

Equipment Basic Configuration

Configuration	Rectangular chambers with separate ice condenser, all models mounted on an open frame, monoblock skid or customized skid containing all components. Control equipment located in a separate cabinet.
Chamber	Mirror finish AISI 316L Roughness of 0.4 µm Ra for product contact parts. Equipped with safety valve, validation flange, drain, illuminated sightglass, instrumentation nozzles. Insulated with vapour barrier and with brush finish metal cover cladding.
Chamber door	Mirror finish AISI 316L Roughness of 0.4 µm Ra for product contact parts hinged door with silicon seal, sightglass, insulated with vapour barrier and clad with brushed finish 304L stainless steel cover.
Shelves	C type shelves manufactured in AISI316L Roughness 0.4 µm Ra with mirror finish.
Ice condenser	Horizontal configurations, coiled pipe refrigerated by direct expansion of refrigerant /diathermic fluid recirculation/Liquid nitrogen rated for approximately 20kg/m2 load. Equipped with safety valve, thermoprobes, drains, illuminated sightglass, instrumentation nozzles, defrost manifold. Insulated with vapour barrier and clad with brushed finish metal.
Main valve	AISI 316L Mirror Finish mushroom type with silicon seal, hydraulically actuated.
Refrigeration system	2 stage reciprocating semi-hermetic/screw compressors. Separate circuits with control and safety instrumentation. Sufficient capacity to provide shelf cooling to -55°C and condenser cooling to -75°C. HFC refrigerants with electronic expansion valves.

Electronic expansion valves	Greater precision in the control of the refrigeration system is provided by electronic expansion valves compared with mechanical equivalents.
Vacuum system	Pumpdown to 0.1 mbar within 30 minutes provided by oil sealed rotary pumps (plus roots blower on some models) fitted with isolation valves and mist filters
Leak tightness	Overall system pressure rise test less than 0.01mabr l/s.
Vacuum measurement	Capacitance manometers MKS type gauge.
Vacuum control	Automatic control using proportional needle valve.
Control system	Manual, semi-automatic and automatic operation. PLC controlled with PC based Graphical user interface with printer and recorder. Slave LYOCORE range control system based on customer request PLC/HMI, DCS.
PLC	Siemens S7-1500
Heat Exchange	Silicon oil circulating medium with hermetic/magnetic drive pump/s and expansion tank; plate exchangers cooled by direct refrigerant expansion; multi-element electrical heating. Shelf temperature control $\pm 1^{\circ}\text{C}$
Process valves	AISI316 Stainless steel product contact surfaces. Diaphragm, butterfly and all type valves with pneumatic actuation.

Sanitary valves	Butterfly and ball valves exposed directly to the product are substituted by sanitary diaphragm valves (except for drain and vacuum valves). This option is included if SIP is selected.
Temperature sensors	RTD product temperature measurement; heat exchange medium; individual condenser circuits.
Electrical standards	NNEC, EN60204-I, JIS alternates
Safety standards	CE
Vendor internal testing	Execution of internal test protocols
Standard documentation package	Standard documentation package: Instruction and maintenance manuals, as built drawings (layout, P&IDs, electrical and pneumatic diagrams, etc.), material and instrumentation calibration certificates. FAT, SAT, IQ and OQ.

Option and Accessories

SIP	Vessels built from AISI316L stainless steel to comply with design codes to enable sterilization of chamber and condenser with steam at up to 126°C。 Includes all controls and instrumentation required for the process. Water ring pump for post-sterilization drying included. sterilization at up to 130°C is available, on request.
Pressure vessel codes	ASME; PED and GB150 alternatives.

