

# Fedegari Counterpressure Autoclaves

## Fedegari FOA and FOW Range Introduction

Sterilisation of aqueous liquids in sealed containers (vials, LVP's, syringes, blister packs etc) can create high internal pressures that required careful pressure control to avoid product or container damage. Terminally sterilised products are often high value and often thermally labile, therefore every feature of the Fedegari units are designed to achieve an optimal, reliable and repeatable cycle

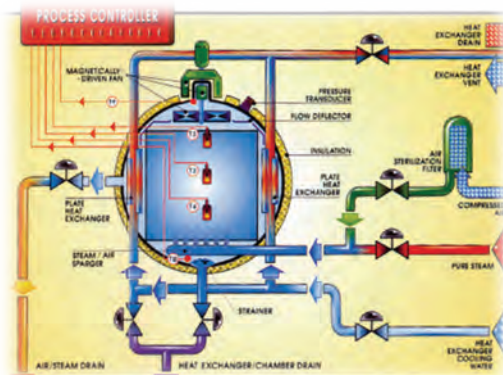
Fedegari have two solutions, the FOA range of steam/air units and FOW range of superheated water sterilisers.

Both ranges are highly customisable and offer the highest level of performance, reliability and GMP validatability.

### Air-Steam or Superheated Water Process?

Selection depends on the nature of the product and processing required and considerations such as thermal lability, criticality of dryness, available utilities. Both processes are finely controlled to ensure that precise sterilisation conditions are achieved by the solutions within the containers.

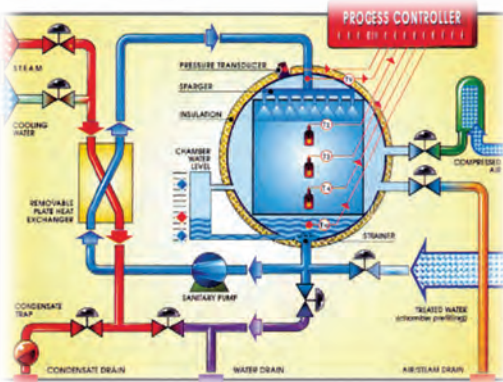
Both processes have 2 PID controlled loops ensure which offer complete process flexibility and performance. Temperature loops are controlled by 2 chamber RTDS, whilst being monitored by a minimum of 3 flexible load probes, sterilisation is controlled on time/temperature or Fo basis or both. Pressure is separately controlled using accurate algorithms associated with each particular load.



#### Fedegari's FOA Air-Steam Process

Magnetically driven fans force a high rate of fluid circulation within the chamber. Internal sanitary plates add additional heating / cooling capacity whilst minimizing condensate creation. Steam and air are injected according to the control algorithms to finely control the cycles.

This system is the usual choice where terminally sterilised product is to be unloaded dry.



#### Fedegari's FOW Superheated Water Process

Water is continuously circulated through the system and cascading over the load. Fine control of heating and sterilisation is achieved by superheating the water using modulated steam. Load cooling is achieved by subsequent cooling of the circulated water. Where fluids are liable to separation, or to assist heat penetration, the whole load can be rotated during the complete cycle. Counter pressure control is as per the steam process.

The process is efficient and faster than the steam process. It is also an ideal process for <math>105^{\circ}\text{C}</math> processing. Wet loads can be overcome using Fedegari's automated drying extension.

## Automated Loading Systems

Loads for terminal sterilisation are invariably heavy and unsuitable for manual handling. Fedegari have a range of loading and unloading conveyers, fully integrated with the Thema4 control system to automatically load and unload pallets of cassettes.

As with all Fedegari's, there is a huge selection of chamber sizes, configurations and options available to tailor each unit to the exact requirements.

### Stilmas Equipment

- Pre-treatment
- Purified Water
- Multi Effect Still
- Vapour Compression Still
- Pure Steam Generators
- PS & WFI Combinations
- Storage & Distribution Systems

### Fedegari Equipment

- Saturated Steam Sterilisers
- Counterpressure Sterilisers
- UltraWashers
- Dry Heat Sterilisation
- Pathogen Sterilisers
- Combined Units
- Laboratory Sterilisers

### Fedegari non-thermal equipment

- Low Temperature Surface Decontamination Stations
- Laminar Flow Carts
- Isolators and Cleanroom Contamination Controls

### Olsa Equipment

- Solids: Filtering, mixing and drying
- Semi-Solids: Mixing and turnkey plants
- Liquids: Preparation vessels, fermenters and bio reactors

