

Pilot freeze drying systems Innovative technology







Successful from proof of principle

to production

Martin Christ Gefriertrocknungsanlagen is a worldwide leader in the development and manufacture of freeze dryers, with over 75 years of experience.

One of our company's most innovative fields of activity is the manufacture of freeze dryers for process development and small-scale production - our pilot freeze drying systems.

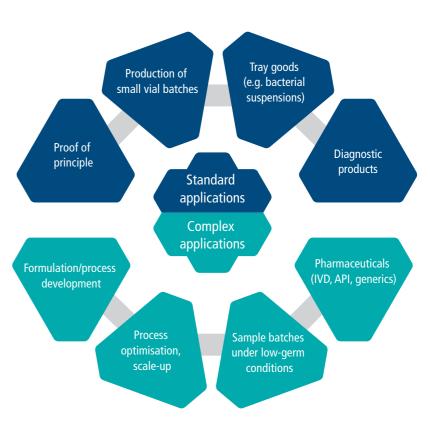
Here as well, the name Martin Christ stands for the highest level of customer satisfaction around the world. We develop and build according to the highest standard of quality to provide superior customer benefits. Our corporate strategy is focussed on your applications.

We see ourselves as a global innovation leader. We are continuously solidifying our outstanding position in the field of freeze drying with technological innovations, such as WTMplus 2.0 wireless product temperature measurement, LyoCoN (controlled nucleation) for crystallization at the push of a button, and LyoCam for process-integrated camera monitoring. Dozens of corporate patents are undeniable proof of our pioneering approach.

Pilot freeze dryers from Martin Christ are ideally suited to research & development. They are also the perfect choice for small-batch series production. Users can choose from various models. Each of them delivers optimal results in the freeze drying of solids or liquids in a wide variety of containers. With similar geometries, comparable temperature control systems and identical user interfaces, these systems follow the same philosophy as our large production units.

Detailed but nevertheless intuitive process control is as much a matter of course for all models as the use of the best available process analytical technologies (PAT tools), which are particularly important for development tasks.

We are at home in virtually all industries, with a strong focus on the pharmaceutical and biotech segments.



Optimal equipment

for R&D and small-batch series production

The Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus freeze dryers are the best choice for routine tasks. The single-chamber system has a 4 kg ice condenser integrated in the product chamber. The large shelf is cooled directly by the refrigerant, resulting in a low shelf temperature as well as cooling and heating rates that are nearly twice as fast as indirectly cooled shelves.

Equipped with stainless steel shelves with a synthetic heat transfer fluid, the larger freeze dryers Epsilon 2-6D LSCplus and Epsilon 2-10D LSCplus systems meet the highest standards of the pharmaceutical and biotech industries.

The integrated intermediate valve separates the specimen chamber from the ice condenser chamber. These double-chamber systems with a separate ice condenser integrate even more PAT functions for process optimization and -development.







Second to none

High-performance pilot systems with large ice capacity



With an ice capacity of 12 kg or 16 kg, the pilot freeze dryers are comparable to larger production units. The refrigeration system is water cooled with generously sized compressors.

The Epsilon 2-12D model with LSCplus, or with a Siemens controller, is often used for recipe development and for scaling up with a maximum number of PAT tools. This freeze dryer is optimally suited to process development







The Epsilon 2-16D offers up to 1.44 m² of shelf area. It is specifically designed for 24/7 production of tray goods (bulk), such as pharmaceutical raw materials or bacterial suspensions, as well as special formats such as MTPs or tall containers that do not require sealing.

Especially suited to development in the pharmaceutical sector

_

7

Individual Your Vision meets precision

Flexible configurations tailored to your application

We work with you to develop your individual solution for your optimal freeze drying process. Our pilot freeze dryers offer a maximum of functions and design features for successful research, process development or small-scale production.

