

APPLICATION

Finn-Aqua TF-Series Pure Steam Generators (PSG) are designed to consistently generate Pure Steam for use in clinical research, and in the 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 TF-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 comply with current Good Manufacturing Practices (cGMP). The quality of the generated pure steam, when condensed, meets or exceeds the latest versions of United States Pharmacopeia (USP), European Pharmacopeia (EP) and Japanese Pharmacopeia (JP) WFI specifications.



(Typical only - some details may vary.)

The Selections Checked Below Apply To This Equipment

CONTROL

- ☐ Siemens
- ☐ Allen-Bradley

VOLTAGE

- ☐ 230-400 Vac, 50 Hz, 3-Phase
- ☐ 208-600 Vac, 60 Hz, 3-Phase

CONTROL SYSTEM AND INSTRUMENTATION OPTIONS

- ☐ Ethernet Industrial Connection (Siemens)
- ☐ Ethernet Industrial Connection (Allen-Bradley)
- ☐ Pure Steam Conductivity Monitoring (Thornton) and Sampling Point
- ☐ Feed Water Conductivity Sensor (Thornton)
- ☐ Two-Channel Pen Chart Recorder for Pure Steam and Feed Water
- ☐ Five Channel Paperless Recorder (21 CFR Part 11 Compliant)
- ☐ Ground Fault Indicator (GFI) for Allen-Bradley Control
- ☐ Audit Trail for Siemens Control
- ☐ UPS Connection for Control System
- ☐ -Audit Trail for Allen Bradley Control

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
- ☐ Loop Diagrams
- ☐ Additional Copy of Documentation
- ☐ Surface Finish Inspection Report (Pressure Vessel and Piping)
- ☐ Endotoxin Challenge Test (WFI and Feed Water)
- ☐ EN 285 Steam Quality Tests optional factory acceptance testing (FAT)
- ☐ Additional FAT per Day

MECHANICAL OPTIONS

- ☐ Plant (Heating) Steam Pressure Reducing Valve
- ☐ Manual Pure Steam Shutoff Valve
- ☐ Blowdown Cooler (Heat Exchanger)
- ☐ Automatic Feed Water On/Off Valve
- ☐ Frame Stainless Steel
- ☐ Seismic Restraints and Calculations

FEED WATER BOOSTER PUMP

SPARE PARTS

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

ENHANCED IQ/OQ SERVICES

- ☐ cGMP Validation Package

Item _____

Location(s) _____

STANDARDS

The Finn-Aqua TF-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
- 21 CFR Part 11/EU Annex 11
- ISO 9001:2015 Certification, Approved by Inspecta Sertifointi Oy
- 2014/68/EU (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 2014/68/EU
 - » Machinery Directive 2006/42/EC
 - » Low Voltage Directive 2014/35/EU
 - » Electromagnetic Compatibility 2014/30/EU
- ASME BPE
- 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 flash evaporation
- Gravity separation by 180° steam flow turn
- Centrifugal separation, where only pure steam flow can enter to the pure steam pipe

Continuous Gas Separation. Finn-Aqua's unique feed water gas separation spray nozzle is a standard feature designed to reduce the content of non-condensable gases (in produced pure steam) to meet HTM2010/EN285 requirements.

Proportional Capacity Control (PCC) enables operation from 0 to 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:

