PRODUCT SPOTLIGHT

TrackSense® LyoPro Wireless Data Loggers

Validation & Monitoring Solutions

In this Product Spotlight we will present you with some of the many advantages of using our new LyoPro Data Logger. LyoPro is designed specifically for validation and batch control of freeze drying units that use automatic vial loading and unloading systems in the pharmaceutical industry.

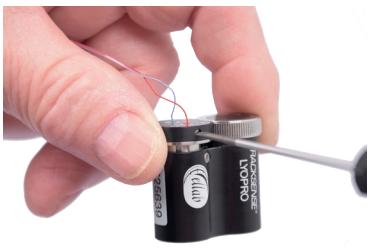
Background

During lyophilization in the pharmaceutical industry, it is very important to measure the critical ice temperature of the product inside of vials. These measurements are crucial to avoid the loss of batch, as well as to determine the end of primary drying and the start of secondary drying – allowing you to save precious time.

To address the challenges of freeze drying, Ellab developed the LyoPro data logger with various fittings and fixtures to reliably measure the product temperature.

All LyoPro systems include a wireless LyoPro data logger, 10-slot reader station and an Access Point for LIVE data transmission.

The data logger is equipped with an extremely thin thermocouple sensor (0.55 x 0.95 mm) that fits perfectly in the special StopperClips designed for pin-point and repeatable placement within various vial sizes. Ultimately, measuring the critical ice sample temperature for controlled validation and batch control.



Achieve Minimum Displacement of Product Inside of Vials

The StopperClip is specifically designed for keeping the data logger and vial together when operating automatic loading and unloading systems. While also simulating the actual sublimation taking place within the sample vial.

Throughout the entire process, the StopperClip firmly holds the thin LyoPro thermocouple sensor in place – ensuring an accurate and repeatable result. Which in turn, also allows the data logger and sensor to safely pass through the process without being damaged.

The StopperClip is equipped with a PEEK tube that allows you to mount the sensor at the exact spot for critical ice temperature (hot spot) inside the vial.

The extremely thin profile of the replaceable thermocouple sensor ensures minimal displacement of the product volume - thereby resulting in little to no impact on the measurements.

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Long Process Duration and Stored Data

The LyoPro data logger not only transmits LIVE data, but simultaneously stores measurements in the data logger memory to avoid data gaps. It does so by incorporating a high-capacity battery designed to function at extremely low temperatures. This battery can easily be replaced by an operator without the use of tools.

Each LyoPro data logger has a non-volatile memory capacity of 100,000 samples, which equals a sampling time of:

- 27 hours with a 1 sec. sampling rate
- 135 hours (6 days) with a 5 sec. sampling rate
- 810 hours (34 days) with a 30 sec. sampling rate

This guarantees trouble-free validation and monitoring of the process, while the memory capacity ensures the availability of your data and full FDA 21 CFR part 11 compliance.

Easily Implement a Large Number of Measuring Points

The validation of freeze dryers usually requires 5 measuring points per shelf (all 4 corners and the center). And batch control could require up to 1 measuring point per shelf or, alternatively, 5 measuring points on the lowest, middle and upper shelf, unless stated otherwise in the SOP.

To ensure a complete study, the ValSuite software and the LyoPro reader station can handle up to 100 channels simultaneously – even when transmitting LIVE data.

Data is transferred to the software through a Reader Station or Access Point using radio frequency transmission with proprietary protocol. Data loggers always keep a backup of the data until being off-loaded.

LyoPro data loggers are pre-equipped with radio frequency transmitters and communicate directly with the LyoPro Access Point – allowing you to view and download your data online.

The transmission range is up to 100 meters in open space, and when loggers are placed inside the freeze-drying chamber, the guaranteed range is 15 meters. The Access Point can therefore be placed anywhere on the outside and re-transmit to any PC located far away by connecting a wireless router or LAN cable.

For large areas or volumes, more LyoPro Access Points can be used to collect and forward the measurements over the required distance.

Due to the proprietary communication protocol, signals will not be disturbed by other radio frequency signals, or vice versa. Only clearly specified user(s) or Access Point(s) can receive the data, ensuring that the system and data are completely secure and compliant.

No Headaches for Automated & Continuous Runs

The LyoPro data logger system is designed for automation. Adding LyoPro is the final step after vials are processed, washed, depyrogenated, filled and finally loaded into the freeze drying unit.

Simply sterilize the LyoPro data logger and appropriate fittings and connect them to the sample vials within the isolator prior to the loading platform. Doing so will ensure that all your predefined measuring points are covered.

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Working with autoloading systems that provide limited manual access to the vials poses many challenges, but these can be overcome through the following 3-step procedure:

1. The LyoPro data logger is configured with a thermocouple sensor and StopperClip, and then sterilized together at 121 °C for a maximum of 30 minutes before being introduced into the isolator area

2. Within the isolator, the LyoPro data logger is placed onto the conveyor belt in line with the other sample vials. This can be done fully automatically through robots

3. Now fully connected, the LyoPro data logger configuration is pushed to the shelf loading plate and introduced into the lyophilizer at the appropriate position according to SOP/ guidelines

Measure Pressure to Supplement Your Temperature Measurements

By using a Pirani type sensor like the TrackSense Pro Vacuum sensor, it is possible to detect water vapor pressure during the primary drying phase. This can be particularly useful to detect when primary drying is ending as the pressure will drop and stabilize.

A Pressure Rise Test (PRT) consists of measuring the pressure rise during the shut off within the isolation of the product chamber to the condenser. It is also an excellent process monitoring tool that can provide estimates as to how much vapor is still sublimating from the samples. This will detect the various phases from primary drying to secondary drying, and the eventual end-point.

Data Analysis, Data Integrity and FDA Compliance all in one

Tying it all together is the FDA 21 CFR Part 11 compliant ValSuite software. Data is collected with LyoPro and then analyzed through the many available tools within ValSuite:

- Database structure that enables complete documentation and procedural control
- Generates a wide range of PDF reports
- Integrated audit trail, access manager and electronic signatures
- And much, much more

The software package includes all the required documentation, including the IQ/OQ.

In-House Calibration is Easy - and Required

For an optimal and documented performance, the ValSuite Software package also includes templates for manual, semi-automatic and fully automatic Calibrations. Calibrations are performed by using oil baths or dry blocks, along with a reference instrument like the Ellab Temperature Standard.

As the LyoPro sensor is a thermocouple type T, it can easily fit into any dry block for pre- and post-calibration. To complete the procedure, a calibration certificate will be issued for full traceability and performance documentation.

For more information on the
TrackSense® LyoPro Data Logger System
or to find the right solution, please contact:

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