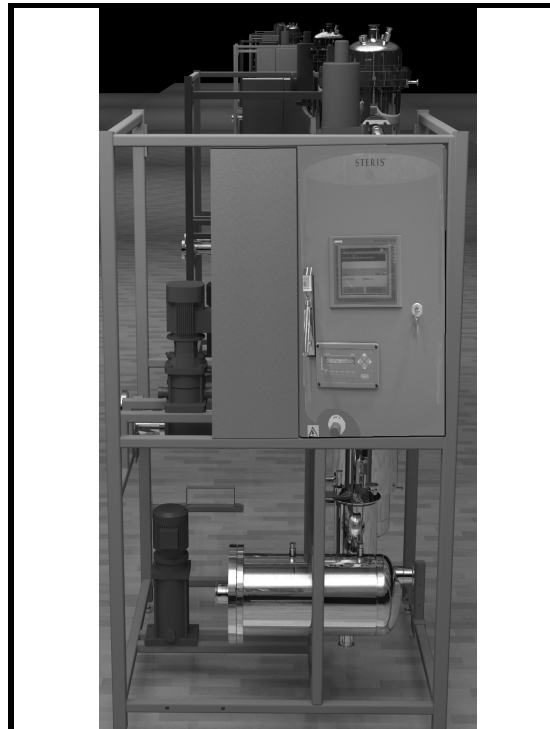


**APPLICATION**

Finn-Aqua T-Series Pure Steam Generators (PSG) are designed to consistently generate Pure Steam for use in clinical research, pharmaceutical and biotech industries. The Pure Steam is used for sterilization applications such as sterilizers, Steam-in-Place (SIP) systems, sterilization of tanks, mixing vessels and Water-for-Injection/Purified Water (WFI/PW) distribution systems as well as for clean room humidification.

**DESCRIPTION**

Finn-Aqua T-Series Pure Steam Generators operate based on Finn-Aqua's original, proven falling film design to remove pyrogenic material. The generators are steam heated and include a Programmable Logic Controller (PLC) for easy operation and monitoring. The Pure Steam Generators are designed, manufactured, tested and documented to current Good Manufacturing Practices (cGMP) compliance. The quality of the generated Pure Steam, when condensed, meets or exceeds the latest versions of U.S., European and Japanese Pharmacopeias WFI specifications.



(Typical only - some details may vary.)

**The Selections Checked Below Apply To This Equipment**

**CONTROL**

- Siemens
- Allen-Bradley

**VOLTAGE**

- 300-500 VAC, 50 Hz, 3-Phase
- 208-480 VAC, 60 Hz, 3-Phase

**CONTROL SYSTEM AND INSTRUMENTATION OPTIONS**

- Control Cabinet Accessories Upgrade
- Siemens Control System Hardware Upgrade to MP277-8 soft PLC
- SCADA Communication (Siemens Control)
- Allen-Bradley Control Panel Upgrade to PV700+
- Allen-Bradley Control System Hardware Upgrade to L32 and PV700+
- Allen-Bradley Upgrade Industrial EtherNet Connection
- Pure Steam Conductivity Monitoring and Sampling Point
- Feed Water Conductivity Sensor
- Feed Water Sample Valve, Diaphragm Type
- Feed Water Sample Valve, Milliflex
- Endress+Hauser Process Instrumentation
- Endress+Hauser Pure Steam Conductivity Monitoring
- Endress+Hauser Feed Water Conductivity Sensor
- One-Channel Pen Chart Recorder for PS
- Two-Channel Pen Chart Recorder for FW and PS
- Six-Channel Paperless Recorder (21 CFR Part 11 Compliant)
- Ground Fault Indicator (GFI)/Allen-Bradley Controls

**MECHANICAL OPTIONS**

- Plant (Heating) Steam Pressure Reducing Valve
- Feed Water Gas Separation Option
- Utilities Monitoring and Measurement Option
- Automatic Feed Water Valve
- Manual Pure Steam Shutoff Valve
- Automatic Pure Steam Shutoff Valve
- Feed Water Booster Pump
- Blowdown Cooling Accessories
- Softened Feed Water Option
- Condenser Unit for PSG (Units 250-T - 850-T)
- Stainless-Steel Frame
- Seismic Restraints and Calculations
- Additional Passivation and FAT

