

APPLICATION

Finn-Aqua Multiple-Effect Water Stills (MWS) are designed to consistently generate Water for Injection (WFI). WFI is intended for use in the preparation of parenteral solutions and for washing and final rinse in Good Manufacturing Practices (GMP) washers and terminal sterilizers.

DESCRIPTION

Finn-Aqua TF-Series Multiple-Effect Water Stills operate based on Finn-Aqua's original, proven falling film design to remove pyrogenic material. The water stills are steam heated and include a Programmable Logic Controller (PLC) for easy operation and monitoring. The Multiple-Effect Water Stills are designed, manufactured, tested and documented to comply with current Good Manufacturing Practices (cGMP). The quality of the generated WFI 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

- 380-415 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)
- Feed Water Conductivity Sensor (Thornton)
- Feed Water Sample Valve, Diaphragm Type
- Three-Channel Pen Chart Recorder
- Ground Fault Indicator (GFI) for Allen-Bradley Control

MECHANICAL OPTIONS

- Plant (Heating) Steam Pressure Reducing Valve
- Distillation Against Back Pressure
- Simultaneous Pure Steam and WFI Production
- Proportional Capacity Control (PCC)
- Reject Distillate Cooler (Heat Exchanger)
- Blowdown and Gas/De-aeration Cooler (Heat Exchanger)
- Closed Loop Cooling Water Recirculation System
- Condenser Size Increase
- Frame Stainless Steel
- Seismic Restraints and Calculations
- Additional Passivation after Factory Acceptance Test (FAT)
- Condenser Size Increase

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)

OPTIONAL FACTORY ACCEPTANCE TESTING (FAT)

- Additional FAT Day

SPARE PARTS

- Spare Parts Kit
- Installation Kit

Item _____

Location(s) _____

STANDARDS

The Finn-Aqua TF-Series Multiple-Effect Water Stills meet the applicable requirements for the following:

- 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 9001:2008 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 2006/42/EC of 17 May 2006
 - » Low Voltage Directive 2006/95/EC of 12 Dec. 2006
 - » Electromagnetic Compatibility 2004/108/EC
- ASME BPE 2012
- 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 WFI 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 next column as heating steam

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.

Continuous Blowdown

Finn-Aqua utilizes an unique distillation process within the water stills. Concentrated feed water containing impurities, pyrogens and harmful particles is considered "blowdown" and is directed to drain. This blowdown removal is continuous, providing the following advantages:

- Reliable distillation in all process conditions
- Highest WFI quality

Blowdown Removal from Each Column

Along with continuous blowdown, Finn-Aqua's unique distillation also has blowdown removal from each column separately, providing the following advantages:

- Impurities are prevented from being transferred to the next stage
- Highest WFI quality

- Reduced plant steam and feed water use: the rejected rate (blowdown) is from 10 to 15%. With special nonevaporated feed water recirculation option, the blowdown amount can be reduced to 5%*.

Unique Pipe Joining Method

Within all the columns, preheaters and condensers, the heat exchanger pipes are expanded to the flanges without welding. This provides:

