

APPLICATION

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

DESCRIPTION

Finn-Aqua T-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 current Good Manufacturing Practices (cGMP) compliance. 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.

STANDARDS

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

- cGMP, CFR Title 21, Part 211, Section D



(Typical only - some details may vary.)

The Selections Checked Below Apply To This Equipment

CONTROL

- ☐ Siemens
- ☐ Allen-Bradley

VOLTAGE

- ☐ 230-415 Vac, 50 Hz, 3-Phase
- ☐ 208-600 Vac, 60 Hz, 3-Phase

CONTROL SYSTEM AND INSTRUMENTATION OPTIONS

- ☐ Control Cabinet Accessories Upgrade
- ☐ Ethernet Industrial Connection (Siemens)
- ☐ Ethernet Industrial Connection (Allen-Bradley)
- ☐ Allen-Bradley ControlLogix
- ☐ Feed Water Conductivity Sensor (Thornton)
- ☐ Feed Water Conductivity Sensor (Endress & Hauser)
- ☐ Feed Water Sample Valve, Diaphragm Type
- ☐ Utility Monitoring and Measurement with Endress & Hauser Process Instrumentation
- ☐ Two (2) Channel Pen Chart Recorder
- ☐ Five (5) Channel Paperless Recorder (21 CFR Part 11 Compliant)
- ☐ Six (6) Channel Paperless Recorder (21 CFR Part 11 Compliant)
- ☐ Three (3) Channel Pen Chart Recorder
- ☐ Ground Fault Indicator (GFI) for Allen-Bradley Control
- ☐ UPS Connection for Control System
- ☐ Audit Trail for Siemens Control System
- ☐ Audit Trail for Allen Bradley Control System

* Not available for 250-T-X

MECHANICAL OPTIONS

- ☐ Plant (Heating) Steam Pressure Reducing Valve
- ☐ Distillation Against Back Pressure
- ☐ Piping Sanitization*
- ☐ Non Evaporated Feed Water Re-circulation
- ☐ Automatic Blowdown measurement
- ☐ Simultaneous Pure Steam and WFI Production (Units 450-T-X to 7500-T-X)
- ☐ Pure Steam Generator (PSG) Operation (Units 450-T-X to 2900-T-X)
- ☐ Proportional Capacity Control (PCC)*
- ☐ Reject Distillate Cooler (Heat Exchanger)
- ☐ Blowdown and Gas/De-aeration Cooler (Heat Exchanger)
- ☐ Closed Loop Cooling Water Re-circulation System
- ☐ Frame Stainless Steel
- ☐ Seismic Restraints and Calculations
- ☐ Additional Passivation after FAT

ENHANCED IQ/OQ SERVICES

- ☐ cGMP Validation Package

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)
- ☐ Boroscope Inspection of Pipe Welding on DVD
- ☐ EP/USP WFI Test
- ☐ Endotoxin Challenge Test (WFI and Feed Water)

OPTIONAL FACTORY ACCEPTANCE TESTING

- ☐ Additional FAT Day

SPARE PARTS

- ☐ Spare Parts Kit
- ☐ Installation Kit

Item _____

Location(s) _____

- 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
 - » Electro Magnetic 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 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 EN285 requirements.

Continuous Blowdown

Finn-Aqua utilizes an unique distillation process within the water stills. Concentrated feed water containing all 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
- WFI production is a continuous process, thus blowdown removal is a continuous process

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 10-15%. With special non-evaporated feed water recirculation option, the blowdown amount can be reduced down 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:

