	Ceramic fibre

## Standard offering:

- Double tube-sheet heat exchanger.
- 316L stainless steel evaporator / separator unit.
- Feedwater level control.
- Pure steam pressure transmitter.
- Plant steam pressure regulation.
- Continuous blowdown.
- Internal mechanical polish to 0.6 µm Ra.
- Carbon steel frame and control cabinet.
- Standard control system (PLC and HMI) non CFR 21 Part 11 compliant.
- Insulation with ceramic fibre.
- 2 days FAT testing.



## Performance data and selection chart

Plant steam pressure bar g	3.5	5	6	7	8.5	9.5	11	12
Available steam pressure (steam pressure available downstream of the control valve) bar g	3	4	5	6	7	8	9	10

## Capacities when the pure steam pressure = 3 bar g and the available steam pressure = 6 bar g

Model	PSG50	PSG100	PSG200	PSG300	PSG400	PSG500	PSG600	PSG750	PSG1000	PSG1500	PSG2000	PSG3000
Capacity kg/h	50	100	200	300	400	500	600	750	1000	1500	2000	3000

## Capacity ratio at actual operating conditions

The pure steam flowrate can be obtained by multiplying the flowrate at nominal operating conditions by the conversion ratio given below at actual operation conditions.

Pure steam pressure bar g	Available steam pressure bar g							
	3	4	5	6	7	8	9	10
1	1.03	1.58						
2	0.37	0.78	1.21	1.64	2.05			
3		0.29	0.62	1.00	1.36	1.72	2.06	
4				0.53	0.85	1.18	1.50	1.81
5					0.49	0.77	1.06	1.35
6						0.40	0.65	0.92

**Example** for a PSG400 with a plant steam pressure = 8.5 bar g and the available pressure = 7 bar g and pure steam pressure = 4 bar g (please allow a 5% margin on the calculated figure):

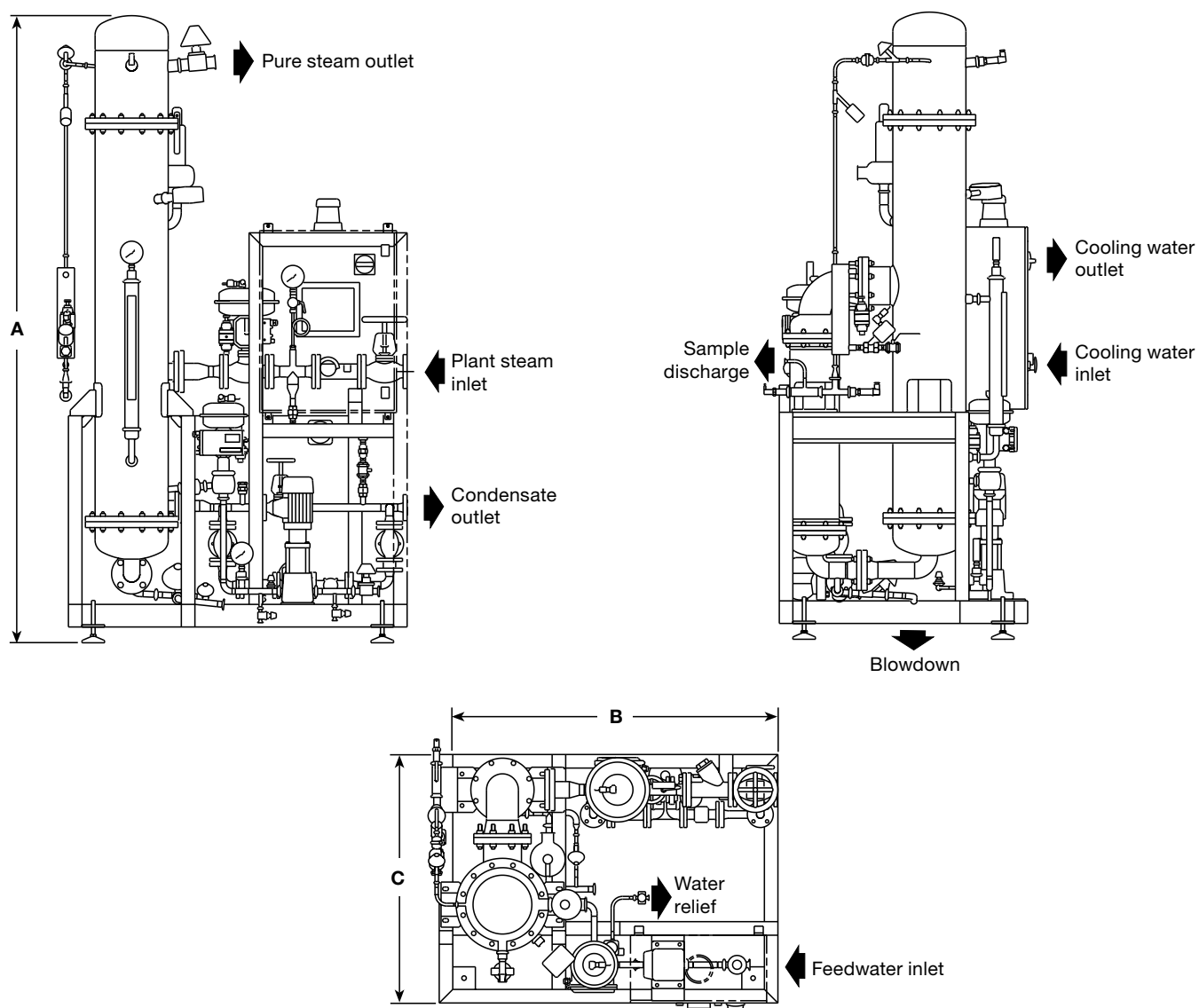
nominal production x conversion factor = 400 kg/h x 0.85 = 340 kg/h capacity