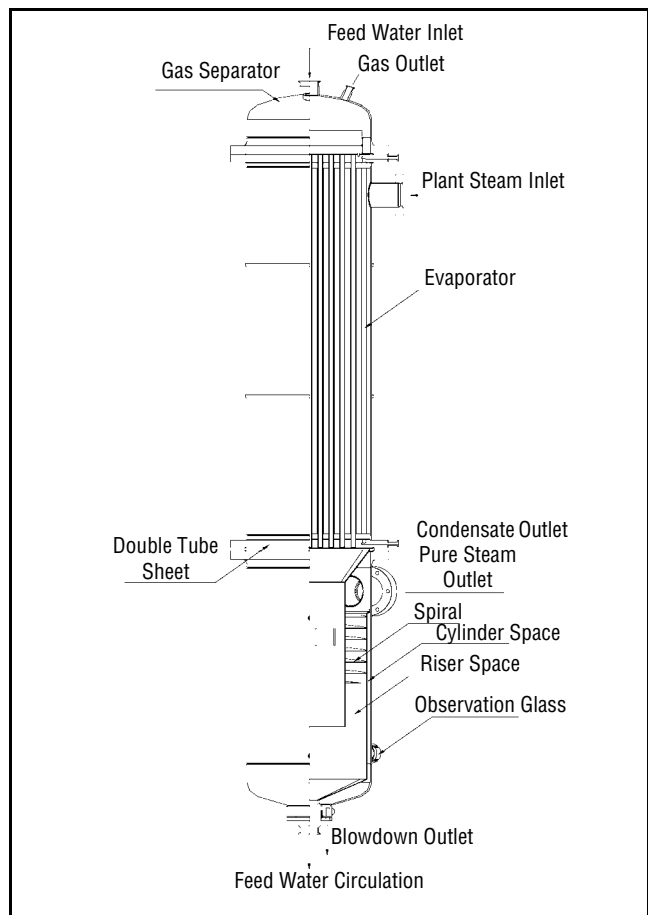
- No thermal cracking
- Less maintenance and shut-down period
- Long heat exchanger life length

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 Multiple-Effect Water Still First Column Cross Sectional Detail

* Finn-Aqua TF-Series Multiple-Effect Water Stills have been shown to reduce plant steam consumption by 5% and feed water consumption by 7-10% over previous models with nonevaporated feed water recirculation option.

Control System Allen-Bradley:

Allen-Bradley CompactLogix™ CPU 1769-L24 with PanelView™ Plus 12.5" Touch Panel Operator Interface¹

Control System Siemens:

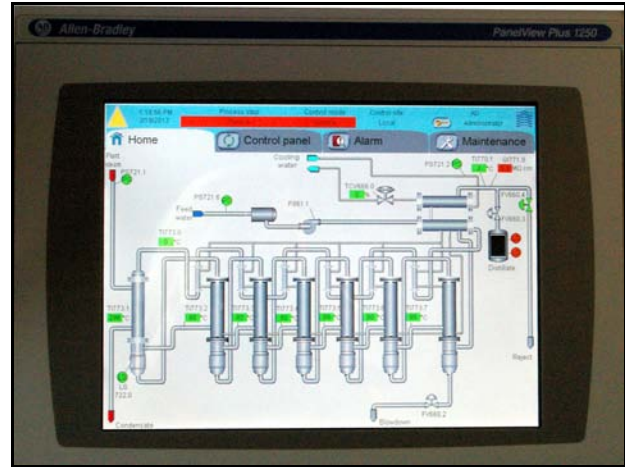
Siemens SIMATIC® TP1200 12" Touch Panel with SIMATIC CPU 315 PLC²

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

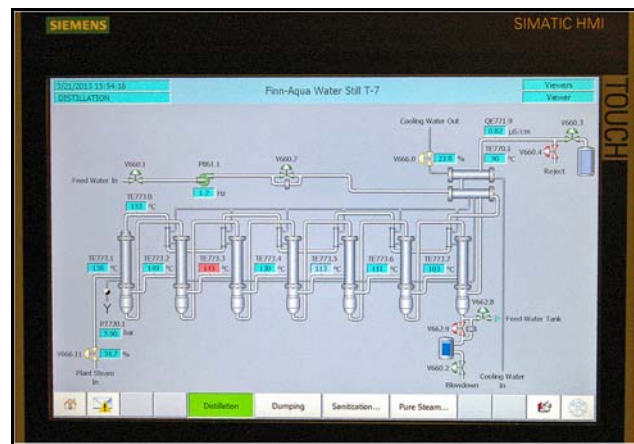
- **Installation Checks (IC)** are performed to verify that the physical aspects of the water still have been manufactured in accordance with applicable design drawings and specifications.
- **Operational Checks (OC)** are performed to test the unit's functionality and guarantee that it is working in 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 Multiple-Effect Water Still is unique and prepared for the specified unit. The 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 6-1250 User Interface



Siemens SIMATIC TP 1200 12" Color User Interface

FAT 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)

1. CompactLogix™ and PanelView™ are trademarks of Allen-Bradley, a Rockwell Automation Company.
2. Siemens SIMATIC® is a registered trademark of Siemens AG.