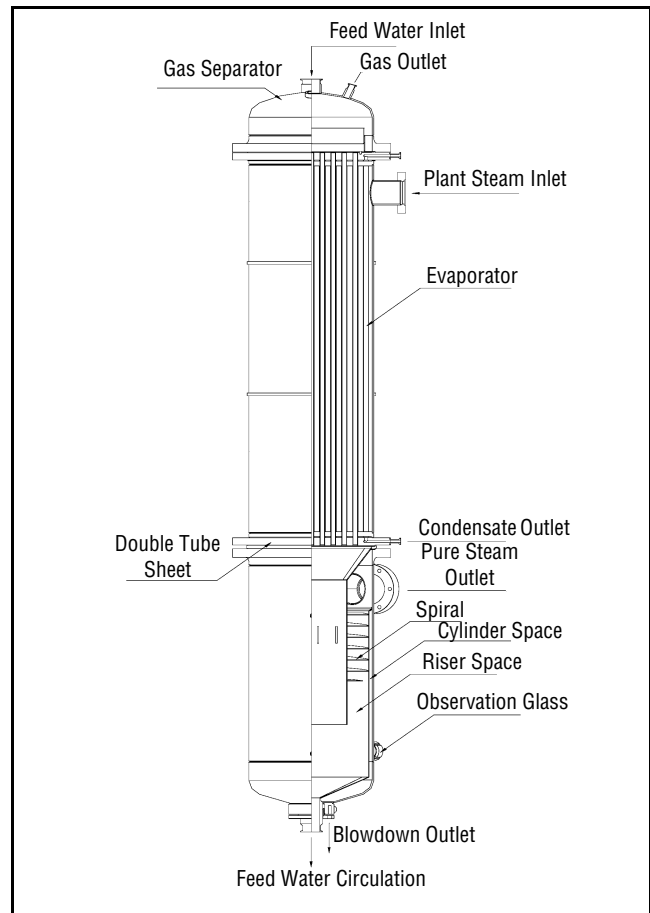
- No thermal cracking
- Less maintenance and shut-down period
- Long heat exchanger life length

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

* The Finn-Aqua T-Series Multiple-Effect Water Stills reduce plant steam consumption by 5% and feed water consumption by 7-10% over previous models with non-evaporated feed water recirculation option.

Control System Allen Bradley:

Allen-Bradley CompactLogix™ CPU 5069-L310ER with PanelView™ Plus 7-900 9" Touch Panel Operator Interface¹

Control System Siemens:

Siemens SIMATIC® 12" Touch Panel with SIMATIC CPU 1511-1PN PLC²

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 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 – 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)

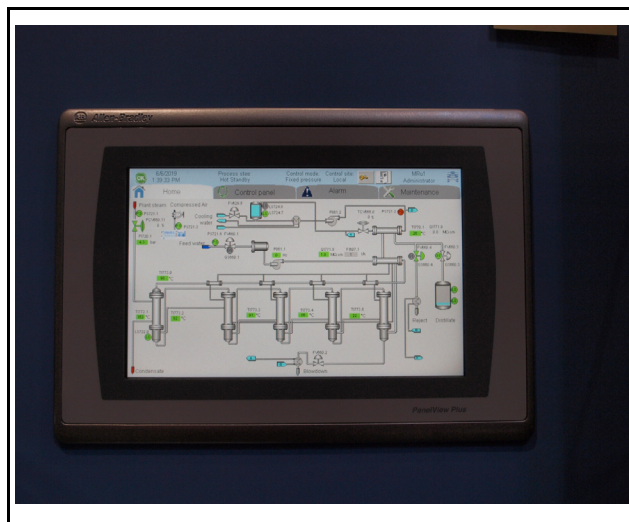
Manufacturing Documentation – The standard Manufacturing Documentation binder provides the following information:

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

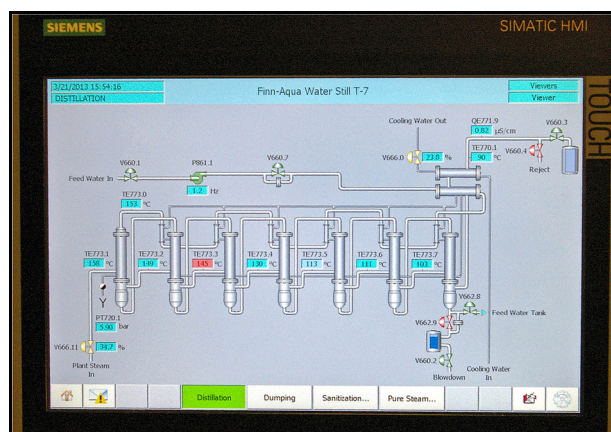
Control System Validation Documentation – The standard Control System Document file provides the following information:

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

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



Allen-Bradley PanelView Plus 7-900 User Interface



Siemens SIMATIC 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.

OPTIONAL FEATURES

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. Ventilation grate and fan are provided also for the supply box.

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 & aborting alarms can be acknowledged.

Allen-Bradley ControlLogix™ with PanelView™ Plus 1000¹ option replaces the standard Allen-Bradley CompactLogix with ControlLogix and PanelView Plus 1000.

Ground Fault Indicator (GFI) for Allen-Bradley Control. Ground Fault Indicator (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 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.

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.

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.

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

Recorder options. Two- or three-channel pen chart recorders are provided to continuously record the distillate and optionally feed water conductivity or resistivity. Also a 21 CFR Part 11 compatible, five- or 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 feed water and distillate conductivity/resistivity and distillate temperature, and to print the position of the diverting valve. Other free channels are available for Customer use.

