Terminal Sterilization, Liquids

FEDEGARI GROUP

EN.1.1.1

FOA and FOW - Series

Sterilization of aqueous solutions in sealed containers (such as LVPs of different formats, vials, PFS, blister packs, etc.) share a well-known common problem: during the process they develop a pressure inside the primary container higher than the pressure of saturated steam at the same temperature. More critical than the phenomenon itself are the consequences on the product and/or the container itself.

Some of the most important features of these sterilizers are related to the control of critical process parameters designed to assure the highest flexibility in process control to prevent any undesired deformation/damage of the containers, while providing the desired thermal treatment to the product. Both types of sterilizers share the same design technology of all Fedegari machines and are capable of the highest performances and undisputed reliability.

Steam-Air Mixture or Superheated Water?

The selection of either one is often critical and, though both are capable of the same general performances, the final choice is dictated by process needs downstream of sterilization (does the load need to be dry? Does the container show any sign of hydration? How can the highest productivity be achieved? Are other loads to be sterilized through the same machine? etc.). Both types of machines are designed for operating with the new RTWS3 wireless temperature sensors that, especially on the large automatically loaded models, offer unrivalled ease of use and optimal process control. Both versions are offered in capacities ranging from few hundred liters to a few tens of cubic metres, all guaranteed for the same process performances.

PROCESSES

Sterilization

Washing

Chemical bio-decontamination

Contamination control

Dense-phase fluids

SPECIAL APPLICATIONS

Rotating sterilizers

Pharmaceutical closures processing

COMPONENTS

Pressure vessels

Doors

Piping

Process controller

Wireless sensors

ACCESSORIES

Un/loading conveyors

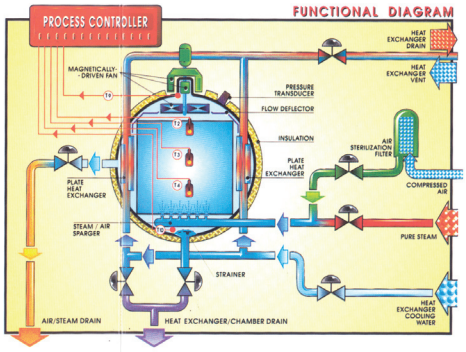
Customized racks

Terminal Sterilization, Liquids

They can also be equipped with fully automatic un/loading conveyors for the highest productivity with virtually no maintenance inside the sterilization chamber. Where the product is liable to separation or for accelerating thermal transition phases the whole load can be rotated during the entire process.

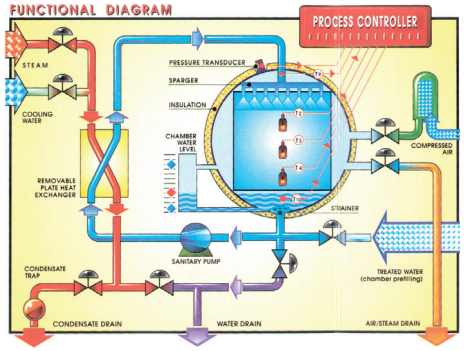
FOA Steam-Air Process

Magnetically driven fans force a high rate of fluid circulation within the chamber. Internal sanitary hollow plates add additional heating/cooling capacity whilst minimizing condensate creation. Steam and air are injected according to the control algorithms to finely control the process. This system is the usual choice where terminally sterilized products are to be unloaded dry.



FOW Superheated Water Process

Water is continuously circulated through the system and sprayed over the load. Fine control of heating and sterilization is achieved by superheating the water using modulated steam. Load cooling is achieved by subsequent cooling of the circulated water. Counter pressure control is as per the steam-air mixture process. The process is efficient and faster than the FOA process. It is also an ideal process for <105 °C processing. Wet loads can be overcome using on automated drying extension with the installation of specific drying solutions downstream of the sterilization chamber.



Standards & Regulatory Compliance

Fedegari has always focused on the regulated pharmaceutical industry; compliance to the following standards is not just 'achievable' but is our standard:

- EN285 & 556 (where applicable)
- EN Directives and associated standards
- ISPE cGMP and GAMP5 compliant (GAMP including supplier pre-validation)
- FDA CFR's including 21 CFR parts 210, 211 and 11
- ISA, ISO and DIN (where required)
- ASTM A240, 213, 270, SA312 for chamber and piping material
- ISO9001 & 13485 for overall manufacturing
- All IMB, MHRA and associated regulations.

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