LYOFAST SERIES

INDUSTRIAL FREEZE DRYERS

IMA LIFE

Aseptic Processing & Freeze Drying Solutions

LYOFAST SERIES

The Lyofast range of freeze dryers provides support for all of your lyophilisation requirements. Lyofast offers superior quality, reduced lead times, cost-effectiveness and simplifies the validation process. The base model specifications meet all leading industry standards and the broad range of configurable options enable Lyofast freeze dryers to be tuned to your specific requirements.

Model	Chamber / Condenser Geometry	Manual Loaded				Auto loaded				Min. condenser capacity (kg @ 12.7mm ice)
		Shelf area up to (m^2)	Minimun Shelf spacing (mm)	Number of usable shelves up to	Maximum vials loading capacity (2R vial)	Usable shelf area range (m^2)	Minimun Shelf spacing (mm)	Number of shelves up to	Maximum vials loading capacity (2R vial)	
Lyofast 1	**Cylindrical Integral**	1.4	80	5	5,700	-	-	-	-	27
Lyofast 3	**Cylindrical Integral**	2.8	80	5	11,500	-	-	-	-	67
Lyofast 5	**Cylindrical Integral**	5.1	80	9	20,700	-	-	-	-	101
Lyofast 7	**Cylindrical Integral**	7.8	80	9	46,600	-	-	-	-	148
Lyofast 5	**Rectangular Integral**	5.4	90	7	24,100	5.4	110	7	23,700	92
Lyofast 7	**Rectangular Integral**	7.4	100	5	30,200	7.0	110	5	30,900	136
Lyofast 10	**Rectangular Integral**	10.4	100	7	42,300	9.7	110	7	43,300	186
Lyofast 15	**Rectangular Integral**	16.3	100	7	66,100	15.4	110	7	68,700	252
Lyofast 20	**Rectangular Integral**	22.3	90	12	90,700	21.2	110	12	94,200	359
Lyofast 25	**Rectangular Integral**	26	100	14	105,800	24.7	110	14	109,900	455
Lyofast 30	**Rectangular Integral**	32.5	90	14	132,300	30.8	110	14	137,500	528
Lyofast 35	**Rectangular Integral**	36.3	100	13	149,700	34.7	110	13	154,700	635
Lyofast 40	**Rectangular Integral**	47.4	80	17	195,800	40	110	15	178,600	731
Lyofast 5	**Rectangular Cylindrical**	5.4	90	7	24,100	5.4	110	7	23,700	101
Lyofast 7	**Rectangular Cylindrical**	7.8	100	7	31,700	7.3	110	7	32,400	148
Lyofast 10	**Rectangular Cylindrical**	12.3	80	11	49,800	11.5	110	11	50,900	194
Lyofast 15	**Rectangular Cylindrical**	17.9	80	12	72,500	16.7	110	12	74,200	263
Lyofast 20	**Rectangular Cylindrical**	22.3	90	12	90,700	21.2	110	12	94,200	389
Lyofast 25	**Rectangular Cylindrical**	26	100	14	105,800	24.7	110	14	109,900	476
Lyofast 30	**Rectangular Cylindrical**	32.5	90	14	132,300	30.8	110	14	137,500	553
Lyofast 35	**Rectangular Cylindrical**	36.3	100	13	149,700	34.7	110	13	154,700	635
Lyofast 40	**Rectangular Cylindrical**	47.4	80	17	195,800	40	110	15	178,600	731

STANDARD EQUIPMENT SPECIFICATIONS

Chamber	Mirror-finished 316L and other inert materials used for product contact parts. Equipped with safety valve, validation flange, drain, illuminated sightglass, instrumentation nozzles. Insulated with vapour barrier and clad with brushed finish metal cover.
Chamber door	The full size chamber main door features internal 316L stainless steel surfaces. Hinged with silicon seal. Sightglass, insulated with vapour barrier and clad with brushed finish, stainless steel cover.
Shelves	Advanced IMA LIFE Fusion™ shelves manufactured form AISI 316L with brushed satin finish, mirror-finished edges. 0.5 mm/m flatness.
Ice condenser	Vertical or integral configurations. Coiled pipe refrigerated by direct expansion of refrigerant. Equipped with safety valve, thermoprobes, drains, illuminated sightglass, instrumentation nozzles, defrost manifold. Insulated with vapour barrier and clad with brushed finish metal.
Main valve	316L stainless steel mushroom type with silicon seal, hydraulically actuated.
Refrigeration system	2 stage reciprocating semi-hermetic, water-cooled. 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 direct expansion.
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 40 minutes provided by oil sealed rotary pump(s) fitted with isolation valves and mist filters.
Vacuum measurement	Active Pirani type gauge.
Vacuum control	Automatic control using modulating valve (MKS).
Control system	Semi-automatic and automatic operation. PLC controlled with PC based Graphical User Interface with printer and recorder. Slave panel for process room operation.
Heat exchange	Silicone oil circulation medium with centrifugal pump/s and expansion tank; plate exchangers cooled by direct refrigerant expansion; multi-element electrical heating. Shelf temperature control precision +/-1°C
Process valves	Main process valves including diaphragm and AISI 316 stainless steel product contact surfaces.
Condenser water regulator valves	Thermostatically controlled valve fitted to the cooling water inlets of the refrigerant condensers to optimise operation efficiency of the refrigeration system and minimise the consumption of cooling water.
Temperature sensors	Type-T Thermocouples are used as product probes, and Class A PT100 are used as process control probes.
Pressure vessel codes	ASME, PED or GB150
Electrical standards	NEC or EN60204-I
Safety standards	CE or OSHA

