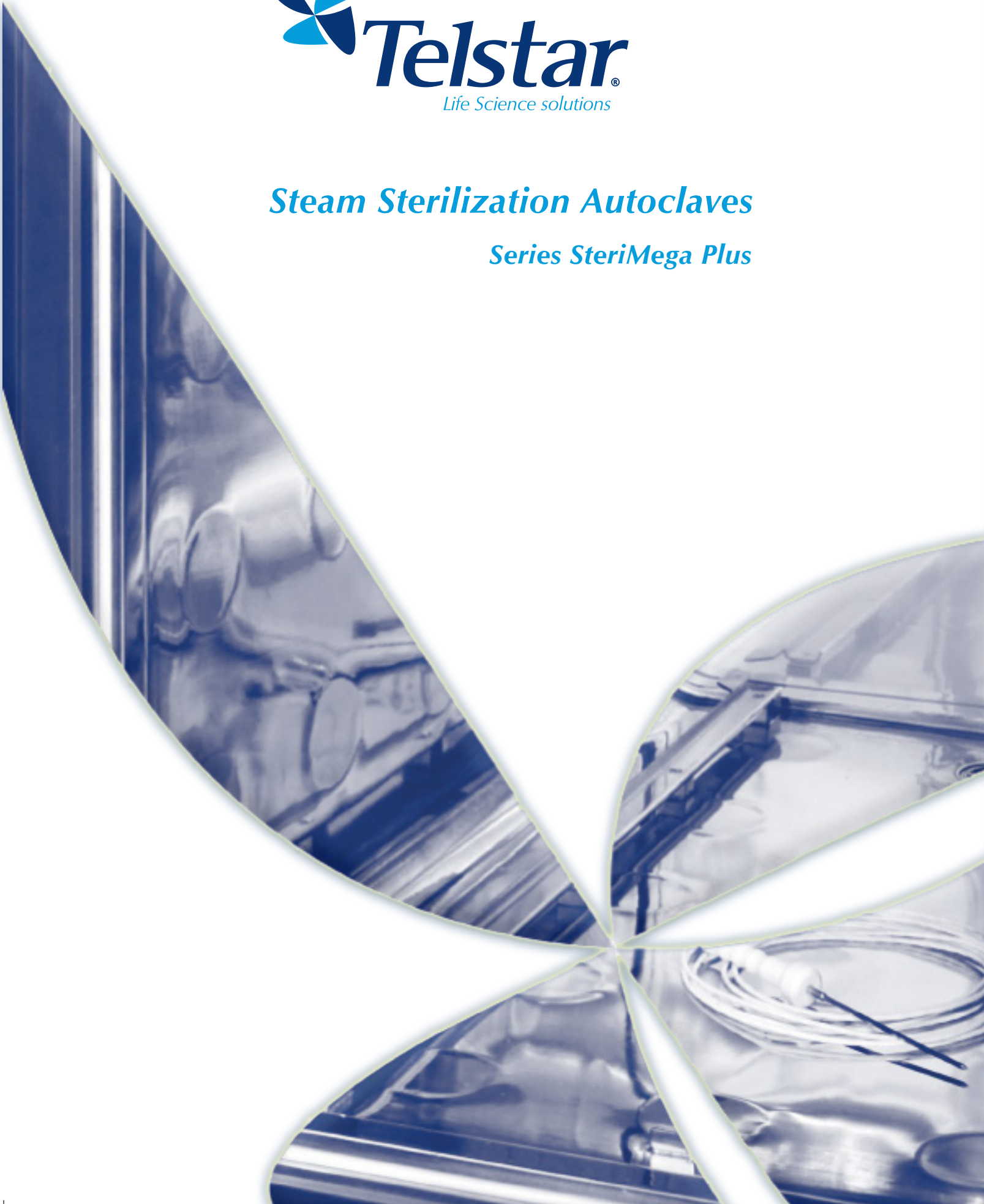




Steam Sterilization Autoclaves

Series SteriMega Plus



Telstar SteriMega Plus

A choice of quality

Telstar has been developing sterilization systems for the pharmaceutical and medical devices industries as well as for R&D laboratories and animal facilities for over 30 years. We have focused our experience in the field of sterilisation equipment under cGMP guidelines so we are nowadays one of the market leaders and trendsetters in this segment worldwide.

