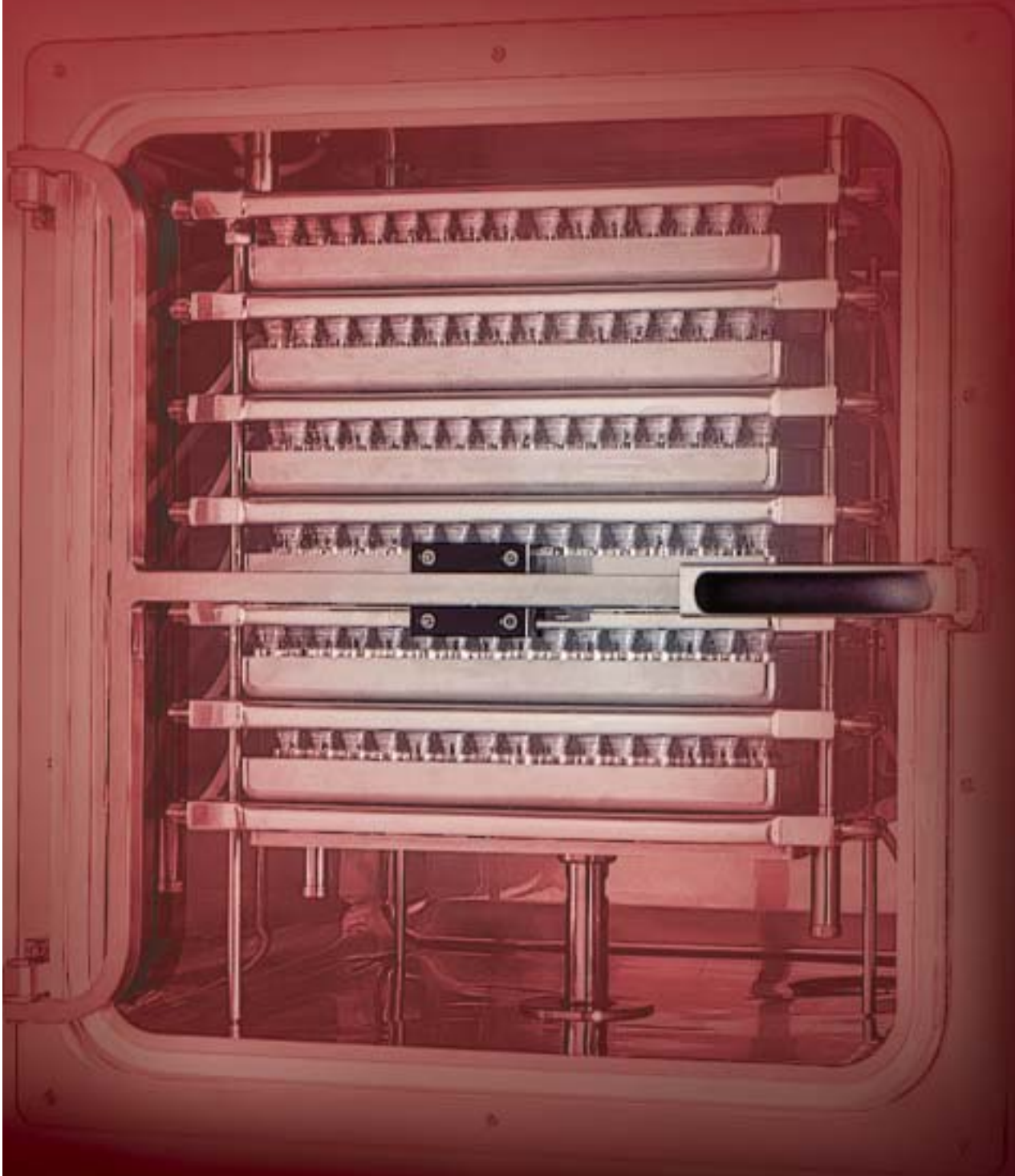




LYOBETA

LABORATORY FREEZE-DRYERS



LYOBETA SERIES



A RESPONSIBLE CHOICE

New demands in R+D centers are related to scale-up feasibility and quality of procedures and research methods. FDA investigators consider that transfer of technology from R+D departments to clinical trials and later commercial production is carried out with lack of strictness and poor documentation practices. Therefore, they are emphasizing on the concept of cGMP as a quality oversight, comprising all practices in R+D and production processes.