Control Cabinet Accessories Upgrade. The control cabinet is equipped with ventilation grate and ventilation fan to cool the cabinet.

Utilities Monitoring and Measurement Option adds temperature elements/transmitters for columns. It also adds pressure switches and pressure gauges to monitor/measure the utilities and their availability.

OPTIONAL FEATURES

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.

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 the unit. If a recorder option is selected, feed water recorder pen and interconnecting wiring are installed in the system to enable the recorder to record the feed water conductivity or resistivity.

Recorder options. Three-channel pen chart recorder is provided to continuously record the distillate and/or feed water conductivity or resistivity.

Plant (Heating) Steam Pressure Reducing Valve. For Multiple-Effect Water Stills, the plant steam pressure is reduced and stabilized by using a Pressure Reducing Valve (PRV) installed in the plant steam line. The PRV allows the plant steam pressure to be manually adjusted between 44 and 116 psig as required. A PRV is also required if Customer's plant steam supply pressure exceeds 125 psig or is unstable.

Distillation Against Back Pressure. As standard, the Multiple-Effect Water Still is designed for gravity discharge of distillate. With this option, the process is designed to operate against 4.35 psig/9 ft back pressure to overcome the WFI distribution system back pressure. This feature eliminates the need for additional sub-frames, distillate pumps or other modifications. This option is typically selected when the distillate outlet from the Multiple-Effect Water Still is lower than the tank inlet or there is back pressure in the WFI tank such as from a nitrogen blanket.

Simultaneous Distillation and Pure Steam Production. This option enables the Multiple-Effect Water Still to produce WFI and pure steam simultaneously. The pure steam outlet pressure from the Multiple-Effect Water Still is at maximum 44 psig \pm 7 psig), based on a minimum plant steam pressure of 72 psig. The control system monitors and automatically adjusts the plant steam and feed water pressures to maintain the user configured

pure steam set pressure. While this feature is activated, the distillate capacity is reduced. The resulting capacity reduction depends on the pure steam consumption. Pure steam production is approximately 30% of the same size Finn-Aqua® TF-Series Pure Steam Generator with same utility values.

Proportional Capacity Control (PCC). PCC provides fast, smooth, continuous operation of the Multiple-Effect Water Still that minimizes dumping of distillate by avoiding repeated cycling (starting and stopping) of the unit. The feature conserves utilities and saves time. PCC increases life cycle and service duty of the equipment because automatic control minimizes operating fluctuations and thermal variations. Two alternative operational modes are available: Pressure mode (fixed parameters for feed water pump frequency and plant steam pressure) and Tank Level Control (proportional operation based on the signal from the WFI tank).

Reject Distillate Cooler (Heat Exchanger)/Blowdown and Gas/De-aeration Cooler (Heat Exchanger). This option is designed to cool the reject distillate from 210°F to temperatures at or below 140°F using a closed loop cooling system. The plate heat exchanger arrangement is designed to use cooling water with an inlet temperature at 59°F. The assembly is manufactured from AISI 316 stainless steel. Activation of the cooling water on/off valve is configured to coincide with the operational status of the Multiple-Effect Water Still.

Closed Loop Cooling Water Recirculation System. The system is used if the facility cooling water closed loop system is not designed to function with significant temperature or pressure differentials and a facility bypass/mixing arrangement cannot be used. The system utilizes the Customer's facility cooling water loop conditions on the secondary side.

The secondary side is designed for small pressure differential (max. 1 bar [14.5 psi] and high flow rates due to small temperature difference, e.g., 10°C (50°F) between inlet and outlet of the secondary (facility cooling water loop) side. The recirculation system is segmented into a primary (water still cooling water loop) and secondary (facility cooling water loop) system.

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 are provided 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 3 and 4 requirements. The provided angle brackets and frame mounting hardware are manufactured from AISI 304 stainless steel.

