LYOFAST MINI SERIES

FREEZE DRYERS FOR CLINICAL TRIALS & PRODUCT DEVELOPMENT





LYOFAST MINI SERIES

The Lyofast MINI range of lyophilisers, with its comprehensive options, will meet many of the requirements of a pilot or small size freeze dryer.

It provides a 'direct line of sight' as required by the FDA, between the pilot type freeze dryer which is suitable for scale-up and the larger full production freeze dryers. The Lyofast MINI range is the ideal solution for pilot work or production for clinical trials.

Its small size also allows for product development and process cycle optimisation.

The product is available in 4 different configurations, with shelf areas going from 1.1 to 2.8 m². Ice condenser capacities range from 28 kg to 58 kg with minimum condenser temperatures of -75°C.

Product shelves are designed and manufactured using the IMA LIFE's patented Fusion design to enhance performance, reduce operating costs and increase reliability.

LYOFAST MINI RANGE PROVIDES THE LINK BETWEEN LABORATORY DEVELOPMENT, PILOT AND INDUSTRIALISED PRODUCTION.

The Lyofast MINI is part of IMA LIFE's wider offering of freeze drying and aseptic packaging equipment. The current line-up includes the standard Lyofast range of pre-engineered lyophilisers, the highend Lyomax range of custom freeze dryers and fully automated loading and unloading systems for single and multiple freeze dryer installations. All equipment can be provided suitable for use in an aseptic area or with isolation technology.

IDEAL SOLUTION FOR PILOT WORK OR CLINICAL TRIAL PRODUCTION.

A RANGE OF STANDARD OPTIONS ARE AVAILABLE, INCLUDING:

- SIP
- CIP
- CIP Re-circulation pump
- CIP drain sample valve
- Drain cooling heat exchanger
- Drain conductivity sensor
- Single or dual vent filter(s) with manual integrity test valves
- Single or dual vent filter(s) WIThin® automatic filter integrity test*
- Slot door
- Integration with semi-auto fence loader / unloader
- Fusion Plus Shelf
- Alternative Refrigerant with low GWP
- Low viscosity & non-flammable heat transfer fluid
- Dry vacuum pump System
- Automatic stoppering pressure control
- iClient SCADA PC
- 21 CFR part 11 compliance with e-signature



- Dual language SCADA screen
- Yokogawa paperless recorder
- Media fill cycle
- Data recovery (RAID 5 for main SCADA PC)
- Maintenance screen
- System performance test cycle
- Device mode
- SECOMEA remote access
- Cycle queue
- UPS
- Various voltage & frequency supplies
- Sterility monitoring
- MKS capacitance manometer (ice-condenser monitor)
- MKS capacitance manometer (vacuum pump group head)
- Pirani vacuum sensor (chamber monitor / comparison with MKS)
- Pirani vacuum sensor (selectable with MKS for chamber control / comparison with MKS)
- Redundant shelf fluid inlet control temperature sensors
- Product probes
- Individual shelf temperature sensors
- IQ/OQ protocols
- GAMP5 documentation package
- Non-aqueous solvent handling
- Potent product handling
- VERISEQ $^{\mbox{\tiny TM}}$ * Ice Fog controlled nucleation system
- Quantum Mass Spectrometer for silicone oil leak detection, sublimation end point determination and system leak check
- Product Loading Trays
- Training

Note: WIThin is a trademark of Sartorius Stedim.

* VERISEQ is a trademark of Linde

KEY FEATURES

- COMPACT FOOTPRINT
- COST-EFFECTIVE
- CIP/SIP AS REQUESTED
- SLOT DOOR SUITABLE FOR RABS/ISOLATOR INTEGRATION AS REQUESTED
- Redundant vacuum system
- MKS ON CHMABER
- SOFTWARE COMPLIANT WITH 21 CFR PART 11
- Lyomaster compact scada
- AUTOMATIC STOPPERING PRESSURE CONTROL
- Sterilizable inlet filter with wit test parts
- Redundant shelf inlet temperature probes
- IDEAL SOLUTION FOR PILOT WORK OR CLINICAL TRIAL PRODUCTION

COMPREHENSIVE DOCUMENTATION, SWIFT VALIDATION

IMA LIFE's internal Quality Management system has, for many years, been accredited with ISO9001-2015. This system provides integrated, comprehensive documentation relating to the manufacture of all products, ensuring the user is provided with full details of the equipment.

In order to assist in swift and painless equipment validation, IMA LIFE can also provide a standardized IQ and OQ documentation package.