**MANUFACTURING TESTING AND DOCUMENTATION OPTIONS**

- Extended Pressure Vessel and Piping Documentation
- Manufacturing Procedures Documentation
- Extended Control System Validation Documentation
- FAT Procedures and Results
- Component Data Sheets/Cut Sheets
- Loop Diagrams
- Additional Copy of Documentation
- Surface Finish Inspection Report (Pressure Vessel and Piping)
- Boroscope Inspection of Pipe Welding on CD
- EP/USP WFI Test
- Endotoxin Challenge Test (Pure Steam and Feed Water)

**OPTIONAL FACTORY ACCEPTANCE TESTING**

- Additional FAT per Day

**SPARE PARTS**

- Spare Parts Kit
- Installation Kit
- Spare Feed Water Circulation Pump

Item \_\_\_\_\_  
 Location(s) \_\_\_\_\_  
 \_\_\_\_\_

## STANDARDS

The Finn-Aqua T-Series Pure Steam Generators meet the applicable requirements for the following:

- Current Good Manufacturing Practices (cGMP), CFR Title 21, Part 211, Section D
- Good Automation Manufacturing Practices (GAMP 5), A Risk-Based Approach to Compliant GxP Computerized Systems
- ISO 9001:2000 Certification, Approved by Lloyd's Register Quality Assurance Limited
- 97/23/EC (Pressure Equipment Directive) Certification, Module H/H1 and SFS-EN ISO 3834-2
- Certification of Authorization to Use ASME Code "U"-stamp
- CE Compliance
  - » Pressure Equipment Directive 97/23/EC
  - » Machine Directive 98/37/EC
  - » Low Voltage Directive 2006/95/EC
  - » Electro Magnetic Compatibility 2004/108/EY
- ASME BPE 2007
- International Electric Code IEC 60204-1/EN 60204-1
- UL 508 Standard for Industrial Control Equipment
- National Electrical Code NEC
- Canadian Standards Association CSA

## FEATURES

### Three-Stage Separation Process

Finn-Aqua's patented three-stage separation technology ensures high quality steam free of endotoxins, pyrogens and droplets. The three-stage separation provides:

- Separation by falling film evaporation
- Gravity separation by 180° steam flow turn
- Centrifugal separation where only pure steam flow can enter to the pure steam pipe

**Proportional Capacity Control (PCC)** enables operation from 0-100% capacity range and provides:

- Fast, smooth, continuous operation that avoids repeated cycling (starting and stopping) of the unit, which conserves utilities and provides a consistent pure steam pressure
- Automatic control and adjustment of the plant steam and feed water that correspond to the selected user configurable pure steam pressure
- Stabilizing time after maximum pure steam demand variations is maximum 30 seconds
- Due to the Finn-Aqua design, a pure steam pressure reducing valve is not needed

**Continuously circulating hot feed water** design concept provides the following advantages:

- Reduced plant steam and feedwater use: the reject rate (blowdown) is from 2-15% of the produced pure steam with a typical value of 5-8%\*
- Fast response during varying pure steam demand
- Keeps the circulation water tank, pump and column and all associated components continuously sanitized, even during

