



**FEDEGARI**  
AUTOCLAVI SPA



# FOW•FOA

**COUNTERPRESSURE STERILIZERS**

## WHY AND HOW TO STERILIZE IN COUNTERPRESSURE

The technology of moist-heat sterilization in counterpressure has been developed specifically for the terminal treatment of solutions in sealed containers.

Its primary aim is to "neutralize" the effects of the overpressure which unavoidably forms inside containers when they are sterilized using conventional saturated-steam autoclaves.

This overpressure tends to make glass containers explode and to lift their stoppers, irreversibly deforms flexible or rigid plastic containers, expels the plungers of prefilled-syringes, etc.

The collateral but not at all secondary aim is to perform load cooling with a sterile fluid, either water or air, thus complying with the CGMP of the FDA for LVP.

Counterpressure autoclaves currently in use belong to two types:

- superheated water spray autoclaves
- steam + air mixture autoclaves

To a certain extent, the two types are complementary and Fedegari has built both for several years. They are also presented together in this brochure, highlighting also the advantages of the two types.

The figure below shows some typical products which can be sterilized with these autoclaves. This presentation is absolutely non-limitative, and new packages which require careful use of counterpressure sterilization are constantly being introduced in the market.

Our Customers should contact us during the development of their new products/packages, since often modest adaptations of these products/packages allows optimization of the results of the sterilization processes.

Our Research & Development Service is available to our Customers for this purpose.

## CONSTRUCTION FEATURES

The chamber is cylindrical, usually single-wall, with thick insulation and an aluminum-sheet outer casing.

The construction materials are class AISI 316 stainless steel.

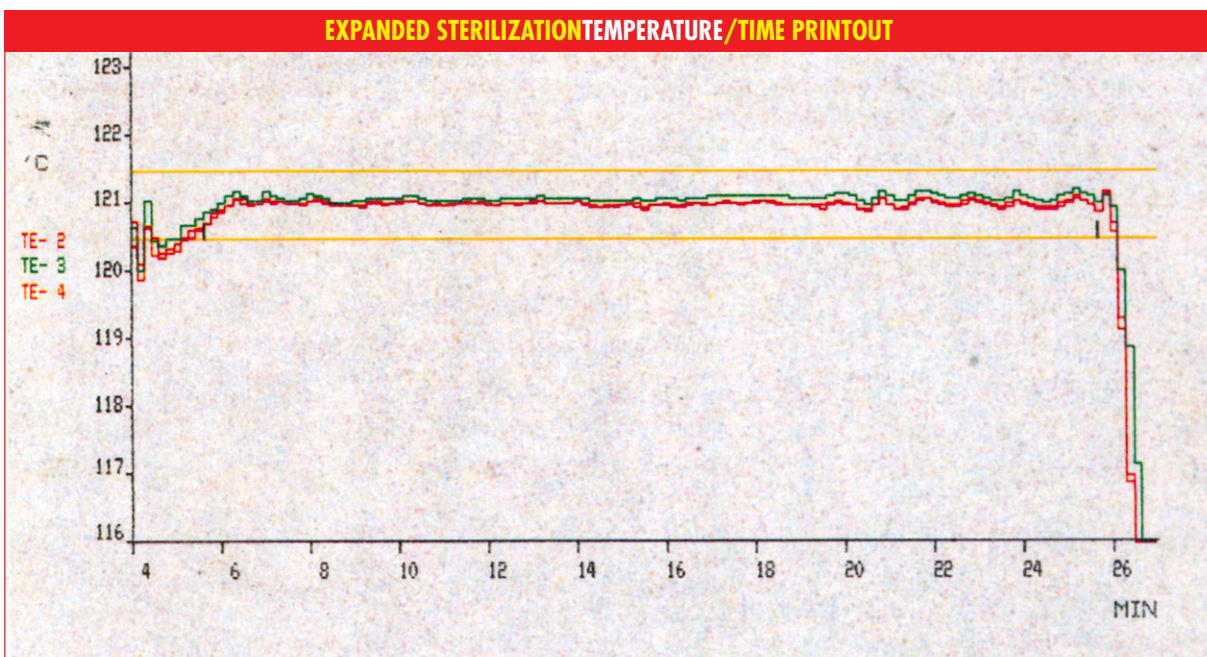
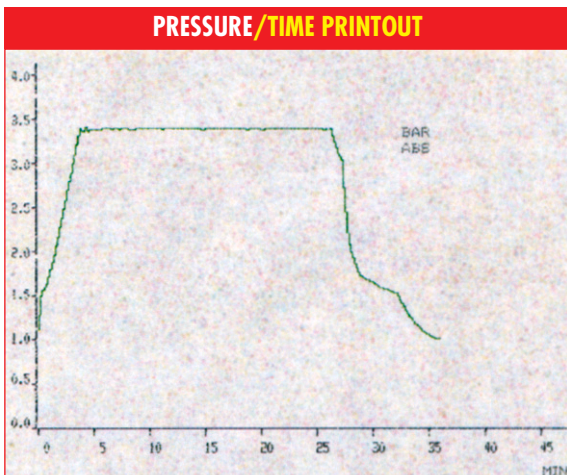
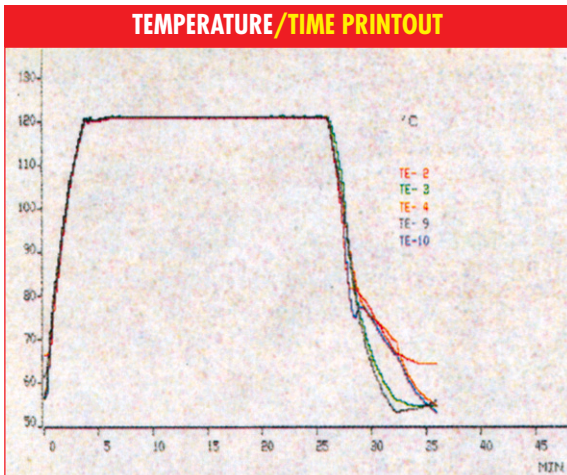
Either one or two rectangular doors, inscribed in the circular cross-section.