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 - 116 psig as required. A PRV is also required if Customer's plant steam supply pressure exceeds 125 psig or is unstable.let

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

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

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.

Piping Sanitation. As standard, the Multiple-Effect Water Still goes through a preconfigured sanitization step. This step sanitizes the pure steam and WFI contact surfaces. This option is designed to sanitize the feed water piping in addition to the pure steam and WFI piping. The water still is equipped with accessories to allow sanitizing above 176°F of all feed water piping, preheaters, columns and condensers.

Nonevaporated Feed Water Recirculation. This option is intended to reduce the total feed water consumption. Two-thirds of the nonevaporated feed water (blowdown) is directed back to the feed water tank for recirculation. The feature decreases the total blowdown percentage to 5%, $\pm 2\%$.

Automatic Blowdown Measurement. With this option, the blowdown is directed to an external graduated container before discharge to drain. The blowdown amount is continuously measured and the blowdown percentage is displayed on the operator panel.

Simultaneous Distillation and Pure Steam Production (Units 450-7500-T-X). 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 ± 7 psi, 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 approx. 30% of the same size PSG-T with same utility values. This option is not available for models 450-T-6, 850-T-6, 1200-T-7, 1600-T-7, 2200-T-7, 2900-T-8, 4700-T-8 or 7500-T-8.

Pure Steam Generator (PSG) Operation (Units 450-2900-T-X). This option enables the Multiple-Effect Water Still to produce pure steam at the capacity of 70% when compared to an equal size T-model pure steam generator capacity at equal operating point (plant steam pressure vs. pure steam pressure). During this process phase, the unit produces pure steam by using the first column only. Simultaneous distillate production is prevented by automatic valves isolating the rest of the unit from the first column.

Proportional Capacity Control (PCC) (Units 450-7500-T-X).

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). This option is designed to cool the reject distillate from 210°F to temperatures at or below 140°F using a plate heat exchanger. 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.

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 plate heat exchanger. 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. A closed loop cooling water recirculation 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 is designed to maintain primary cooling water temperature difference of the condenser cooling water loop by utilizing the Customer's facility cooling water loop conditions on the secondary side. The secondary side of the process is designed for small pressure differential (max. 14.5 psi) and high flow rates due to small temperature difference, e.g., 18°F between inlet and outlet of the secondary (facility cooling water loop) side. The closed cooling water recirculation loop system is segmented into a primary (water still cooling water loop) and secondary (facility cooling water loop) system.

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 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 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).

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 .

Boroscope Inspection of Pipe Welding on USB Memory Stick. 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 USB memory stick for reference purposes.

European Pharmacopeia/United States Pharmacopeia [EP/USP] WFI Test. A sample of the distillate is extracted from Finn-Aqua Multiple-Effect Water Still 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 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

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 (IQ/OQ) 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 131 psig at 361°F. Pressure vessels built according to ASME/PED or 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 clamp 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 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. ±5% Pressure Variations

Feed Water

- 30-88 psig
- Temperature 50-68°F
- Conductivity < 5µS/cm at 77°F
- pH 5-7
- Silica < 1 ppm
- Chloride < 100 ppb
- Chlorine < 100 ppb

Electrical

- 230-415 V, 50 Hz, 3-Phase
- 208-600 V, 60 Hz, 3-Phase

Compressed Air

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

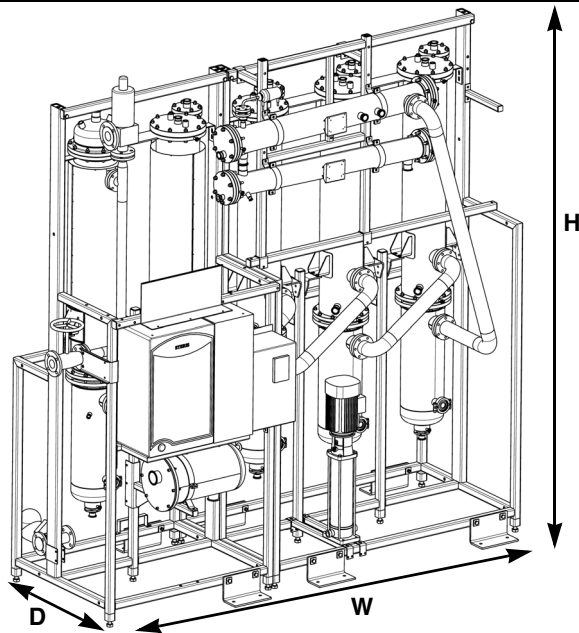
Cooling Water

- 44-102 psig
- Temperature 41-68°F
- Hardness not to exceed 125 ppm as CaCO₃ (7° dH)