low steam consumption periods

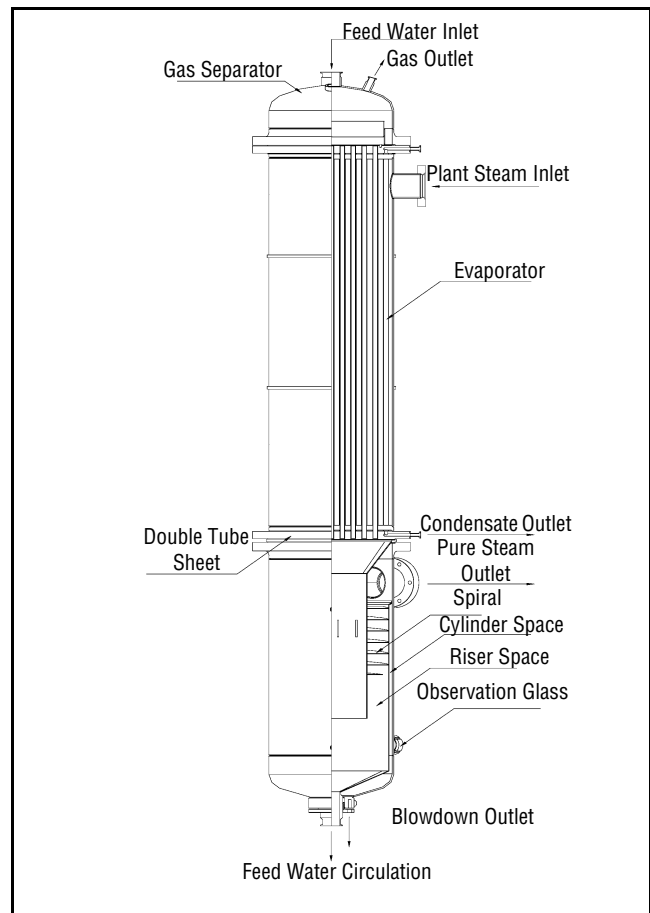
- Continuous high velocity flushing of the heat transfer surfaces during operation minimizes the risk of fouling and reduced heat transfer efficiency
- Continuous separation of pyrogens and other impurities during normal operation

### Single point power supply

- Requires only one power connection to the unit

### Small footprint and height

- Reduced external dimension enables the equipment to be installed in rooms with limited space



**Typical PSG Column Cross Sectional Detail with Feed Water Gas Removal Option**

\* The Finn-Aqua T-Series Pure Steam Generators reduce plant steam consumption by 10-12% and feed water consumption by 8-12% over previous models.

### Control System Alternatives Allen Bradley:

- Allen-Bradley CompactLogix™ 1769-L23 with C300 Touch Panel Operator Interface<sup>1</sup>.
- Optional: Allen Bradley CompactLogix™ 1769-L32 with PanelView™ 700 6.5" Color Touch Panel Operator Interface<sup>1</sup>

### Control System Alternatives Siemens:

- Siemens Simatic S7-300 PLC, CPU 313C with TP177B 4.3" Wide Screen Color Touch Panel
- Optional Siemens Simatic MP277-8 7.5" Color Touch Panel with the software PLC Simatic WinAC MP 2007

**Factory Acceptance Test (FAT) / qualification** is included for all Finn-Aqua T-Series models. The FAT includes:

- **Installation Checks (IC)** are performed to verify that the physical aspects of the pure steam generator have been manufactured in accordance with applicable design drawings and specifications.
- **Operational Checks (OC)** are performed to test the unit's functionality and guarantee that it is working in accordance with the functional specification. Multiple test bays are designed to test the unit using simulated site conditions. All tests are documented in the qualification documentation.

**Validation Documentation** – Documentation supplied with the Pure Steam Generator is unique and prepared for the specified unit. Following documentation is supplied as standard (also in electronic format):

**User's Manual (Operation and Maintenance Manual)** – A standard User's Manual is provided to guide the end user to install, operate, configure, calibrate, troubleshoot and service the unit. It is divided into the following sections:

- Transportation, uncrating and installation instructions
- Operation Manual
- Maintenance Manual
- Equipment Drawings and Parts Lists
- Manufacturer's component data sheets (only in electronic format)

**Manufacturing Documentation** – The standard Manufacturing Documentation binder provides the following information:

- ISO 9001 Certificate
- Pressure Vessel Design Drawings and Parts Lists
- Material Certificates (Pressure Vessels)
- Certificate of Compliance for Piping Materials
- Surface Treatment Certificate

**Control System Validation Documentation** – The standard Control System Document file provides the following information:

- Software Development Guideline SOP E-4039
- Continuous Development of Products SOP E-4040
- PLC Source Code (only on CD)
- Functional Specification



**Allen-Bradley PanelView Plus 700 User Interface**

**FAT (Factory Acceptance Test) Results** – The standard FAT results file is created for the tests performed during the factory qualification process. FAT documentation includes:

- **General Information:** Documentation defines the format of the qualification documents such as testing prerequisites, format of test procedures, recording of results, action on test results, acceptance of test results, reference documents, document approval and personnel involved in the FAT process.
- **Installation Check (IC) Functions** specify the objectives and results of the items performed as previously described in the FAT Phases IC.
- **Operation Check (OC) Functions** specify the objectives and results of the items performed as previously described in the FAT Phases OC:
- **Calibration Certificates:** For instruments delivered and tested.
- **Each test procedure or report** is segmented with the following information fields:
  - » Document title
  - » Alphanumeric test reference identification
  - » Test objective
  - » Results block (pass/fail).

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*1. CompactLogix™ and PanelView Plus™ are trademarks of Allen-Bradley, a Rockwell Automation Company.*

## OPTIONAL FEATURES

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**Control Cabinet Accessories Upgrade.** The control cabinet is equipped with cabinet light, electrical socket, 240 V or 120 V, and ventilation grate and ventilation fan to cool down the cabinet.

**Allen-Bradley Industrial EtherNet connection** includes hardware components to enable data reading from Central Processing Unit (CPU) (all Operator Interface [OI's], process steps and alarms). Additionally the unit can be stopped/started and acknowledge the active alarms.

### **Supervisory Control and Data Acquisition (SCADA)**

**Communication (Siemens)** contains hardware component (SIMATIC NET SCALANCE S602-module) for the data communication between the control system of T-PSG and the Customer's SCADA system.

### **Pure Steam Conductivity Monitoring and Sampling Point.**

The Pure Steam Generator is equipped with a two-channel conductivity analyzer, sensor and a cooler to allow quality monitoring using conductivity or resistivity. The conductivity analyzer has individual temperature compensation and non-compensated mode. The pure steam monitoring line is equipped with a heat exchanger and a sample valve to enable condensed pure steam sampling at a maximum of 2L/h (0.5 gal/h).

**Feed Water Conductivity Sensor.** Feed water line is fitted with a conductivity probe to monitor the feed water quality in conductivity or resistivity. This probe is used with the two-channel conductivity analyzer provided with pure steam conductivity monitoring option.

**Endress+Hauser Process Instrumentation Option.** The standard instrumentation of the unit is replaced by Endress+Hauser Process Instruments. Temperature, pressure, conductivity and flow instruments are changed.

**Recorder options.** One- or two- channel pen chart recorders are provided to continuously record the pure steam and/or feed water conductivity or resistivity. Also a 21 CFR Part 11 compatible, six-channel paperless recorder is available. The acquired process information can be stored onto a Compact Flash card or transferred online to the client's network for further analysis. Typically, this recorder is used for recording pure steam pressure, circulation water temperature and the pure steam and feed water conductivity/resistivity values. Other free channels are available for Customer use.

**Plant (Heating) Steam Pressure Reducing Valve.** For Pure Steam Generators the plant steam pressure can be reduced and stabilized by use of a Pressure Reducing Valve (PRV) installed in the plant steam line. The PRV allows the plant steam pressure to be manually adjusted between 3 - 8 bar (44 - 116 psig) as required. A PRV is also required if Customer's plant steam supply pressure exceeds 8.6 bar (125 psig) or is unstable.

**Feed Water Gas Separation Option** adds Finn-Aqua unique Gas Separation system to the feed water line before the column. A feed water spray nozzle for gas separation and a feed water distribution plate are installed to the top of the column. Piping and necessary components are installed from the column top to the drain line. With this option, the produced pure steam fulfills the HTM2010 (EN285) requirements.

**Utilities Monitoring and Measurement Option** adds feed water flow meter and blowdown 3-way valve. It also adds pressure switches and pressure gauges to monitor/ measure the utilities and their availability.

**Automatic Feed Water On-Off Valve** adds an automatic feed water on-off valve to the feed water line. The unit control system controls the function of this valve.

**Manual Pure Steam Shutoff Valve.** The pure steam line is equipped with a sanitary shutoff valve to enable isolation of the facility piping system for maintenance and shutdown purposes.