**Note:** for an accurate sizing at any other operating condition, please contact your nearest Spirax Sarco office.

## Sizes and dimensions (approximate) in mm

Connection sizes refer to the standard work conditions (Plant steam: 7 - 8 bar g, pure steam: 3 bar g). Any different work condition could cause variations to the connection sizes.

Model	Plant steam inlet	Condensate outlet	Sanitary clamp connections			A Height	B Width	C Depth
			Feedwater inlet	Pure steam outlet	Blowdown			
PSG50	DN20 PN16	DN15 PN16	1"	¾"	1"	1790	1350	1100
PSG100	DN25 PN16	DN15 PN16	1"	1"	1"	2100	1450	1100
PSG200	DN32 PN16	DN20 PN16	1"	1½"	1"	2350	1450	1100
PSG300	DN40 PN16	DN25 PN16	1"	2"	1"	2500	1500	1100
PSG400	DN40 PN16	DN25 PN16	1"	2"	1"	2650	1500	1100
PSG500	DN50 PN16	DN32 PN16	1"	2½"	1"	2780	1750	1250
PSG600	DN50 PN16	DN32 PN16	1"	2½"	1"	2900	1750	1300
PSG750	DN65 PN16	DN40 PN16	1"	3"	1"	2900	2000	1500
PSG1000	DN65 PN16	DN40 PN16	1"	3"	1"	3130	2050	1600
PSG1500	DN80 PN16	DN50 PN16	1½"	4"	1½"	3500	2200	1650
PSG2000	DN100 PN16	DN65 PN16	1½"	5"	1½"	3850	2400	1750
PSG3000	DN100 PN16	DN80 PN16	1½"	6"	1½"	4300	2550	1950



## Product nomenclature / selection

<b>Pure steam generator</b>	PSG	<b>PSG</b>
	0050 0100 0200 0300 0400 0500 0600 0750 1000 1500 2000 3000	<b>3000</b>
<b>Model number</b>		
<b>Pressure vessel code</b>	A = ASME C = CE - PED	<b>C</b>
<b>Frame / control cabinet material</b>	CS = Carbon steel (standard) SS = Stainless steel 304	<b>SS</b>
<b>Control system</b>	S1 = Standard control system S2 = Siemens S7-300 c/w touch screen panel CFR 21 Part 11 compliant	<b>S1</b>
<b>Recorder</b>	0I = No recorder IP = 1 channel paper recorder 6P = 6 channel paper recorder 6PL = 6 channel paperless	<b>6PL</b>
<b>Communications</b>	COMD = No communications COM1 = Ethernet COM2 = Profibus	<b>COM 1</b>

### Documentation (1 off hard copy)

- Quality plan.
- Design specifications.
- Functional specifications.
- Operational and maintenance instructions.
- Control panel instructions.
- General arrangement drawing.
- Pipe and instruments diagrams.
- Control schematic and panel layouts.
- List of components.
- Components manuals.
- Certificate of conformance for applicable product contact components.
- Mill certificates for all welded components.
- Welder and weld inspector certificates.
- Calibration certificates.
- Standard orbital weld logs and inspection reports.
- Passivation reports.
- Recommended spares parts list.
- Factory Acceptance Test (FAT) protocol.