UNIT DIMENSIONS

Finn-Aqua T Series Multiple-Effect Water Still's 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)				
	Number of Columns								Number of Columns				
	4	5	6	7	8				4	5	6	7	8
250-T	54	54	N/A	N/A	N/A	38	86.5	70	1,520	N/A	N/A	N/A	N/A
450-T	77	96	115	N/A	N/A	45	112	89	2,180	2,620	3,200	N/A	N/A
850-T	79	98	117	N/A	N/A	45	112	97	2,890	3,440	4,170	N/A	N/A
1200-T	N/A	125	151	176	N/A	53	125	98	N/A	4590	5600	6360	N/A
1600-T	N/A	125	151	176	N/A	53	136	110	N/A	4,940	6,020	6,860	N/A
2200-T	N/A	129	154	179	N/A	53	125	106	N/A	6720	8140	9330	N/A
2900-T	N/A	129	154	179	204	53	136	118	N/A	7,190	8,660	9,920	10930
4700-T	N/A	N/A	170	197	225	72	169	144	N/A	N/A	10,760	12,390	13,710
7500-T	N/A	N/A	N/A	240	274	69	189	161	N/A	N/A	N/A	24,461	27,667

CAPACITIES AND CONSUMPTIONS

Finn-Aqua Medium and Large T-Series Multiple-Effect Water Stills are heated by steam supplied at any pressure from 44-116 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. Distillate outlet temperature may be lower than 99°C with 7,8 columns.

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	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)
	Capacity US gal/h	Number of Columns					Number of Columns					Feed Water Max. Consumption gal/h Deionized or RO Feed Water
Model		4	5	6	7	8	4	5	6	7	8	
250-T	143	562	344	N/A	N/A	N/A	97	48	N/A	N/A	N/A	164
450-T	235	666	536	450	N/A	N/A	165	81	32	N/A	N/A	270
850-T	441	1,250	1,005	847	N/A	N/A	309	153	60	N/A	N/A	507
1200-T	687	N/A	1,541	1,268	1,091	N/A	N/A	246	101	0	N/A	790
1600-T	911	N/A	2,079	1,746	1,504	N/A	N/A	316	124	0	N/A	1,048
2200-T	1,245	N/A	2,793	2,385	2,053	N/A	N/A	446	184	0	N/A	1,432
2900-T	1,585	N/A	3,616	3,038	2,612	2,302	N/A	549	216	0	0	1,823
4700-T	2,839	N/A	N/A	5,443	4,683	4,125	N/A	N/A	387	0	0	3,265
7500-T	4,491	N/A	N/A	N/A	6,975	6,461	N/A	N/A	N/A	0	0	5,030

102	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)
	Capacity US gal/h	Number of Columns					Number of Columns					Feed Water Max. Consumption gal/h Deionized or RO Feed Water
Model		4	5	6	7	8	4	5	6	7	8	
250-T	126	516	315	N/A	N/A	N/A	84	41	N/A	N/A	N/A	145
450-T	214	628	507	425	N/A	N/A	147	72	27	N/A	N/A	246
850-T	415	1,221	983	827	N/A	N/A	286	140	53	N/A	N/A	477
1200-T	640	N/A	1,493	1,228	1,056	N/A	N/A	223	89	0	N/A	736
1600-T	856	N/A	2,028	1,704	1,466	N/A	N/A	288	109	0	N/A	984
2200-T	1,161	N/A	2,705	2,313	1,986	N/A	N/A	404	162	0	N/A	1,335
2900-T	1,455	N/A	3,448	2,897	2,491	2,194	N/A	490	186	0	0	1,674
4700-T	2,560	N/A	N/A	5,095	4,383	3,860	N/A	N/A	327	0	0	2,944
7500-T	4,247	N/A	N/A	N/A	6,507	6,057	N/A	N/A	N/A	0	0	4,757

