



Validation & Monitoring
Solutions

TrackSense[®] LyoPro

Revolutionize your Freeze Drying Process



Global Expertise with Local Reach

Revolutionize the Validation and Monitoring of your Freeze Drying Process with Ellab's LyoPro Data Loggers

Designed with a single application in mind, [LyoPro addresses all your lyophilization challenges](#), specifically when operating automatic loading and unloading systems



What Makes Freeze Drying so Special?

Freeze drying is a critical process for producing biological drugs in vials within the pharmaceutical industry. The FDA estimates that more than 45% of all approved biological drugs produced today are manufactured using this approach.

Each of these vials hold a high life-sustaining and monetary value, making the act of preserving every single batch extremely vital. When combined with the immense energy consumption, a production batch of 50-100,000 vials could easily represent millions of dollars/euros – so failure is not an option.

To avoid batch loss, the freeze drying process must be accurately validated and the batch must be carefully monitored. Achieving this requires following FDA, GMP(A) and ISO guidelines, and using high-end validation and monitoring equipment, like LyoPro.



How does Ellab Match Your Requirements?

With [LyoPro](#) you get the ultimate solution for [lyophilization](#). Whether this is for validating the process, temperature mapping the equipment or batch control, LyoPro is your solution from pilot to production.



- Include more than **100** transmitting data loggers in a single study for a complete overview of the process
- **Eliminate data gaps** and ensure FDA compliance from start to finish with an internal memory
- **Comply** with norms for shelf mapping and batch monitoring even in large industrial scale lyophilizers
- Ensure **sample integrity** by using ultra-thin exchangeable thermocouple sensors with high accuracy and pin-point positioning
- Avoid **down-time** by performing on-site user calibrations via an embedded ValSuite software functionality
- Save time by accessing **live data** directly from your PC in real-time
- **Compact design** enables easy sensor configuration, handling and placement within the automatic loading process
- Ensure **FDA compliance** by using an industry leading software that focuses on data integrity and SCADA/Citrix/AWS system compatibility for central access and control

Optimize Your Lyophilization Process by Making it Smarter and More Efficient

Within the compact start-up suitcase, you get everything you need to setup a complete validation or monitoring session. The setup includes:

- **LyoPro Reader Station**
Start, stop and read your LyoPro data loggers
- **Multiple LyoPro Data Loggers**
To appropriately cover your freeze dryer's design and layout
- **Exchangeable thermocouples**
Measure temperature accurately
- **StopperClips**
Keep your measuring point fixed and consistent in the desired position within the vial
- **Batteries**
Ensure constant performance during long studies - and power internal memory
- **Various accessories to complete the setup**
LyoStoppers, LoggerClips, LoggerNests and more...





Replaceable Thermocouples with Pinpoint Accuracy

The patent pending [LyoPro data logger](#) is designed with the shape and operation of moving vials in mind - specifically for automatic loading and unloading systems. At 0.55 x 0.95 mm, the ultra-thin LyoPro thermocouple sensor has little to no impact on the samples once inserted

These pre-calibrated thermocouple sensors have an accuracy of $\pm 0.3^{\circ}\text{C}$ and are highly robust despite their small dimensions. While available in standard lengths, the sensors can easily be shortened and/or replaced.

Consistent and Repeatable Measurements

Consistency is king when working with very fine comparisons and accuracies. To be the most consistent in the business, Ellab developed a special [LyoStopper™](#) (patent pending) for introducing the sensor into the vial.

The LyoStopper is fitted with a PEEK tube that allows you to reach the same measuring point repeatedly. Along with a uniquely designed stopper that effortlessly locks the sensor cable in place - while protecting the sensor during stoppering.



Software Setups for Every Situation - With or Without LIVE Data Transmission

Programming and monitoring your LyoPro units is made easy with [the ValSuite Pro software](#). The [LyoPro 10-slot Multi Reader Station](#) is simply connected via USB or LAN and the software does the rest. The data loggers communicate using radiocommunication according to Ellab proprietary protocols, ensuring rapid start times and fast data uploads.