**Selection example:** **PSG** **3000** - **C** - **SS** - **S1** - **6PL** - **COM 1**

**How to order example:** 1 off Spirax Sarco PSG3000 being CE-PED compliant. The frame and control panel is to be stainless steel 304. The control system is to be Siemens S7-300 c/w touch screen panel and the recorder is to be 6 channel paperless. Ethernet communications.

**Please note:** Any further options (see page 5) must be stated on your order request.

## Optional extras

Item	Code	Description
<b>Pure steam outlet valve</b>		
Manual diaphragm valve	0101	Manually operated sanitary diaphragm valve for isolation of pure steam outlet.
Actuated diaphragm valve	0102	Pneumatically actuated sanitary diaphragm valve for automatic open and closure of pure steam outlet valve.
Manual ball valve	0103	Manually operated sanitary ball valve for isolation of pure steam outlet.
Actuated ball valve	0104	Pneumatically actuated sanitary ball valve for automatic open and closure of pure steam outlet valve.
STERI-TROL (PID control valve)	0105	Pneumatically actuated sanitary PID control valve for modulated control of pure steam outlet valve.
<b>Surface finish</b>		
Electropolish to 0.4 µm Ra	0201	Internal surfaces electropolished to 0.4 µm Ra.
<b>Pure steam conductivity</b>		
Pure steam condenser	0301	Sanitary pure steam condenser.
Conductivity measurement	0302	Standard sanitary conductivity cell and transmitter.
<b>Feedwater</b>		
Sanitary pump	0401	Vertical, multistage centrifugal, sanitary pump mounted on the PSG skid frame. Intergrated for automated control. All wetted parts 316L.
Feedwater conductivity measurement	0402	Sanitary conductivity cell and transmitter for feedwater conductivity monitoring.
<b>Feedwater preheater / degasser</b>		
Preheater with relevant pipework, valves and documentation	0501	Sanitary double tube sheet heat exchanger, condensate as heating fluid.
Preheater and degasser with relevant pipework, valves and documentation	0502	The complete pre-heating and degasification unit includes a buffer tank and a second sanitary double tube sheet heat exchanger that uses the plant steam as heating fluid.
<b>WFI condenser</b>		
316L stainless steel WFI condenser with relevant pipework, valves and documentation	0601	The unit includes one or more sanitary double tube sheet heat exchangers for production of WFI by condensation of a percentage of produced pure steam.
<b>Blowdown</b>		
Blowdown cooler	0701	Blowdown cooler option allows the reduction of blowdown temperature to a defined value. All the water contact parts are in 316L stainless steel.
<b>Documentation options</b>		
Boroscope inspection of welds	0801	Boroscope 100% visual inspection of welds, digital format.
IQ, OQ, and DQ protocols	0802	IQ, OQ and DQ protocols provided on Spirax Sarco standard templates.
Additional hard copies (1 supplied as standard)	0803	Additional hard copies available on request.
Electronic copy (not supplied as standard)	0804	Electronic copies supplied on compact disc available on request.
<b>Test options</b>		
Client witnessed FAT	0901	
SAT	0902	Site Acceptance Test, documentation and execution.
LAL test	0903	Limulus Amebocyte Lysate (LAL) test for detection and quantification of bacterial endotoxin.
EU / USP WFI test	0904	EU/USP compliance laboratory WFI testing.
HTM 2010/EN285 steam quality testing (on site)	0905	
<b>Service and Maintenance</b>		
Additional days for FAT	1001	Additional days for FAT execution.
Supervision of installation	1002	
Commissioning	1003	
Operator / maintenance staff training	1004	
One year operation spare parts	1005	
One year maintenance contract	1006	
Critical spare parts	1007	Critical spare parts including plant steam and feedwater control valves, feedwater level control system and PLC with relevant configuration software.
IQ, OQ, DQ execution	1008	