



FOF

INDUSTRIAL SATURATED STEAM STERILIZERS

In the early 1950s, the pharmaceutical industry entered a highly dynamic stage of evolution which required machines and production process that had been unthinkable up to then.

Fedegari immediately realized that the autoclaves begin used at the time in pharmaceutical work were hospital machines which had been modified only in a few details of their operation and proposed the first saturated-steam sterilizer specifically designed for the pharmaceutical industry, introducing construction and process-control concepts which were absolutely innovative in those years.

This spirit has been a constant trait of Fedegari since then; the company chose to grow thanks to continuing innovation, despite being aware of the risk of being later imitated by many competitors.

Since those early years, and despite the adoption of more specific sterilization processes, such as superheated water spray or steam-air mixture methods, the steam autoclave is still among the favorite staples of Fedegari production. Even today it is still the simplest, cheapest, and most flexible process for treating most of the products and items ordinarily used in pharmaceutical work.

Faithful to its principle of innovation, Fedegari offers this folder to present its saturated-steam autoclaves in their latest development.

PROCESS

The high operating flexibility of these autoclaves arises from the intrinsic characteristics of the saturated-steam process, from the features of the autoclave's construction and from the process controller's flexibility.

Every sterilizer is equipped with a water-ring vacuum pump which operates during various steps of the process, such as:

- initial evacuation of the air by vacuum/steam pulses or by steam injection
- constant draining of the condensate from the chamber, according to the principle of "dynamic steam"
- treatments below 100°C
- final drying of the loads.

Another special feature - one which used to be opposed but is now adopted by other manufacturers as well - is the control of the sterilization stage according to a pressure signal, rather than temperature.

Obviously, the temperature readout varies as a function of the position of the sensor, whilst the pressure is uniform throughout the chamber. However, process control is performed by detecting in the chamber (and from inside the product) temperature signals whose match with the pressure value, as constantly verified by the controller, demonstrates that the autoclave is operating correctly. This principle, in saturated-steam conditions, that is to say, when there is a two-way T/P correspondence, allows to obtain uniformities in sterilization temperature which are far better than the currently required level of $\pm 0,5^{\circ}\text{C}$. Fedegari can certify this uniformity also thanks to the availability of sophisticated instruments.



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The flexibility of the sterilizers of the FOF series, once the suitable plant options have been selected, makes them suitable for a wide range of treatments, some of which are mentioned below:

- sterilizations of various solid materials.
- sterilizations of porous materials.
- sterilizations of filled ampoules with fast vacuum for tightness test.
- sterilizations of filled ampoules, vials or bottles with cooling by means of D.I. water spray under counter-pressure of sterile air.
- sterilizations as above, with cooling by means of:
 - heat-sterilized and cooled D.I. water spray
 - circulation of cold water in jacket with optional circulation of the air by magnetically driven fan(s).
- tyndallizations, pasteurizations, inactivations.
- ampoule tightness test with penetration of dye solutions.
- chamber vacuum/pressure tightness tests.
- programmed developments of vacuum/steam pulsing and heating/cooling phases.

When treating LVP, especially if stored in deformable containers, it is often convenient to use superheated water spray or steam-air mixture sterilization processes in order to prevent the effects of differential pressures between the inside and the outside of the containers.

Accordingly, we strongly suggest to discuss every potential application with the Supplier.

CONSTRUCTION

Fedegari has introduced innovations not only in processes but also in construction. Over time, these innovations have become established standards. In 1980 Fedegari acquired the first CAD workstations to study, by means of finite-element programs, the fatigue behavior of rectangular chambers

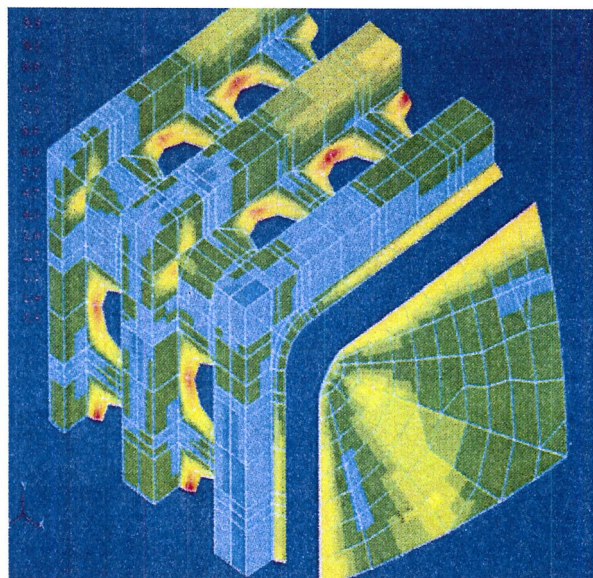


fig.1

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and of new doors, solving the problems that at the time affected these structures (FIG 1).

