

## GEA Lyophil LYOPLUS™

Multipurpose measurement device  
for pharmaceutical freeze dryers



LYOPLUS™ is a mass spectrometer that is fitted with advanced software enabling it to provide multiple process and equipment measurement data. The system is able to work alongside any existing PLC/SCADA system as a stand alone unit or fully integrated within the control system. It can also be operated independently as a monitoring system that does not interfere with any qualified processes.

### Silicone oil detection

Top of the list of system benefits is its unique ability to detect very small traces of silicone oil within the dryer. Silicone oil is used to transfer the required heat energy to the product. After years of operation and many cycles the arduous conditions within the dryer could lead to small leaks. As a consequence oil can contaminate the final product.

After the leak in the circulation system has reached a certain size this contamination will be detected during end product testing in quality control. That particular batch is of course lost but additionally suspicion immediately rises about the purity of previous batches.

Using LYOPLUS™, however, it is possible to detect very small traces of silicone oil leaking within the dryer during the operating cycle. No additional batches are at risk as the leak would have been detected immediately.

### Moisture content

The LYOPLUS™ system can also monitor moisture levels within the drying chamber during the drying cycle. At the beginning of the drying process the chamber will be filled with a saturated water vapour as water is removed rapidly from the product. During the later stages, however, the moisture level in the chamber reduces significantly. LYOPLUS™ measures this drop very accurately and correlates the measurement with the actual average product moisture inside the vials. This information can be used to refine drying recipes and avoid any unnecessary drying time. One of our customers has reported a three-hour saving per cycle providing improved productivity and a reduction in power consumption.

An additional benefit comes from being able to predict the drying curve of the product through the moisture content in the chamber. Drying behaviour for each batch can be compared with a 'qualified batch' to confirm that the process is progressing normally.

#### Technical data:

Fully automated

Fail-safe operation to protect sterility, the lyophilization equipment and the measurement device

Standalone or optional full SCADA Implementation

High performance quadrupole mass spectrometer system

Mass range: 1-100 standard  
(1-200 AMU or 1-300 AMU optional)

High conductance inlet system

Max. operating pressure: 1 mbar

Detection limit: 1ppm of non-interfering species

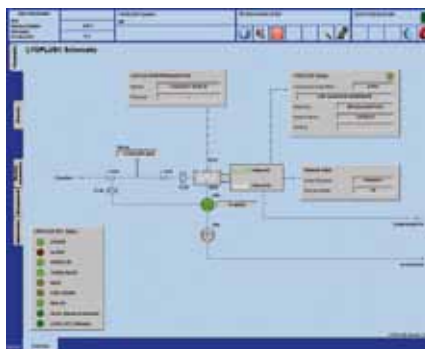
### Chamber leak tests

To prevent any contamination through a vacuum leak in the system, it is mandatory to perform a leak test after each critical process, i.e. after sterilization. This can take up to four hours, depending on the type of test performed, causing loss of productivity and consuming additional energy to create the necessary test conditions. By using LYOPLUS™ it is possible to reduce the time for this standard procedure down to approximately one hour owing to its very high sensitivity.

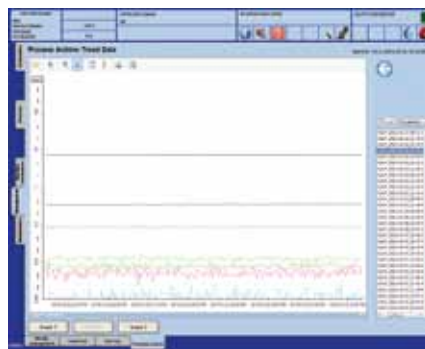
If during the test a leak is detected it is necessary to perform a helium leak test to find the source of the leakage. Using standard external equipment for helium leak testing sometimes takes several hours to set up; LYOPLUS™ is permanently connected to the system so the helium leak test can begin instantly, detecting leaks much faster thereby saving valuable time.

LYOPHIL™	Type 1	Type 2	Type 3
Contamination monitoring	Yes		
Drying endpoint verification	Yes		
Leak Check	Yes		
Operation	Standalone		Integrated
PLC update required	No	No	-
SCADA	Process Eye	WinCC	FALCO*
Multilingual	No	Yes	
21 CFR Part 11	No	Yes	
Audit trail, User log	No	Yes	
Batch report	No	Yes	
Data export	Yes		
Connection	Tri Clamp or customer demand (<3d)		
IQ / OQ	Yes		
PC Hardware	Laptop	Desktop	Desktop or Server
Power supply	240V / 115V ; 50/60Hz		
Portable	Restricted	No	No

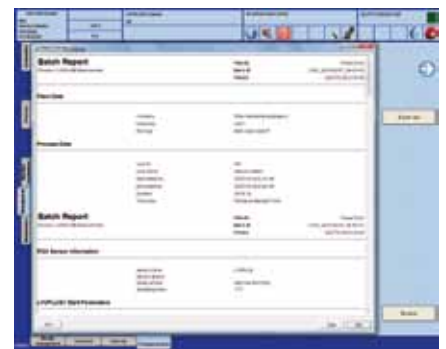
\*Depending on Freeze Dryer: WinCC, InTouch or iFix



Schematic system overview



Online / History data trend view



Batch Report preview

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