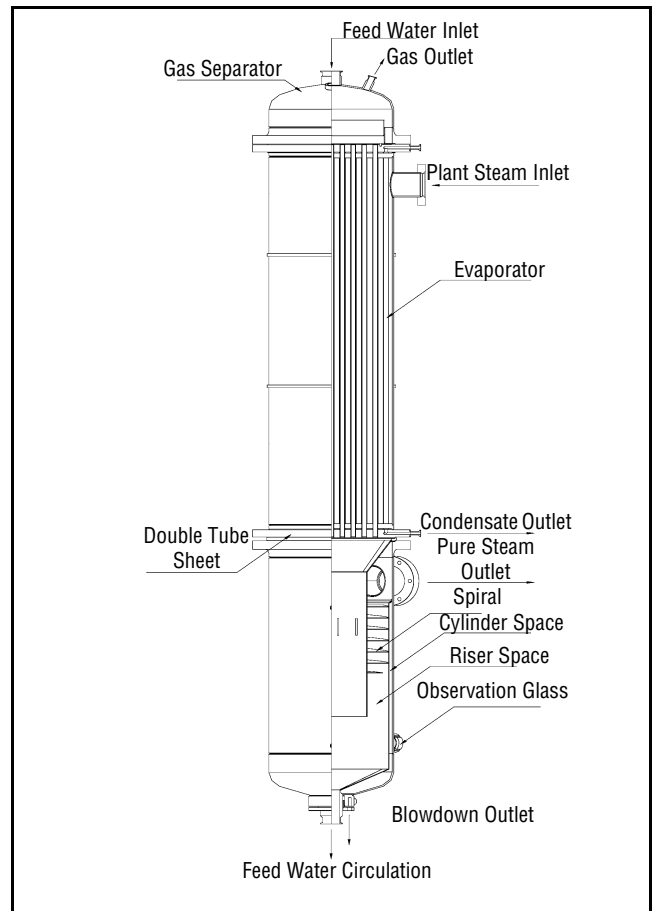
- Reduced plant steam and feed water use: the reject rate (blowdown) is 2-15% of the produced pure steam with a typical value of 5-8%*
- Fast response during varying pure steam demand
- Keeps the circulation water tank, pump and column and all associated components continuously sanitized, even during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

** Finn-Aqua TF-Series Pure Steam Generators have been shown to reduce plant steam consumption by 10-12% and feed water consumption by 8-12% over previous models.*

Control System Allen-Bradley:

Allen-Bradley CompactLogix™ CPU 5069-L310ER with PanelView™ Plus 7 9" Touch Panel Operator Interface¹

Control System Siemens:

Siemens SIMATIC® 1511C-1PN CPU with TP1200 12" Touch Panel Operator Interface²

Factory Acceptance Test (FAT)/ qualification is included for all Finn-Aqua TF-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:

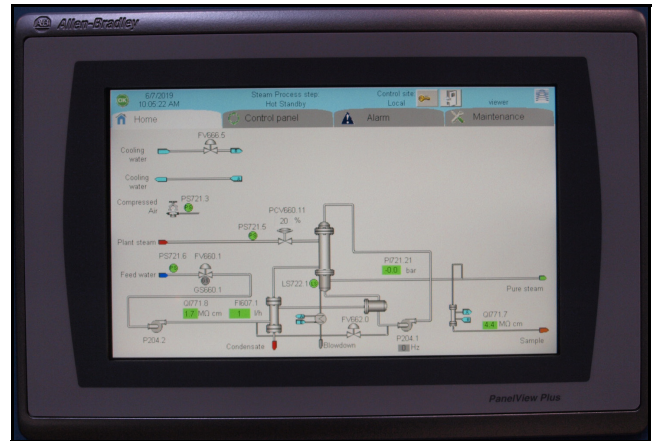
- Transportation, uncrating and installation instructions
- Operation Manual
- Maintenance Manual
- Equipment Drawings and Parts Lists
- Manufacturer's component data sheets (only in electronic format)

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

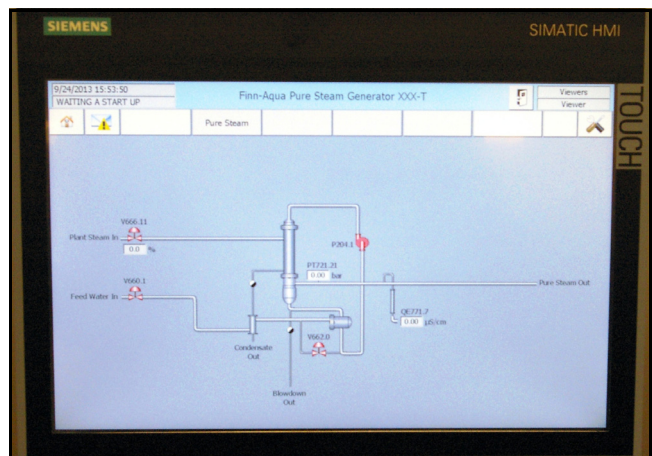
- ISO 9001 Certificate
- Pressure Vessel Design Drawings and Parts Lists
- Material Certificates (Pressure Vessels)
- Certificate of Compliance for Piping Materials
- Surface Treatment Certificate