Vent filter	A-Hydrophobic sterile filter housing, piping and valves to filter gas vented into chamber for vacuum break and control; B-as A configured for manual in- situ integrity test; C-as A with two housing in series; D-as C configured for manual in -situ integrity test.
Auto FIT-WITHin	The optional vent filter configurations B and D may be further enhanced with an embedded test protocol providing results of the filter element integrity test within LYOCORE's SCADA and batch report.
cooling jacket	For accelerating the cooldown of a chamber after SIP by flowing cooling water/diathermic fluids through an external jacket.
CIP	Fixed and rotary nozzles mounted on manifolds to enable water to be sprayed at pressure onto internal surfaces of the chamber and condenser. AISI316L material
CIP recirculation	System comprising a clean pump with instrumentation and controls to increase efficiency by recirculating water used during the CIP process.
Loading trays	AISI316L stainless steel trays and /or fences for products in bulk and containers. Various sizes available.

Hydraulic shelf movement	Hydraulically actuated system employing a stainless steel piston for moving the shelves, to utilize the easy loading 'of larger machines with vials or bulk trays.
Hydraulic stoppering	Hydraulically actuated system employing a stainless steel piston for moving the shelves to enable vials to be sealed within the chamber.
Stoppering bellows	AISI316L bellows shroud for the hydraulic shelf movement piston to further reduce the possibility of extraneous contamination. Includes controls and instrumentation for testing the bellows' integrity.
Main valve bellows	AISI316L bellows shroud for the actuating rod of the main value to further reduce the possibility of extraneous contamination. Includes controls and instrumentation for testing the bellows' integrity.
Variable shelf interdistance	Shelves can be latched to provide double shelf interdistance or variable shelf interdistance to accommodate large product containers.
Variable frequency driver	VFD system allows better control of refrigeration screw compressors optimizing shelf set point temperature control and shelves uniformity. Smoother compressors start up minimizing mechanical wear. Considerable energy saving during freeze drying cycle.

Additional compressor	It can be supplied to improve the redundancy to the cooling system.
Screw compressors	Substitution of 2-stage, semi-hermetic, screw compressors for the standard reciprocating models. Compared with reciprocating types, screw compressors provide greater efficiency and reliability whilst requiring less maintenance and generating lower noise.
Compressor variable speed drives	The compressor's speed can vary between 30Hz and 60Hz.Soft starting and stoppering reduces, and operation at low speed extends maintenance periods. Controlling the compressor speed reduces electrical power consumption as well as system noise.
Fluid circulation condenser	Instead of the standard coil direct expansion of refrigerant, condenser cooling can be performed by low viscosity silicone oil through plate heat exchangers. This solution allows full condenser redundancy.
Enhanced heater	Capable of heating shelves from -40°C to +40°C(measured when shelves are empty) at a rate of 2 °C/minute.
Back-up vacuum pump	For systems supplied with a single primary vacuum pump, dual pump are supplied to provide back-up should the duty pump fail
Dry vacuum system	To eliminate the possibility of oil backstreaming from rotary pumps and reduce maintenance, dry vacuum pumps may be substituted for the standard oil sealed type.
UPS	An uninterruptible power supply to provide electrical powder to the control system for at least 20 minutes should the main power supply fail
eSignature	Software compliant with 21 CFR part 11

GAMP5	Documentation regarding the control system compliant with GAMP5 standard
Alternate layout	The refrigeration group may be mounted on a discrete frame and located separately from the chamber and condenser, including separate floors. Configurations may also be adapted to accommodate loading and unloading requirements
Solvent handling	LYOCORE may be configured to handle non-aqueous solvents. Your sales contact will be pleased to arrange a proposal for specific requirements.
Potent product	LYOCORE may be configured to handle toxic materials. Your sales contact will be pleased to arrange a review to enable a proposal to be provided for specific product requirements.
Liquid nitrogen refrigeration system	Shelf and condenser be cooled by liquid nitrogen instead of compressor refrigeration. The redundant magnetically driven seal-less centrifugal pumps will be utilized in liquid nitrogen system for shelf circulation. Ultimate shelf temperatures: -65°C (in conjunction with 1.6cSt silicone oil); Condenser ultimate temperature, direct liquid nitrogen cooled: -100°C.