Lyofast Series range is conceived to address the critical supply chain issues of cost effectiveness and timely supply. IMA LIFE's Lyofast freeze dryers provide customers with a range of popular process capacities and accessories.

Model	Condenser Layout				
	Cylindrical Back Integral	Rectangular Bottom Integral	Rectangular Side Integral	Rectangular chamber Separated Condenser	Two-story
Lyofast 1	√				
Lyofast 3	√				
Lyofast 5	√	√		√	
Lyofast 7	√	√		√	
Lyofast 10		√		√	
Lyofast 15		√		√	
Lyofast 20			√	√	√
Lyofast 25			√	√	√
Lyofast 30			√	√	√
Lyofast 35			√	√	√
Lyofast 40			√	√	√

LYOFAST OPTIONAL ACCESSORIES

SIP	Vessel built from AISI 316L stainless steel to comply with design code to enable sterilisation 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-sterilisation drying included. Sterilisation at up to 130°C is available on request. F_0 process control and dual drain temperature probes for redundancy are ready for options.
Vent filter	One (1) or two (2) hydrophobic sterile filter housing, piping and valve to filter gas vented into chamber for vacuum break and control. Filters are sterilized in place on SIP machines only.
Off-line manual WIT integrity testing (A)	The filter housing(s) is/are mounted with tri-clamp connections to the clean piping section, in order to allow off-line integrity testing or SIP of the filter(s).
In-situ manual WIT integrity testing (B)	Optionally the integrity of the vent filter(s) can be checked in-line via manual WIT integrity test valves, a tester is not provided.
Auto FIT- External (C)	The optional vent filter configuration "B" may be further enhanced with automatic valves and signal interface connections enabling communication with an external filter element integrity test device. The remote tester is programmable to control the test and records the detailed test data/report, and the freeze dryer will display a pass/fail result.
Auto FIT- WITHinTM * (D)	The optional vent filter configurations "B" may be further enhanced with an embedded test protocol providing results of the filter element integrity test within Lyofast's SCADA and batch report. The system also includes a sterilisable tank for collecting the test water, designed to condense the clean steam by 7°C cooling water supplied by customer.
Cooling jacket	To speed up chamber cooldown after SIP by passing cooling water or fluid medium 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. AISI 316L material.
CIP recirculation	System comprising a clean pump with instrumentation and controls: a sanitary, non-sterilised, CIP re-circulation pump with piping system, or Sterilisable CIP re-circulation systems are available on request.
Drain cooling heat exchanger	To reduce the maximum drain temperature to less than 60°C for SIP/CIP option.
Drain sampling valve	Allows the sampling of CIP drain water.
Loading options	Freeze dryer is pre-arranged for different automatic loading and unloading system, including fixed or flexible system.
Slot door	A sliding slot door enables loading onto the shelves whilst minimising exposure of the chamber to the environment. Useful when loading onto chilled shelves or interfacing with an assisted loading system. Slot door can be supplied fitted to a main chamber door or within a chamber wall. A fixed bridge plate is included with the slot door to assist with loading and unloading of trays. A tilting slot door allows cleaning of the rear side of the slot door in critical applications.
Loading trays	AISI 316L stainless steel trays and/or fences for productions in bulk and containers. Various sizes available.
Hydraulic stoppering	Hydraulically actuated system employing a stainless steel piston for moving the shelves to enable vials to be sealed within the chamber.
Automatic stoppering pressure control	Being a recipe parameter, the stoppering pressure can be set within the SCADA and is automatically controlled using a pressure transducer and a proportional pressure regulator valve.
Main valve bellows	AISI316L bellows shroud for the actuating rod of the main valve to further reduce the possibility of extraneous contamination. The pump down time of the bellows can be automatically monitored as a check of the bellows' integrity.
Stoppering bellows	An AISI 316L stainless steel bellows can be provided to isolate the hydraulic ram from the drying chamber to further reduce the possibility of extraneous contamination. The pump down time of the bellows can be automatically monitored as a check of the bellows' integrity.
Variable shelf inheritance	Shelves can be latched to provide double shelf interdistance or variable shelf interdistance to accommodate larger product containers.
Fusion™ Plus shelves	The bottom surfaces of the shelves are provided with a surface treatment to greatly reduce the probability that stoppers will stick to the shelf after stoppering.
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 less noise.
Additional compressor	Can be supplied to improve the redundancy of the cooling system.
Compressor variable speed drives	The compressor's speed can be varied between 30 and 60 Hz (depending on local specification). Soft starting and stopping reduces stress and operation at low speed extends maintenance periods, controlling the compressor speed reduces electrical power consumption as well as system noise.
Different refrigerant	Different type of refrigerant, such as R410A/R448A, can be proposed for different application.
Compressor pressure transducers	To replace standard pressure switches and mechanical gauges for screw compressor option.
Back-up vacuum pump	For systems supplied with a single primary vacuum pump, dual pumps are supplied to provide back-up should the duty pump fail.

