

# E-Val™ Pro



*The next  
generation  
in real-time  
thermal  
validation*

# E-Val™ Pro Thermal Validation System



The E-Val Pro Thermal Validation System is designed for validation applications that require compliance with FDA guidelines and international GMP standards. The E-Val Pro greatly simplifies and correctly documents the entire validation process. The ValSuite Pro software keeps a complete database on all aspects of your validation requirements - tracking thermocouples, calibration reports, test setup, data analysis, specific user access and final compliance reports.

## Flexibility for Different Validation Applications

The E-Val Pro is designed as a single solution for all thermal validation applications. It can be run as a stand-alone unit or networked in connection with your PC and handle up to 120 channels. For applications that require tight compliance control, the software documents and controls each step which reduces errors. The easy expandability makes this a complete validation solution for a facility with a variety of applications.

## Pharmaceutical:

- Autoclave Validation
- Lyophilization
- Depyrogenation
- Freezers
- Stability Chambers
- Incubators
- Alarm Monitoring
- Warehousing

## Food:

- Retorts
- Pilot Vessels
- Freezers
- Alarm Monitoring
- Smoke Houses
- Ovens
- Roasters
- Aseptic

## Quality

The highest grade electronics are incorporated into the design, greatly improving quality and accuracy. With 512MB of memory and a battery backup, data will not be lost due to a power outage. Cold junction compensation is integrated into each smart USB connector. The case is made of aluminum, ensuring durability and reducing interference in the electronics, making the unit suitable for a wide range of validation environments.



Features	Benefits
Stand-alone	Runs without PC on factory floor
4 to 40 Channel Modules	Expandable up to 120 channels logging every second
Wide Measuring Range	-200 to +1,300 °C (ready for -270 °C to +1,820 °C)
USB and Ethernet Network	Fast and reliable data transmission / Compatible with most PC's
Premium grade thermocouple	High accuracy $\pm 0.05$ °C for type T / NIST traceability between -50 and +150 °C
Smart USB connection with ID and cold junction	Calibration offsets travel with the thermocouple / Dramatic time savings during set-up / Compliance tracking and error reduction
512 MB Memory	10 sessions with 40 channels using 1 sec. sample rate / 8 hours can be stored
8" touch display	Display real-time data without the use of a PC for all channels / Real-time statistics
Battery Power	8 hours. Backup if power failure occurs or electricity is not available.
Small size (3.0 kg / 6.6 lbs)	Easy portability
Aluminum housing	Durable
Compliance Reports	Standard F-value reports (EN17665) / Calibration report
Custom Reports	Ability to summarize and report key data as required
Print Reports	Print directly to PDF file format with print preview feature
Security	Encrypted data / User IDs and passwords
Compliance	21 CFR Part 11 / International GMP standards
Same Software Platform for E-Val Pro and TrackSense® Pro Data Loggers	Less validation work / Less training. Ability to combine wired and wireless data into one session
Noise level	Very low / No fans

### Accuracy

High accuracy is ensured by the implementation of ID chips that enable factory certification and calibration offsets to be stored in each individual thermocouple.

Accuracy of the E-Val Pro modules is  $\pm 0.05$  °C between -100 and +400 °C and  $\pm 0.1$  °C between -200 °C and <-100 °C in an operating environment of  $+23$  °C  $\pm 3$  °C.

Accuracy of calibrated Ellab type T smart USB thermocouples is  $\pm 0.05$  °C from -50 to +150 °C.

Total system accuracy using Ellab type T smart thermocouples is  $\pm 0.10$  °C.

### Saving Time

Using E-Val Pro saves valuable time in a variety of situations. Set-up time is minimized by using USB connectors. These connectors quickly snap into the module saving time during set-up and when thermocouples are in need of replacement. The software automatically identifies the channel because of the ID chip in the connector, eliminating the need to label each thermocouple manually.

