

# Validation Solutions



*Welcome to our world of validation...*

# Ellab Validation Solutions

## - your validation partner



Ellab has been your validation partner since 1949, offering wireless data loggers and thermocouple systems for thermal validation processes.

We serve both small and large companies within the Pharmaceutical, Medical and Food industries. We have solutions for many applications such as sterilization, freeze drying, heat tunnels, pasteurization 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 that are supported by a responsive and competent service team.

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

Ellab A/S is ISO 9001 & ATEX IEC 80079-34 certified. Our calibration laboratories are accredited according to ISO 17025 by DANAK under registration no. 520.

*"We provide the world's leading life science and food companies with high quality thermal process validation and monitoring solutions"*

# A Global Business

## - with local presence and support

Our comprehensive range of wireless data loggers, thermocouple systems, calibration equipment, temperature indicators, software solutions and accessories are inclusive of an impressive customer support program that includes technical support, field and factory calibrations, service capabilities and much more.

Combined with our hardware and software engineering and research office in Denmark, our various sales and service centers, and over 120 distributors around the globe, our world-wide presence allows us to provide outstanding service, validation and qualification services, rentals and calibrations no matter where you are!



*“We strive to be the leading validation solution and service provider”*



# TrackSense® Pro

## Wireless Data Logging System

Our high quality wireless TrackSense Pro data loggers consist of high resistance stainless steel and offer high-end technology that allows for stable and highly accurate measurements within different thermal processes.

Our wireless data loggers are built with the unique feature of having interchangeable sensors, making it possible to configure the loggers with sensors for any specific application to measure temperature, pressure, vacuum, relative humidity, CO<sub>2</sub> and conductivity.

This unique feature is highly beneficial in regard to flexibility and lowered operation costs.

Starting and reading loggers can be done in seconds when using the Multi Reader Station, where up to 16 loggers can be started or read simultaneously. Hundreds of data loggers can be started in a single validation study and each individual logger can store thousands of data points within the logger itself.

Standard operating temperatures are -80 to +150°C, but with the correct accessories, our wireless data loggers can operate from -196 to +400°C. They can also withstand up to 10 Bar of pressure.

### Highlights

- Interchangeable sensors
- Small loggers and sensors to minimize the thermal impact on products
- Multi Reader Station can be expanded to program or read 16 loggers simultaneously
- Stainless Steel ANSI 316 L housing, which can be fully immersible in steam, water and oil
- Sealed electronics protection
- Large logger memory capacity
- Real Time Data communication with SKY option
- Rigid, Flexible and Internal sensor options
- High industry leading accuracy