While up to 10 [LyoPro data loggers](#) can be started by a Reader Station simultaneously, you can easily run up to 128 in the same study by adding more LyoPro loggers to the session.

The ValSuite Pro software can be operated from a single laptop or integrated into large-scale IT systems, meaning full compatibility with:

- Client server solutions with a central server database, e.g. Citrix solutions
- Virtual servers and remote desktops
- Cloud solutions, like Amazon Web Service (AWS)

The transmission range between data logger and [Access Point](#) is up to 100 meters in open space. However, once inside a closed vessel such as a Lyophilizer, the transmission range is guaranteed to be at least 15 meters.

The Access Point can therefore be placed anywhere outside the freeze dryer and still be able to send data to a PC. The Access Point can either be connected via a wireless router or by connecting a LAN cable - or alternatively via USB.

If the Lyophilizer is very large, more Access Points can be connected.



The portable LyoPro reader station is completely maintenance free. It consists of a strong anodized aluminum shell with a polymer base and built-in ethernet port. The Internet Protocol (IP) and Media Access Control (MAC) addresses are clearly shown on the underside of the reader station - allowing you to easily connect and define the device in ValSuite. Alternatively, the reader station also functions as a plug-and-play device via USB.

Each LyoPro loggers is equipped with a RF (Radio Frequency) transmitter and can transmit LIVE data to a LyoPro Access Point.



Due to the proprietary transmission protocol, the data transmission will not be disturbed by other radio signals or vice versa. Only specified Access Points will be able to receive the encrypted data, thereby guaranteeing total system security and data validity.

In case an unlikely situation happens wherein a signal is lost during transmission, data will be saved in the data logger memory. This data will then be transmitted once the connection is re-established.



One Data Logger for All Vial Sizes

Different sized vials are no problem for the LyoPro data logger. The device can be adapted to every standard vial from 2R all the way up to 100R, as well as custom vials. All in accordance with ISO 8362-1:2008. By introducing a combination of [LyoStopper](#), [LoggerNest](#) and [LoggerClip](#) components, the LyoPro will fit any vial size.



Strengthen Your Freeze Drying Data Coverage

Boost the wireless signal strength of your [LyoPro data loggers](#) to ensure a steady supply of measurements. With the [LyoPro Dual Antenna](#), your crucial live data can even transmit through heavily insulated freeze dryers and freeze dryers without sight windows.

The antenna can easily be fitted onto any freeze dryer to keep your processes running smoothly.



To accommodate various vial sizes, the LyoPro is effortlessly mounted, or 'clicked', onto the [LoggerNest](#). The nest is shaped exactly like the vial in question, allowing data loggers to easily follow the operation on the conveyor belt as if they were vials. Shelf stoppering is also a breeze for LyoPro, as the nest ensures that the device has the same height as the vials.

As an added feature, the LoggerNests will also secure your LyoPro device in place, even during rough handling and automated loading systems.

LyoPro - Main Technical Specifications

Temperature Measuring Range:	-62 to +62 °C
Sensor Element:	Thermocouple - Type T
Accuracy:	± 0.3 °C (-60 to +60 °C)
Operating Temperature:	-65 to +140 °C Can be sterilized at 121 °C for up to 30 min.
House Material:	PEEK
Diameter:	18 mm (each compartment)
Length:	32 mm
Memory Capacity:	100,000 samples
Minimum Sample Rate:	1 Second
Time Accuracy:	± 5 Seconds per 24 hours
Battery:	TSL 150 Special Battery

Attach and Detach with Ease

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Secure Your Setup

With the [LyoPro](#) suited to fit the exact size of the vials, the only thing missing is the connection between the data logger and vial. To do this, we use different types of clips.

StopperClip

The [StopperClip](#) provides an effortless connection between the LyoPro data logger and the vial - ensuring that they are safely steered together. The clip comes with an integrated stopper system, while simultaneously fixing the position of the sensor at the predefined measuring point. The StopperClip is easy to handle within aseptic procedures, making it the ideal choice when using fully automatic robotic systems.