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

- Software Development Guideline SOP E-4039
- Change Control SOP E-4040
- PLC Source Code Listing
- Functional Specification



Allen-Bradley PanelView Plus 7-900 User Interface



Control Cabinet Accessories Upgrade. The control cabinet and supply box are equipped with ventilation grate and ventilation fan to cool down the cabinet.

Utilities Monitoring and Measurement includes feed water flow meter, pressure switches and pressure gauges to monitor/measure the utilities and their availability.

OPTIONAL FEATURES

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 2 bar (29 psig) above the pure steam pressure setpoint value. This feature ensures that feed water system meets the requirements.

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

Ethernet Industrial Connection (Siemens) contains hardware component for data reading from the unit (all IO's, measurements, process steps and alarms) via standard data blocks. Unit can be stopped / started and active informative and aborting alarms can be acknowledged.

Ground Fault Indicator (GFI) for Allen-Bradley Control. GFI is installed to sense low level (arcing) ground faults that are below the fuse or circuit breaker rating and may therefore go undetected. GFI is intended for equipment protection only. GFI system consists of a relay and a sensor. Operation of the ground fault detection system is indicated on the operator interface.

UPS Connection for Control System. Connection for an auxiliary UPS to provide a single-phase power supply for the control system. With this option, the control system will stay powered on despite the possible power outages.

Audit Trail for Siemens control. Audit trail functionality is for monitoring certain operator activities when the HMI application is running.

Audit trail entries include occurred time, username and information about a specific operator action. An entry for tag value modification will contain the name of the tag being modified and the tag's previous and new values.

Audit trail file is temporarily stored in a CSV file on memory card of the HMI.

Audit trail file can be read with external PC with a SIEMENS viewer tool called Simatic WinCC Audit Viewer. The validity of the Audit trail file can be checked by the same program (check sum is used). There are no audit trail functionalities to display on the HMI. The user is responsible for long term data archiving of audit trail (CSV files) and is also responsible to meet any regulatory requirements for electronic data security once the files are removed from the STERIS control system. The audit trail file is exported manually from the HMI into the customer's computer. Transfer of the file does not alter the contents of the record. UPS is recommended to ensure Audit trail logging is successful in case of a power outage.

Audit Trail for Allen Bradley Control System. Audit trail functionality is for monitoring certain operator activities when the HMI application is running.

Audit trail entries include occurred time, username and information about a specific operator action. An entry for tag value modification will contain the name of the tag being modified and the tag's previous and new values. FactoryTalk View Machine Edition software version 10 and higher includes audit trail feature. It allows to record certain operator actions, such as tag value changes and user login/logout to an audit trail log. Each HMI panel has its own local audit trail. The audit trail log is an open file and it must be closed and exported to a CSV file at certain intervals to prevent the file becoming full. Before the maximum number of entries in the open audit trail log is reached, the log will automatically be exported to a CSV file and then emptied. The user can also select daily or weekly export to CSV file. The CSV files will be saved to the HMI panel's limited local memory. The audit trail CSV files can be moved from the system either manually to a storage media using the Windows CE user interface or over network by using an external computer. UPS is recommended to ensure Audit trail logging is successful in case of a power outage.

Automatic Feed Water On-Off Valve. An isolation valve is needed to the feed water line of the Pure Steam Generator. This option must be selected if there is no feed water shut-off valve in the user's line.

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 2 L/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.

Recorder options. Two-channel pen chart recorder is provided to continuously record the pure steam and/or feed water conductivity or resistivity. Also a 21 CFR Part 11 compatible, five-channel paperless recorder is available.