# E-Val™ Pro

## Wired Thermocouple System

### Highlights

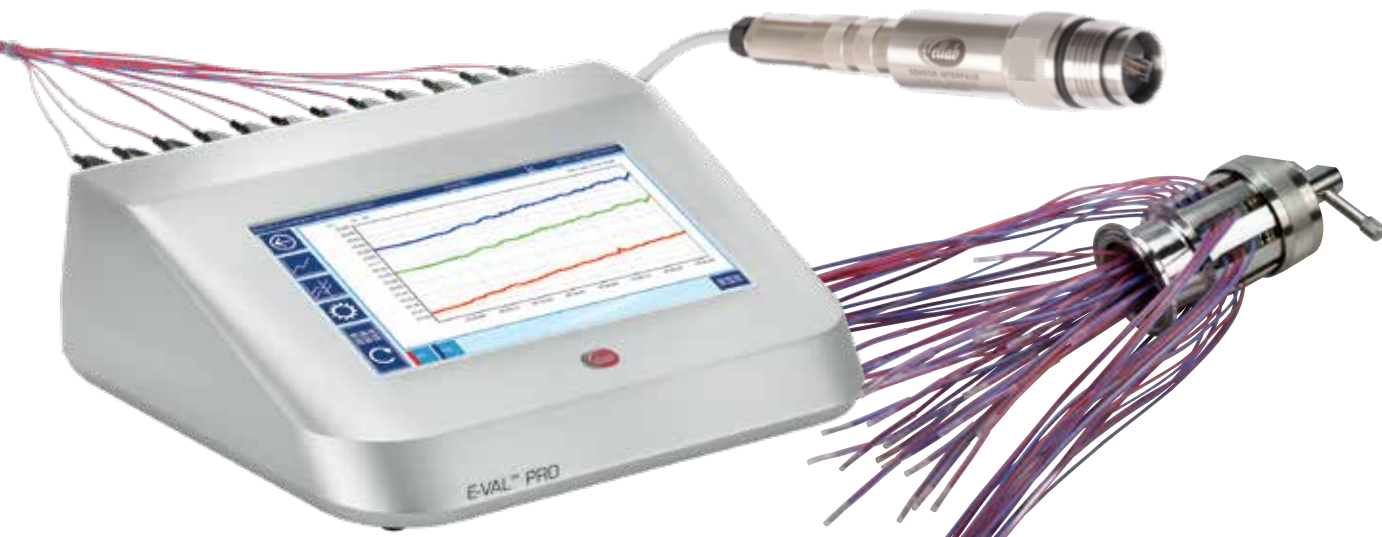
- Compact and light design without built-in fan
- 8" touch screen with full operator interface and graphical data
- Up to 3 modules (120 channels) can be used together to have one cumulative study
- Wide measuring range
- Traceable Smart Thermocouples with stored calibration offsets and cold junction temperature compensation in USB connector
- High industry leading accuracy
- Digital pressure sensor
- Sensor Interface that connects TrackSense Sensors for more parameters such as relative humidity, CO<sub>2</sub>, conductivity, etc.
- Various Analog & Digital screw terminal plugs for a wide range of sensors

Our E-Val Pro thermocouple system is designed as a perfect solution for validation applications that require compliance with FDA guidelines and international GAMP standards. It can run as a stand-alone unit or be networked to your PC and can handle up to 120 channels in one session.

E-Val Pro simplifies and documents the entire validation process, while the software keeps a complete data-base on all aspects of your validation requirements. The software tracks thermocouples, calibration reports, study parameters, data analysis, specific user access and final compliance reports.

The flexible configuration can handle up to 40 thermocouples per module, and its large internal memory can hold up to 10 studies. The E-Val Pro contains a rechargeable internal battery that can power the module for eight hours after fully charging the battery.

Automated calibration and pre/post-verification is a great time saving feature. Once the calibration template is set-up, our ValSuite software auto-ramps the bath to automatically calibrate the selected thermocouples and saves the offsets in the thermocouple ID chips. Additional thermocouples can be pre-calibrated, avoiding the need to run a system calibration if a thermocouple fails during a study.



# ValSuite™

## Validation Software

ValSuite is our very reputable validation and calibration software. This intuitive software combines all our equipment into a single platform, opening the door to a vast amount of new possibilities by allowing users to combine data loggers with the traditional thermocouple systems.

We offer multiple versions of ValSuite to meet different industry needs, most notably ValSuite Pro which is FDA 21 CFR Part 11 compliant and data integrity approved.

ValSuite offers features like customized reports with clear pass/fail criteria, test setups, data analysis, monitoring, live data and much more.

ValSuite is developed according to GAMP principles and is available in multiple languages.

We also offer a ValSuite app that allows users to view their ongoing sessions or completed validation reports.

### Highlights

- Intuitive and user-friendly
- Secure storage in world class Microsoft SQL server
- Data Integrity
- Excellent documentation features with numerous reports with pass/fail criteria, many templates and output to PDF or Excel
- Useful monitoring features such as real-time statistical calculations, limit alarms, online notifications, 3D heat map and more



# Calibration

## Dry Block or Liquid Bath

### Highlights

- DANAK accredited factory calibration
- Same software for validation and calibration
  - Manual, Semi- or Full-automatic mode
  - Calibration certificates available from our encrypted V-Lims cloud solution
- LiquiCal uses high quality liquid baths
- Reliable and fast dry block solutions
- ETS - Ellab Temperature Standard

To ensure the validity and accuracy of measured data, it is highly recommended that all equipment is calibrated regularly. This can easily be performed by users, as Ellab offers calibration equipment that includes liquid baths, dry blocks and temperature standards. These instruments work together with the calibration function in our ValSuite software, saving operators a lot of time as the full-automatic calibration feature does not require manual input from the operator.