Automated calibration or pre- and post-verification is the greatest time saving feature. Once the calibration template is set-up, the software is capable of auto-ramping the bath and streaming data from the reference standard directly into ValSuite Pro. This will automatically calibrate the selected thermocouples and save the offsets in the thermocouple ID chips. Additional thermocouples can be pre-calibrated alleviating the need to run a system calibration if one of the thermocouples fails during a validation study.

# E-Val™ Pro System



The E-Val Pro modules are available with 4 to 40 channels that can handle any type of thermocouple, analog or digital sensors (pressure/RH), as well as digital input/output signals.

The LCD display automatically shows all active channels showing time, temperature, pressure, and lethality for each channel. Real-time statistics are also available on the display.

Measuring range from -200 to +1,300 °C.  
Operating range from +5 to +50 °C.  
Resolution 0.01 °C.

The sampling rate can be set from 1 second to 24 hours independent of the number of channels.

## USB or LAN Connection

The modules contains easy plug and play USB connection. Each module samples data independently from other modules. It is possible to connect 3 E-Val Pro modules simultaneously.

The modules can also communicate through a standard ethernet connection directly to your PC. If a wireless network is available, a standard wifi adapter can be plugged into the module for wireless communication. The open network configuration has the advantage that it can run via a LAN connection or a wireless network. The latter is particularly useful if the use of wires is deemed impractical or impossible.

## Stand-alone

The module can be operated as a stand-alone unit. The memory can contain 10 sessions (up to 8 hours per session) with 40 channels at a sample rate of 1 second or individual sessions can contain up to 80 hours of data with a 1 second sample rate. There is password protection and data can be transferred to a PC by connecting to the PC or by using a USB key.





Since the late 1940's Ellab has been combining hardware, software, probes and fittings in order to provide customers with customized "turn-key" Thermal Validation Solutions. The ValSuite Pro software is compatible with E-Val Pro, TrackSense® Pro loggers, temperature standards and a variety of baths/dry blocks.

# Fittings & Accessories



## Custom Fittings

Packing glands and other fittings are available for probe placement in a variety of packaging materials. The glands are threaded to accept the tips and will maintain the seal when pressurized. It is very important that the tips are placed correctly in the “cold/hot zone” to obtain true lethality values. See examples of typical applications and configurations below.



## ID Label

ID labels are sold in sets of 1-16 pieces for easy identification during thermocouple placement.



## Feed Through

Provides support for up to 16 temperature thermocouples and a pressure sensor.



## High Temperature

Probes can be mounted in vials for depyrogenation applications.

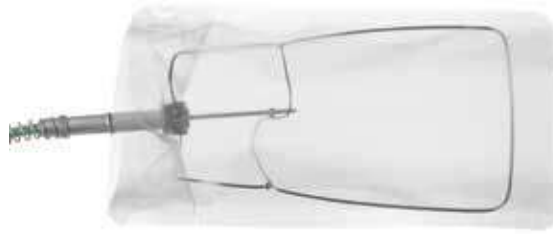


## Feed Through for STC Thermocouples

Performs leak proof insertions of STC thermocouples. Available for 20 and 40 thermocouples.

**GLK**

Probes can be mounted in plastic ampoules in moist heat sterilization applications.

**TPJ**

Probes can be mounted in pouches for sterilization applications.

**GVJ**

Measurements inside ampoules and vials is possible with this packing gland.

**GPK**

Probes can be mounted in vials for terminal sterilization.

**GEJ**

This fitting is ideal for very small plastic containers.

**GVK**

This packing gland can be mounted on bottle necks for liquid applications.

**GNK**

Probes can be mounted on ampoules in moist heat sterilization applications.

**GKJ**

Probes can be mounted externally with this packing gland.

# Probes & Sensors



## High Precision Thermocouple Probes

Using premium grade probes dramatically improves accuracy and stability, resulting in more successful studies. Ellab develops and manufactures a wide range of type T thermocouples for a variety of purposes (probes for frozen applications, special probes for liquids and air, probes for hot air ovens and autoclaves, high temperature probes, etc). The standard and penetration probes are supplied with threads that fit into packing glands for a leak-free seal into packages or cans.



