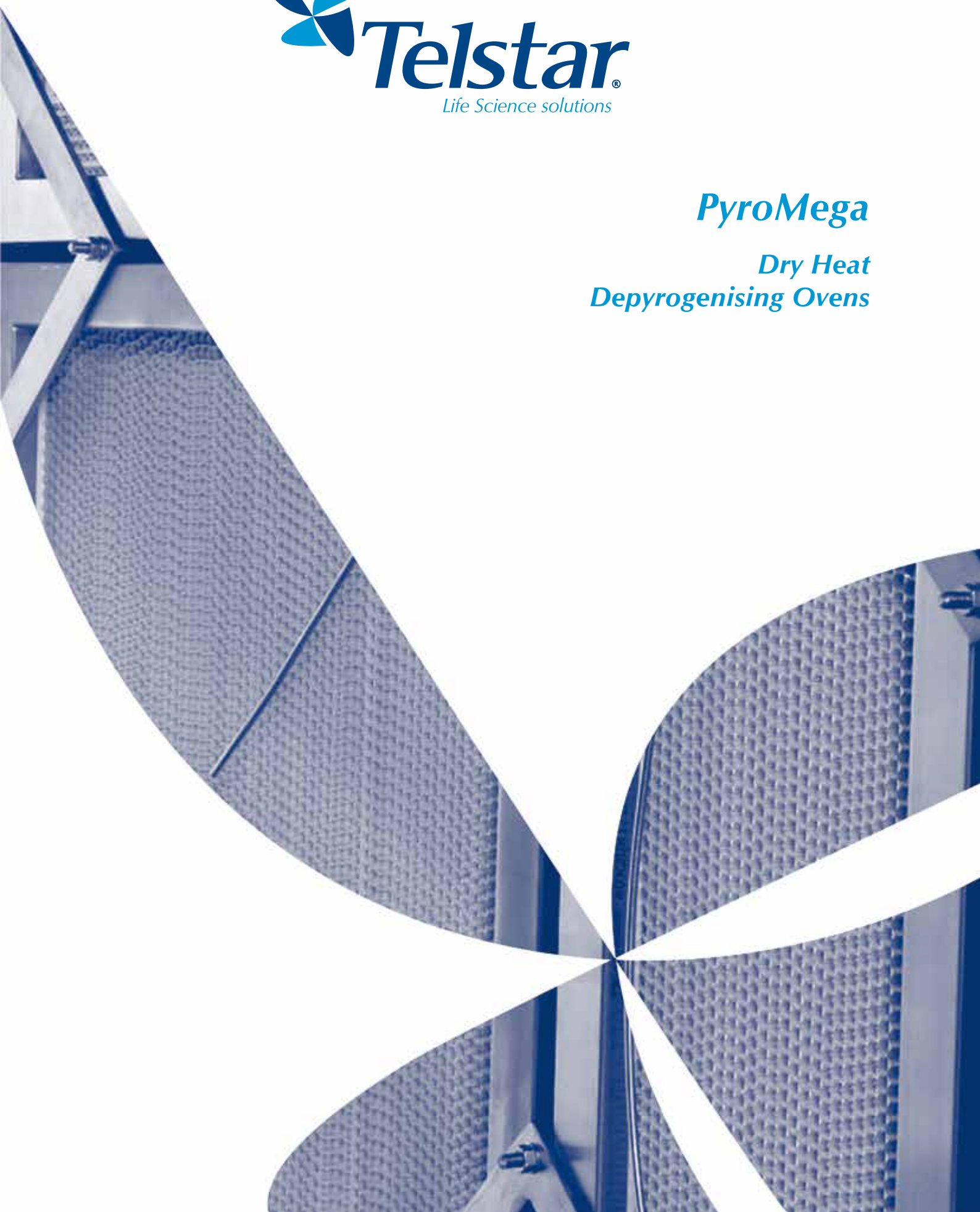
Telstar®
Life Science solutions

PyroMega

Dry Heat Depyrogenising Ovens



Telstar PyroMega

A choice of quality

Telstar 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, USP and EU pharmacopoeias, GAMP guidelines, etc. Our aim is to make your validation faster, easier and efficient for you.