Equip your freeze dryer with a wide range of options:

- Expandable PAT tools
- Sample extraction system
- Cleanroom installation
- Glovebox connection
- Stoppering device for vials (manual/hydraulic)
- Safe, guided semi-automatic loading and unloading systems
- H₂O₂ disinfection
- Cleaning flange
- Solvent-resistant version
- Inertisation
- Adjustment shelf spacing
- Drying manifold
- IQ/OQ qualification
- .

You can rely on our years of experience. We are here for you and will always provide you with professional and competent advice.





Special Solutions for individual projects

Compact Our Plug-and-Play concept solutions

Efficient serial systems with individual PAT tools



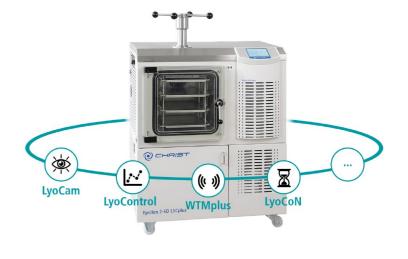
Our popular pilot freeze dryers Epsilon 1-4 LSCplus, Epsilon 2-4 LSCplus, Epsilon 2-6D LSCplus and Epsilon 2-10D LSCplus pilot freeze dryers offer predefined features. Optionally, you can customize these packages with our innovative and intelligent PAT tools for process optimization.

Depending on the specific freeze dryer, the following PAT tools can be selected as standard options:

- LyoCam innovative camera system
- WTMplus wireless temperature measurement
- RFID reader very simple identification of temperature sensors
- LyoCoN controlled freezing of all vials
- MTMplus temperature measurement across all vials
- Comparative pressure measurement detection of the end of the main drying phase
- LPC plus process visualisation

The base units are also equipped for the retrofitting of additional options, making them future-proof in terms of extensions.

Modular structure for short delivery times and easy retrofitting



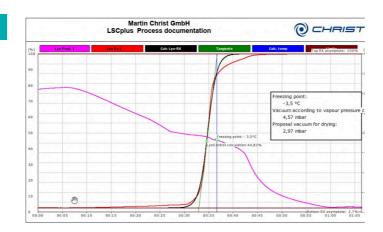
Smart solutions for optimal process observation

PAT tools

LyoControl – freezing point determination

The LyoRx sensor monitors the electrical resistance and product temperature. From the curves of both of these variables, you can automatically determine the freezing point of your product. Our LyoLogplus software with LyoControl makes this possible.

The LyoRx sensor allows automated control of the energy supply to the shelves during the main drying phase, so you can avoid critical temperatures during the main drying phase. This reduces the risk of defrosting effects on the product.



LyoCam 2.0 – camera system

Video recordings of the product at variable intervals, depending on the process steps or as event-driven recording. LyoCam enhances the transparency of the freeze drying process. Freeze drying monitoring and analysis are easy and uncomplicated with this technology from Martin Christ.

- High-end full HD industrial camera
- Cold-light LED lamps to avoid energy input
- Fully integrated in LPCplus process visualisation
- Smart image storage with frame rate linked to specific process results



Well-conceived, fully integrated tools

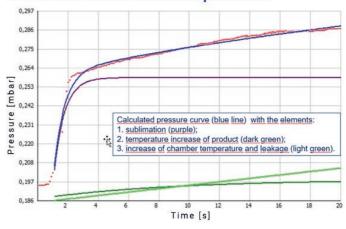
PAT tools

MTMplus – manometric temperature measurement method

The product temperature is one of the critical parameters in freeze drying. It influences the form of the ice structure and the speed of the freeze drying process, and it can initiate a thawing process. Optimal temperature monitoring is possible with the MTMplus dynamic manometric temperature measurement system optimized by Martin Christ.

- The product temperature is calculated online during the measurement process.
- Non-invasive method for determining the product temperature
- Reduced risk of product damage
- Easily retrofitted in many Christ freeze dryers

Calculated versus measured pressures



WTMplus 2.0 – wireless temperature measurement

The WTMplus 2.0 wireless temperature measurement system from Martin Christ enables wireless product temperature measurement for freeze drying. The wireless sensors are placed directly in the vials and report the product temperature to the system controller during the entire drying process.

