

FOB4 Serie TS



highlights

- user-oriented, functional and ergonomic design
- highly innovative modularity by design and construction with extremely flexible configuration
- enhanced safety, operating ease and high sterility assurance
- fast processing and improved productivity
- versatility: broadest selection of programs and applications
- excellent quality standards and most-advanced sterilization technology

**Horizontal high pressure steam sterilizer
FOB4 Serie TS fully automatic**

The **NEW** Fedegari **FOB4 serie TS** is suitable for use in many different applications in Laboratory, Industry as well as in Healthcare sector as:

- Microbiology and Analytical Labs
- Research Institutes and Examination Agencies
- Bio-Technologies and Life Sciences
- Animal facility and Test Laboratories
- Pharmaceutical, Food and Chemistry industries, Q.C. Labs and small production batches
- Hospital operating Theatre and Medical care

Its use in highly specialised fields and attractive niche markets worldwide that demand exclusive, reproducible and validated processes is assured.

The valued results derive from know-how, expertise and continuous improvement and renewal of the products and services which satisfy customer's expectations and FEDEGARI AUTOKLAVEN AG is proud to present the new floor cabinet steam sterilizer **FOB4 serie TS** which combines excellent performance with overall high quality materials, simplicity of use and optimum consumption.

The **FOB4 serie TS** sterilizer has specially designed with ergonomical features for easy handling of higher volume sterilization treating materials and goods as: Glassware, media preparation, liquids in open and sealed containers, mixed wastes/regular and high risk, as well as surgery instruments, textiles, rubber articles, etc. for Hospital use.

www.fedegariautoklaven.ch

designing

- Free standing single door or recessed with double doors for pass-through application.
- Vertically Automatic sliding doors, effortless pneumatically operated, for efficient use of Laboratory and Hospital space.
- 650 mm inner chamber diameter for easy accommodation of internal loading equipment with optimal processing capability and throughput.
- Built-in, External or combined steam source.
- High-tech chamber and doors system construction.
- Superior quality of materials with first class finishing and components all rigorously tested at Fedegari, for long term reliability and process safety.
- Massive, long-lived pressure vessels PED certified, exclusive pneumatic valves and hydraulic components made of high corrosion resistant 316L S.S., sanitary grade.
- Unique opening / closing door system with patented pneumatic gasket seal - perfect airtight, safety and maximum reliability.
- Lowest loading height, reduced overall dimensions.
- Rolling wheels for easy moving during installation and service.
- Operation of the unit from both ends by operator panel and display fitted on loading and unloading sides.



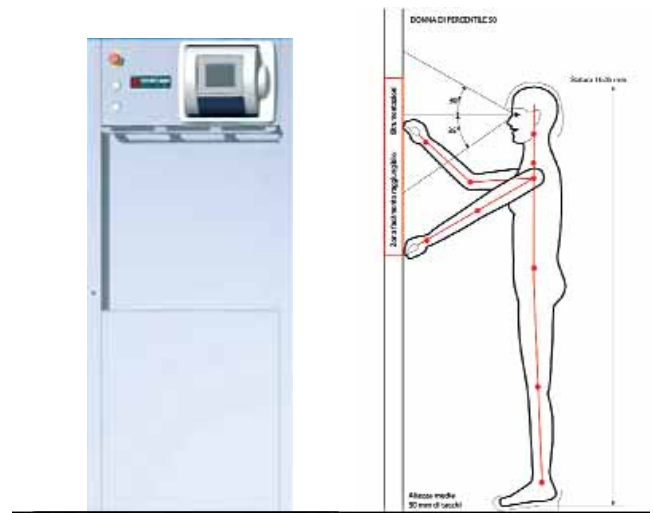
model overview

Model	Type	Nominal chamber volume (litres)	Chamber dimensions ØxD mm.	Overall dimensions (WxHxD) mm.	Useful capacity litres / STE (1)
FOB4-TS	1-door	260	650 x 700	860x1850x1012	147 / 2
FOB4S-TS	2-doors	360	650 x 950	890x1923x1270	210 / 3
FOB4/L-TS	1-door	360	650 x 950	860x1850x1270	210 / 3