These doors may be of two kinds:

- laterally sliding and automatic
- laterally hinged and semiautomatic;

the doors engage and disengage their clamping devices with a diagonal movement automatically produced by a gearmotor, but the opening and closing action relative to the vertical hinges is manual.





In both cases, the silicone gasket slides in a special slot formed by NC milling in the frame of the chamber and it is activated by compressed air.

The gasket and the slot have specially designed dovetail cross-sections to ensure perfect operation and tightness without requiring lubrication and vacuum for gasket retraction.

All valves and the entire piping are made of stainless steel.

## AUTOMATIC LOADING/UNLOADING SYSTEMS

When it is necessary to sterilize large and heavy loads, it is sensible to resort to palletization systems featuring automatic handling.

The handling solution is extremely simple and efficient.

It consists of a loading bench located in front of the autoclave, where the train of pallets is prepared.

The bench has two rows of free rollers on which the pallets rest, and it is also provided with an underlying rod with a rack-like movement which pushes the pallets into the autoclave. The autoclave is also internally equipped with two rows of free rollers and therefore inside the chamber there are no sealed shafts, chains or gear: this means that all the risks of leaks and all lubrication problems have been eliminated.

Usually, a second bench, arranged in front of the unloading door of the autoclave, removes the pallets by means of an extractor rack-rod.

## PROCESS CONTROL

As all the other sterilizers, also the counterpressure autoclaves are equipped with the Thema3 process controller, specifically developed for monitoring and controlling sterilization processes. Also for these sterilizers, in order to ensure top process and safety performance, Fedegari offers its standard process controller (for its description, refer to the relevant brochure).

Distribution system for the circulation water. Equipped with nozzles producing a "solid" spray cone, mounted so as to avoid water stagnation in the ducts of the sparger.