### Bano Equipment

- Stainless Steel Cleanroom Furniture
- Specialist Cleanroom Equipment

### SteriTech Limited

- Complete Turn-Key Projects

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## Standards & Regulatory Compliance

As Fedegari have always focused on the regulated pharmaceutical industry, compliance to the following standards is not just 'achievable' but is their standard:

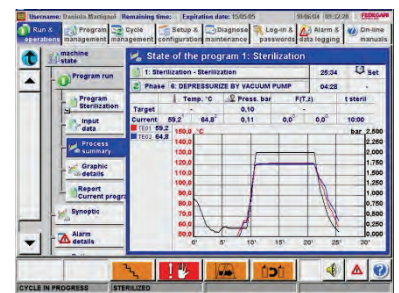
- EN285 & 556 (where applicable)
- EN Directives and associated standards
- ISPE cGMP and GAMP5 compliant (GAMP including supplier pre-validation)
- FDA CFR's including 21CFR parts 210, 211 and part 11
- ISA, ISO and DIN where required
- ASTM A240,213, 270, SA312 for chamber and piping material
- ISO9001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

....plus other local and international standards as applicable.

## Thema 4 Control System

All Fedegari process machines are supplied with the Thema 4 Controller. Designed by Fedegari using over 50 years of specific process knowledge, the Thema 4 controller offers the following features and benefits over conventional PLC based controllers:

- User friendliness, colour touch screen with windows style operation
- Core-philosophy that other than safety, the process has priority over all actions and events
- Pre-validated Gamp 5 compliance, 21 CFR Part 11 built in.
- Real-time operating system & open systems architecture
- Practically unlimited memory and storage capacity
- Full functionality open to customers under password control
- Advanced control, monitoring and reporting functions including parametric release options
- Complete integration for SCADA, as future-proofed as possible
- Commercially available hardware



The screenshot displays the 'Description of the equipment 1: Flexi-O' window. It shows a table of parameters for the equipment. The table has columns for 'HW physical view', 'Equipment type', 'Alarm', 'Parameters', 'Data time', 'Language', and 'Software'. The 'Alarm' section is expanded, showing a list of alarm codes and their descriptions.

Alarm	Code	Description
000	317	016 216 000 362 016 009
001	316	017 216 000 362 016 011
002	314	018 290 000 360 016 012
003	313	019 061 000 361 016 066
004	311	020 187 004 367 000 306
005	312	021 332 005 368 001 307
006	302	022 291 006 360 002 091
007	281	023 - 007 360 003 290
008	304	024 - 008 001 281
009	304	025 - 009 002 287
010	305	026 - 010 003 287
011	306	027 123 011 004 027 013
012	321	028 290 012 005 028 284
013	309	029 232 013 006 029 295
014	306	030 232 014 007 030 017
015	310	031 308 015 008 031 009

As Fedegari use the same configurable software across all their units, customers with multiple units have significant advantages in terms of quality control, validation and supervision.

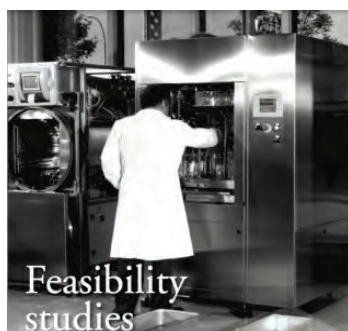
The pre-validation ensures minimal project risk and lower customer effort required to qualify.

## SteriTech/Fedegari Customer Support

SteriTech have been Fedegari's sole local partners for over 20 years. Within that we have built a strong reputation for total customer support, such as:

- Feasibility studies, process and selection guidance
- Full project management from order to PQ
- Start-up, commissioning and validation from local engineers
- Preventative maintenance, calibration and routine validation
- Local spares and technical support.

A full lifetime support.



## SteriTech Services

SteriTech, like our suppliers are solely dedicated to the regulated pharmaceutical sector. This enables us to fully understand not only the quality of performance required, but the documented evidence of all activities.

## Project Management

A dedicated Project Manager follows each sale through to OQ handover. Liaison with customers, suppliers and field operations team to ensure effective project delivery.

## Project Sitework

From our local highly trained team offering

- Installation Assistance
- Start-up & Commissioning
- SAT, IQ/OQ
- Calibration
- Thermal Mapping
- Cycle & Process Development

## After-Sales

Full life-time local support for equipment including

- Full Training Packages
- Technical & Process support
- Spare parts supply
- Preventative Maintenance
- Calibration
- Routine Validation
- Upgrades and revampings