**Automatic Pure Steam Shutoff Valve** is typically selected when multiple pure steam generators are connected to a common pure steam distribution header. The pure steam line is equipped with a sanitary shutoff valve to enable automatic isolation of the PSG from the facility piping for maintenance and shutdown purposes.

**Feed Water Booster Pump.** The unit is equipped with an AISI316 stainless-steel multi-stage centrifugal pump. The pump is equipped with a Variable Speed Drive to enable stable feed water supply into the unit. The pure steam generator requires feed water pressure that is 1-2 bar (14.5-29 psig) above the pure steam pressure setpoint value. This option is typically selected if the Customer's feed water system does not meet this requirement.

**Blowdown Cooling Accessories** option is selected if the temperature of the water led to the site drainage systems is not allowed to increase over 60°C (140°F). Temperature difference between cooling water in/out is approximately 30°C (86°F).

**Softened Feed Water Option** allows the unit to be fed with a softened or single pass reverse osmosis feed water supply instead of the standard deionized or Reverse Osmosis (RO) water quality supply. The incoming feed water quality must be documented before placing an order so the Pure Steam Generator can be provided with necessary components.

**Condenser Unit for PSG (unit sizes 250-T - 850-T)** is designed to produce small amounts of distillate from pure steam output by equipping the pure steam generator with a condenser unit. Distillate is produced only at times when the pure steam demand is low. Distillate production is interrupted whenever pure steam demand exceeds specific operational limits. Distillate output capacity of the condenser unit is max. 150 L/h [39 gph] at 99°C [209°F] temperature. Distillate quality is sterile, pyrogen-free, pure steam condensate that meets WFI quality standards.

**Stainless-Steel Frame.** The standard epoxy painted carbon steel framework is replaced with framework manufactured of AISI 304 stainless steel. The construction is fully welded with an external glass beaded surface finish.

**Seismic Restraints and Calculations** provide seismic anchorage restraints and calculations for the unit per latest California Uniform Building Code (UBC) as standard and certified by a California registered Engineering Company. Calculations are designed to meet seismic, zone three and four requirements. The provided angle brackets and frame mounting hardware are manufactured from AISI 304 stainless steel.

## MANUFACTURING, TESTING, DOCUMENTATION OPTIONS AND SPARE PARTS

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**Extended Pressure Vessel Documentation** adds the following material to the standard Manufacturing Documentation:

- Pressure Vessel Welding Logs
- Welders' Qualifications
- Welding Procedure Specifications (WPS) for Pressure Vessels
- Passivation Certificate
- Electropolishing Certificate

**Extended Piping Documentation binder** adds the following material to the standard Manufacturing Documentation:

- Isometric Drawings and Welding Logs
- Welders' Qualifications
- Welding Procedure Specifications (WPS) for Piping
- Material Certificates (Piping)
- Component Certificates
- Surface Treatment Certificate

**Manufacturing Procedures Documentation** provides the Standard Operating Procedures (SOP) used during Manufacturing steps.

**Extended Control System Validation Documentation** package adds the following material to the standard package:

- Software Design Specification
- Hardware Design Specification
- Software Test Documentation
- PLC Change Control Documentation
- Input/Output (I/O) List

**FAT Procedures and Results** package integrates detailed written procedures and test plans into the FAT report. This material may then be used as a basis for the Customer's SOP's used to complement their IQ/OQ requirements during Site Acceptance Test (SAT).

With this option, the blank forms are provided on a CD (Microsoft Word format).

The FAT Procedures and Results package adds the following material to the standard package:

- Specification reference source
- Installation Checks step-by-step procedures
- Operational Checks step-by-step procedures

**Component Data Sheets** for main process instruments and components supplied on the system. The data sheet information consists of critical data such as Finn-Aqua item numbers, component type/usage, manufacturer, model number, pressure and temperature range, material of construction, functional connections, etc.

**Loop Diagrams** include individual loop diagrams that are provided for each control loop or inter-connecting wiring between associated equipment and apparatus in the system. The components tag number(s), terminal number(s) and wire colors are indicated in each diagram.