87	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)
	Capacity US gal/h	Number of Columns					Number of Columns					Feed Water Max. Consumption gal/h Deionized or RO Feed Water
Model		4	5	6	7	8	4	5	6	7	8	
250-T	111	452	276	N/A	N/A	N/A	73	35	N/A	N/A	N/A	127
450-T	191	558	450	377	N/A	N/A	129	62	23	N/A	N/A	220
850-T	366	1,067	860	721	N/A	N/A	247	119	43	N/A	N/A	421
1200-T	590	N/A	1,365	1,122	963	N/A	N/A	199	77	0	N/A	678
1600-T	766	N/A	1,799	1,512	1,301	N/A	N/A	250	91	0	N/A	881
2200-T	1,069	N/A	2,474	2,114	1,814	N/A	N/A	361	139	0	N/A	1,229
2900-T	1,289	N/A	3,027	2,544	2,187	1,927	N/A	420	153	0	0	1,482
4700-T	2,281	N/A	N/A	4,500	3,871	3,408	N/A	N/A	270	0	0	2,623
7500-T	3,830	N/A	N/A	N/A	5,782	5,436	N/A	N/A	N/A	0	0	4,290

73	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)
	Capacity US gal/h	Number of Columns					Number of Columns					Feed Water Max. Consumption gal/h Deionized or RO Feed Water
Model		4	5	6	7	8	4	5	6	7	8	
250-T	97	392	238	N/A	N/A	N/A	63	30	N/A	N/A	N/A	112
450-T	169	485	390	328	N/A	N/A	112	53	18	N/A	N/A	194
850-T	317	908	730	613	N/A	N/A	209	99	34	N/A	N/A	364
1200-T	531	N/A	1,210	995	853	N/A	N/A	173	64	0	N/A	611
1600-T	670	N/A	1,545	1,299	1,116	N/A	N/A	210	72	0	N/A	770
2200-T	964	N/A	2,194	1,674	1,607	N/A	N/A	314	115	0	N/A	1,109
2900-T	1,149	N/A	2,652	2,227	1,914	1,687	N/A	360	124	0	0	1,321
4700-T	2,002	N/A	N/A	3,880	3,336	2,937	N/A	N/A	216	0	0	2,302
7500-T	3,374	N/A	N/A	N/A	5,080	4,783	N/A	N/A	N/A	0	0	3,779

58	Plant Steam Consumption (lb/h) 58 psig/310°F (73 psia)						Cooling Water Consumption (gal/h) 44 psig/59°F					Feed Water Pressure 29-87 psig/59°F (44-102 psia)
	Capacity US gal/h	Number of Columns					Number of Columns					Feed Water Max. Consumption gal/h Deionized or RO Feed Water
Model		4	5	6	7	8	4	5	6	7	8	
250-T	79	311	190	N/A	N/A	N/A	50	23	N/A	N/A	N/A	91
450-T	141	181	399	320	N/A	N/A	91	42	13	N/A	N/A	163
850-T	267	752	604	507	N/A	N/A	172	80	26	N/A	N/A	307
1200-T	466	N/A	1,045	860	736	N/A	N/A	145	50	0	N/A	536
1600-T	574	N/A	1,303	1,093	939	N/A	N/A	172	55	0	N/A	661
2200-T	845	N/A	1,894	1,618	1,385	N/A	N/A	263	91	0	N/A	972
2900-T	989	N/A	2,240	1,881	1,616	1,424	N/A	296	95	0	0	1,137
4700-T	1,722	N/A	N/A	3,278	2,818	2,480	N/A	N/A	165	0	0	1,980
7500-T	2,878	N/A	N/A	N/A	4,291	4,040	N/A	N/A	N/A	0	0	3,223

44	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)
	Capacity US gal/h	Number of Columns					Number of Columns					Feed Water Max. Consumption gal/h Deionized or RO Feed Water
Model		4	5	6	7	8	4	5	6	7	8	
250-T	62	247	150	N/A	N/A	N/A	38	17	N/A	N/A	N/A	71
450-T	118	333	267	225	N/A	N/A	74	33	10	N/A	N/A	135
850-T	208	589	472	397	N/A	N/A	130	59	17	N/A	N/A	239
1200-T	390	N/A	877	723	617	N/A	N/A	115	37	0	N/A	448
1600-T	481	N/A	1,093	917	789	N/A	N/A	135	35	0	N/A	553
2200-T	707	N/A	1,592	1,360	1,162	N/A	N/A	209	67	0	N/A	813
2900-T	829	N/A	1,887	1,585	1,360	1,199	N/A	233	60	0	0	954
4700-T	1,442	N/A	N/A	2,754	2,366	2,083	N/A	N/A	105	0	0	1,658
7500-T	7500-T Not Applicable for 44 PSIG Capacity											

For Further Information, contact:

STERIS®



STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-444-9009
www.steris.com