



Telstar® ***Celester***
SteriMega

*GMP Steam
Sterilisation Autoclaves*



A choice of quality

Telstar Celester represents nowadays one of the most advanced and quality alternatives worldwide in the field of sterilisation equipment under cGMP guidelines.

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).

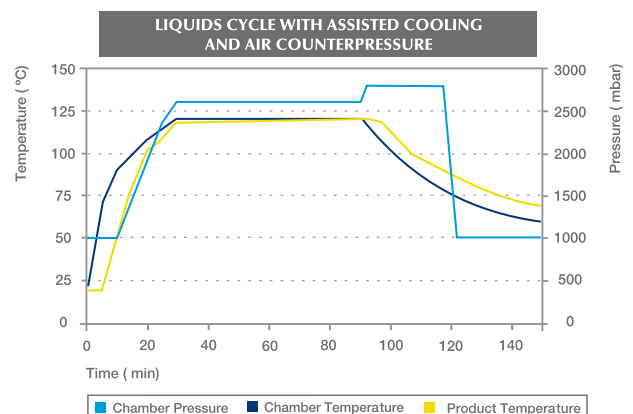
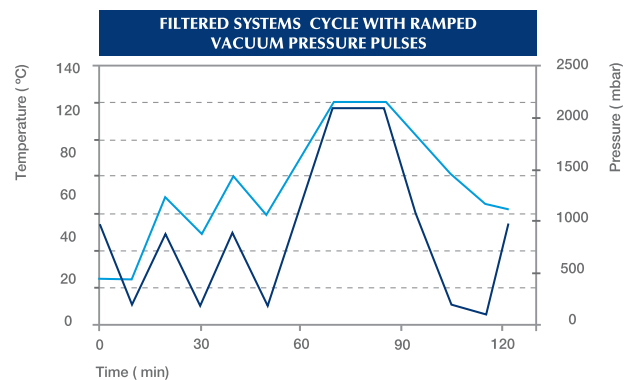


Multiple cycle possibilities

SteriMega 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 vent filter SIP.

Cycle Options

- Cycles for liquids in vented containers: Indirect jacket cooling with air counter pressure.
- Cycles for liquids in sealed containers: Direct cooling with water shower, with or without ΔT control.
- Cycles for rubber stoppers: Heated pressurised pulse drying or complete processing.
- Decontamination cycles: Containment of chamber drain and aerosols for processing contaminated materials (BSL3).



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.

The supervisory and control system has two versions:

HMI MicroSter[®]



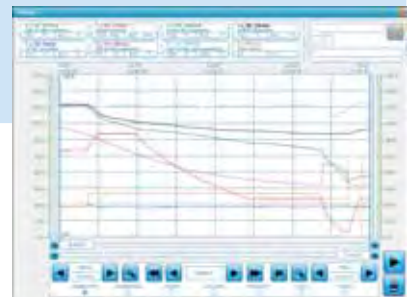
The MicroSter is the simplest, accurate and easy to use version, ideal for research laboratories, quality control and auxiliary service equipment. This version includes a thermal printer for recording main events and parameters of the cycle: Operator identification, Batch No., Batch description, Cycle parameters, readings, etc.



SCADA PharmaSter[®]

As option, the unit is supplied with our complete SCADA control system PharmaSter. This system includes an industrial PC with sensitive-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.



Design & construction features

Durable Construction

The chamber is constructed in stainless steel AISI 316L for better resistance to stress fatigue and corrosion. Jacket, door/s, door frame and process pipe work are constructed in stainless steel AISI 316L.

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

Hygienic Design

Chamber and door inner surfaces are mechanically polished to $Ra \leq 0.5 \mu\text{m}$, with the longitudinal edges rounded to facilitate cleaning.

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.

A SPF seal (bioseal) separates the technical area from the clean room or contained laboratory.





Process Reliability

The chamber is insulated with a full dimple jacket, heated with separated steam for better pressure control. Steam inlet is controlled by a PID valve and condensates are continuously evacuated through the drainage offering you an excellent uniformity of temperatures; better than $\pm 0.5^{\circ}\text{C}$ during all the sterilisation phase.

Safety and Ergonomic Design for Users

The double door chambers incorporate the necessary interlocks, and each door has precaution mechanisms to ensure maximum operator safety.

The technical area is designed for ergonomic maintenance, with enough access to components and ease replacement of spares without almost using tools. Potential hot piping is insulated with chloride free mineral wool within an external stainless steel AISI 304 sheet.

OEM components like valves, filters and measuring instruments are of the highest quality and represent state of the art technology, which makes them widely available in the marketplace. Full material certificates, instrumentation calibration certificates are traceable to national standards and certificates of conformity are provided.



