

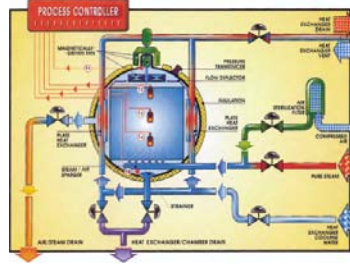


# Counterpressure Autoclaves

## Fedegari FOA and FOW Ranges

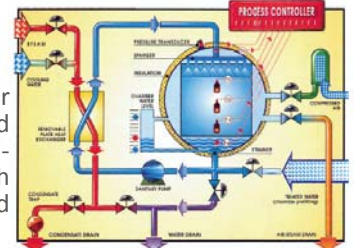
The sterilisation of aqueous liquids in sealed containers (large vials, LVPs, syringes, blister packs) needs careful pressure management. Enclosed air in the headspace increases the pressure inside the container. Where this could rupture the container it becomes critical to apply compressed air to the chamber steam outside the container, to equalise the pressures.

Fedegari counterpressure sterilisers are the result of 50 years continuous development in the field of regulatory compliant sterilisers. See also "Fedegari Build Standards" and "Fedegari Process Control".



Fedegari FOA Steam+Air autoclaves – Steam and sterile filtered compressed air are continuously mixed by the chamber fans and flow deflectors

Fedegari FOW Superheated Water autoclaves – Water is superheated and sprayed over the load by solid-cone spray nozzles, again with additional air pressure. Load cooling is by water spray.



Water shower sterilisation is faster; the choice of these two methods depends on the tolerance of the loads, in particular their need to be dry at cycle end.

Standard ranges for both extend from 200 to 28,000L chamber capacity.



## Design Features

**Assured sterilisation.** Detailed design of the steam injection spargers, fans, ducting & spray nozzles all contribute to an exceptionally tight control of sterilisation, throughout the load & over time.

**Assured load integrity.** Control algorithms accurately manage the applied overpressure, matching overpressure to the changing load temperature.

**Rapid cooling.** Internal plate heat exchangers, air cooling, sterile water spray. Fedegari offer the full range of techniques to keep cycles short,, maximise productivity and protect thermolabile products.

**Regulatory Compliance.** Fedegari specialise in supplying the regulated bio-pharma industry. All units are designed for full compliance to cGMP, control systems pre-validated to GAMP, 21CFR11.

**Design Customisation.** Processing cycles are fully configurable to meet the needs of the loads and load types, finished dimensions matched to the installation.

**Full complement of service cycles.** As standard, all units include sterilisation-in-place of the chamber air filter and chamber pressure cycles for chamber testing.

**Long Term Reliability.** Fedegari autoclaves have an unequalled reputation for long term service reliability.

**Wide range of options.** Examples include:

- Combined FOA/FOF autoclaves, - counterpressure and saturated steam sterilisation from one unit.
- Utility saving recirculation tank for plate cooling water.
- Fully automated integrity testing of the sterile air filter.



**Load Handling.** Loads can be rotated using magnetically coupled drives to ensure rapid, uniform heating and cooling.

Fedegari expertise extends to the design of complete turnkey systems including bespoke load handling.



**Customer Support.** SteriTech and Fedegari have been partners for over 20 years, offering :

- Feasibility studies, guidance on machine specifications*
- Project management, DQ/HAZOP expertise*
- Commissioning, validation*
- Preventative maintenance*
- Process Development*
- Ongoing Thermal Revalidation.*



Feasibility studies

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