**Additional Copy of Documentation.** An additional hard copy of the complete documentation set is provided, including the user's manual, FAT documentation, as well as the manufacturing and control system documentation (standard and optional). Manufacturer's booklets and CDs for installation, operation and maintenance for control systems, instrumentation and components are excluded.

**Surface Finish Inspection Report (Pressure Vessel and Piping).** This option provides surface finish instrument documentation, test procedures, inspection report and surface finish measurement data in  $\mu\text{mRa}$ .

**Boroscope Inspection of Pipe Welding on DVD.** As standard, all feed water, pure steam and distillate line welds are visually inspected during manufacturing according to STERIS Finn-Aqua procedures.

With this option, isometric diagrams are created and all welds are logged. Each weld is then sequentially inspected using a boroscope. The inspection is recorded on a DVD for reference purposes.

**European Pharmacopeia/United States Pharmacopeia [EP/USP] WFI Test.** A sample of the pure steam is extracted from Finn-Aqua Pure Steam Generator and analyzed for the following constituents:

- Current EP water monograph substances
- Colony Forming Units (CFU)
- Total Organic Carbon (TOC) level

**Endotoxin Challenge Test (WFI and Feed Water).** In order to demonstrate an effective reduction of endotoxins, a Limulus Amebocyte Lysate (LAL) test method can be performed during FAT. To demonstrate the reduction, feed water to the unit is spiked with a minimum of 10 EU/mL endotoxins. The distillate produced must contain less than 0.25 EU/mL (as defined by United States Pharmacopoeia [USP] as acceptance level). An independent laboratory performs the LAL test in accordance to international standards. Test procedure and test certificate are supplied with the documentation.

**Additional FAT per Day.** As standard, a STERIS Finn-Aqua FAT is scheduled for two days. FAT is extended by one day to allow the Customer to perform additional tests.

**Spare Parts Kit** is provided that contains selected mechanical components to fulfill the requirement for two years of normal maintenance and operation of the Pure Steam Generator.

**Installation Kit** supports an effective installation on the Customer site by providing:

- Gaskets for the utility connections
- Counter (matching) flanges and fittings for all the utility connections

**Spare Feed Water Circulation Pump.** One complete feed water circulation pump manufactured from AISI 316 stainless steel with electric motor is provided for fast replacement.

## CONSTRUCTION

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### • Pressure Vessels:

- » AISI 316L Stainless-Steel Pressure Vessels. Pressure vessels are designed to a pressure rating of 8.6 bar (125 psig) at 178°C (352°F). Pressure vessels built according to ASME/PED or many other international standards
- » Process contact heat exchangers including the evaporator are of a double-tube-sheet design preventing cross-contamination from lower purity media to higher purity media. The heat exchanger tubes are expanded into the end of tube sheet.
- » Surface finish in contact with Pure Steam and Feed Water is polished / electropolished to Ra < 0.6 µm (25 µinch).
- » Column, preheater and re-circulation tank are insulated with non-corrosive mineral wool (in compliance with ASTM C 795) with 304 stainless-steel bright annealed sheathing.

### • Piping:

- » AISI 316L Stainless-Steel or better piping and components for feed water and pure steam. All piping located outside of the pressure vessels are according to ASTM A269 or A270, ASME SA213/312.
- » Sanitary Flange Connections for clean utilities
- » Orbital Welded Pipes and Components (where technically possible)
- » Automatic orbital welding techniques are utilized wherever technically possible. Argon of minimum 99.998% purity is used as protective inert gas.
- » Surface finish in contact with Pure Steam and Feed Water is polished/electropolished to Ra < 0,6 µm (25 µinch).
- » A maximum of 3D for dead legs is maintained on the pure steam and feed water lines wherever technically possible.
- » A capped tri-clamp drain port is located in the lowest point of the system. All horizontal pipe runs are sloped a minimum of 1-2° to promote drainage wherever technically possible.
- » All gaskets used are of pharmaceutical grade conforming to Food and Drug Administration (FDA) regulations, e.g., Polytetrafluoroethylene (PTFE), Ethylene Propylene Diene Monomer (EPDM) or silicone.