The PEEK StopperClip is also designed to offer room for an additional buffer vial that can be placed between the data logger and vial - and can be manufactured according to any vial dimension.

Flexible LoggerClips

If more flexibility is required on conveyor belts, the LyoPro data loggers can alternatively be fitted with [LoggerClips](#) instead. These simple yet crucial PEEK devices function as dual clips, connecting the LyoPro and vial neck.



Introduce Buffer Vial

To remove any and all doubt in regard to whether the LyoPro data loggers have a temperature impact on the measured vial, a special BufferClip is available. While similar in material and functionality as the regular LoggerClips, the Buffer version allows you to have a 'buffer vial' between the LyoPro and sample vial.



Measure Shelf Temperature

Accurately measure shelf temperature and [map your freeze dryer with the LyoPuck](#). This special contact puck is an extension of the LyoPro fitting range and is designed to be used together with the TrackSense® LyoPro data loggers. The LyoPuck is ideal for shelf temperature mapping of freeze dryers, and offers an excellent performance at ambient conditions as well as in a vacuum. It is easy to clean and maintain, and can be completely sterilized.

The sensor is placed through a hole in the bottom, while the PEEK screw keeps the sensor firmly connected and the weight of the contact puck secures a steady position within the freeze dryer during the entire operation.



ValSuite® Pro

The Ultimate Time-saving Software Solution



Tying it all together is our [ValSuite Pro validation and calibration software](#) – which is ideal for lyophilization.

This intuitive software is fully FDA 21 CFR Part 11 compliant and combines all our equipment systems into one, opening the door to a vast number of new possibilities.

ValSuite Pro offers features like:

- Customized reports with clear pass/fail criteria
- Test templates
- Data analysis
- Monitoring
- Live data
- And much more...

ValSuite Pro also comes with an outstanding Datapoint Process Report Generator (DPRG). Thereby producing fully compliant user reports in accordance with current norms and standards.



Optimize Your Freeze Drying Process with ValSuite® Pro

Features Designed for Freeze Drying

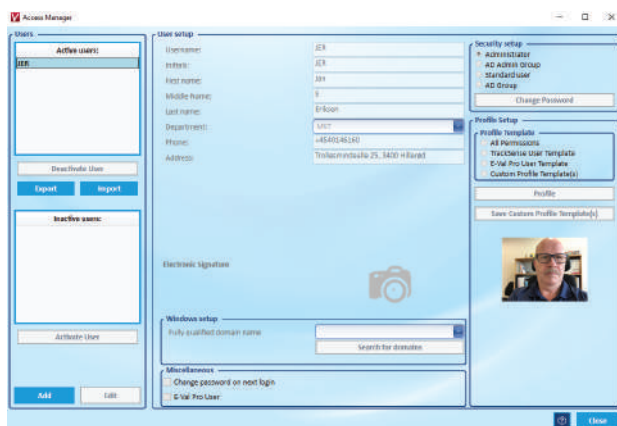
Security Modes and Access Manager

ValSuite Security uses an advanced access manager function to define users and configure their rights. It defines, lists and controls the access to application setups, session execution, file handling and more.

[ValSuite](#) has individual profiles that are used to allow or restrict the functionalities depending on the selected profile - thereby ensuring integrity.

The access manager can also be linked to Windows Login, making ValSuite users part of an AD group. Providing the following benefits:

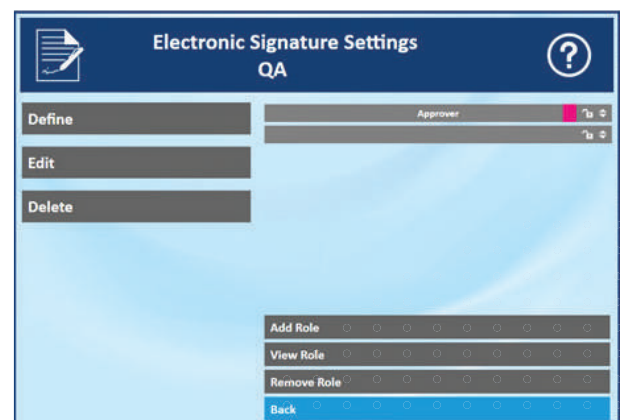
- Administrators and standard users will be sorted into their designated groups
- Passwords will be handled by Windows
- Decide whether passwords should be prompted at startup or predefined points