In addition to this, recalibration services from Ellab's own metrology labs are available - some of these labs comply with ISO 17025, providing accredited calibrations.

All measuring devices leaving Ellab's production either are or can be factory calibrated. Therefore, calibration certificates with full traceability are included in shipment to prove initial performance.





# ETI

## Ellab Temperature Indicator



The Ellab Temperature Indicator, or ETI, is a high quality digital temperature-indicating device designed for displaying and documenting the processing temperature in retorts and other chambers.

The ETI is FDA 21 CFR, part 113 compliant and ideal for thermal processes involving low-acid canned foods. The stainless-steel sensor, digital display and documenting features result in a great alternative for mercury-in-glass thermometers, as it eliminates any potential mercury contamination.

The ETI is available in different versions, offering both temperature, dual temperature and pressure measurements. These sensors are all interchangeable and pre-calibrated for plug and play use. The temperature indicator can also be connected to an internal network and to a PC, which provides data gathering and analysis, and offers external alarm functions that notifies operators of any errors or temperature/pressure deviations.

Just like our other equipment, the ETI can be connected to ValSuite and in this case, also ETISuite. This ETI specific software is ideal for users who do not require additional features for other Ellab products.

## On-site Calibration Services

On-site Calibration Services are ideal for avoiding downtime caused by having to send equipment to an external calibration laboratory or for measuring devices that cannot be moved from their location. These calibrations outside a conditioned laboratory, require a high level of metrological knowledge and experience, which Ellab offers. We ensure that the calibrations and documentation conform with standards and are reproducible and traceable.





# Qualification & Validation Services

Ellab's qualification and validation services are available all around the world.

Our validation team consists of engineers with years of experience validating equipment that our temperature mapping equipment is made for. Clients that utilize Ellab's qualification services are those who desire a professional, independent and efficient team, with well documented practices and expert knowledge of the equipment that requires qualification.

We are committed to providing world-class qualification and validation services that leverage our expertise to meet all the validation needs for your cGMP/cGLP facility.



## Rental Services - as supplement or complete turn-keys

Equipment systems are available for trial and rental. This is a perfect way to get acquainted with the equipment - or simply reduce the cost of ownership for validation studies that are only required sporadically.

If you already own Ellab equipment, you can rent additional supplementary devices. This option is great for a large project that requires additional or new types of sensors.

Complete Turn-Key Rentals are also offered, supplying you with everything needed to perform qualification processes.



# Fittings and Accessories

## - for every need

To ensure high accuracy, reliability and repeatability of measurements, we offer a large and unique selection of fittings and accessories. These include feed through systems, packing glands, fixtures and other tools that enable users to correctly mount sensors and probes in all kinds of chambers and containers.

Ellab constantly develops new fittings (which can be tailor-made on demand) for improving measurements - consider that a systematic error of just 1°C in temperature measurement corresponds to an inaccuracy of 26% in the lethality value.

Besides ensuring that probes and sensors are calibrated, choosing appropriate fittings and accessories to perform accurate and correct measurements is of paramount importance to the validity of the recorded data.





## Ellab Academy Exchange Ideas - Share Knowledge

As industry standards become stricter and more regulated, Ellab recognizes the increasing demand for training and knowledge sharing between Ellab operators and system administrators.

Ellab Academy offers comprehensive training courses for individuals in the pharmaceutical, medical, and food industries, as well as for service providers, by covering all aspects of Ellab hardware, software and applications. These courses are all conducted by experienced Ellab staff.

Annually, Ellab Academy offers more than 25 different training courses, available through our eight training centers around the world.

The training consists of mixed presentations, “hands-on” exercises, directive focused group work, applicable standards and other requirements. Detailed introductions to operating and maintaining the various hardware & accessories is also included.

For more than 10 years, Ellab Academy has provided and shared specialized knowledge with Ellab operators. The academies are available in multiple languages and are customized for the participants attending.

We also offer on-site individual training courses if requested.





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