Technical data

| MODEL | Inner chamber dimensions | | | Chamber | Overall dimensions | | | Approx. | Door sliding motion |
|-----------|--------------------------|-----------|----------|----------|--------------------|-----------|----------|-----------|---------------------|
| | Width mm | Height mm | Depth mm | Volume l | Width mm | Height mm | Depth mm | Weight Kg | |
| SM 5510 | 500 | 500 | 1.000 | 250 | 1.270 | 2.000 | 1.410 | 1.350 | vertical |
| SM 6610 | 600 | 600 | 1.000 | 360 | 1.370 | 2.000 | 1.410 | 1.400 | vertical |
| SM 6612 | 600 | 600 | 1.250 | 450 | 1.370 | 2.000 | 1.660 | 1.450 | vertical |
| SM 7710 | 700 | 700 | 1.000 | 490 | 1.470 | 2.000 | 1.410 | 1.500 | vertical |
| SM 7712 | 700 | 700 | 1.250 | 613 | 1.470 | 2.000 | 1.660 | 1.600 | vertical |
| SM 7715 | 700 | 700 | 1.500 | 735 | 1.470 | 2.000 | 1.910 | 1.800 | vertical |
| SM 71010 | 700 | 1.000 | 1.000 | 700 | 2.090 | 2.000 | 1.410 | 1.900 | horizontal |
| SM 71012 | 700 | 1.000 | 1.250 | 875 | 2.090 | 2.000 | 1.660 | 2.050 | horizontal |
| SM 71015 | 700 | 1.000 | 1.500 | 1.050 | 2.090 | 2.000 | 1.910 | 2.150 | horizontal |
| SM 71020 | 700 | 1.000 | 2.000 | 1.400 | 2.090 | 2.000 | 2.450 | 2.450 | horizontal |
| SM 81010 | 800 | 1.000 | 1.000 | 800 | 2.380 | 2.000 | 1.450 | 2.100 | horizontal |
| SM 81020 | 800 | 1.000 | 2.000 | 1.600 | 2.380 | 2.000 | 2.450 | 2.700 | horizontal |
| SM 101010 | 1.000 | 1.000 | 1.000 | 1.000 | 2.690 | 2.200 | 1.450 | 2.500 | horizontal |
| SM 101012 | 1.000 | 1.000 | 1.250 | 1.250 | 2.690 | 2.200 | 1.700 | 2.650 | horizontal |
| SM 101015 | 1.000 | 1.000 | 1.500 | 1.500 | 2.690 | 2.200 | 1.950 | 2.800 | horizontal |
| SM 101020 | 1.000 | 1.000 | 2.000 | 2.000 | 2.690 | 2.200 | 2.450 | 3.200 | horizontal |
| SM 101210 | 1.000 | 1.250 | 1.000 | 1.250 | 2.690 | 2.450 | 1.490 | 2.400 | horizontal |
| SM 101212 | 1.000 | 1.250 | 1.250 | 1.563 | 2.690 | 2.450 | 1.740 | 2.700 | horizontal |
| SM 101215 | 1.000 | 1.250 | 1.500 | 1.875 | 2.690 | 2.450 | 1.990 | 2.900 | horizontal |
| SM 101220 | 1.000 | 1.250 | 2.000 | 2.500 | 2.690 | 2.450 | 2.490 | 3.600 | horizontal |
| SM 101510 | 1.000 | 1.500 | 1.000 | 1.500 | 2.690 | 2.500 | 1.490 | 3.150 | horizontal |
| SM 101512 | 1.000 | 1.500 | 1.250 | 1.875 | 2.690 | 2.500 | 1.740 | 3.300 | horizontal |
| SM 101515 | 1.000 | 1.500 | 1.500 | 2.250 | 2.690 | 2.500 | 1.990 | 3.500 | horizontal |
| SM 101520 | 1.000 | 1.500 | 2.000 | 3.000 | 2.690 | 2.500 | 2.490 | 4.200 | horizontal |

Note: Other chamber sizes are available. Please contact sales.pharma@telstar.eu for further information.

Options and accessories

- Indirect jacket cooling.
- Direct cooling with water.
- Additional temperature probes.
- Additional channels in standard chart recorder
- Loading accessories: racks, pallets, trolleys, etc.
- Air detector.
- Complete panelling.
- Maintenance access door.
- SCADA PharmaSter supervision and control system.

Special Designs

- Customised chambers according to existing loading accessories.
- Design for decontamination applications in biosafety laboratories (BSL3).
- Fans and cooling coils for liquid loads processing.
- Integrated pure steam generators.
- Chamber with CIP system.
- Integration to isolators.
- Automatic loading/unloading system.



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