# FOW

## SUPERHEATED WATER SPRAY AUTOCLAVES

FOW sterilizers are based on an extremely straightforward principle which is implemented with a highly reliable and mechanically very simple unit.

When the program begins, after the load to be sterilized has been introduced, only the lower part of the chamber is filled with treated water of adequate microbiological quality. The chamber has a circular cross-section with a single wall, but has rectangular doors. The air inside the chamber is not removed.

The water, which is drawn from the bottom of the chamber by a sanitary-type centrifugal pump, is circulated through a moving-plate heat exchanger, also of the sanitary type, which is indirectly heated in countercurrent with mains steam.

The water is then fed back into the upper part of the chamber and is distributed onto the load by a system of solid-cone spray nozzles.

Water redistribution onto the lower layers of the load is ensured by appropriate shelves.

Heating of the circulation water and thus of the load is gradual but quite fast. The sterilization temperature of 121° C is reached within approximately 25-30 minutes inside 500 ml containers.

After the sterilization time has elapsed, the circulation water, which by then is sterile as well, continues to circulate through the exchanger, which however in this step is fed with cold cooling water.

Roller system for automatic load handling. The rollers are mounted on special roll-bearings with a cage made of plastic material accepted by F.D.A.

All metal parts are made of stainless steel and require no lubrication.

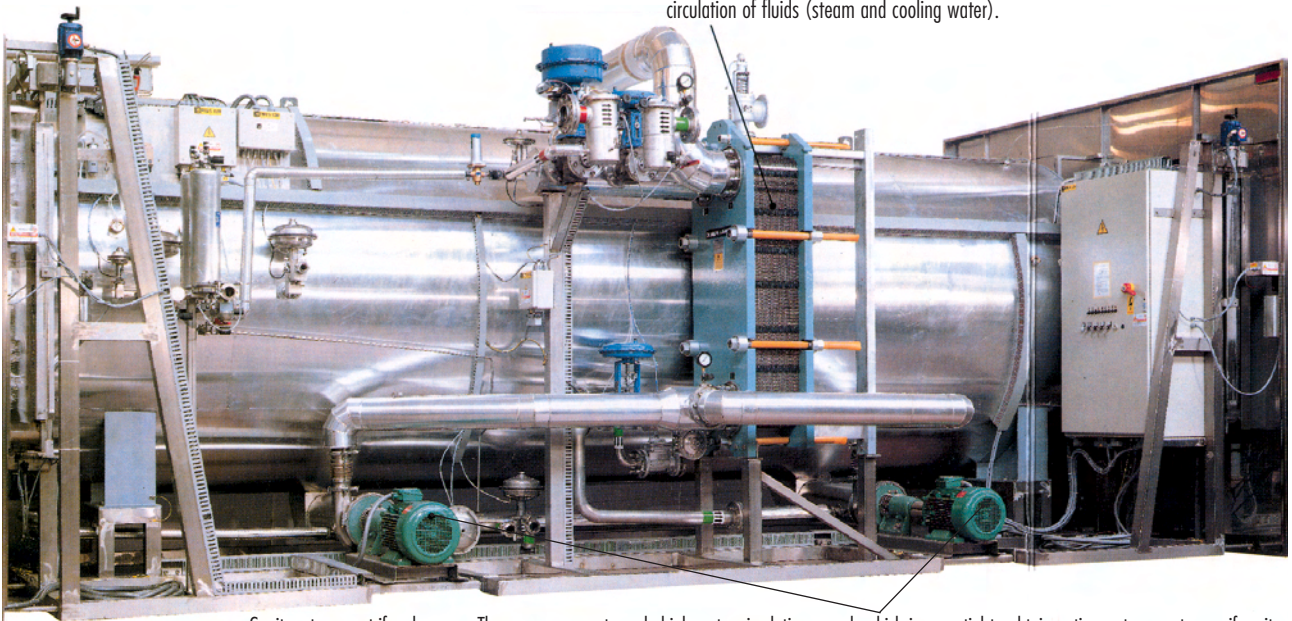
Within approximately 10 minutes, the temperature inside the containers gradually drops to approximately 80° C, which is the ideal temperature to also obtain rapid and spontaneous drying of the load, when extracted from the autoclave.