The new **LyoBeta Series** lyophilizers are laboratory units that have been designed specifically for advanced research their centers, keeping in mind that initial development of new drugs is one of the most critical issues for their final commercial success.

CONTROL SYSTEM

Based on PLC and user
Friendly
TOUCH-SCREEN

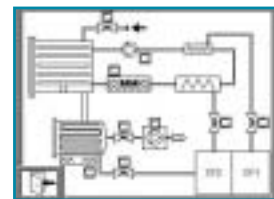


One of the main new feature of the **LyoBeta Series** freeze-dryers is the incorporation of a non-proprietary PLC, instead of the classic microprocessor, more commonly used in this type of equipment. This system, fully proven in the industrial models, **guarantees maximum reliability and reproducibility in the process**, totally adapting the equipment to cGMP.

The system allows control of the freeze-dryer functions via a graphic HMI (Human Machine Interface) user interface, which offers the following possibilities:

- Displaying of information on system elements (valves, motors, indicators, etc.)
- Receiving information from alarms
- Acting within the parameters of the freeze-dryer cycle
- Eliminating the possibility of error in operation
- Protecting the system from unauthorized use
- Recipes development

The user interface presents information in an attractive and intelligible manner on a graphic 6" touch screen, through which different data screens can be accessed by means of touch zones.



OPTIONALLY, THE EQUIPMENT CAN BE CONNECTED TO DIFFERENT PERIPHERALS, SUCH AS A CHART RECORDER, PRINTER OR PC. WHEN CONNECTED TO A PC, WE OFFER TWO POSSIBILITIES FOR WORKING IN THE WINDOWS ENVIRONMENT:

LYOLOGGER

A DATA LOGGING PROGRAMME WHICH ENABLES COLLECTION OF DATA SUCH AS GRAPHS, EVENTS, ALARMS AND HISTORY (ASCII FILES) THROUGH A SERIAL PORT.

LYOSTAR/LAB

A SCADA SOFTWARE PROGRAM DESIGNED SPECIFICALLY FOR SCIENTIFIC R+D STUDIES. IT ALLOWS DESIGNING, LOADING AND STORING RECIPES, GENERATING REPORTS, HISTORICS, LISTS OF ALARMS, ETC.



Time	Event	Description
10:00:00	Start	Process started
10:05:00	Alarm	Temperature out of range
10:10:00	Event	Valve opened
10:15:00	Event	Motor started
10:20:00	Event	Pressure increased
10:25:00	Event	Flow rate adjusted
10:30:00	Event	Temperature stabilized
10:35:00	Event	Valve closed
10:40:00	Event	Motor stopped
10:45:00	Event	Pressure decreased
10:50:00	Event	Flow rate returned to normal
10:55:00	Event	Temperature out of range
11:00:00	End	Process ended

Time	Severity	Description
10:05:00	High	Temperature out of range
10:15:00	Medium	Valve opened
10:25:00	Low	Pressure increased
10:35:00	High	Temperature out of range
10:45:00	Medium	Motor stopped
10:55:00	High	Temperature out of range

DESIGN FEATURES

The **LyoBeta** is a compact unit with castors, constructed in a steel estove-enamelled cabinet. The equipment is supplied fully assembled, including the vacuum and refrigerating system and all necessary elements, ready for operation after connecting to the utility services.

EFFICIENT DESIGN

THE DESIGN OF THIS UNIT OFFERS THE BEST CAPABILITIES FOR R+D ACTIVITIES. The LyoBeta has been equipped with the appropriate components, devices and sensors to control processing conditions: temperature, pressure and time. This allows defining the process variables to achieve adequate control and reproducibility.

The equipment includes brazed plate heat exchangers, that used in combination with other high quality components, YIELDS COOLING AND HEATING RATES OF 1°C/MIN as the same our production freeze-dryers.

OPTIMIZATION OF PROCESS RECIPES IS EASILY PERFORMED BY MEANS OF THE CHAMBER TO CONDENSER VALVE, which allows for pressure rise testing and thermodynamic control. This valve also permits proceeding with the product loading and unloading without defrosting the condenser if it has not reached full capacity.

The refrigeration system is capable of reaching -80°C in the condenser and -57°C on the shelves. It only uses HFC gases, which are authorized for use both at the moment and in the long term.

FLEXIBILITY OF USE

By using the stoppering device, the distance between the shelves can easily be modified, so THE UNIT CAN BE ADAPTED TO DIFFERENT PRODUCT FILL VOLUMES, VIAL SIZES AND/OR VIAL TYPES. Moreover, a lateral inlet port allows the connection of a three way valve manifold for the freeze-drying of CN 29/32 open flasks.