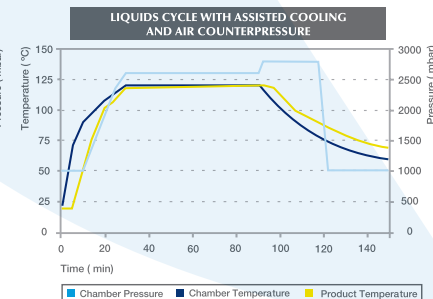
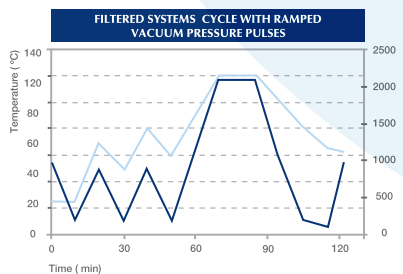
Engineering and manufacturing practices follow ISO 9001 procedures, ASME BPE criteria, GAMP guidelines, etc. Design and construction meets the most stringent Regulations and Codes from Europe, USA and others concerning Safety and Pressure Vessels.

To ensure the equipment meets your requirements, we work in partnership with you and a dedicated team follows your order as a unique project. We develop specific Quality Plans (DQ, IQ and OQ) and undertake factory acceptance testing (FAT).



Multiple cycle possibilities

SteriMega Plus steam autoclaves offer you a high degree of cycle versatility: dry goods and porous loads are available as standard. The control system allows you to adjust vacuum/pressure rates, number of pulses, dwell time, etc. Standard configuration also includes pre-programmed cycles such as Bowie & Dick test, Automatic chamber leak test and Automatic SIP vent filter.



Standard and Cycle options

| Cycle types available | Type of load | SM-V | SM-H |
|---|--------------|----------|----------|
| Gravity displacement (fast exhaust) | S | Standard | Standard |
| Gravity displacement (slow exhaust) | LV, SV | Standard | Standard |
| Saturated steam with vacuum drying | S, P | Standard | Standard |
| Saturated steam with assisted cooling by water in jacket | LV, SV | Option | Option |
| Saturated steam with heated pressurised pulses | BRS | Option | Option |
| Saturated steam with assisted cooling by direct water cooling with/without ΔT control | LS | - | Option |
| Saturated steam with assisted cooling by fan and cooling coils | LS | - | Option |
| Steam + Air mixture with smart ΔP control | LS | - | Option |
| Superheated water shower with smart ΔP control | LS | - | Option |

SteriMega Plus Autoclaves Range

S: Solid items
P: Porous loads
LV: Liquids in vented containers
LS: Liquids in sealed containers
BRS: Bagged rubber stoppers

Design & construction features

Durable Construction

The chamber, doors and process pipe work are constructed in stainless steel AISI 316L for better **resistance to stress fatigue and corrosion.**

Door seals by means of a special silicone gasket which does not require permanent lubrication. Option it is coupled with a compressed air back up system.

Design for GMP

The chamber and door inner surfaces are mechanically polished to $Ra \leq 0.76 \mu\text{m}$ as standard, with the longitudinal edges rounded to facilitate cleaning. Option to $Ra \leq 0.51$ is also available.

Piping joints are orbital or TIG welded. Removable connections are preferred, with in-line sanitary fittings sealed with pharmaceutical grade gaskets.

All pipe work connected to the chamber and chamber floor slopes towards the drainage and dead legs are minimised to **avoid fluids stagnation.**

An air differential seal separates the technical area from the cleanroom or contained laboratory.





Process Reliability

The chamber internal surfaces are insulated and heated by means of separated black steam flowing through a full dimple jacket. Pure steam inlet is controlled with a PID valve and condensates are continuously evacuated through the drainage offering you **excellent uniformity of temperatures**; better than $\pm 0.5^{\circ}\text{C}$ during all the sterilisation phase. Fulfilling the requirement of EN-285.

Safety and Ergonomic Design for Users

The double access hinged panels at the front-side of the equipment are unique feature in that they provide unrestricted access for maintenance without the need to provide additional space at the side of the equipment. This enables installation in a very compact space compared to the more traditional approach. In fact, 95% of the steam autoclaves on the market are designed access to the technical area from the side, which means providing space additional to the footprint of the equipment.

The compact technical area is designed to save space but keeping in mind ease of maintenance, allowing access to components and replacement of spares. Potential hot piping is insulated.

Option in addition to the hinged front-facing access panels, the chamber access door is also able to be swung on hinges when in the open position, irrespective of whether its motion is side-to-side or vertical. This action further facilitates maintenance access and enables a more thorough cleaning process.

The OEM components like valves, filters and measuring instruments and so, are of the highest quality and state of the art technology. They are sourced from first brands widely available in the marketplace. Full material certificates, instrumentation calibration certificates are traceable to national standards and certificates of conformity are provided.



Control systems

The unit is controlled by a PLC, which contains the operating programme and parameters for creating and storing recipes or cycles. The control panel features:

- Colour touch-screen that displays the main functions and performs as human-machine interface (HMI).
- Control lights: Locked doors, Alarm, Cycle running, End of cycle
- Push buttons: Open/Close door, Alarm acknowledgement
- Chart recorder (option)

The supervisory and control system has **two versions**:

HMI MicroSter®

The Microster® is the simplest version, accurate and easy to use, ideal for research laboratories, quality control and auxiliary service equipment. This version includes a thermal printer for recording main events and parameters of the cycle: Cycle parameters, readings, alarms, etc.