The entire process therefore lasts approximately 60 minutes.

Throughout the process, an adequate counterpressure of sterile air is maintained inside the chamber in order to counterbalance, in the most appropriate and automatic manner, the overpressure within the product.

Moving-plate heat exchanger made of stainless steel, sanitary type, double function (heating/cooling). Combines maximum efficiency and maximum safety.

Plate cleaning is spontaneously ensured by the turbulence, speed and alternation of the circulation of fluids (steam and cooling water).



Sanitary-type centrifugal pumps. They ensure an extremely high water circulation speed, which is essential to obtain optimum temperature uniformity.

# FOW•FOA

## COUNTERPRESSURE STERILIZERS

# FOA

## STEAM-AIR MIXTURE AUTOCLAVES

FOA sterilizers have a chamber with a circular cross-section, generally with a single wall, and with rectangular doors. In these autoclaves, too, the air inside the chamber is not removed.

The process begins by introducing steam directly in the chamber by means of the sparger located at the bottom of the chamber.

One or more fans are located in the upper sector, based on the length of the chamber.

Fedegari's widely tested magnetic coupling is used in this case as well. The action of the fans, combined with the action of the flow deflectors, generates a continuous and rapid homogenizing and circulation of the steam-air mixture, which forms in the chamber (see the functional diagram).

At equal temperature and pressure, air is in fact on the average 1.5 times denser than steam and would tend to stratify on the bottom of the chamber, producing unacceptable temperature gradients.

Once the heating and sterilization phases have ended, the cooling phase begins and develops as follows:

- the steam-air mixture in the chamber is replaced with sterile compressed air at controlled pressure; this air continues to circulate by virtue of the fans
- cold cooling water circulates in the batteries of cooling plates located on the sides of the chamber.

However, the cooling rate is unavoidably much lower than in FOW autoclaves, since in this case it is based on two solid/gas heat exchanges, which notoriously have a low efficiency. Nonetheless, we try to improve their efficiency by keeping the air pressure in the chamber at a high value (within the limits set by the characteristics of the product) and by maintaining its circulation rate at high level.

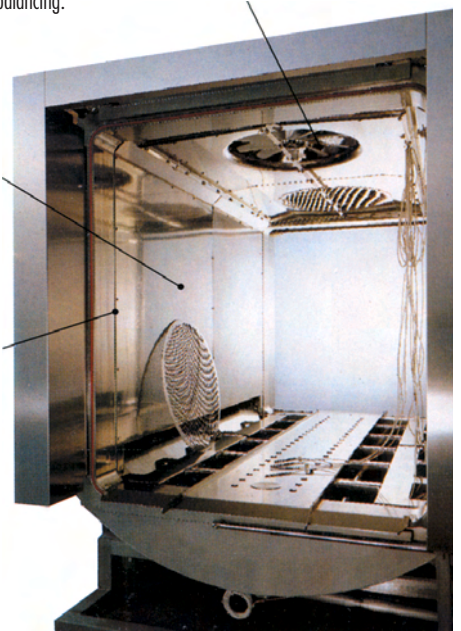
Throughout the phases of the program, air counterpressure in the chamber is adjusted in the same manner as in FOW sterilizers.

The pictures at the bottom of the page refer to a FOA sterilizer with two peculiarities. It is a mixed machine, i.e. suitable to run not only counterpressure processes with steam-air mixture but also saturated steam processes. To this end it is also equipped with a vacuum pump and with a sparger in the upper part of the chamber for the load water spray cooling.