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 and 8 bar (44 and 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.

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.

Blowdown Cooler (Heat Exchanger) option is selected if the temperature of the water going 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).

Stainless-Steel Frame. Framework is 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 requirements. The provided angle brackets and frame mounting hardware are manufactured from AISI 304 stainless steel.

MANUFACTURING, TESTING, DOCUMENTATION OPTIONS AND SPARE PARTS

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®¹ 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 μmRa .

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 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.

EN 285 Steam Quality Tests. A sample of pure steam is extracted from Finn-Aqua Pure Steam Generator. Tests listed below are performed according to EN 285:

- Non-Condensable gas test
- Superheat test
- Dryness test

Test elbow used in the testing is made as per EN 285 standard, and is included in the delivery if this option is purchased.

Additional FAT per Day. As standard, a STERIS Finn-Aqua FAT is scheduled for three 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

1. Microsoft Word® is a registered trademark of Microsoft Corporation.

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.

cGMP Validation Package- Document and Execution

The STERIS current Good Manufacturing Practice (cGMP) Validation Package is designed to provide a comprehensive and efficient approach to validation. This package was developed using current guidelines set forth in GAMP 5: A Risk-Based approach to Compliant GxP Computerized Systems, 2008. Validation documentation consists of scalable versions of our STERIS Factory Acceptance Test (FAT), Site Acceptance Test (SAT) and Installation Qualification/Operational Qualification (IQOQ) documents leveraging one another to ensure the unit functions as intended from the factory to the Customer site. It is sold as a complete validation package – document and execution, including detailed equipment and site-specific documents, labor and materials required to execute the procedures/tests within the documents, and a NIST or National Metrology Institute (NMI) traceable calibration.

The Execution of a Customer's pre-approved STERIS cGMP validation documentation package (ordered separately) is performed on-site by a STERIS Service representative. The Execution follows the cGMP Document to validate proper equipment operation and includes a NIST or NMI traceable calibration. The STERIS calibration service will be performed on appropriate process measuring equipment used in manufacturing and manufacturing-support environments. Qualified STERIS Service personnel using NIST or NMI traceable instrumentation perform all program services according to documented STERIS protocols and procedures.

CONSTRUCTION

• 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 as well as 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 feasible)
- » Automatic orbital welding techniques are utilized where feasible. Argon of minimum 99.998% purity is used as protective inert gas.
- » Surface finish for pipes 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 where feasible.
- » 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 where feasible.
- » 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

Electrical

230-400 Vac, 50 Hz, 3-Phase
208-600 Vac, 60 Hz, 3-Phase

Steam

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

Feed Water

Conductivity <5.0 pS/cm at 25°C (77°F)
Pressure 2 bar (29 psig) Higher than Pure Steam Pressure Setpoint
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) Gp min 2 bar
Hardness not to exceed 125 ppm as CaCO₃ 7° dH

UNIT DIMENSIONS

Finn-Aqua TF-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*
450-TF	1220 mm (48")	1200 mm (47")	2300 mm (91")	480 kg (1058 lb)
850-TF	1220 mm (48")	1200 mm (47")	2700 mm (106")	620 kg (1367 lb)
1600-TF	1600 mm (63")	1290 mm (51")	3090 mm (122")	855 kg (1885 lb)
2900-TF	1600 mm (63")	1290 mm (51")	3450 mm (136")	1175 kg (2590 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 TF-Series Pure Steam Generators are heated by plant steam supplied at a pressure from 3 to 8 bar (44 to 116 psig). The production capacity of the TF-Series PSG is based on the plant steam to pure steam pressure relationship. The pure steam out pressure is configurable from 2 to 5 bar (29 to 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.

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

Finn-Aqua TF-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.