TECHNICAL DATA







LYOFAST MINI	Weight (Kg)	LxWxH (mm)	Power (Kw)	
1.1	4700	3600x2300x3200	25	
1.5	1.5 4700		25	
2.2	5000	3700x2300x3200	27	
2.8	5000	3700x2300x3200	27	



LYOFAST MINI	Total Weight (kg)	Main Frame LxWxH (mm)	Refrigeration Skid LxWxH (mm)	Power (Kw)
1.1	4900	2200x2300x3200	2600x1700x2800	25
1.5	4900	2200x2300x3200	2600x1700x2800	25
2.2	5200	2300x2300x3200	2600x1700x2800	27
2.8	5200	2300x2300x3200	2600x1700x2800	27

TECHNICAL DATA

Lyofast Mini Layout 3 – Slot door & integral refrigeration skid

LYOFAST MINI	Weight (kg)	LxWxH (mm)	Power (Kw)
1.1	5000	4600x3000x3100	25
1.5	5000	4600x3000x3100	25
2.2	5300	4800x3000x3100	27
2.8	5300	4800x3000x3100	27



LYOFAST MINI	Total Weight (kg)	Main Frame LxWxH (mm)	Refrigeration Skid LxWxH (mm)	Power (Kw)
1.1	5200	2800x2800x3100	2600x1700x2800	25
1.5	5200	2800x2800x3100	2600x1700x2800	25
2.2	5500	3000x2800x3100	2600x1700x2800	27
2.8	5500	3000x2800x3100	2600x1700x2800	27

NAME	ITEM	LYOFAST MINI 1.1	LYOFAST MINI 1.5	LYOFAST MINI 2.2	LYOFAST MINI 2.8	
Door	Geometry	Rectangular				
	Shell Material		Stainless ste	eel AISI 316L		
	Internal Finish	Mirrored, < 0.4 μm Ra				
oer 8	Insulation	Glass fiber + Polymer foam				
Jamł	Operating Pressure		0 - 3.0 BarA (f	or SIP option)		
Ъ	Door Locking	Automatically operated with manual latch				
	Door Material	Stainless steel AISI 316L				
	Geometry	Cylindrical and vertically mounted				
	Material	AISI 316L				
	Internal Finish	Satin, < 0.75 μm Ra				
5	Insulation		Glass fibre + I	Polymer foam		
lense	Operating Pressure		0 - 3.0 BarA (f	or SIP option)		
Conc	Defrost	Hot Water or Steam				
Ū	Coil Material		Stainless ste	eel AISI 316L		
	Surface Area	1.5 m ²	1.5 m ²	3.2 m ²	3.2 m ²	
	Capacity at 12.7 mm Ice Thickness	28 kg	28 kg	58 kg	58 kg	
	Material		AISI	316L		
	Finish	Satin to the	upper and lower surfaces and m	nirror to the boundary surface, 0.	4-0.6 μm Ra	
~	Number of Shelves	3+1	4+1	4+1	5+1	
embl	Inter-distance	130 mm	110/130 mm	130 mm	110/130 mm	
Asse	Shelf Dimensions	643 × 615×18 mm	643 × 615×18 mm	643 × 916×18 mm	643 × 916×18 mm	
/es &	Total Shelf Area	1.1 m ²	1.5 m ²	2.2 m ²	2.8 m ²	
Shelv	Maximum vials loading capacity (2R vial)	4 536	6,048	9,216	11,520	
	Shelf Temperature Uniformity		2 °C between	-40 and + 40°C		
	Vial Stoppering		Yes (fro	om top)		
	Compressor Type		Two-stage semi-her	metic Reciprocating		
	Power	5HP x 2	5HP x 2	8HP x 2	8HP x 2	
tem	Cooling Exchangers		Stainless steel b	razed plate type		
ation sys	Shelf Cooling Time 20°C to −40 °C		50 minutes, dry,	50 minutes, dry, clean and empty		
riger	Shelf Minimum Temperature		-55°C , dry, cle	an and empty		
Ref	Condenser cool down time		20 minutes to -40°C,	dry clean and empty		
	Condenser minimum temperature	-75°C, dry, clean and empty				
	Primary Pump		Oil sealed two-sta	ige rotary vane x 2		
tem	Pump Capacity	28 m³/h	28 m³/h	40 m³/h	40 m³/h	
Vaci Sysi	Chamber Vacuum Sensor Type		Capacitance manomet	er sensor (MKS Brand)		
	Pump Down to 0,1mbar	30 minutes (clean dry system, condenser below -40°C)				
umentation	Control Architecture	PLC + SCADA Interface				
	User Interface	SCADA PC				
	PLC Type	SIEMENS				
Instr	Control Mode	Manual and Auto				
0 &	Shelf Temperature Control	Class A PT100 located on shelf inlet				
ontr	Vacuum Control	Modulating valve, via PLC				
Ŭ	Product Temperature Probes	T type thermocouples				
Utility	Electrical Power Supply	3P/AC400V/50Hz				

*Above data are subject to change.

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