Electronic Signatures & Electronic Master Report

In addition to password login requirements, audit trails and controlled user permissions, the electronic signature feature is a cornerstone of FDA 21 CFR Part 11 compliance. Approve, control and lock every session with time stamps and user ID's with our workflow function that define users as Operator, Reviewer or Approver.

The Electronic Master Report feature allows you to automatically apply an electronic (digital) signature to report pages. Ultimately making your approval process faster and safer.



Audit Trail for Complete Traceability

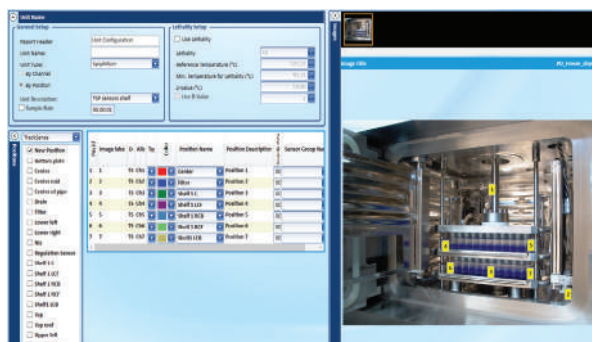
The audit trail in [ValSuite Pro](#) functions as a record of who has accessed and used the software – presenting the following information:

- Unique ID number
- Actions performed according to the access points
- Category definition
- Operator initials
- Time stamps

Due to the database structure, it is possible to facilitate convenient searches for e.g. user ID's or dates. Every single session has an individual audit trail that summarizes the entire study in chronological order.

Units with Pictures

ValSuite gives you the option to document the sensor number in relation to its position by adding a Unit with pictures. Perfect for systematic repetition, as it allows multiple pictures or graphical schematics to be added.



Advanced Phase Statistic Report

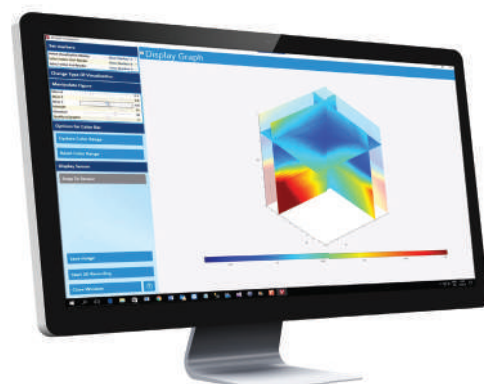
The Advanced Phase Statistics report is ideal for shelf mapping. The flexible analyzation tool can either be manually defined, setup using time markers or to automatically detect phases to perform statistics such as:

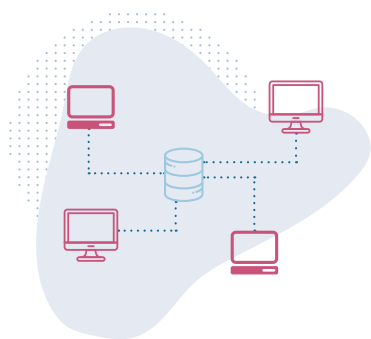
- Min./Max. standard deviation
- Average
- Delta T
- Limit tests

In addition to the wide range of tests, an overall pass/fail report can then be generated for a complete overview.

3D Heat Map Analysis

Temperature mapping has never been easier. With the optional 3D Analysis tool ValSuite can generate a 3D temperature map. By showcasing hot and cold areas based on a change in color, gaining insight into the process becomes faster than ever.