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Booster vacuum pump	A booster may be added to reduce pump down time.
Dry vacuum system	To eliminate the possibility of oil back streaming from rotary pumps and reduce maintenance, dry vacuum pumps may be substituted for the standard oil sealed type.
Absolute pressure measurement	A heated (125°C) capacitance manometer provides greater vacuum measurement accuracy.
Redundant absolute pressure measurement	Redundant chamber capacitance manometers and condenser capacitance manometer are available on request.
Drying end point package	In addition a Pirani gauge is also installed on the chamber. Comparison of the chamber capacitance manometer and Pirani gauge readings can be used to determine when primary freeze drying is complete.
Redundant fluid inlet probes	A second PT100, class A RTD for redundancy.
Redundant circulation pump	A second circulation pump provides redundant back up for the circulation of heat transfer fluid. A redundant magnetic coupling circulation pumps is also available when required.
Isolation valves around circulation pump(s)	To be used for troubleshooting or maintenance.
Dual heater elements	Includes dual heater elements and SCR controls.
Enhanced Heater	Capable of heating shelves from -40 to +40°C (measured when shelves are empty) at a rate of 2°C/minute.
Low viscosity heat transfer oil	1.6cSt silicone oil will improve the shelf minimum temperature uniformity.
Non flammable heat transfer fluid	SafeTherm, a non flammable alternative, not only has equivalent performance compared to low viscosity silicone oils but has the added benefit of being non-flammable.
Fluid circulation condenser	1.6cSt silicone oil, or SafeTherm can be supplied in fluid circulation condenser.
PLC	Allen Bradley RS Logix 5000 PLC can be provided as an alternative to Siemens S7 series.
iClient	It allows full access to the main SCADA system, and provides the basic main operation function same as the main SCADA. Desktop PC or touch screen PC are available as option selected.
eSignature	Software compliant with 21 CFR part 11.
Dual language	The batch report can be generated in two languages. The SCADA is provided with two switchable interface languages.
Chart recorders	A Yokogawa 60 math channel recorder.
Media fill cycle	A programmed cycle for aseptic process validation.
Configurable batch report	This option provides the flexibility for a user to easily configure batch reports to their specific needs at any time during the system's lifecycle. With over 100 user selectable parameters., this opting provides the ultimate solution to satisfy changing needs.
Data recovery	RAID PC Level 5, other level options possible.
Additional security levels	7 security groups are included (administrator, developer, maintenance 1, maintenance 2, supervisor, operator and public).
Maintenance Screen	It provides motor run details, maintenance intervals, and temperature sensor calibration.
System performance test cycle	A test cycle can be performed to check the machine performance automatically.
Device Mode	It provides controlling individual motors or valves with incorporating all necessary interlocks for maintenance purpose.
SECOMEA Remote Access	Using a Secomea Site Manager, which is an internet modem that provides controlled access to installed IMA equipment from our offices and creates a secure connection between the IMA engineer and the equipment.
Cycle Queue	Some cycles may place into a queue for consecutive execution without operation input to start each cycle.
Editable Format for Historic Data Export	Historic data export to WINDOWS Excel® format is available for analysis.
UPS	An uninterruptible power supply to provide electrical power to the control system for at least 10 minutes should the main power supply fail.
Sterility Monitoring	After the completion of a successful SIP cycle, any function that affects machine sterility is monitored.
Integration with IMA Line SCADA Supervisor	Freeze dryer control system integration with IMA line SCADA supervisor.
IQ/OQ	A package of IQ/OQ protocols that integrates with Lyofast's Vendor Internal Test package provides a seamless structure for equipment validation. IMA Life is able to assist with undertaking IQ/OQ activities as site.
GAMP5	Documentation regarding the control system compliant with GAMP5 standard.
Non-aqueous solvent handling	Lyofast may be configured to handle non-aqueous solvents. Your sales contact will be pleased to arrange a proposal for specific requirements.
Potent product	Lyofast may be configured to handle potent materials. Your sales contact will be pleased to arrange a review to enable a proposal to be provided for specific product requirements.
VERISEQTM * Ice Fog	Integration with VERISEQ Ice Fog controlled nucleation system.
Quantum Mass Spectrometer	Integration with smart miniature Quantum Mass Spectrometer.

Note: *WITHin is a trademark of Sartorius Stedim/VERISEQ is a trademark of Linde.

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