(1) 1 STE = 300 x 300 x 600 (mm)

special benefits

- improved performances thanks to more efficient and faster processings.
- short batch times and optimum drying.
- small foot print with superior loading capacity.
- slim width (less than 900 mm) allowing easy installation in narrow area with reduced access.
- ergonomic positioning of adjustable operator display and built-in process printer on the eye level.
- full and easy accessibility to technical area from the front and lateral side for service and regular maintenance.
- Wide variety of loading trolleys, internal racks, shelves, transfer cars, trays and containers, customized solutions for individual needs.
- high level of programming and application flexibility with fully configurable cycles.
- multilevel password management for authorized access only.
- special standard test programs (i.e. Bowie-Dick, vacuum, pressure leak test, heating programs, etc.) for routine check of sterilizer efficiency.
- **GMP / GLP** compatible data management offering full traceability and documentation meeting the most stringent worldwide safety and quality standards.



most comfortable ergonomics

technical key-features

- custom-made solutions and process upgrading in very short time for extended technological life of product
- energy and water cost-saving devices for optimal consumption of services
- high-efficiency internal 316 L stainless steel plate heat-exchanger system for steam pre-heating, perfect final drying and water accelerate cooling
- supporting pressure device by compressed air for preventing solutions over-boiling during forced cooling
- reliable, high-efficiency vacuum system
- extra safety device in compliance with TRB402, thermal interlock to prevent door opening
- maximum precision and stability of temperature sensor and pressure transducers for highest level of safety and reproducibility
- all sterilization cycles clearly documented by a compact built-in process printer or in graphic form with a A4-deskjet printer (by customer)
- datalogger for separate systems for process control and recording
- fully programmability: 15 standard sterilization programs easy to customize in a multi-user environment.
- automatic delayed start-up and stand-by mode programmed for utility saving
- **NEW CMA** PLC controller with large touch-screen color video-graphic display for maximum using comfort and more intuitive interface
- operating software fully validated and documented to conform with the rigorous pharma standards for reproducible processes
- exclusive new management software for **CFR21 part11** compliant with electronic signature, audit trail and data archiving with **ethernet protocol** connection
- **optional MDD** certification and **CE mark** according to European Medical Directive and EN285 / EN554 for hospital theatre use and medical device batches



Color touchscreen with synoptic display



Graphic cycle display



Decontamination of exhaust air with sterile filter



Separate steam generator



Sanitary diaphragm valve in 316L stainless steel with pneumatic actuator for maximum reliability and tightness.

optional kits tailored to suit your technical and budgetary needs

All the models can be configured using various customised systems guaranteed by the wide range of process and software options and the extensive choice of accessories.

The basic version of the sterilizer can already be used for standard processes and is easy to configure, thanks to its design concept and modular construction, with a series of interesting and exclusive options kits, the most important of which are:

1. integrated 316L st. steel electric steam generator fully automatic with independent operation and control.
2. pre- and post-vacuum processes, single or fractionated with high-output water-ring vacuum pump.
3. exclusive high-efficiency fast cooling module for liquid programs.
4. unique decontamination cycle for high-risk pathogenic wastes.
5. **NEW** sterilization program with complete cycle by steam / air - mixture in counter-pressure for delicate treatment of small batches as blister packs, contact lenses, carpules, syringes, solutions in glass / plastic bottles or bags (PVC, PP, PE), etc.
6. effluent discharge air filtration kit for wastes treatment with automatic filter sterilization
7. special execution with single or double sealing flange plate (sterile and / or non sterile side) for laboratory risk category L3 and L4 and operating theatre
8. **NEW** air detector and sample steam kit for compliance to **HTM 2010**
9. **NEW** automatic program for pharmacopea cycle on hydrolytic resistance of glass containers
10. **NEW** management software **CMA-link** for remote supervision and downloading to external user PC, data archiving, A4-size printout with cycle diagram, synoptic display, etc.
11. **NEW** exclusive conformity kit to **CFR21 part11** with **ethernet protocol** interface
12. precise and detailed documentation and **IQ/OQ/PQ** validation procedures