



FINN-AQUA[®] T-series

Pure Steam Generator 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. 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. The FINN-AQUA Pure Steam Generator (PSG) was introduced in 1979 in response to market demands for pyrogen-free steam.

PURE STEAM TECHNOLOGY — WHEN CLEAN STEAM IS NOT ENOUGH, THINK STERIS.



WHAT IS PURE STEAM?

Just because purified water is fed into a steam generator doesn't necessarily mean that the "clean steam" produced is free of endotoxins and other impurities that can threaten your operations. Endotoxins cannot be separated by all technologies that are used in clean steam generators. Pure Steam facilitates the delivery of the highest level of sterility in the manufacture of parenteral or injectable drugs.

The term, Pure Steam, was coined by FINN-AQUA to define this new level of purity when condensed. It exceeds the requirements of the latest U.S. Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for Water-for-Injection (WFI) guidelines. The FINN-AQUA PSG'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
- ASME BPE
- FDA
- GAMP 5
- 21 CFR Part 11
- EU Annex 11
- cGMP
- EN 285

PURE STEAM ENSURES RELIABLE STERILIZATION

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).

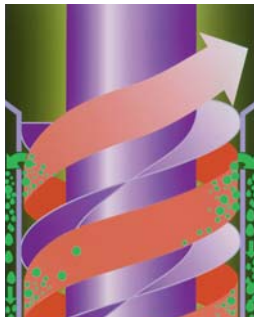
By choosing the FINN-AQUA Pure Steam Generator, you are taking a proactive step in eliminating instances of contamination, thus safeguarding your company and the end-consumer from products that could be potentially harmful.

HOW DOES STERIS DELIVER THE PUREST STEAM?

- Patented three-stage separation
- Tight pressure control to optimize sterilization performance
- Fast response time to Pure Steam demand
- Patented gas separation method
- Continuous circulation of non-evaporated feed water
- Proportional capacity control

Sterilization processes in the pharmaceutical industry require high-quality Pure Steam with accurate pressure control and fast response times. Additionally, the removal of non-condensable gases is an important challenge for Pure Steam Generators because gas in the feed water causes high conductivity. Dissolved gas in incoming feed water is removed by a patented gas separation method, ensuring the highest-quality Pure Steam and fulfilling HTM2010 (EN285) standards during all process conditions and Pure Steam demands.

The core of the FINN-AQUA Pure Steam Generator is its column – a compact design falling-film evaporator and a separator that removes impurities at high centrifugal velocities at the spiral. The impurities are removed as blowdown is directed away from the Pure Steam outlet.



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

1. Separation by falling film evaporation
2. Gravity separation by 180-degree flow turn
3. Centrifugal separation

Separator Column





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 Pure Steam Generators 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, to prove the high quality of Pure Steam, are validated LAL tests and ensure the highest purity of steam is generated.

COMPREHENSIVE DOCUMENTATION, TECHNICAL EXPERTISE AND GLOBAL SUPPORT

STERIS's 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 Pure Steam Generator, STERIS's global service is available in close proximity to provide maintenance when you need it.

FAT CENTER

Within our FAT Center, we can simulate all 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
- Pure Steam output demand conditions
- All global voltage and current combinations



STERIS PROVIDES OPERATIONAL OPTIMIZATION AND POSITIVELY IMPACTS OUR ENVIRONMENT

FINN-AQUA Pure Steam Generators are designed with our environment in mind. Lower utility consumption means less operating costs for you and saves energy for our environment. FINN-AQUA Pure Steam Generators use:

Less Plant Steam The effective falling film evaporation and patented water distribution to the column enables a high performance from the column, optimizing plant steam consumption.

Less Feed Water The patented spiral design, which effectively removes endotoxins impurities and droplets, operates proportionally. Less Pure Steam flow means less blowdown and less feed water rate.

Less Blowdown Blowdown rate (typically 5-8% of Pure Steam produced) is reduced by proportional capacity control operation.

Less Cooling Water If reduced blowdown temperature is needed, a heat exchanger is used that consumes much less cooling water than is used in a traditional mixing chamber construction.



With lower utility consumption & feed, FINN-AQUA Pure Steam Generators are friendly to the environment and your operating budget!

STERIS FITS YOUR NEEDS

At STERIS, we make every effort to accommodate your varying process needs. We offer the FINN-AQUA PSG in a range of sizes and options. Our wide unit portfolio has a solution for every application – ranging from small sizes for the bioprocess industry up to large units for pharmaceutical sterilization applications with capacities up to nearly 7,000 kg/h [15,000 lb/h].

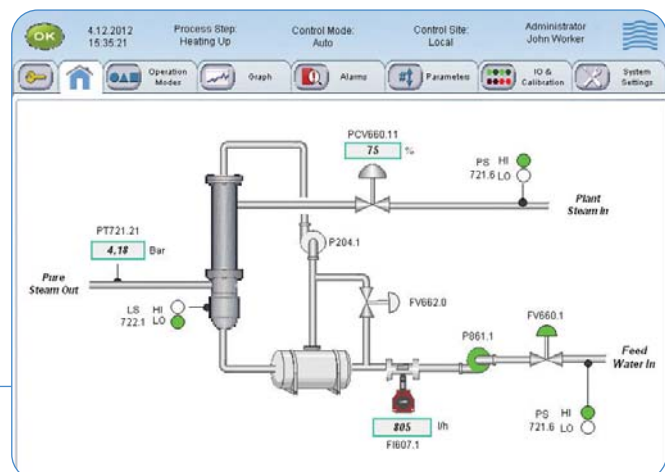
T-SERIES	250	450	850	1200	1600	2200	2900	4700	7500
Capacity Maximum at 8 bar (116 psig) kg/h / (lb/h)	230 (500)	440 (970)	800 (1.760)	1.100 (2.420)	1.600 (3.520)	2.050 (4.510)	2.600 (5.730)	4.750 (10.470)	ON SPECIAL REQUEST