## UTILITY REQUIREMENTS

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### Electrical

- 300-500 VAC, 50 Hz, 3-Phase
- 208-480 VAC, 60 Hz, 3-Phase

### Steam

- 3-8 bar (44 - 116 psig)
- 97-100% Saturated Steam
- Max. ±5% Pressure Variations

### Feed Water

- 1-2 bar (14.5-29 psig) Higher Than Pure Steam Setpoint
- Conductivity <5.0 µS/cm at 25°C (77°F)
- Resistivity >0.2 MOhm-cm
- 5-7 pH
- Silica <1 ppm
- Chloride <100 ppb
- Chlorine <100 ppb

### Compressed Air

- 6-8 bar (87-116 psig )
- Clean, dry, oil free

### Cooling Water (with Pure Steam Quality Control and Blowdown Cooling Options)

- 2-5 bar (29 - 73 psig) Δp min 2 bar
- Hardness not to exceed 7° dH

## UNIT DIMENSIONS

Finn-Aqua T-Series Pure Steam Generators reduced external dimensions enables the equipment to be installed in rooms with limited space.

**Table 1. Dimensions and Weights**

Model	Width (W)	Depth (D)	Height (H)	Weight*
150 T	700 mm (28")	1200 mm (47")	2000 mm (79")	315 kg (695 lb)
250-T	700 mm (28")	1200 mm (47")	2000 mm (79")	345 kg (761 lb)
450-T	1220 mm (48")	1200 mm (47")	2300 mm (91")	480 kg (1059 lb)
850-T	1220 mm (48")	1200 mm (47")	2700 mm (106")	620 kg (1367 lb)
1600-T	1600 mm (63")	1290 mm (51")	3090 mm (122")	855 kg (1885 lb)
2900-T	1600 mm (63")	1290 mm (51")	3450 mm (136")	1175 kg (2590 lb)
4700-T	1750 mm (69")	1750 mm (69")	4050 mm (159")	1670 kg (3680 lb)

*NOTE: Because of STERIS's continuing program of research and development, all specifications and descriptions are subject to change without notice. Obtain approved drawings for design and installation.*

\* Weight = operational weight

## CAPACITIES AND CONSUMPTIONS

Finn-Aqua T-Series Pure Steam Generators are heated by plant steam supplied at a pressure from 3 - 8 bar (44 - 116 psig). The production capacity of the T-Series PSG is based on the plant steam to pure steam pressure relationship. The pure steam out pressure is configurable from 2 - 5 bar (29 - 73 psig). A greater pressure difference between the plant steam and pure steam pressure results in increased capacity. Maximum capacity is based on 8 bar (116 psig) plant steam pressure and 3 bar (44 psig) Pure Steam set pressure.

T-model Pure Steam Generator plant steam consumption is in average 1.15 x pure steam capacity.

T-model Pure Steam Generator feed water consumption is in average 1.06 x pure steam capacity.

**Table 2** indicates select capacity examples of typical Heating Steam/Pure Steam pressure values.

Each Pure Steam Generator has a specific Capacity Curve. Please consult with a STERIS Sales Representative for additional capacity alternatives.