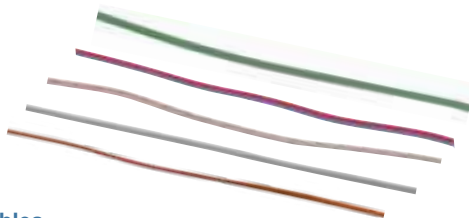
## Smart USB Connectors

The USB connectors consist of copper/constantan to minimize the source of errors. The connector is waterproof which means no liquid will enter the equipment. All connectors are fitted with an ID and contain calibration offsets along with cold junction compensation. Combining these three elements yields high accuracy.



## Sensor Arrays

The arrays are interchangeable. There are two types of interchangeable sensor arrays. One is the 4 channel multi purpose array which accommodates thermocouples, 4-20 mA, 0-10V and I/O relay. The second type is a 12 channel array for thermocouples and other low power analog/digital probes.



## Cables

The standard cables are type T, other types, like type K, are a possibility upon request.

## Screw Terminal Sensor Plug

To expand the use of E-Val Pro to include more than temperature measurements using type T thermocouples, screw terminal sensor plugs for analogue as well as digital input/output signals are available.





### Digital Pressure Sensor

Piezoresistive measuring principle  
 Temperature compensated to +150 °C  
 Material: Stainless steel  
 Cable length: 5 m  
 Operating range: 10 mBar to 4 bar ABS  
 Accuracy:  $\pm 10$  mBar



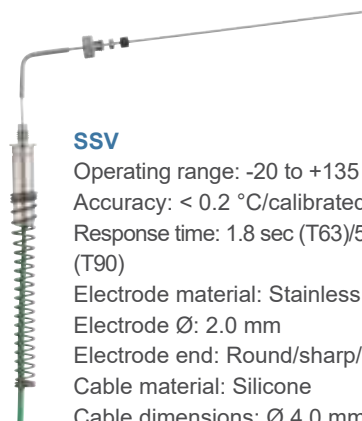
### SSA-TS

Operating range: -20 to +135 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 1.0 sec (T63)/1.8 sec (T90)  
 Electrode material: Stainless steel  
 Electrode  $\varnothing$ : 1.2 mm  
 Electrode end: Round/sharp/conic  
 Cable material: Silicone  
 Cable dimensions:  $\varnothing$  4.0 mm



### SSA-TF

Operating range: -50 to +135 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 1.0 sec (T63)/1.8 sec (T90)  
 Electrode material: Stainless steel  
 Electrode  $\varnothing$ : 1.2 mm  
 Electrode end: Round/sharp/conic  
 Cable material: PTFE  
 Cable dimensions: 2.6x1.6 mm



### SSV

Operating range: -20 to +135 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 1.8 sec (T63)/5.9 sec (T90)  
 Electrode material: Stainless steel  
 Electrode  $\varnothing$ : 2.0 mm  
 Electrode end: Round/sharp/conic  
 Cable material: Silicone  
 Cable dimensions:  $\varnothing$  4.0 mm



### SSS

Operating range: -20 to +135 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 1.8 sec (T63)/3.6 sec (T90)  
 Electrode material: Stainless steel  
 Electrode  $\varnothing$ : 3.0 mm  
 Electrode end: Round/sharp/conic  
 Cable material: Silicone  
 Cable dimensions:  $\varnothing$  4.0 mm



### SSR

Operating range: -20 to +135 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 1.8 sec (T63)/3.6 sec (T90)  
 Electrode material: Stainless steel  
 Electrode  $\varnothing$ : 3.0 mm  
 Electrode end: Round/sharp/conic  
 Cable material: Silicone  
 Cable dimensions:  $\varnothing$  3.0 mm



### SD4

Operating range: -20 to +135 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 5.1 sec (T63)/10 sec (T90)  
 Electrode material: Polyoxymethylen  
 Electrode  $\varnothing$ : 3.0 mm  
 Electrode end: Round  
 Cable material: Silicone  
 Cable dimensions:  $\varnothing$  8.0 mm by probe with 4 measuring points