The best Solutions for Advanced Research Center



HIGH QUALITY AND SUPERIOR CRAFTSMANSHIP



THE CHAMBER AND SHELVES HAVE BEEN CONSTRUCTED WITH THE SAME PHILOSOPHY AS PRODUCTION UNITS. They are made entirely from stainless steel AISI 316 L and they are fully accessible inside for cleaning purposes. The condenser, which is also made of AISI 316 L, has a rapid ice-defrosting device, which works by means of a group of external electrical resistors. Both the chamber and the condenser have transparent acrylic doors to facilitate viewing of the process.



PRECISE CONTROL AND TEMPERATURE UNIFORMITY



The thermal fluid circulates inside the sandwich type channels of the shelf. This allows prior product freezing and later heating during sublimation phase. An additional shelf thermally balances the equipment. THIS FEATURE FOR LABORATORY FREEZE-DRYERS GUARANTEES UNIFORM HEAT TRANSFER AT ALL THE SHELVES.

Research lyophilizers often have the pressure sensors located on the vacuum line, reflecting the pressure of the line to the vacuum pump rather than in the chamber. The LyoBeta has the vacuum sensor in the chamber, which makes possible monitoring and control the pressure which comprises the environment where the product is exposed. THIS ALLOWS STUDYING AND OBTAINING THE FINEST SCALE-UP RESULTS.

TECHNICAL DATA

FEATURE	UNIT	LYOBETA 15	LYOBETA 20	LYOBETA 25	LYOBETA 35
NUMBER OF SHELVES	UD	3+1	4+1	4+1	6+1
SHELVES DIMENSIONS	W X D MM	338 x 450	338 x 450	338 x 450	338 x 450
	INCHES	13.3 x 17.7	13.3 x 17.7	13.3 x 17.7	13.3 x 17.7
USEABLE SHELF AREA	M ²	0.46	0.61	0.68	1.03
	SQ.FT	4.94	6.56	7.31	11.08
CLEARANCE	MM	93	66	100	60
	INCHES	3.7	2.6	3.9	2.4
SHELF TEMPERATURE RANGE	°C	-65 TO +80	-65 TO +80	-65 TO +80	-65 TO +80
CONDENSER CAPACITY	KG	30	30	40	40
	IB	66	66	88	88
CONDENSER CAPACITY IN 24 H	KG	12	12	18	24
	IB	26	26	39	39
FINAL CONDENSER TEMPERATURE	°C	<-80	<-80	<-80	<-80
ELECTRIC POWER	KW	6.8	6.8	6.5	68.1
POWER SUPPLY	V/HZ	230/I/50/60	230/I/50/60	230/I/50/60	400/III/50/60
		(OTHERS UNDER REQUEST)	(OTHERS UNDER REQUEST)	(OTHERS UNDER REQUEST)	(OTHERS UNDER REQUEST)
VACUUM PUMP FLOW	M ³ /H	9.6	20.5	20.5	20.5
	CFM	5.65	12	12	12
WEIGHT	KG	630	660	1050	1100
	IB	1389	1445	2315	2425
DIMENSIONS	WIDTH (MM/INCHES)	1160/45.7	1160/45.7	1340/52.8	1340/52.8
	HEIGHT (MM/INCHES)	1815/71.5	1815/71.5	1975/77.8	1975/77.8
	DEPTH (MM/INCHES)	750/29.5	750/29.5	860/33.9	860/33.9

AVAILABLE OPTIONS

- VIAL STOPPERING AND SPACING DEVICE (THIS OPTION IS STANDARD IN LYOBETA 15 AND 20)
- VENT FILTER
- ISOLATION VALVE CHAMBER TO CONDENSER
- SPACING DEVICES FOR SHELF CLEARANCE ADJUSTMENT
- SAMPLING THIEVE DEVICE
- CLEAN ROOM CONFIGURATION
- SIDE MANIFOLD
- PRODUCT SUPPORT TRAYS
- MODULES FOR ADDITIONAL TEMPERATURE PROBES (4 AND 8)
- DEW POINT MONITOR
- CHART RECORDER
- DATA ACQUISITION SOFTWARE - LYOLOGGER
- SCADA R+D (YOPHILIZATION SOFTWARE - LYOSTAR/LAB
- IQ/OQ DOCUMENTATION SERVICE