At the same time, Fedegari began to manufacture the autoclave piping using only stainless steel (AISI 316L), introduced the dovetail-shaped section pneumatic gasket and the machining of the door frames by NC milling.

And more, our welding methods: by using the latest automatic and robotized system, over 90% of all the welds on an autoclave of this kind are performed automatically. This has led to the standardization of construction models which flawlessly withstand the repeated heat and pressure cycles as well as localized and diffused corrosion.

Depending on the dimensions and/or kind of process, the chambers can have a circular or rectangular cross-section; they have a jacket which surrounds them almost entirely and the inside surface of the chambers is mechanically polished until a roughness $Ra < 0,1 \mu m$ is achieved.

The doors can be of the automatic sliding type or of the semiautomatic hinged type. Both versions use the same construction model, with the characteristics outward camber and the same type of patented gasket (fig. 2-3).

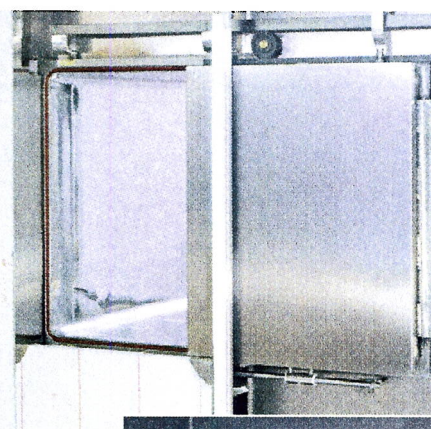


fig.2

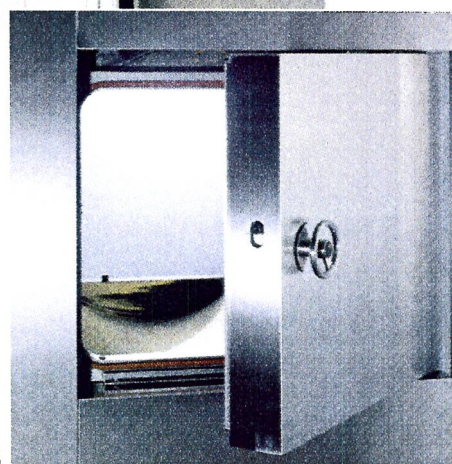


fig.3

These constructive solutions are highly sophisticated yet conceptually very simple, being the result of years of experience and of a fair dose of original thinking.

The difference between the two versions lies in the opening method. In the first version, a motor provides horizontal or (in smaller sterilizers) vertical sliding of the door. In the second version, the motor moves the door through 45°, disengaging/engaging it with respect to the recesses of the chamber and leaving it to the operator to manually open/close the door by rotating it on hinges.

There is no difference in price between the two versions.

SPECIAL CONSTRUCTIONS

ROTATING LOAD (FIG. 4)

The load constantly rotates by virtue of a special drum which revolves inside the chamber - which contains the trolleys. The drum is rotated through a magnetic coupling and its speed, direction and intermittent motion can be adjusted. Some of the possible applications of the system are:

- treatment of suspensions and emulsions
- better performance in vacuum tightness tests for ampoules
- better transmission of heat into the load.

AUTOMATED LOADING/UNLOADING SYSTEMS (FIG. 4)

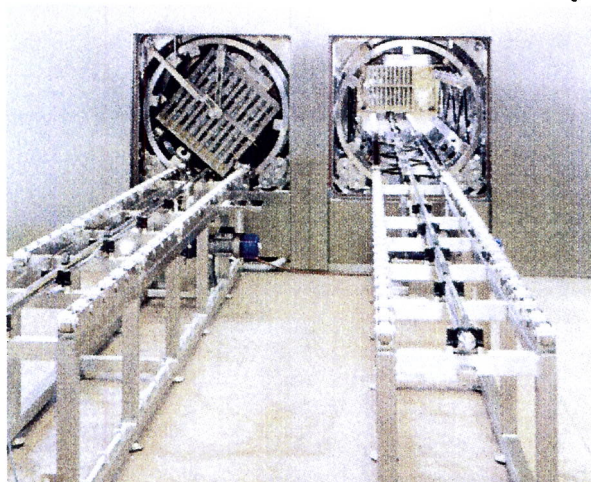
Our solution is simple and reliable like no other.

The pallets travel on benches which have freewheeling rollers made of solid stainless steel. A rack-rod, coupled with a motor provided with a pinion outside the autoclave, automatically pushes the load into the chamber or pulls it out. The entire system requires no lubrication.

LOADING SURFACE AT FLOOR LEVEL

This solution is sometimes required to allow direct loading/unloading of the chamber by using external/internal trolleys and requires an installation pit.

fig.4



COMPLETE ELASTOMERIC STOPPER TREATMENT

This treatment includes washing, rinsing, siliconizing, sterilization, thorough drying and automatic unloading into the sterile area.