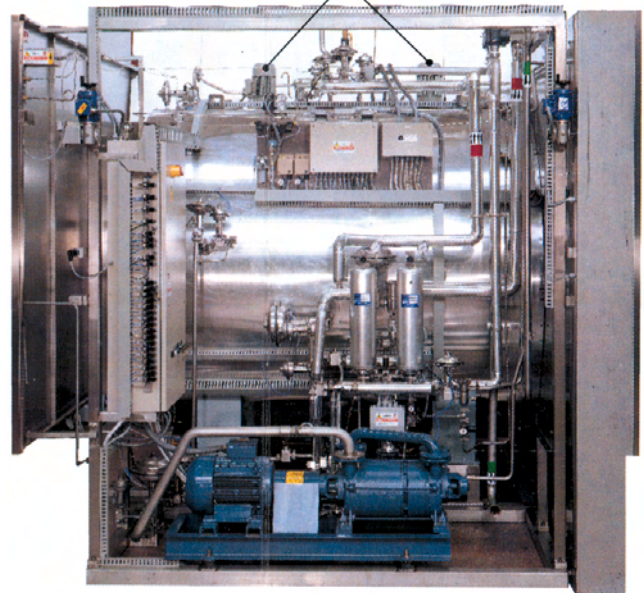
The internal impeller of the fan (the protection grid is removed). The vanes are made of a plastic material: they reduce the weight of the impeller and ensure extremely high efficiency and perfect static and dynamic balancing.

The flow deflectors. Ensure efficient and uniform circulation of the steam-air mixture during heating/sterilization and of the air during cooling.

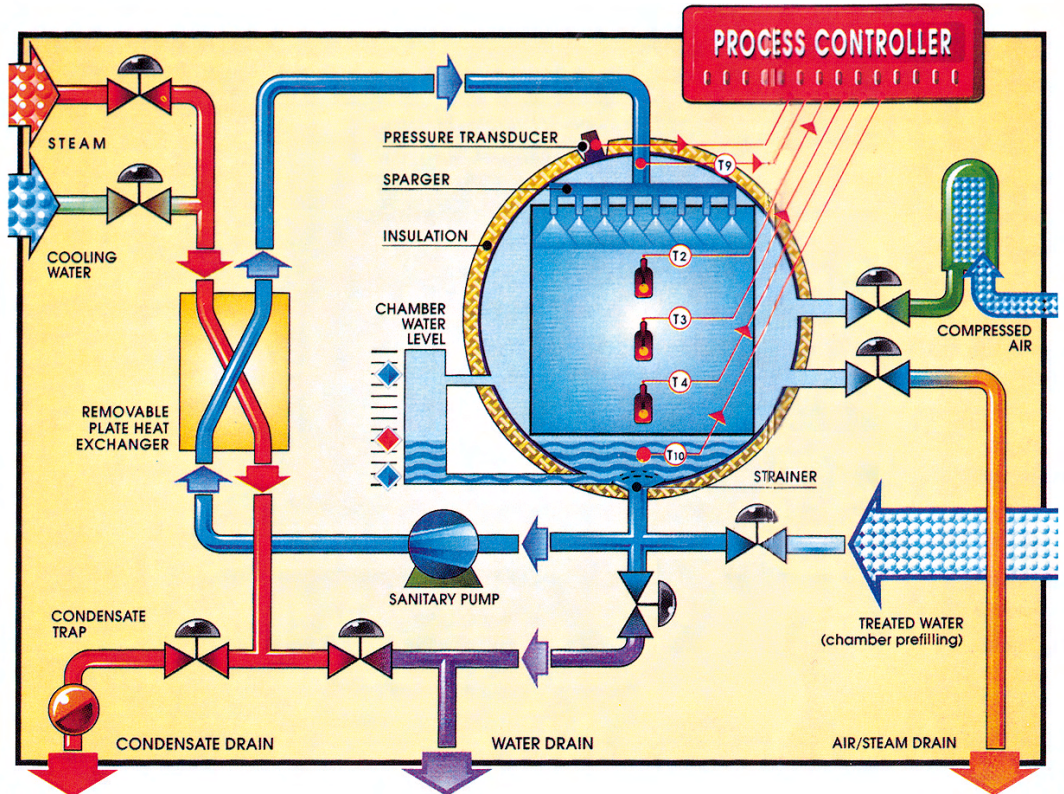
The battery of stainless-steel hollow plates for circulating the cooling water. These are definitely preferable to tube-type exchangers, since they produce high turbulence in the circulating water and thus improving heat exchange. They are also easy to disassemble and inspect. The plates are hidden by the flow deflector.