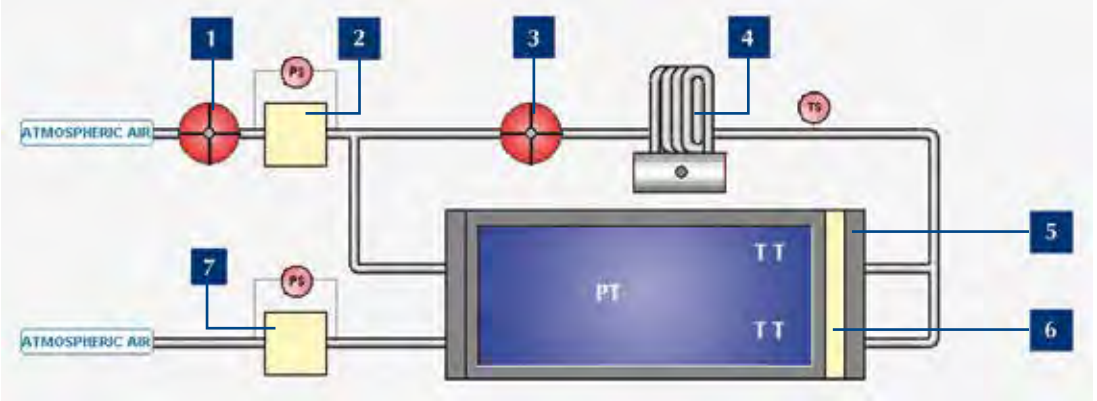
To ensure the equipment meets your requirements, we work in partnership with you and a dedicated team follows your order as a unique project. We develop specific Quality Plan (DQ, IQ and OQ) and undertake factory acceptance testing (FAT).

Operating principle

Air is blown by a centrifugal fan (1) to a stage one filtering box (2) and heated up by a set of electrical heaters (4). Before entering into the chamber air passes through a stage two HEPA set of filters DOP efficiency ≥ 99.99% at 0.3 µm rated for working at high temperatures (5). As a result, our depyrogenising chambers are rated ISO 5.

Chamber air is then recycled by a fan (3) through a drilled stainless steel plate (6), designed for adjusting hot air flow according to the load level. This design allows achieving a uniform distribution of air inside the chamber.

Another HEPA filter (7) is placed at the air outlet to prevent the entry of possible non-sterile air that could contaminate the load. To achieve a rapid and effective cooling, there is a proportional air renewal.



Design & construction features

Durability, Ease of Maintenance

All parts submitted to high temperatures are made of mirror polished AISI 316L stainless steel, with an external cladding in AISI 304. Thermal insulation with 120 mm rock wool is procuring better yields and energy savings.

Ergonomic and Reliable Design

Standard models feature chamber dimensions to provide easy handling of the load and maximum filtration area. The loading cart has to be sized for being transported by one person and the load should be fully processed under ISO-5 air flow. The chamber dimensions are directly influencing these factors.

Validable, Meets GMP Requirements

Telstar uses only first class OEM components which are widely available in the market, making easier its maintenance and replacement operations. Our internal filters have unique advantages:

- Meet FDA requirements - continuous 350°C, 99.99% at 0.3 µm.
- Pass exclusive treatment process at 300°C carried out in the plant.
- Efficiency tested after treatment.

Telstar ovens are designed to attain temperature uniformity better than ± 5°C rated at 250°C with the empty chamber. These results ensure obtaining temperature distributions in a repetitive way throughout the whole chamber, as per United States Pharmacopoeia (USP) statements.

Productivity, Monitoring, Operational Safety

A differential pressure transducer controls the chamber overpressure with regard to the clean room. Another one controls the chamber filter pressure drop, warning automatically in case of HEPA filters clogging. There is a side port for Pt100 probes for validation purposes.