STERIS OFFERS OPTIONS

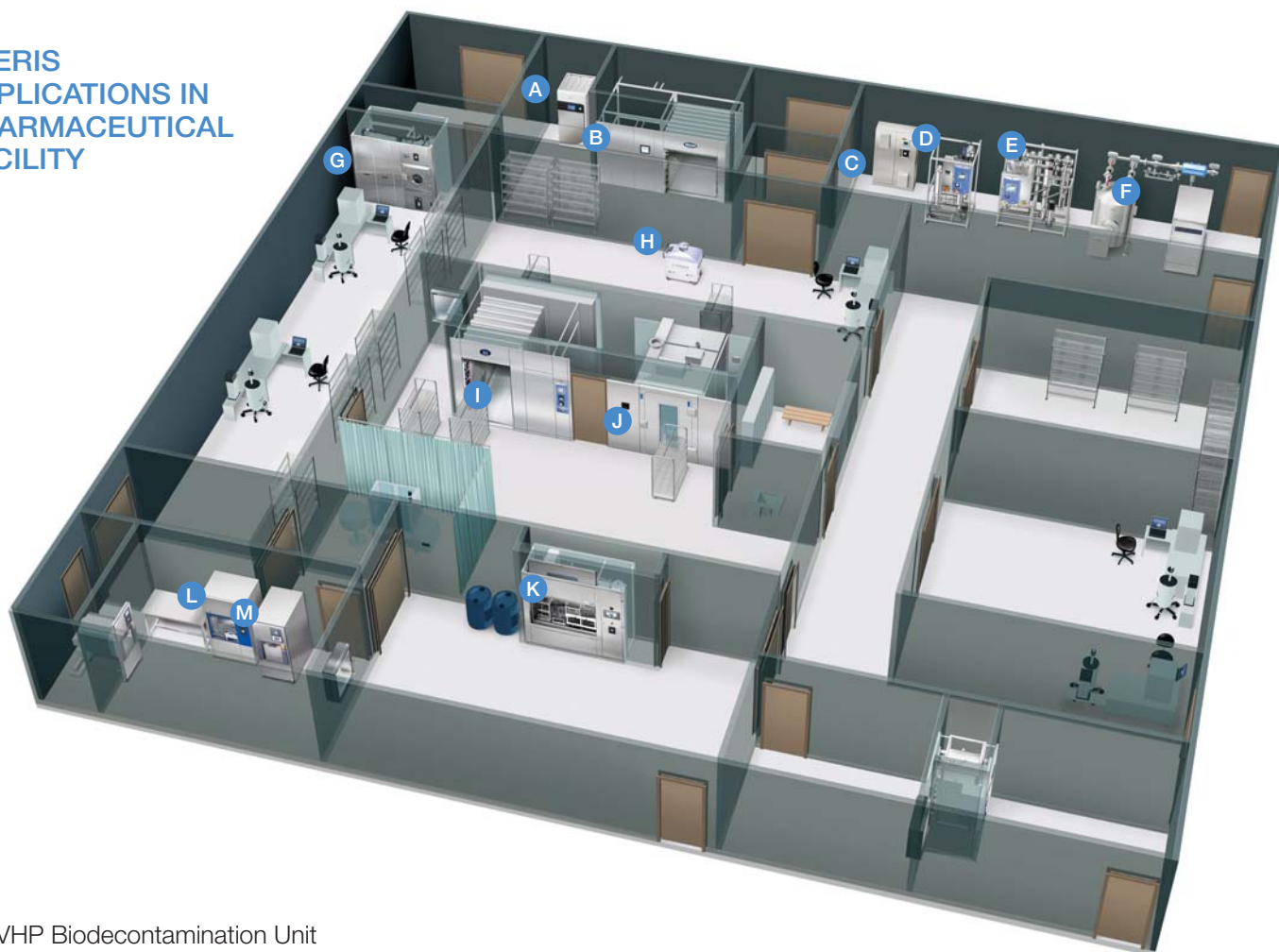
We offer a variety of standard options to help you maximize operational flexibility and customize the equipment for specific application needs:

- An additional condensing unit enables simultaneous WFI and Pure Steam production. This capability is ideal for the bioprocess industry where small amounts of WFI are required in addition to Pure Steam.
- Our Pure Steam Generator can also be fed with softened feed water which helps reduce your total cost of ownership.

Our Pure Steam Generator includes a user-friendly touch screen and is available to order with either the latest Siemens or Allen-Bradley control system platform.



STERIS APPLICATIONS IN PHARMACEUTICAL FACILITY



- A VHP Biodecontamination Unit
- B VHP Low Temperature Sterilizer
- C VHP Integrated Room Decontamination System
- D Pure Steam Generator
- E Multiple-Effect Water Still
- F Continuous Effluent Decontamination System
- G VHP Decontamination Chamber
- H VHP Mobile Room Decontamination System
- I Steam Sterilizer
- J VHP Pass-Through Chamber
- K Pharmaceutical Grade Washer
- L Glassware Washer
- M Lab Research Sterilizer



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STERIS Life Sciences | Science & Solutions for Life

For over 100 years, STERIS has been known as a global leader, trusted partner and solutions provider in the field of sterilization and contamination control. **Today**, STERIS continues building on this heritage by advancing the **Science** of sterilization, cleaning and infection control while offering **Solutions** that meet our Customers' needs and high standards. STERIS is dedicated to helping you enhance the **Life** of your patients and the life of your equipment. From Formulated Chemistries, to Capital Equipment, to Parts and Services, STERIS Life Sciences is **Science & Solutions for Life**.

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