

STERIS FINN-AQUA®
Multiple-Effect Water Stills
for Pharmaceutical Manufacturing



STERIS Corporation has achieved worldwide leadership in the pharmaceutical and biotech industries by understanding customers' requirements and providing the highest quality, most productive systems in the industry. Our integrated systems of products, services and technologies provide solutions for customers by minimizing contamination risks, improving operational efficiencies, containing costs and improving workplace conditions.

In 1971, FINN-AQUA water stills were introduced to provide the world's first pharmaceutical grade multiple-effect distillation system. With nearly 3,000 installations worldwide, the original patented Falling Film evaporator has proven reliability.

Optimum Performance Meets Reliable Operation

The FINN-AQUA Multiple-Effect Water Still produces distillate that meets U.S. Pharmacopeia (USP), European Pharmacopeia (EP) and Japanese Pharmacopeia (JP) for Water-for-Injection (WFI) guidelines. The FINN-AQUA Multiple-Effect Water Still is equipped with a range of features to ensure that your installation and qualification is quick and trouble-free, and that your WFI production remains efficient and reliable throughout your unit's life. The STERIS FINN-AQUA Multiple-Effect Water Still combines optimum performance with reliable operation, reduced utility consumption and a minimal need for maintenance.

The FINN-AQUA Multiple-Effect Water Still's design, manufacturing and performance is in accordance with many global requirements and guidelines, including:

- > ISO 9001:2008
- > ISO 14001:2004
- > OHSAS 18001:2007
- > EN-ISO 3834-2
- > HTM 2010
- > EN 285
- > GAMP 5
- > 21 CFR Part 11
- > EU Annex 11
- > cGMP
- > ASME BPE
- > FDA

STERIS Safeguards Your Company

As the pharmaceutical industry continues to grow and change, STERIS continues to deliver superior-quality products that are manufactured in accordance with current Good Manufacturing Practices (cGMP).

By choosing FINN-AQUA Multiple-Effect Water Stills, you are taking a proactive step in eliminating instances of contamination, thus safeguarding your company and the end-consumer from products that could be potentially harmful.



Proven Technology for Consistent Efficiency

FINN-AQUA's patented three-stage separation technology ensures high quality WFI free of endotoxins, pyrogens and droplets. Three-stage separation provides:

- > Separation by falling film evaporation
- > Gravity separation by 180-degree flow turn
- > Centrifugal separation
- > Continuous blowdown
- > Blowdown removal from each column

Unique Pipe-Joining Method Ensures Longer Life

The first columns as well as all pre-heaters and both condensers in the FINN-AQUA Multiple-Effect Water Still are manufactured with a double-tube-sheet (DTS) design. Within the columns, the pipes are expanded to the flanges without welding to avoid thermal cracking. By doing so, your FINN-AQUA Multiple-Effect Water Still will require less maintenance and prove efficient for years to come.

Testing Saves Time and Money

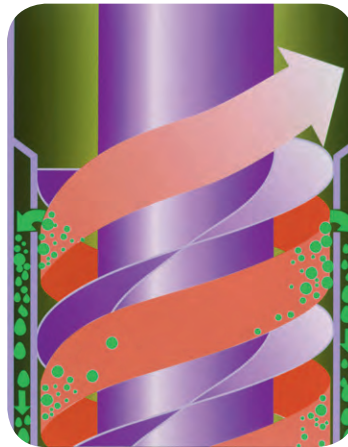
The unique Factory Acceptance Testing (FAT) center at our factory in Tuusula, Finland, brings together the latest technologies and our experienced team. Our test protocols are structured to give all FINN-AQUA Water Stills a full evaluation before shipment, ensuring that the design, manufacture and operation are 100 percent as specified.

Test bays fully simulate the customers' specific plant conditions and all test results are precisely documented for smoother and faster on-site verification, thus saving you time and money. Our unique test bay is also equipped with a piping system for in-line CIP and passivation of the whole unit. Endotoxin challenge tests use a validated LAL test method to ensure the highest WFI quality is produced.