- Battery-free passive design for low influence on product temperature
- Temperature sensors powered by an interference-free radio signal
- Sensor positions can be documented with LPCplus
- Up to 16 sensors at various positions for process monitoring
- Guaranteed service life of 100 cycles for the entire sensor
- GMP design of antennas and sensors
- Easy sensor identification with RFID reader



Smart solutions for optimal process observation

PAT tools

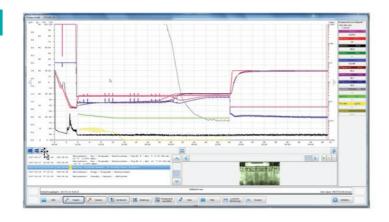
Pressure rise test

The transition between main drying and final drying can be determined using the pressure rise test. This is done by briefly closing the valve between the product chamber and the ice condenser. If the pressure rise in the product chamber with the intermediate valve closed remains below a defined limit, moisture is no longer sublimating from the product and final drying can be started automatically.



Comparative pressure measurement

The end of the main drying phase can be detected by using two different vacuum measurement sensors (Pirani gauge and capacitive sensor). When the difference between the pressure measurements falls below a preselected threshold, final drying is started automati-



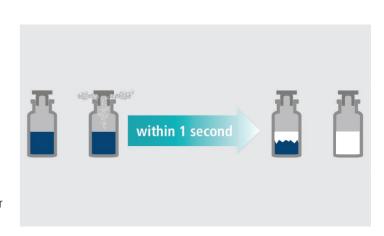
Fully integrated tools

PAT tools

LyoCoN – controlled nucleation

The LyoCoN controlled freezing function from Martin Christ ensures the simultaneous freezing of all vials. The crystallization of all vials in the freeze dryer is initiated at the press of a button.

- The ice fog is generated directly by the product, eliminating the need for additional external substances.
- GMP compliant method
- No release of gas (with potential product content) from the chamber
- Can be deployed in almost pilot systems

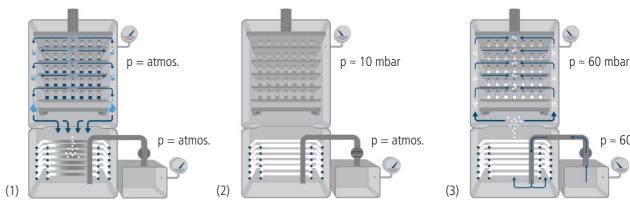


 $p \approx 60 \text{ mbar}$

Functionality of LyoCoN

After loading of the machine, the cold ice condenser accumulates ice crystals (pict. 1). Simultaneously the liquid product is cooled down close to the freezing point. In the next step a slight vacuum is established in the freezedryer (pict. 2). The external recipient is kept under atmospheric pressure. Finally a pressure equilibration between recipient and freezedryer is started by opening a valve to the ice condenser. The air/gas from the recipient is injected into the ice condenser. The resulting ice fog infiltrates all vials (pict. 3). These crystal nuclei immediately start homogenious crystallisation in all vials.

After this, the freezedryer is aerated completely to atmospheric pressure. Freezing of all crystallized vials can be continued in a conventional way, e.g. further freezing down, annealing etc.



Convenient and intuitive

LSCplus system controller



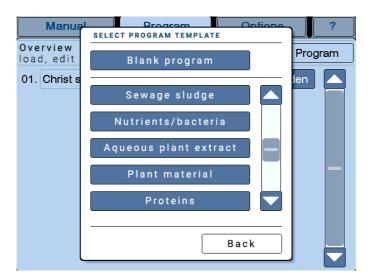
Future-oriented technologies are brought together in the LSCplus system controller to make an easy-to-use and intuitive user interface. All of the extensive accessories are also integrated.