SCADA PharmaSter®

As option, the unit is supplied with our complete SCADA control system PharmaSter®. This system includes an industrial PC with touch-screen colour display. The software allows not only for supervision and control of the process, but also compiling, storing and processing the whole information in a batch oriented mode. The system is fulfilling 21 CFR Part 11 guidelines.

Technical data

| MODEL | Inner chamber dimensions | | | Chamber Volume l | Overall dimensions | | | Approx. weight kg | Door sliding motion |
|----------|--------------------------|-----------|----------|------------------|--------------------|-----------|----------|-------------------|---------------------|
| | Width mm | Height mm | Depth mm | | Width mm | Height mm | Depth mm | | |
| 5512 V | 500 | 500 | 1.200 | 300 | 1.345 | 2.200 | 1.620 | 1.200 | Vertical |
| 6612 V | 600 | 600 | 1.200 | 432 | 1.545 | 2.200 | 1.620 | 1.500 | Vertical |
| 6617 V | 600 | 600 | 1.700 | 612 | 1.545 | 2.200 | 2.120 | 1.700 | Vertical |
| 8812 V | 800 | 800 | 1.200 | 768 | 1.785 | 2.200 | 1.620 | 2.100 | Vertical |
| 8817 V | 800 | 800 | 1.700 | 1.088 | 1.785 | 2.200 | 2.120 | 2.350 | Vertical |
| 81012 H | 800 | 1.000 | 1.200 | 960 | 2.250 | 2.200 | 1.620 | 2.700 | Horizontal |
| 81017 H | 800 | 1.000 | 1.700 | 1.360 | 2.250 | 2.200 | 2.120 | 3.000 | Horizontal |
| 101212 H | 1.000 | 1.250 | 1.200 | 1.500 | 2.650 | 2.500 | 1.660 | 3.500 | Horizontal |
| 101217 H | 1.000 | 1.250 | 1.700 | 2.125 | 2.650 | 2.500 | 2.160 | 4.200 | Horizontal |
| 101512 H | 1.000 | 1.500 | 1.200 | 1.800 | 2.750 | 2.500 | 1.660 | 3.900 | Horizontal |
| 101517 H | 1.000 | 1.500 | 1.700 | 2.550 | 2.750 | 2.500 | 2.160 | 5.100 | Horizontal |
| 101520 H | 1.000 | 1.500 | 2.000 | 3.000 | 2.750 | 2.500 | 2.460 | 5.300 | Horizontal |
| 122112 H | 1.200 | 2.100 | 1.200 | 3.024 | 3.280 | 3.000 | 1.700 | 5.900 | Horizontal |
| 122117 H | 1.200 | 2.100 | 1.700 | 4.284 | 3.280 | 3.000 | 2.200 | 7.600 | Horizontal |
| 122120 H | 1.200 | 2.100 | 2.000 | 5.040 | 3.280 | 3.000 | 2.500 | 7.800 | Horizontal |

Note: Other chamber sizes are available under request. Please contact telstar@telstar.com for further information.

Options and accessories

Beside of the optional cycles already stated, these are the different P&ID, layout or mechanical options available under request.

- Additional temperature probes for control/monitoring/independent recording
- Additional pressure transducer for back-up/independent recording
- EN 285 steam test connectors
- EN 285 air detector
- FWIT front panel connections
- Hinged door instead of sliding motion type
- Chamber mechanical polished to Ra < 0.51 µm
- Pit mounted arrangement
- Left-hand sided chamber
- Delivery in two pieces
- Gas-tight barrier (bioseal), one or both sides
- Integrated electric steam generator
- Automated cart loading-unloading systems



Headquarters

Av. Font i Sagué, 55
Parc Científic I Tecnològic Orbital 40
08227 Terrassa (Spain)
☎ +34 937 361 600
☎ +34 937 861 380

United Kingdom

Unit 4, Shaw Cross
Business Park
Horace Waller VC Parade
Dewsbury West Yorkshire
WF12 7RF (UK)
☎ +44 (0) 1924 455 339

North America

1504 Grundy's Lane
Unit 1
Bristol, PA 19007 (USA)
☎ +1 215 826 0770
☎ +1 215 826 0222

China

No. 30 Jin Wen Road,
Zhu Qiao Airport
Ind. Zone, Nanhui District
201323 Shanghai
☎ +86 21 58 093 731
☎ +86 21 58 092 857

www.telstar-lifesciences.com

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