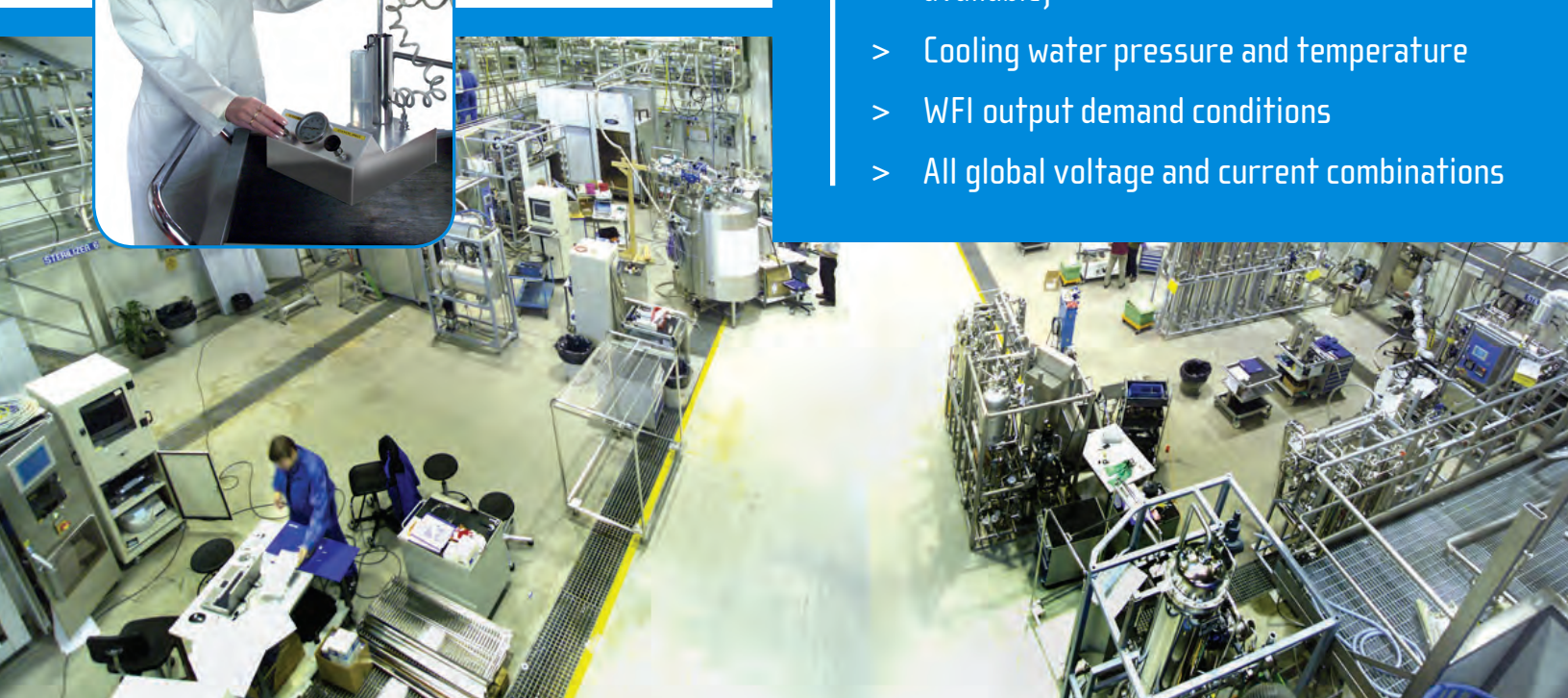
Unique Continuous Blowdown Process from Each Column Separately

STERIS FINN-AQUA utilizes a unique distillation process within our water stills. Concentrated feed water containing all impurities, pyrogens and harmful particles is considered "blowdown" and is redirected to drain. Only pure water, WFI, is allowed to flow into the WFI storage and distribution tank. This unique distillation process removes blowdown from each column separately. Impurities are prevented from being transferred to the next stage, ensuring the highest WFI quality.



Within our FAT center we can simulate critical final installation conditions such as:

- > Plant steam pressure
- > Feed water pressure and temperature (softened water and RO/CDI water available)
- > Cooling water pressure and temperature
- > WFI output demand conditions
- > All global voltage and current combinations





Comprehensive Documentation, Technical Expertise and Global Support

STERIS global field project management together with our factory-based project manager organization is committed to supporting you through the whole project. From design specification submittal to drawing package review to project hand-over, we will oversee your needs from start to finish. STERIS also provides comprehensive documentation in order to assist in validation. Our design, manufacturing testing and documentation processes are all validated and ISO-9001 certified and audited by Lloyd's. Documentation structure, content and format are detailed and cross references are logical and clear. Within our documentation, you will discover that data is easy to locate, thus speeding your validation time. From the time you purchase your FINN AQUA Multiple-Effect Water Still, STERIS's global service is available in close proximity to provide maintenance when you need it.