The method uses a special drum which is slowly turned inside the autoclave chamber by a magnetic coupling. The special internal shape of the drum ensures:

- highly effective washing, siliconizing and drying
- automatic unloading of the product into the sterile area by reversing the direction of rotation and by means of the special self-sterilizing chute on the unloading door.

TREATMENT OF HIGH PATHOGEN (HP) RISK MATERIALS

These materials require highly specialized processes which must completely avoid any risk of external contamination. The principle applied by Fedegari is the most reliable since:

- the air that is initially present is kept in the chamber until sterilization ends and is mixed with the steam by fans driven by a patented magnetic coupling (Fig. 2)
- the condensate which accumulates on the bottom of the chamber is discharged, when sterile, only at the end of the sterilization process.

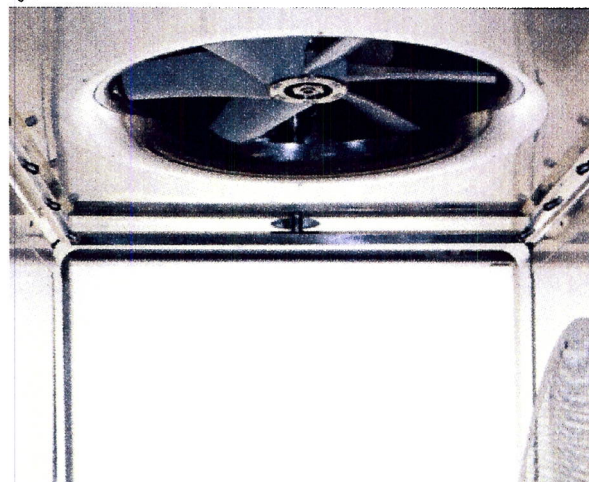
PROCESS CONTROLLER

A high-performance process controller (described in a separate folder) is provided.

ACCESSORIES AND OPTIONS

- various kinds of external and internal trolley
- boxes for ampoules and bottles of various kinds
- built-in electric steam generator (available for chambers up to 1 m³)
- water pump for supplying steam generator and/or for spray in chamber
- mains steam filtration system
- system for the closed-circuit sterilization/cooling of the load cooling spray water.

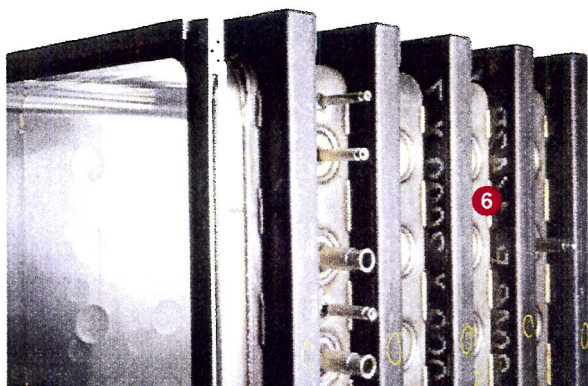
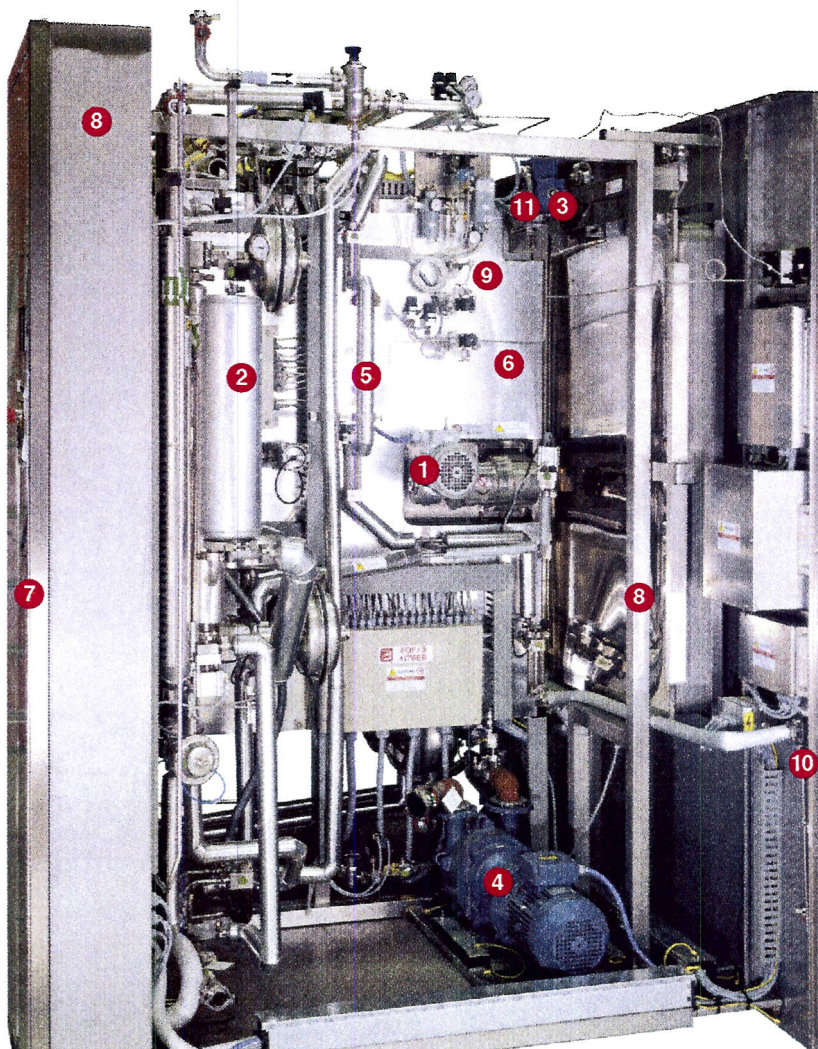
fig.5