Condenser Size Increase is required if there is a significantly greater difference from the given standard cooling water temperature and pressure values. The second condenser is enlarged to match the Customer-specific operating conditions.

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 component 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.

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 water still.

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.

CONSTRUCTION

- **Pressure Vessels:**

- » AISI 316L Stainless-Steel Pressure Vessels. Pressure vessels are designed to a pressure rating of 131 psig at 361°F. Pressure vessels built according to ASME/PED as well as many other international standards.
- » All heat exchangers in contact with heating steam or feed water, first column, and preheaters and condensers are made of a double-tube sheet design preventing cross-contamination from lower purity media to higher purity media. The heat exchanger tubes are expanded, not welded, into the end of tube sheet to avoid thermal cracking.
- » Surface finish in contact with distillate, pure steam and feed water is polished/electropolished to Ra <25 µinch.
- » Columns and preheaters are insulated with noncorrosive 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, pure steam and distillate. All piping located outside of the pressure vessels are according to ASTM A269 or A270, ASME SA213/213M.
- » 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 distillate, pure steam and feed water is polished/electropolished to Ra <25 µinch.
- » A maximum of 3D for dead legs is maintained on the distillate, 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 U.S. Food and Drug Administration (FDA) regulations, e.g., Polytetrafluoroethylene (PTFE), Ethylene Propylene Diene Monomer (EPDM) or silicone.

UTILITY REQUIREMENTS

Steam

- 44-116 psig
- 97-100% Saturated Steam
- Max. $\pm 5\%$ Pressure Variations

Feed Water

- 30-88 psig
- Temperature 50-68°F
- Conductivity $< 5\mu\text{S/cm}$ at 77°F
- pH 5-7
- Silica < 1 ppm
- Chloride < 100 ppb
- Chlorine < 100 ppb

Electrical

- 380-415 Vac, 50 Hz, 3-Phase
- 208-600 Vac, 60 Hz, 3-Phase

Compressed Air

- 88-116 psig
- Clean, dry, oil free

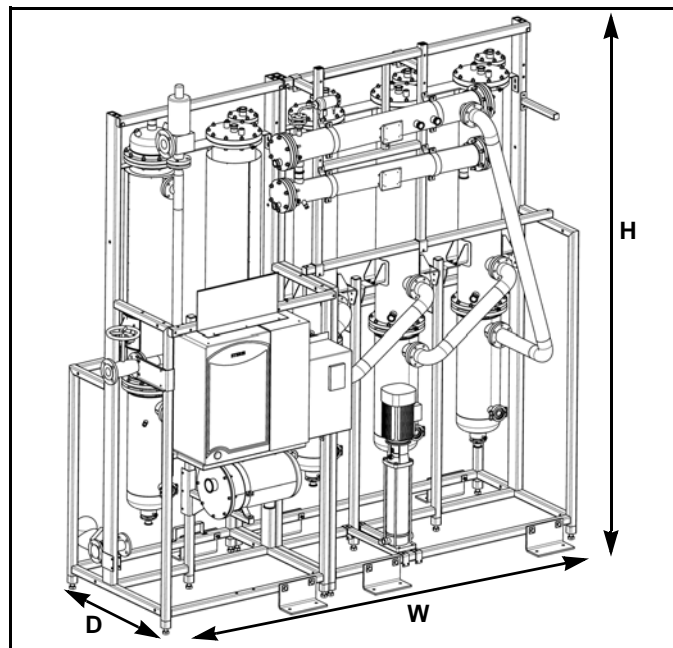
Cooling Water

- 44-102 psig
- Temperature 41-68°F
- Hardness not to exceed 125 ppm as CaCO_3 (7° dH)

UNIT DIMENSIONS

Finn-Aqua TF-Series Multiple-Effect Water Stills reduced external dimensions enables the equipment to be installed in rooms with limited space

NOTE: Typical only. Not for construction.