Proven Technology Is Just the Start

STERIS Provides Operational Optimization and Positively Impacts Our Environment

FINN-AQUA Multiple-Effect Water Stills are designed with our environment in mind. Lower utility consumption means less operating costs for you and saves energy for our environment. FINN-AQUA Multiple-Effect Water Stills use:

- > **Less Plant Steam** – The effective falling film evaporation and patented water distribution to the column enables a high performance from the column with less plant steam consumption.
- > **Less Feed Water** – The patented spiral design, which effectively removes endotoxins impurities and droplets, enables a high performance with less feed water consumption.
- > **Less Blowdown** – Efficient separation process enables a low blowdown rate of 12 to 15 percent. With a specially designed option the percentage of rejected feed water can be reduced down to 5 percent.
- > **Less Cooling Water** – If reduced blowdown temperature is needed, cooling by heat exchangers is employed using much less cooling water than is used in a traditional mixing chamber construction.

STERIS Fits Your Needs

At STERIS, we make every effort to accommodate your varying process needs. We offer the FINN-AQUA Multiple-Effect Water Still in a range of sizes and options. Our wide unit portfolio has a solution for every application – starting from small sizes for the bioprocess industry (available with capacities starting at 140 l/h) up to large units for pharmaceutical manufacturing with capacities up to 15,000 l/h.

T-Series	150	250	450	850	1200	1600	2200	2900	4700
Capacity 3 bar (44 psig) L/h (gal/h)	140 (37)	170 (44)	450 (118)	790 (208)	1.470 (390)	1.820 (481)	2.680 (707)	3.140 (829)	5.460 (1.442)
Capacity 8 bar (116 psig) L/h (gal/h)	230 (60)	380 (100)	890 (235)	1.670 (441)	2.600 (687)	3.450 (911)	4.700 (1.245)	6.000 (1.585)	10.750 (2.839)
No. of columns	4	4-5	4-6	4-6	5-7	5-7	5-7	6-8	6-8

STERIS Offers a Wide Range of Process Options

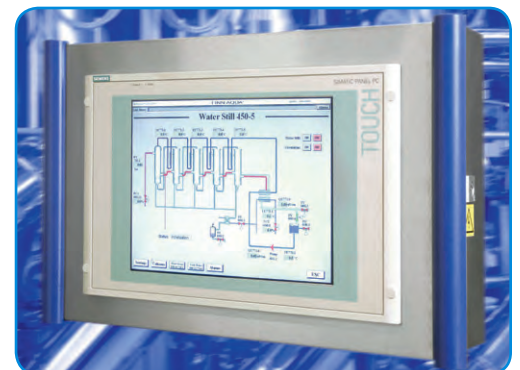
- > Distillation against back-pressure
- > Operation with softened feed water
- > Pure Steam Generator mode
- > Simultaneous WFI and Pure Steam production
- > Adjustable distillate outlet temperature
- > Automatic blowdown measurement
- > Proportional capacity control



With lower utility consumption & optional soft water feed, FINN-AQUA Multiple-Effect Water Stills are friendly to the environment and your operating budget!



Our FINN-AQUA Multiple-Effect Water Still includes a user-friendly touchscreen and is available to order with either the latest Siemens or Allen-Bradley control system platform. Process display also available.