Client/Server Solution

Having several ValSuite installations spread across a wide range of PC's/clients is no problem with our Client/Server Solution. This ValSuite feature allows all sessions from the various sources to share a single database. Thereby connecting all your PC's to the same server to provide access to all data simultaneously.



LyoPro Communication Hub (OPC-UA Server)

Transmit your live data directly from your LyoPro data loggers into your SCADA system.

The Communication Hub also allows you to start and pause the transmission of data to the servers through the SCADA system.

User Calibrations

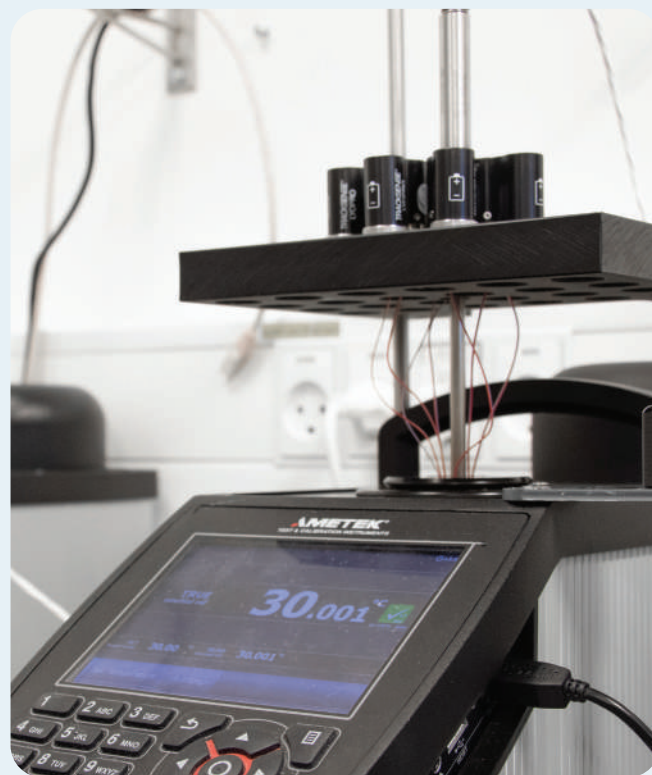
[ValSuite also acts as a calibration software](#) that secures the validity of your data. This means that all your [LyoPro data loggers](#) can be user-calibrated at predefined intervals and easily have their offset values stored in the software.

A report is automatically generated with the overall calibration results. Pre- and post-calibration reports can also be generated and merged to form a complete study report.

The identified offset values are linked directly to the sensor ID and will be considered for future measurements.

All calibration reports are available in the Ellab cloud.

Fully automatic calibrations can also easily be performed by simply inputting the calibration criteria – allowing you to walk away until the calibration is complete.





Validation & Monitoring
Solutions

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Global expertise with local reach

Ellab has been your validation and monitoring partner since 1949, offering both validation equipment and validation services as well as environmental wireless monitoring solutions.

We serve both small and large companies within the Life Science and Food industries and have solutions for almost all applications such as sterilization, freeze drying, environmental chamber testing, depyrogenation, warehouse mapping, pasteurization, controlled temperature units (CTU) and many more.

Ellab develops unique and innovative solutions based on input from close interactions and dialogues with our customers. Our goal is to help our customers overcome challenges and increase their productivity by providing reliable and efficient solutions.

Ellab also offers complete turn-key or supplemental rental solutions, equipment qualification and validation services and our specialized training courses within Ellab Academy.

Ellab has a long tradition and dedication for delivering the highest performance and quality in our industry. Our user friendly and flexible validation and monitoring solutions are recognized and used by thousands of customers worldwide.

Ellab A/S in Denmark is ISO 9001, ISO 14001 & ATEX IEC 80079-34 certified. Ellab A/S Calibration facilities are accredited according to ISO 17025 by DANAK under registration no. 520 and our affiliates in UK, Germany and Italy also carry the ISO 17025 accreditation executed by local authorities.

For further information all certificates for the Ellab Group can be found [here](#).



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