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- 1 Magnetic coupling for rotating the stopper treatment drum.
- 2 Sterilizing and filtration system for chamber air; can be sterilized in place with an automatic program. An automatic filter integrity control system can be added.
- 3 Two ports for validation sensors.
- 4 Vacuum pump with safety against lack of water, equipped with special silicone connections to eliminate the transmission of vibrations.
- 5 Piping entirely made of AISI 316L stainless steel, equipped with sanitary-type quick couplings with automatic orbital welds and sanitary-type valves made by Fedegari.
- 6 AISI 316Ti stainless steel sterilization chamber and AISI 304 (optionally AISI 316) jacket with external reinforcements. Steam supply and temperature control are separate for the two chambers.
- 7 Patented pneumatic door gasket ensures flawless operation without requiring vacuum for retraction. Requires no lubrication.
- 8 Self-supporting cabinet made of AISI 304 stainless steel, formed on a bending press and satin-finished externally. All supporting structures are made of AISI 304.



- 9 Pt100 four-wire flexible RTDs, class 0.1, IEC 751, which can be calibrated by means of the process controller by comparison with a reference instrument - Standard version: 3 product RTDs+3 fixed plant RTDs, expandable total of 24.
- 10 Safety thermometer with independent flexible RTD: ensures redundant temperature measurements with functional safeties which are independent of the process controller.
- 11 Thin-film pressure transducer with separation membrane; can be calibrated by means of the process controller by comparison with a reference instrument.

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MODEL	CHAMBER SECTION	CHAMBER NOMINAL DIMENSIONS				OPERATIVE PRESSURE [abs. barr]	SELECTABLE DOORS		
		WIDTH [cm]	WEIGHT [cm]	DEPTH [cm]	CAPACITY [l]		SEMI-AUT. HINGED	VERTICAL SLIDING	HORIZONTAL SLIDING
FOF 1/A	CIRCULAR	45	45	100	200	3,5		•	
FOF 2/A	CIRCULAR	66	66	100	430	3,5	•	•	
FOF 3/9 FOF 3/1 FOF 3/2 FOF 3/3 FOF 3/4	RECTANGULAR	80	80	125 150 175 200 225	800 960 1.120 1.280 1.440	3,5	•		•
FOF 3/A FOF 3S/2 FOF 3/B FOF 3/C	CIRCULAR	80	80	125 150 175 200 225	800 960 1.120 1.280 1.440	3,5	•		•
FOF 4/9 FOF 4/1 FOF 4/2 FOF 4/3 FOF 4/4	RECTANGULAR	80	100	125 150 175 200 225	1000 1200 1400 1600 1800	3,5	•		•
FOF 5/9 FOF 5/1 FOF 5/2 FOF 5/3 FOF 5/4	RECTANGULAR	90	130	150 175 200 225 250	1.750 2.040 2.340 2.630 2.920	3,5	•		•
FOF 6/9 FOF 6/1 FOF 6/2 FOF 6/3 FOF 6/4	RECTANGULAR	106	115	200 225 250 275 300	2.430 2.740 3.040 3.350 3.650	3,5	•		•
FOF 7/9 FOF 7/1 FOF 7/2 FOF 7/3 FOF 7/4	RECTANGULAR	126	140	200 225 250 275 300	3.500 3.950 4.400 4.850 5.300	3,5	•		•
FOF 8/9 FOF 8/1 FOF 8/2 FOF 8/3 FOF 8/4	RECTANGULAR	130	150	250 275 300 325 350	4.850 5.350 5.850 6.300 6.800	3,5	•		•

The above mentioned data are to be intended as indicative. The manufacturer reserves itself the right to change them without notice.
Other models available. Slightly lower working pressure for pressure vessels with ASME testing.



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