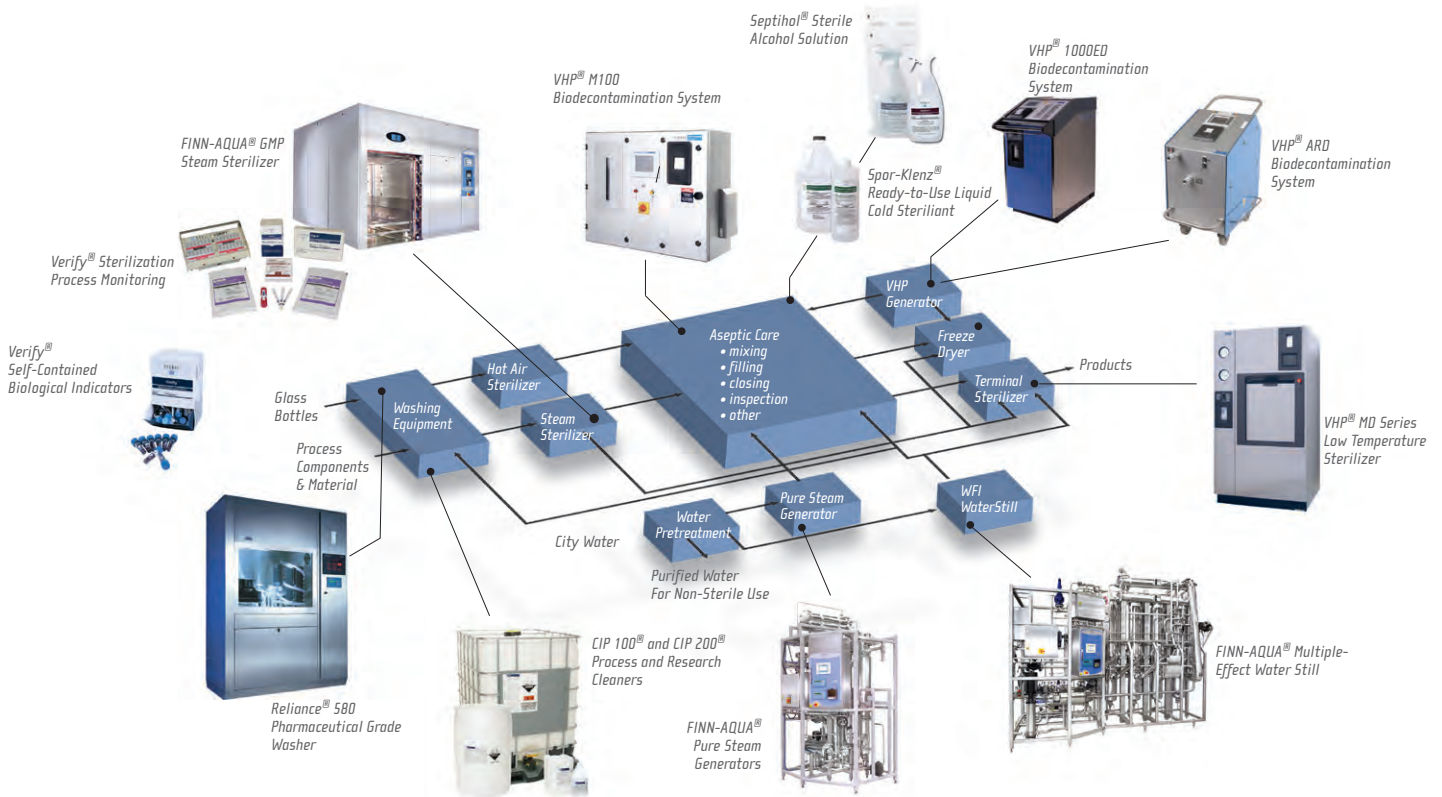


The STERIS Difference

STERIS's Life Sciences division provides solutions to help prevent contamination at virtually **every critical point in your manufacturing process**. Our systems are specially designed to answer the contamination challenges associated with regulated pharmaceutical environments, including research laboratories, aseptic processing, and bulk biopharmaceutical manufacturing.

Our expert resources offer integrated solutions to help you achieve faster process validation, more efficient operations, and greater cost control. We also provide onsite training, educational seminars, and technical support to keep your employees current with regulatory compliance issues, product safety and new technologies and protocols. Our support is available when and where you need it through our worldwide manufacturing presence and broad distribution channels.

STERIS Corporation is a leading provider of infection prevention, contamination prevention, microbial reduction, and surgical support systems, products, services, and technologies to healthcare, life sciences, research, food, and industrial customers throughout the world.



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

STERIS OFFICES WORLDWIDE

Belgium	32 2 523 2488	Italy	39 022 130341
Brazil	5511 5053 9823	Japan	81 78 321 2271
Canada	800 661 3937	Latin America	800 884 9550
China	86 21 6137 1166	Nordic	358 9 25851
France	33 2 38 70 83 50	Singapore	65 68 41 7677
Germany	49 2203 890 6969	Spain	34 916 585 920
Greece	30 210 6800848	Switzerland	41 32 376 0200
		United Kingdom	44 1256 840400

Document # M3213EN 2008-09, Rev. B

©2011 STERIS Corporation.
 All rights reserved. Printed in USA.