Motor fans with magnetic coupling: this solution removes any tightness problem deriving from seal wear, and minimizes maintenance, without requiring any lubrication.

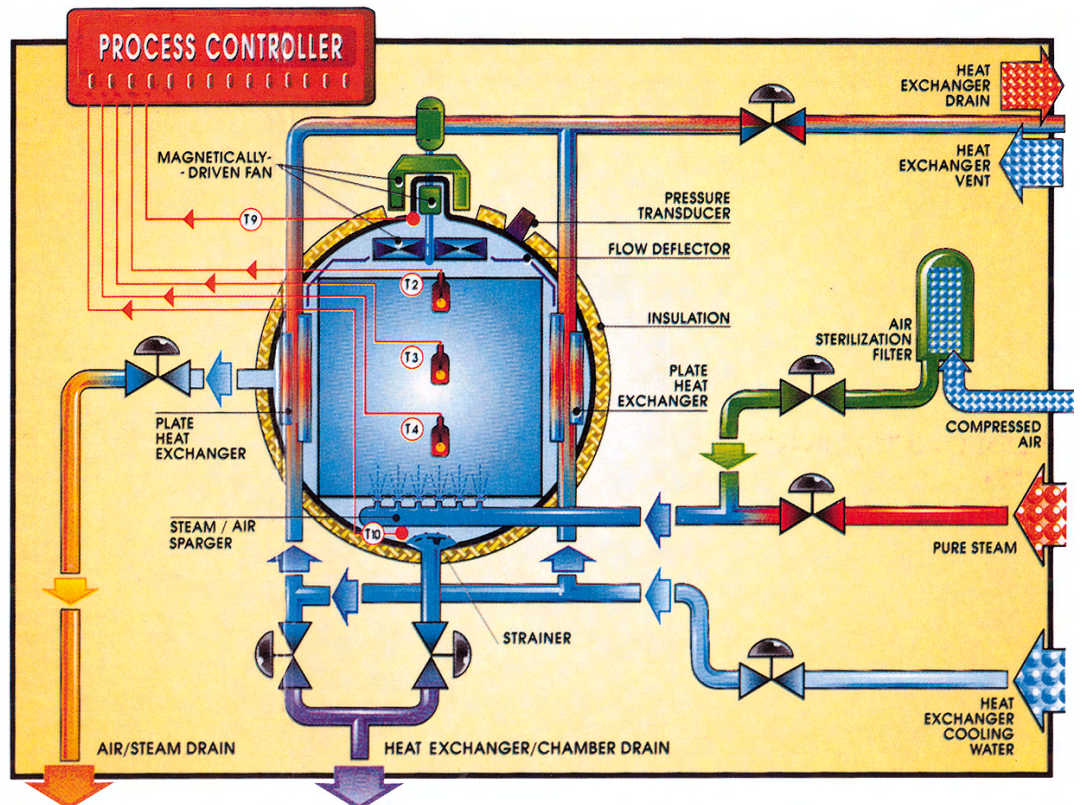


**FOW**



**SUPERHEATED WATER SPRAY STERILIZERS**

**FOA**



**STEAM-AIR MIXTURE STERILIZERS**

**FOW-FOA**  
**COUNTERPRESSURE STERILIZERS**

CRITICAL COMPARISON	FOW	FOA
Temperature uniformity in time	Very good	Very good
Temperature uniformity in space	Very good	Very good
Total pressure uniformity in time	Very good	Very good
Counterpressure management flexibility	Excellent	Excellent
Consumption of high-microbiological-quality water	Yes, modest, for initial filling	No
Consumption of top water for cooling	Yes, acceptable	Yes, approx. 3 - 4 times higher than FOW
Consumption of compressed air	Yes, acceptable	Yes, acceptable
Consumption of industrial steam	Yes, acceptable	No
Consumption of ultraclean steam	No	Yes, acceptable
Condensate recovery	Possible and easy	Not possible.
Cooling water recovery	Possible, recovered water is initially very hot.	Possible, recovered water is initially very hot.
Autoclave price	Acceptable	Approx. 10% higher than FOW
Total process duration	Short	Approx. 30% higher than FOW
Autoclave productivity/price	High	Approx. 30% lower than FOW
Operating principle	Very simple and straightforward	Plus FOW complex
Mechanical construction	Simple	Plus FOW complex
Qualification/Validation	Normal	Normal
Operating flexibility according to type of load	Suitable for any kind of container with the following remarks: <ul style="list-style-type: none"> <li>• upward concavities collect water</li> <li>• product is unloaded wet</li> <li>• PVC bags can produce "blushing" phenomena</li> </ul>	Suitable for any kind of container with the following remarks: <ul style="list-style-type: none"> <li>• upward concavities collect condensate only</li> <li>• other kind of container can be unloaded lightly damp</li> <li>• "blushing" phenomena of PVC bags is limited</li> </ul>