Control systems

The unit is PLC controlled, which contains the operating software 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.
- Graphic register.

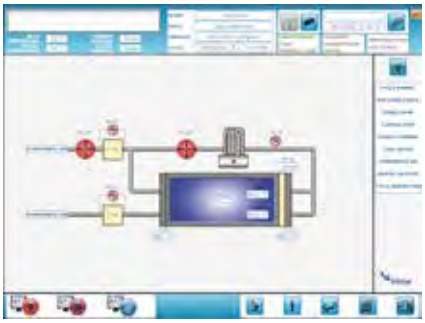
The supervisory and control system has two versions:

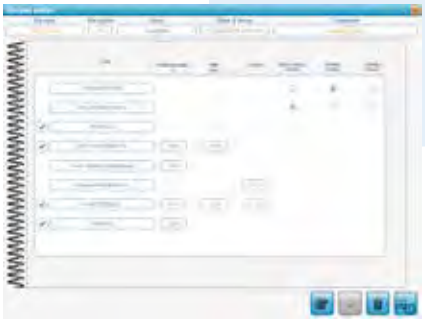
HMI MicroSter®

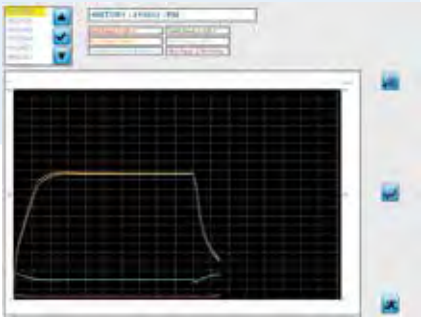
The MicroSter® is the simplest version, accurate and easy to use, ideal for research laboratories, quality control and auxiliary service equipment. This version includes a thermal printer for recording main events and parameters of the cycle: Operator identification, Batch No., Batch description, Cycle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

SCADA PharmaSter®

This system includes a PC and TFT colour display. The hardware and software package solution 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 fully compliant with 21 CFR Part 11 guidelines.







Technical data

MODEL	Inner chamber dimmensions			Chamber Volume	Overall dimmensions			Approximate Weight
	Width mm	Height mm	Depth mm	l	Width mm	Height mm	Depth mm	Kg
PM 350	600	680	830	339	1.600	2.000	1.080	1.200
PM 500	700	840	830	488	1.700	2.000	1.080	1.300
PM 1000	900	1.000	1.150	1.035	1.900	2.000	1.400	1.600
PM 1500	1.030	1.300	1.140	1.526	2.030	2.150	1.390	1.900
PM 2000	1.030	1.300	1.450	1.942	2.030	2.150	1.700	2.200
PM 2500	1.030	1.620	1.450	2.419	2.030	2.470	1.700	2.500
PM 3000	1.030	1.620	1.770	2.953	2.030	2.470	2.020	2.800
PM 3500	1.030	1.620	2.070	3.454	2.030	2.470	2.320	3.100
PM 4000	1.030	1.620	2.390	3.988	2.030	2.470	2.640	3.400
PM 5000	1.030	1.620	3.010	5.022	2.030	2.470	3.260	4.000

Please contact **telstar@telstar.com** for further information.

Options and accessories

- Cooling design by integrating a water heat exchanger, or by air renewal.
- Additional temperature probes.
- Additional data registering devices in standard graphic register.
- Loading accessories: loading carts, trolleys, trays, etc.
- Complete panelling.
- Maintenance access door.
- SCADA control systems, 21 CFR Part 11 compliant.

Check for the nearest Telstar office at
https://www.telstar.com/international/

Headquarters
Av. Font i Sagué, 55
08227 Terrassa (Spain)

T +34 937 361 600
F +34 937 861 380

www.telstar.com
marketing@telstar.com

Telstar
Life Science solutions

ISO 9001: Certified Company

BR-PYROMEGA-EN-0621
Telstar reserves the right to improvements and specifications changes without notice.