Model	Width (W) (in)	Depth (D) (in)	Height (H) (in)	Height of Distillate Outlet (in)	Net Weight (lb)
450-TF-4	77	45	112	89	2,180
450-TF-5	96	45	108	89	2,624
850-TF-5	98	45	111	97	3,439
1600-TF-5	126	53	136-1/2	110	4,938
2900-TF-6	154	53	136	118	10,760

CAPACITIES AND CONSUMPTIONS

Finn-Aqua TF-Series Multiple-Effect Water Stills are heated by steam supplied at any pressure from 44 to 116 psig. The following tables reflect the still capacity and consumptions for steam delivered at 116, 102, 87, 73, 58 and 44 psig pressure and distillate output temperature at 210°F.

All plant steam pressure values of these tables indicate the pressure inside the first column. Please add 4% to these values to obtain the pressure level required in the plant steam supply. This is to compensate for the pressure losses in the plant steam inlet.

116	Capacity US gal/h	Plant Steam Consumption (lb/h) 116 psig/347°F (131 psia)	Cooling Water Consumption (gal/h) 44 psig/59°F	Feed Water Pressure 29-87 psig/59°F (44-102 psia)
Model				Feed Water Consumption gal/h Deionized or RO Feed Water
450-TF-4	235	666	165	270
450-TF-5	235	536	81	270
850-TF-5	441	1,005	153	507
1600-TF-5	911	2,079	316	1,048
2900-TF-6	1,585	3,038	216	1,823

102	Capacity US gal/h	Plant Steam Consumption (lb/h) 102 psig/338°F (116 psia)	Cooling Water Consumption (gal/h) 44 psig/59°F	Feed Water Pressure 29-87 psig/59°F (44-102 psia)
Model				Feed Water Consumption gal/h Deionized or RO Feed Water
450-TF-4	214	628	147	246
450-TF-5	214	507	72	246
850-TF-5	415	983	140	477
1600-TF-5	856	2,028	288	984
2900-TF-6	1,455	2,897	186	1,674

87	Capacity US gal/h	Plant Steam Consumption (lb/h) 87 psig/329°F (102 psia)	Cooling Water Consumption (gal/h) 44 psig/59°F	Feed Water Pressure 29-87 psig/59°F (44-102 psia)
Model				Feed Water Consumption gal/h Deionized or RO Feed Water
450-TF-4	191	558	129	220
450-TF-5	192	450	62	220
850-TF-5	366	860	119	421
1600-TF-5	766	1,799	250	881
2900-TF-6	1,289	2,544	153	1,482

73	Capacity US gal/h	Plant Steam Consumption (lb/h) 73 psig/318°F (87 psia)	Cooling Water Consumption (gal/h) 44 psig/59°F	Feed Water Pressure 29-87 psig/59°F (44-102 psia)
Model				Feed Water Consumption gal/h Deionized or RO Feed Water
450-TF-4	169	485	112	194
450-TF-5	169	390	53	194
850-TF-5	317	730	99	364
1600-TF-5	670	1,545	210	770
2900-TF-6	1,149	2,227	124	1,321

58	Capacity US gal/h	Plant Steam Consumption (lb/h) 58 psig/306°F (73 psia)	Cooling Water Consumption (gal/h) 44 psig/59°F	Feed Water Pressure 29-87 psig/59°F (44-102 psia)
Model				Feed Water Consumption gal/h Deionized or RO Feed Water
450-TF-4	141	181	91	163
450-TF-5	141	320	42	163
850-TF-5	267	604	80	307
1600-TF-5	575	1,303	172	661
2900-TF-6	989	1,881	95	1,137

44	Capacity US gal/h	Plant Steam Consumption (lb/h) 44 psig/289°F (58 psia)	Cooling Water Consumption (gal/h) 44 psig/59°F	Feed Water Pressure 29-87 psig/59°F (44-102 psia)
Model				Feed Water Consumption gal/h Deionized or RO Feed Water
450-TF-4	118	333	74	135
450-TF-5	118	267	33	135
850-TF-5	208	397	59	239
1600-TF-5	481	1,093	135	553
2900-TF-6	829	1,585	60	954

For Further Information, contact:



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