Reproducible results are assured by automatic process sequences.

- Colour touchscreen with clear presentation
- Automated or manual sequencing of freeze drying processes
- Intuitive program entry using various freeze drying sequences or recipes
- Capacity for 32 user-defined programs
- Graphical display of freeze drying sequence (set values)
- Choice of several continuation conditions, depending on the system configuration
- Extensive message texts and explanations
- Multiple language options
- Selectable units for temperature (°C, °F) and pressure (mbar, hPa, Torr)
- Optional password protection
- Process data acquisition and optional data exchange over USB or Ethernet



LSCplus colour touchscreen



Sample programs for a wide range of applications

Processes monitoring

For precise documentation and evaluation

Our experience shows: processes must be precisely monitored and documented. This is the only way to achieve exact and precise analysis of a wide range of applications — regardless of the drying recipe and batch size.

Documentation and archiving of all process data is possible with the LyoLogplus software, which can be installed on a separate PC. Data can be transferred from the freeze drying system to the PC via USB storage media or directly over Ethernet. LyoLogplus enables seamless documentation and post-process analysis with an intuitive user interface.

With LPCplus, programs for freeze drying can be developed and process data can be viewed in real time in graphical format.

Operation is consistent and uniform across all unit sizes, as LPCplus is also used with larger production freeze drying systems.

| Part |

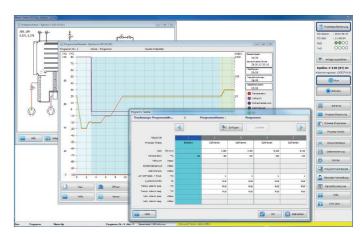
LyoLogplus software for process documentation

Are you planning to scale up?

Take advantage of easy platform migration from pilot scale to production scale with a uniform user interface and the same software solutions.

- Data recording on USB medium
- Simple process documentation with LyoLogplus
- LPCplus for process control and documentation
- Process monitoring with the LyoRx sensor to avoid undesired defrosting effects
- Automatic freezing point determination with LyoControl for reliable process control
- Wireless product temperature measurement WTMplus 2.0 for easy operation with improved sensor technology
- LyoLogplus and LPCplus with multilingual interface

The system concept of our freeze drying systems is based on the cGMP/GLP guidelines. The LPCplus software conforms to the current GAMP guidelines.



