

Equipment Basic Configuration

Leak tightness	Overall system pressure rise less than 2×10^{-2} mbar l/s. Largest individual leak less than 1×10^{-7} mbar l/s.
Vacuum measurement	Pirani type vacuum gauge at chamber (1) and at vacuum system (1).
Vacuum control	Via automatic opening and closing of the vacuum system valve.
Venting filter	0.22 μ m
Internal CIP	Chamber and condenser internal piping and nozzles. Liquid ring vacuum pump.
Process valves	AISI 316L angle seat valves on process side. Pneumatic actuation.
Control system	Manual, semiautomatic and automatic operation. PLC controlled with touch screen interface and chart recorder. UPS included.
Internal testing	Execution of internal test protocols.
Standard documentation package	Instruction and maintenance manuals, as built drawings (layout, P&IDs, electrical and pneumatic diagrams, etc.), material and instrumentation calibration certificates.

Options and Accessories*

1	SIP	Pressure vessel. Sanitary diaphragm valves in process piping. Sterilizable filter. Liquid ring pump for condensate draining and drying. SIP temperature sensor PT100, pressure transducer and sterilizable chamber vacuum sensor. Door locking with peripheral pins. GB pressure directive.
2	PED directive	Design and construction of chamber and condenser.
3	Jacket cooling	Water circulation through chamber reinforcements for fast cooling after sterilization.
4	FSIP	Automatic filter sterilization in place (FSIP) and valves for manual WIT.
5	Independently controlled FSIP	Configuration for filter sterilization cycle independent from equipment SIP.
6	Redundant filter	Second venting filter installed in series.
7	Internal CIP	Included in the basic unit. Customer to supply the water at the required flow and pressure. CIP control not included.
8	Integrated CIP impulsion system	Condenser vessel is utilized as a water tank. Includes a sanitary centrifugal impulsion pump and integration with control system.
9	CIP external impulsion system	Comprises an external skid with tanks, a sanitary centrifugal impulsion pump and a sanitary suction pump. Includes integration with control system.
10	Stoppering device	Hydraulically operated ram. Pressure applied at the shelves adjustable up to 1.5 kg/cm^2 . Zero clearance system (shelves can be fully closed). Unbraided flexible hoses for thermal fluid.
11	Stoppering bellows	Stainless steel 316L.
12	Bellows leak test	Automated bellows leak test integrated with the control system.
13	Constant height	Constant height loading and unloading system. Built-in position transducer for fine shelf height positioning.
14	Main door automatic locking	Pneumatically operated mechanically linked set of peripheral pins. Automatic door latching. Position detectors to ensure correct locking.
15	Slot door	Manual locking hinged slot door.
16	Slot door automatic locking	Automatic upward opening/downward closing slot door with mechanical locking device.
17	Shelf interdistance manual changeover	Set of spacer rods to change the standard shelf interdistance by stacking two or more shelves, provided that stoppering device or shelf movement system is included.
18	Back-up compressor	Additional compressor operating in back-up mode.
19	Screw compressors	Replacement of the standard reciprocating compressors with screw type compressors. Includes variable frequency drives (VFD) for motors.
20	Electronic expansion valves (Coolstar)	Replacement of the standard mechanical expansion valves with electronic type valves for improved accuracy and efficiency.
21	Back-up fluid circulation pump	Installation of an additional circulation pump operating in back-up mode.
22	Dry vacuum pumps	Replacement of the standard oil-sealed vacuum pumps by dry pumps.
23	Back-up vacuum pump	Installation of an additional vacuum pump operating in back-up mode.
24	Microbleed vacuum control valve	Substitution of the standard vacuum control of on/off valve between vacuum system and condenser with a PID controlled microbleed valve.

*Tick your selections

Options and Accesories*

25	Capacitance vacuum gauge	Substitution of the chamber Pirani vacuum gauge by a capacitance manometer.
26	Loading/unloading automation (Lyogistics)	Manual and semi-automatic solutions for bulk and vial applications.
27	Product trays	Set of AISI 316L stainless steel internally polished trays for vial or bulk applications.
28	SCADA package	Substitution of the touch screen HMI by a PC and SCADA control system with user-friendly graphical interface.

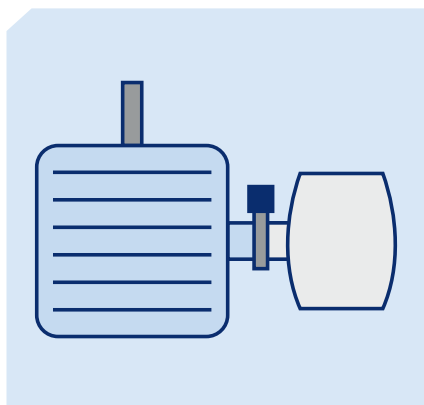
Documentation and Validation Options*

29	FAT	Includes a one-week FAT at Telstar's premises in Shanghai, China with client present (upon request FAT can be performed in Europe).
30	System qualification documentation (QPP, FS, DQ and FAT)	Generation and delivery of the QPP, FS and generation of DQ and FAT protocols compiled and executed by Telstar in accordance with GAMP 5.
31	System qualification documentation (QPP, FS, DQ, FAT and IQ/OQ protocols)	Generation and delivery of the QPP, FS; generation of DQ and FAT protocols compiled and executed by Telstar in accordance with GAMP 5 and preparation of IQ/OQ protocol templates.
32	IQ/OQ execution	To complement the system qualification documentation option, IQ/OQ protocols are executed at customer site by Telstar.
33	Software validation documentation	Generation of a complete set of documentation qualifying design and testing of the software modules in accordance to GAMP 5.

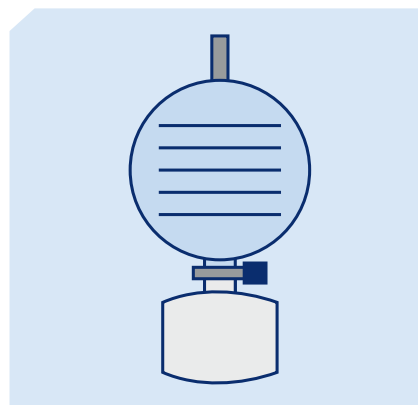
Service Options*

34	Freeze-drying support services	Development and/or optimization of freeze drying recipes available upon request.
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Lyonomic Configurations*



Lyonomic DH/RC
Horizontal configuration:
2 Vessels,
Rectangular chamber,
Cylindrical condenser.



Lyonomic DV/CC
Vertical configuration:
2 Vessels,
Cylindrical chamber,
Cylindrical condenser.

Remarks & Comments

*Tick your selections

