Polaris CSG
cGMP Clean Steam On Demand
Applications
• Up to 6 barg Clean Steam for autoclave steam supply
• SIP (Sterilization In Place), bio reactors, make up vessels
• Sterile facility HVAC humidification
• Lyophilizer sanitization

Quantity and Quality of steam
• Standard units available between 50 - 10,000 kg/hr
• Rapid response steam production
• Low velocity, droplet free steam production via internal labyrinths
• Integrated thermal degasser for non condensable gases removal, in compliance with HTM 2010, 2031 & EN285 compliance

Service & support
• Local support & service from our global offices
• Yearly service & protection plans

Flexibility & choice
• Vertical and horizontal (Kettler) steam generators
• Additional condenser units for small scale, simultaneous steam & WFI production
• Siemens or Allen Bradley PLC, with large touchscreen panel & SCADA option
• Electric or steam heated units, integrated pre-treatment, RO, CEDI & UF for custom build packages
Clean Steam Needs...

Polaris Solution
Standard Features

**Mechanical**
- ASME BPE piping
- Steam sample point EN285 compliance
- Thermal insulation
- Stainless steel frame and control panel IP 54
- Surface finishing Ra<0.6 μm
- Feed water pump
- Drain cooling system

**Functional**
- PID pressure and flow control
- Automatic blow down
- Clean steam available from 3 to 6 bar

**Controls and Instrumentation**
- PLC control + HMI interface
- Automatic pressure, temperature and level controller

**Validation and Documentation**
- Operating manual in English, qualification documentation in English

Optional Features

**Mechanical**
- Electropolishing Ra<0.4 μm
- Feed water tank
- Clean Steam outlet check valve
- Non compensated conductivity meter with automatic sample condensing and cooling system
- Integrated thermal degasser
- Membrane degasser

**Controls and Instrumentation**
- SCADA supervision system (2 month operating data recording) / HMI in 4 language + printer (only interface required)

**Validation and Documentation**
- DQ, IQ, OQ, PQ protocols
- Operating manual

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**POLARIS - Service & Support**

All POLARIS solutions are designed in accordance with GAMP, cGMP, ISPE and FDA guidelines and will meet the product quality specifications of all of the world’s major pharmacopeia, including the USP and Ph Eur, giving you peace of mind and compliance assurance, wherever your facility is.

POLARIS systems are backed by a comprehensive range of service maintenance products.

Standardised Performance Qualification Maintenance Contracts (PQMC) are tailored to your system and ensure continuing compliance.

Scheduling service on a pre-planned basis coupled with time-based replacement of specific parts and consumables significantly reduces the risk of downtime. This approach enables us to guarantee the quality and value of your system for a lifetime.
Polaris CSG Treated Water Quality

- Conductivity < 1.3 μS/cm @ 25° C
- TOC < 500 ppb
- Bacterial Endotoxins < 0.25 EU
- Bacteria < 10 CFU / 100 ml
- Nitrate < 0.2 ppm
- Heavy Metals < 0.1 ppm

Feed Water Requirement (Minimum)

- Potable Water
  - Total Hardness < 0.1° F (1 ppm as CaCO₃)
  - Conductivity < 5 μS/cm
  - Silica < 1 ppm

Material Specification

- Evaporating Columns: Inox 316L ASME BPE
- Heat Exchanger (Pre-heater): Inox 316L (EN 1.4435) ASME BPE
- Heat Exchanger (Condenser): Inox 316L ASME BPE
- Feed Pump: Inox 316
- Support Frame: Inox 304
- Pipeline and Fittings: Inox 316L (EN 1.4435) ASME BPE
- Control Panel: Inox 304
- Valve: 316L/EPDM FDA approved
- Sealing and Gaskets: PTFE
- Pipe Welding: Orbital

Services Required

- Feed Water Temperature 15-25° C
- Feed Water Pressure 1 < P < 6 bar
- Power Supply 380/480 V; 3 Phase; 50/60 Hz
- Compressed Air 6-8 bar
- Water Drainage By gravity
- Cooling Water 15° C (if necessary)
Resourcing the world