LPCplus software for process control and documentation



Technical data

Specifications	Epsilon 1-4 LSCplus	Epsilon 2-4 LSCplus	Epsilon 2-6D LSCplus	Epsilon 2-10D LSCplus	Epsilon 2-12D LSCplus	Epsilon 2-16D LSCplus
Ice condenser: Max. capacity Performance Temperature (approx.) Chamber volume (approx.)	Single-chamber system 4 kg 3 kg/24 h –55°C 41 l	Single-chamber system 4 kg 3 kg/24 h –85°C 41 l	Double-chamber system 6 kg 4 kg/24 h <-85°C 23 l	Double-chamber system 10 kg 8 kg/24 h <-85°C 50 l	Double-chamber system 12 kg 10 kg/24 h <-78°C 95 I	Double-chamber system 16 kg 10 kg/24 h <-78°C 116 l
 Shelf system: Dimensions (W x D) Temperature range (approx.) Temperature accuracy Cooling rate (+20°C to -40°C) 	270 x 400 mm -45°C to +60°C <±2 K 2 K/min	270 x 400 mm -70°C to +60°C <±2 K 2.3 K/min	225 x 300 mm -50°C to +60°C <±1 K 1.6 K/min	350 x 400 mm -60°C to +60°C <±1 K 1.3 K/min	350 x 450 mm -60°C to +50°C <±1 K 1.3 K/min	300 x 400 mm -60°C to +50°C <±1 K 1.3 K/min
Dimensions (W x H x D) with sealing device (mm)	780 x 975 x 550	780 x 975 x 550	860 x 1,374 x 788	1,190 x 1,303 x 968	1,570 x 1,974 x 1,397	1,562 x 1,910 x 847
Weight (approx.)	110 kg	140 kg	330 kg	750 kg	1,200 kg	1,200 kg
Electrical connection (other voltages available upon request)	230 V / 50 Hz 230 V / 60 Hz 208 V / 60 Hz	230 V / 50 Hz 230 V / 60 Hz 208 V / 60 Hz	3 x 400 V / 50 Hz 3 x 208 V / 60 Hz 3 x 230 V / 60 Hz	3 x 400 V / 50 Hz 3 x 208 V / 60 Hz 3 x 230 V / 60 Hz	3 x 400 V / 50 Hz 3 x 480 V / 60 Hz	3 x 400 V / 50 Hz 3 x 480 V / 60 Hz
Water cooling	0	0	0	0	•	•
Noise level as per DIN 46535 (approx.)	54 dB(A)	51 dB(A)	61 dB(A)	64 dB(A)	80 dB(A)	65 dB(A)
Defrosting	Hot gas	Hot gas	Hot gas	Hot gas	Hot gas	Hot gas
Vial closureManualHydraulicAutomatic function "venting-sealing-storage"	O O O	0 0 0	• • •	- • •	- • •	- - -
Process control and PAT tools: Safety functions Safety pressure LyoRx monitoring to prevent defrosting PAT tools: MTMplus LyoCoN WTMplus 2.0 with RFID LyoCam 2.0 LyoControl Comparative pressure measurement	• • 0 0 0	• • 0 0 0				
Pressure rise testCommunication	-	_				
 Programming module for up to 32 recipes Ethernet interface USB LyoLogplus software for process documentation LPCplus software for process control and documentation 	• • • •	• • • •	• • • •	• • • •	• • • •	• • • •

ullet = Basic configuration \bigcirc = Option - = Not available

15

Capacities and shelf dimensions

Epsilon 1-4 LSCplus & Epsilon 2-4 LSCplus

	Shelf dimensions (W x D x H): 270 x 400 x 20 mm									
	Vial volume (total)	2 ml	6 ml	10 ml	20 ml	50 ml	100 ml		
Number of shelves	Area (m²)	Spacing (mm)	Max. number of vials ^{a)}							
1	0.108	140	430	225	180	120	50	30		

Epsilon 2-6D LSCplus

	Shelf dimensions (W x D x H): 225 x 300 x 15 mm									
	Vial volume (tota	l)	2 ml	6 ml	10 ml	20 ml	50 ml	100 ml		
Number of shelves	Area (m²)	Spacing (mm)	Max. number of vials ^{a)}							
1	0.07	250	280	130	115	72	36	21		
2	0.14	117	560	260	230	144	72	42		
3	0.21	73	840	390	345	216				
4	0.27	51								
5	0.34	40	For trays, MTP/deep well plates, etc.							
6	0.40	31								

Epsilon 2-10D LSCplus

	Shelf dimensions (W x D x H): 350 x 400 x 15 mm									
1	Vial volume (total	l)	2 ml	6 ml	10 ml	20 ml	50 ml	100 ml		
Number of shelves	Area (m²)	Spacing (mm)	Max. number of vials ^{a)}							
1	0.14	354	613	326	266	165	83	49		
2	0.28	170	1226	652	532	330	166	98		
3	0.42	108	1839	978	798	495	249			
4	0.56	77	2452	1304	1064	660				
5	0.70	59	3065	1630						
6	0.84	47			For trave MTD/do	on wall plates ats				
7	0.98	38			rui iiays, ivi1P/dei	ep well plates, etc.				

a) Data for maximum load; subtract 10% of standard configuration when using loading frames

