

# Epsilon 1-4 LSCplus Epsilon 2-4 LSCplus



**Pilot Freeze Dryers** 

www.martinchrist.de



# **Advanced System Technology** for Best Drying Results

The benchtop freeze dryers Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus are high performance, universal laboratory and pilot systems for lyophilisation of solid or liquid products in ampoules, vials, glass flasks, plasma bottles or dishes.

Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus set the standard for pilot systems of the highest quality and performance. They share a geometrical likeness with large production machines and use similar temperature-controlling systems.

# All operations are possible inside the unit:

- Prefreezing of products on temperature-controlled shelves
- Freeze drying (sublimation) of products according to preselected desired time, temperature and pressure profiles
- Final drying of products

Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus units have an internal ice condenser temperature with a minimum of -55°C and -85°C respectively and is available with one shelf with 0.11 m<sup>2</sup> useable surface area.

New cooling techniques provide for shelf temperatures of -45°C or -70°C (prefreezing) in the very compact chamber. This permits extremely sensitive pharmaceutical and biotech products, e.g. amorphous structures with a low glass transition point to be freeze dried safely.

Simple, process-specific documentation is possible on all systems as a For special applications a wide range of approved solutions is result of the LSCplus Lyo-Screen-Control and LyoLogplus interface. An available. This includes solvent freeze drying, glove-box and isolator added option is the Windows-based LPCplus software for PC-based connection, VHP decontamination. process control and documentation. LPCplus is widely used in typical pilot freeze dryers up to large-scale productions systems and follows Made in Germany GAMP and cGMP guidelines. CHRIST freeze dryers are 100% engineered and manufactured in

# **Design Features**

# Vial stoppering plus flask drying

Multi-purpose device with optional connections for up to 4 flasks. Controlled and safe vial stoppering via manual operation (automatic as option).

# Powerful shelf temperature control

Liquid cooled and heated shelves, control range -45 (Epsilon 1-4 LSCplus) resp. -70°C (Epsilon 2-4 LSCplus) to +60 °C, shelf temperature accuracy better than +/-2K – can be improved by used of aluminum thermoblocks.

### Defrosting without water

Radiation from shelf defrost ice condenser coils fast and efficient. No production of additional waste.

### Most efficient condenser design

Ice condenser coils directly inside drying chamber improves drying time and prevents vapour bypass to vacuum pumps.

# Uncompromising Process Control

Via intuitive, simple to control interface LSCplus (Lyo-Screen-Control). Can be combined with process visualization LPCplus, complying with the most current GMP/CFR-guidelines

# **Customized configurations**

Osterode/Germany, QMS system according to ISO 9001:2008 since 1994.

# **Comfortable and Intuitive**

# **Process Optimisation in Detail**

### LSCplus – colour touchscreen and intuitive operation

To aid in designing your process run we have integrated our highly regarded production optimised interface – the LSCplus control system into every model. All of our accessories are plug and play and the integrated automatic process sequences ensure reproducible results.

- Picture driven touchscreen control
- Automatic or manual sequence of freeze drying processes
- Intuitive input of programs based on different freeze drying sequences/recipes
- Graphical diagram of the freeze drying process
- Selection of different switching conditions, depending on system configuration
- Storage memory for up to 32 user-defined programs
- Detailed messages

4

- Wide selection of languages already integrated
- See table unit of measurement for temperature (°C/°F) and pressure (mbar/hPa/Torr)
- Password protection possible (up to 3 levels)
- Process data acquisition and convenient data exchange via USB or Ethernet



#### Process monitoring

We understand process monitoring and documentation is crucial to the validation of many applications regardless of the run and the run size.

Therefore process data collected during a run on our system can be documented and archived with the aid of the LyoLogplus software available for installation on an external PC. Complete run data and settings can be transferred from the freeze dryer via USB or Ethernet. LyoLogplus enables the subsequent analysis of the processes by way of an intuitive user interface.

For further versatility it is also possible to use LPCplus to develop your freeze drying process. LPCplus delivers an online view of process data in a graphical format.

#### Need to scale up?

Enjoy easy platform migration from pilot through to production scale with uniform interface and software solutions.

- Data storage on USB memory stick
- Easy process documentation with LyoLogplus
- LPCplus (Lyophilisation Process Control) for process control and documentation
- Avoid unwanted thawing thanks to our reliable process monitoring and innovative LyoRx sensor
- Automatic determination of the freezing point with LyoControl for safe process control
- LyoLogplus and LPCplus with a multilingual user surface

We design and manufacture our freeze dryers to follow the published cGMP/GLP guidelines. The optional LPCplus software complies with the current GAMP standard guidelines.

System qualification (IQ/OQ) is therefore possible upon request.

Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus offer a variety of options to optimise your freeze drying processes. In addition to documentation and key parameter analysis, the automatic determination of critical product data is also available.

Our intelligent systems even offer the option of automatic tuning for set values based on current process conditions. As a result Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus offer numerous options for supporting process development and optimisation, which can provide important findings designed to enable confidence in scale-up conditions.