Possibility of combination with saturated steam processes	Possible, but involves significant and rather expensive solutions	Feasible and moderately expensive

# FOW·FOA

## COUNTERPRESSURE STERILIZERS



Testing of a cluster of three counterpressure sterilizers, with individual capacity of 20 m<sup>3</sup> each.

	FOW 3 FOA 3				FOW 4 FOA 4				
MODEL	450	720	900	1.080	1.200	1.440	1.800	2.160	2.700
<b>USEFUL CHAMBER DIMENSIONS</b>									
WIDTH (cm)	80	80	80	80	106	106	106	106	106
HEIGHT (cm)	80	80	80	80	115	115	115	115	115
DEPTH (cm)	130	210	250	310	165	210	250	310	370
CAPACITY ( l )	830	1.350	1.600	1.980	2.010	2.560	3.050	3.780	4.510
CYLINDER(Ø cm)	118	118	118	118	158	158	158	158	158
OPER. PRESSURE (abs bar)	4	4	4	4	4	4	4	4	4
OPER. TEMPERATURE (°C)	128	128	128	128	128	128	128	128	128

	FOW 5 FOA 5									
MODEL	2.160	2.700	3.240	3.600	4.500	5.400	6.300	7.200	8.100	
<b>USEFUL CHAMBER DIMENSIONS</b>										
WIDTH (cm)	130	130	130	130	130	130	130	130	130	
HEIGHT (cm)	150	150	150	150	150	150	150	150	150	
DEPTH (cm)	220	260	325	350	430	530	600	680	760	
CAPACITY ( l )	4.300	5.000	6.300	6.900	8.300	10.000	11.700	13.300	14.800	
CYLINDER(Ø cm)	200	200	200	200	200	200	200	200	200	
OPER. PRESSURE (abs bar)	4	4	4	4	4	4	4	4	4	
OPER. TEMPERATURE (°C)	128	128	128	128	128	128	128	128	128	

The above mentioned data are to be intended as indicative. The manufacturer reserves itself the right to change them without notice.

These tables list the basic characteristics of standard models.

Overall dimensions are not stated as they depend on the type door that is chosen; consumption figures are also not listed because they vary according to the type of load that is processed.

The full identification of the autoclave Model is e.g. FOW.4.1800. The last number (1800) is the approximate number of 500-ml glass bottles (according to DIN standard) that forms a complete load for that autoclave.

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