Epsilon 2-12D LSCplus

	Shelf dimensions (W x D x H): 350 x 450 x 15 mm										
,	Vial volume (total)	2 ml	6 ml	10 ml	20 ml	50 ml	100 ml			
Number of shelves	Area (m²)	Spacing (mm)		Max. number of vials ^{a)}							
1	0.16	381	688	357	294	189	96	60			
2	0.32	183	1376	714	588	378	192	120			
3	0.47	117	2064	1071	882	567	288	180			
4	0.63	84	2752	1428	1176	756	383				
5	0.79	64	3440	1785	1470						
6	0.95	51	4128								

Epsilon 2-16D LSCplus

Epsilon 2 Tob Esepius								
Shelf dimensions (W x D x H): 300 x 400 x 14.5 mm								
Number of shelves	Area (m²)	Spacing (mm)						
1	0.12	963						
2	0.24	474						
3	0.36	311						
4	0.48	230						
5	0.60	181						
6	0.72	148						
7	0.84	125						
8	0.96	107						
9	1.08	94						
10	1.20	83						
11	1.32	74						
12	1.44	67						

Primarily used with trays and other formats; vials can also be lyophilized but not automatically sealed.

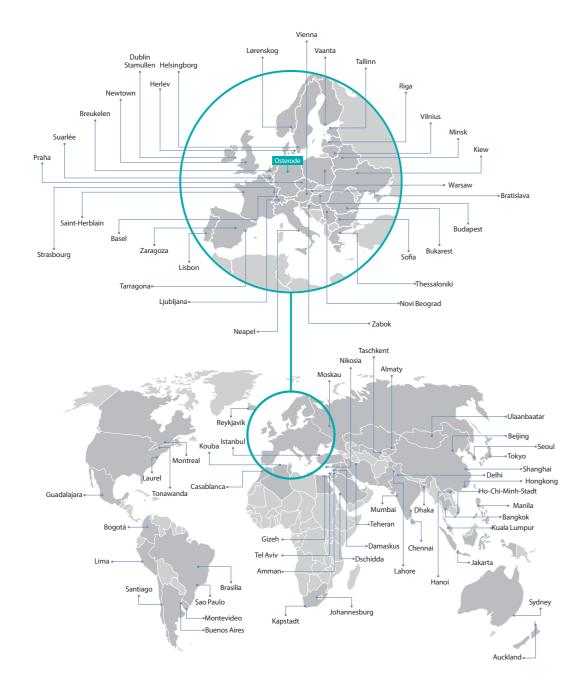


Vial size overview

Total vial volume	2 ml	6 ml	10 ml	20 ml	50 ml	100 ml
Vial type	2R	6R	10R	20R	50H	100H
\$\tag{mm vial only} \$	35	40	45	55	73	95
↑ mm with Lyo plug	45	50	55	65	83	105
ømm	16	22	24	30	43	52
Net fill volume at 1 cm fill height (ml)	1.2	2.2	4.0	4.6	6.0	7.0

Global service for local production reliability

Our systems are operating successfully in over 70 countries around the world. An international network of partners is available for service and qualification tasks. Our specialists can also be engaged quickly around the world, either remotely or on site in person.



Selected locations of our representatives.

An overview of all representatives with detailed contact information can be found at www.martinchrist.de

Our product range

With a unique and broad graduated range of devices and accessories, we can supply freeze drying systems and vacuum concentrators for every application. Let us show what we can do!



- 1 Freeze drying systems for industrial production with ice condenser capacity from 20 to 500 kg; custom system design including loading and unloading systems.
- 2 Pilot freeze drying systems for process development and/or optimization with ice condenser capacity from 4 to 16 kg.
- 3 Freeze drying systems for routine applications or research and development with ice condenser capacity from 2 to 24 kg.
- 4 Rotational vacuum concentrators for applications ranging from routine to evaporation concentration in the high-end range of pharmaceutical research.



Martin Christ Gefriertrocknungsanlagen GmbH

An der Unteren Söse 50 37520 Osterode am Harz

Phone +49 (0)552-250-070

info@martinchrist.de www.martinchrist.de