### Freezing point

Our LyoRx sensor monitors electrical resistance as well as the product temperature. The resulting profile data can be utilised by our LyoControl software for the automatic determination of your product freezing point.

The benefit to your process is a reliable estimation of the critical product temperature tolerances during the main drying phase to prevent product melting.

### Product resistance

The LyoRx sensor enables the automatic control of the energy supply of the individual shelves during the main drying phase, which makes it possible to limit the thawing effects of the product, for example.

# Product temperature

In order to measure the product temperature, the unit can be equipped with up to three PT-100 sensor (more on request). The product temperatures on the various shelves can be viewed in the LSCplus control system. WTMplus is possible.

#### Comparative pressure measurement

The use of two different vacuum sensors (Pirani and capacitive principle of measurement) enables conclusions to be made concerning the end of the main drying phase. When the difference of the pressure measurement falls below a predefined limit, the secondary drying phase will be started automatically.

LSCplus colour touchscreen

### LyoBalance – easy to use

The microbalance provides the ultimate direct measurement of the weight loss during the entire process. As innovation, the Operation is integrated in LSCplus with data monitoring via the LyoLogplus or LPCplus-software of the pilot unit. Furthermore, the speed of drying is documented. Comparative trials can be assessed instantaneously.



LyoControlplus



LyoBalance

# **Comprehensive Range** of Customized Solutions

# With the Epsilon 1-4 LSCplus and Epsilon 2-4 LSCplus Martin Christ has set a standard for high-quality and flexible entry pilot-models. Units provide the highest level of functions for successful research and process development. Systems with customized configurations have been supplied to global acting pharmaceutical companies and Biotech start-ups.

Modifications include:

- Clean-Room Integration
- Isolator / Glove-Box integration
- Automatic vial stoppering
- H<sub>2</sub>O<sub>2</sub>-decontamination
- Special systems for solvents, including GN<sub>2</sub>-inerstisation option

# Further high quality and high performance pilot freezedrying systems

- Drying chamber and shelves are manufactured to the same standard as pharmaceutical production systems
- Shelf areas ranging from 0.2 m<sup>2</sup> to 1.2 m<sup>2</sup> with ice condenser capacity from 6 kg to 16 kg
- Comprehensive system monitoring with LSCplus interface
- Large range of process optimisation tools (PAT)
- Validation packages available for GMP/FDA guidelines



To show the sh	C	· · · · · · · · · · · · · · · · · · ·
<b>Technica</b>	Spec	citicat

	Epsilon 1-4 LSCplus	Epsilon 2-4 LSCplus
lce condenser		
- max. capacity	4 kg	4 kg
- performance	4 kg / 24 h	4 kg / 24 h
- temperature	approx55°C	approx85°C
- chamber volume	approx. 40 l	approx. 40 l
Shelf system		
- dimensions (W x D)	270 x 400 mm	270 x 400 mm
- area	0.108 m <sup>2</sup>	0.108 m <sup>2</sup>
- temperature range	approx45 to $+60^{\circ}$ C	approx70 to +60°C
- temperature accuracy	<±2K	<±2K
Refrigeration system		
- performance	1 x 0.51 kW	2 x 0.51 kW
- refrigerant	CFC-free	CFC-free
Dimensions (W x H x D)		
- without sealing device/manifold	780 x 520 x 530 mm	780 x 520 x 530 mm
- with sealing device/manifold	780 x 975 x 530 mm	780 x 975 x 530 mm
Weight	approx. 110 kg	approx. 145 kg
Power supply	230 V/50 Hz	230 V/50 Hz
(other voltages upon request)	220 V/60 Hz	220 V/60 Hz
	208 V/60 Hz	208 V/60 Hz
Nominal power	1.5 kW	2.0 kW
Noise level as per DIN 45635	54 dB(A)	54 dB(A)
Defrosting function	hot shelf radiation	hot shelf radiation
Vial stoppering		
- manual	$\checkmark$	$\checkmark$
- hydraulic	•	•
LyoControl	$\checkmark$	✓
End point determination		
- product temperature measurement	$\checkmark$	$\checkmark$
- capacitive pressure measurement	•	•
Additional functions		
- safety pressure	$\checkmark$	$\checkmark$
- Lyo-Rx – resistance safety value	$\checkmark$	$\checkmark$
- $\Delta T$ product and shelf	$\checkmark$	$\checkmark$
Programmer module		
32 programs with 64 sections each	$\checkmark$	$\checkmark$
USB	•	•
LyoLogplus	•	•
LPCplus	•	•



7

• = option  $\checkmark$  = standard

Subject to technical changes





Martin Christ Gefriertrocknungsanlagen GmbH An der Unteren Söse 50 37520 Osterode • Germany Tel. +49 (0) 55 22 50 07-0 Fax+49 (0) 55 22 50 07-12 info@martinchrist.de www.martinchrist.de