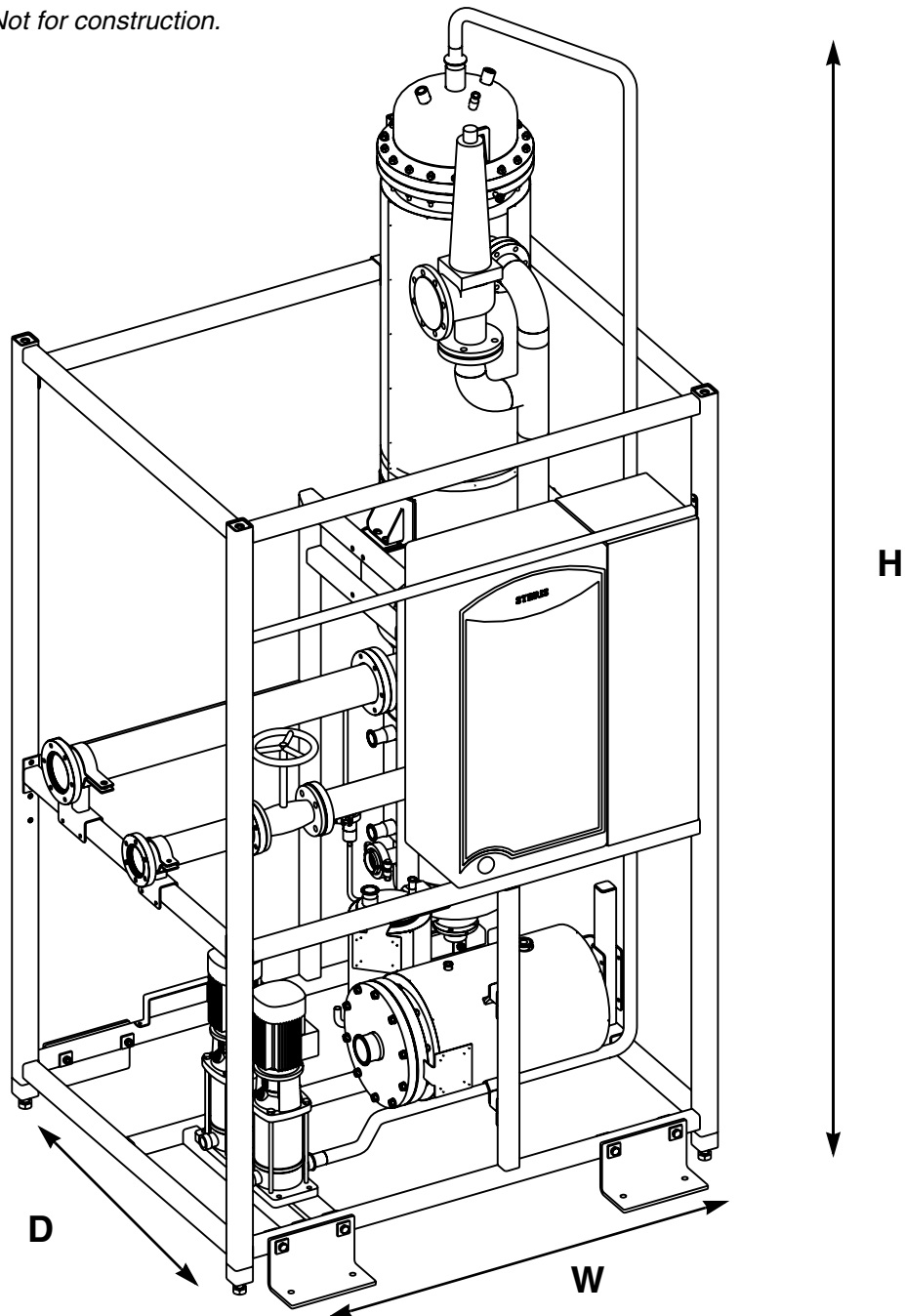
Table 2. Heating Steam and Pure Steam Pressure Capacities

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
450-TF	440 kg/h (970 lb/h)	280 kg/h (617 lb/h)
850-TF	800 kg/h (1760 lb/h)	535 kg/h (1180 lb/h)
1600-TF	1600 kg/h (3520 lb/h)	1020 kg/h (2249 lb/h)
2900-TF	2600 kg/h (5730 lb/h)	1675 kg/h (3690 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.



For Further Information, contact:



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