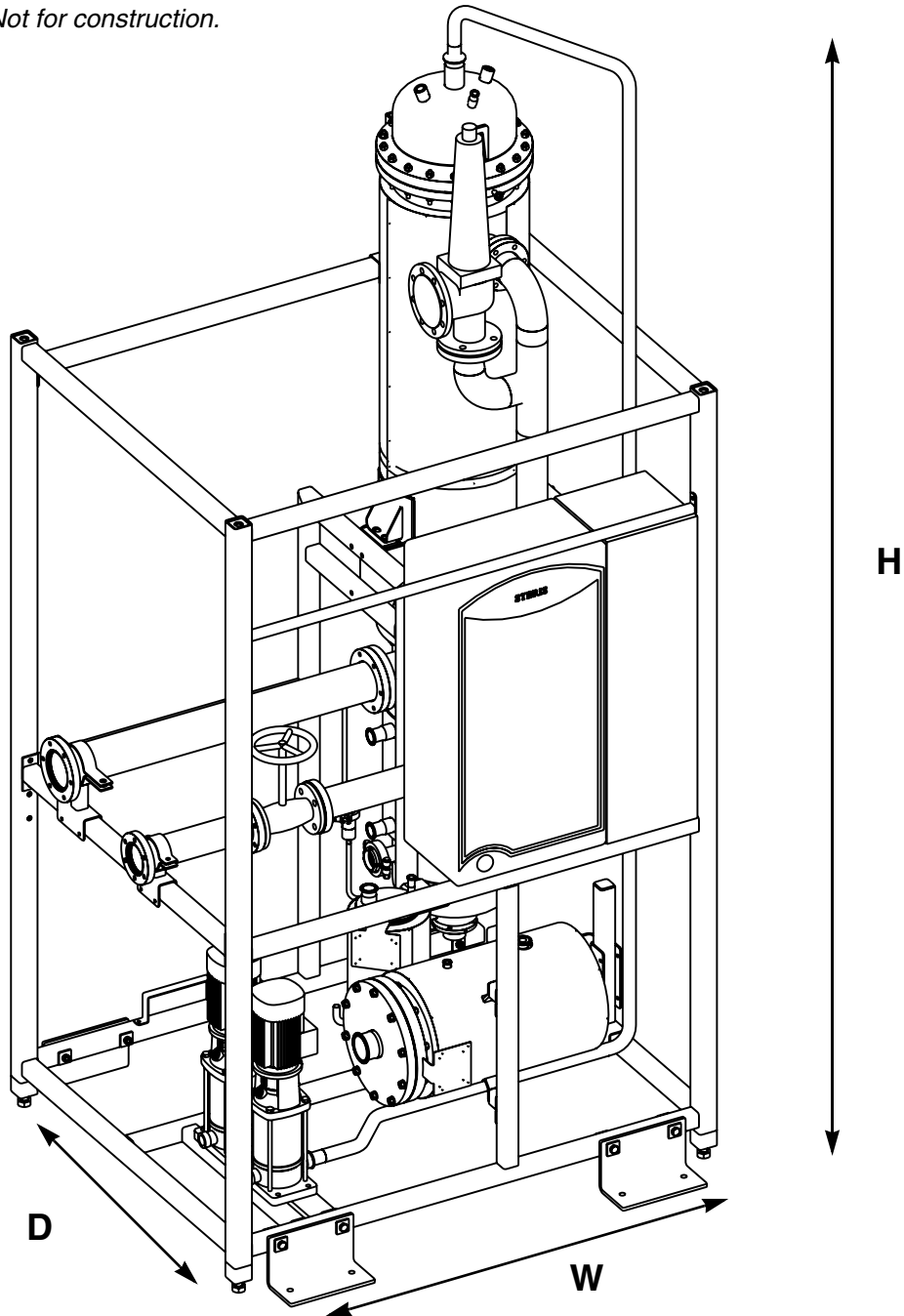
**Table 2. Heating Steam and Pure Steam Pressure Capacities**

Model	Capacity at 8 bar (116 psig) Heating Steam and 3 bar (44 psig) Pure Steam Pressure	Capacity at 6 bar (87 psig) Heating Steam and 3 bar (44 psig) Pure Steam Pressure
150-T	150 kg/h (330 lb/h)	100 kg/h (220 lb/h)
250-T	230 kg/h (500 lb/h)	145 kg/h (320 lb/h)
450-T	440 kg/h (970 lb/h)	280 kg/h (670 lb/h)
850-T	800 kg/h (1760 lb/h)	535 kg/h (1170 lb/h)
1600-T	1600 kg/h (3520 lb/h)	1020 kg/h (2240 lb/h)
2900-T	2600 kg/h (5730 lb/h)	1675 kg/h (3690 lb/h)
4700-T	4750 kg/h (10470 lb/h)	3100 kg/h (6830 lb/h)

*NOTE: 97 - 100% saturated steam is required with pressure variations max.  $\pm$ 5%. Heating steam pressure measured in the column.*

*NOTE: Because of STERIS's continuing program of research and development, all specifications and descriptions are subject to change without notice. Obtain approved technical specifications and drawings for design and installation.*

NOTE: Typical only. Not for construction.



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