### STC22-TF

Operating range: -196 to +200 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 3.4 sec (T63)/6.6 sec (T90)  
 Electrode material: PTFE  
 Electrode  $\varnothing$ : 2.5 mm  
 Electrode end: Round  
 Cable material: PTFE  
 Cable dimensions: 2.1x1.3 mm



### STC32-TF

Operating range: -196 to +200 °C  
 Accuracy: < 0.2 °C/calibrated  $\pm 0.05$  °C  
 Response time: 4.2 sec (T63)/9.3 sec (T90)  
 Electrode material: PTFE  
 Electrode  $\varnothing$ : 3.2 mm  
 Electrode end: Round  
 Cable material: PTFE  
 Cable dimensions: 3.0x2.0 mm



### SSU-MM

Operating range: -196 to +300 °C (+400 °C short term)  
 Accuracy: 1.0% of measuring range/calibrated  $\pm 0.5$  °C  
 Response time: 0.20 sec (T63)/0.25 sec (T90)  
 Electrode and cable material: Mineral insulated, Metal sheathed  
 Electrode  $\varnothing$ : 1.0 mm  
 Electrode end: Round  
 Cable dimensions:  $\varnothing$  4.0 mm



### STC-AC

Operating range: -67 to +400 °C  
 Accuracy:  $\pm 2$  °C/calibrated  $\pm 0.5$  °C  
 Response time: 1.4 sec (T63)/2.7 sec (T90)  
 Electrode material: Stainless steel  
 Electrode  $\varnothing$ : 2.5 x 12 mm  
 Electrode end: Round  
 Cable material: Fibre glass  
 Cable dimensions: 1.8 x 1.1 mm



### STC-KT

Operating range: 0 to +260 °C (+350 °C short term)  
 Accuracy:  $\pm 2$  °C/calibrated  $\pm 0.5$  °C  
 Response time: 2.5 sec (T63)/5.2 sec (T90)  
 Electrode material: Stainless steel  
 Electrode: 2.5 x 20 mm/3.0 x 20 mm  
 Electrode end: Round  
 Cable material: Kapton  
 Cable dimensions: 1.2 x 1.9 mm / 1.4 x 2,4 mm

# ValSuite® Software

## The Ultimate Time-saving Software Solution

ValSuite is our reputable validation and calibration software. It combines all our equipment systems 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 secures full data integrity.

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

ValSuite is available in multiple languages and can run with Windows 7, 8 and 10 32/64-Bit.

## Detailed Control of Validation Studies

ValSuite guides you through the complete thermal validation process. The database structure within the software provides operators with complete documentation and procedural control.

## Test Setup

The report function allows detailed test criteria to be programmed into the software. Information on sensor placement, operator, test, vessel, required temperature limits, start and stop times, monitoring interval and specific calculations can all be saved in templates, uploaded and repeated. This ensures accurate documentation and correct implementation of the required procedures for consistent and repeatable tests.

## Software Data Analysis Features

- The data analysis tools, reduces the time required to locate critical data
- The ability to zoom in the graphs and display multiple windows at a time
- Multiple calculations, such as min/max, standard deviation, average, delta T and lethality can be calculated using any block of the displayed data - eliminating the need to export data and compromise data security

## Compliant to FDA Guidelines

- SQL database where complete sessions and individual data cannot be deleted or manipulated
- Serialized sensor ID, providing complete traceability
- Customized report generator that eliminates the need to export data into a different program

## ValSuite® Basic

- targeted small or midsized food companies

- ✓ Basic set of analytical tools and reports including Lethality Calculations
- ✓ Manual Calibration
- ✓ Database back-up and Restore

## ValSuite® Medical

- targeted hospitals and medical companies

- ✓ All **ValSuite Basic** features
- + Unit report with pictures
- + Bowie Dick Test for routine control of autoclaves

## ValSuite® Plus

- targeted larger food companies and hospitals

- ✓ All **ValSuite Medical** features
- + Automatic calibration including optional OEM configuration
- + Moderate set of analytical tools and reports including Heat Factors/Ball Simulation
- + Access Manager/Individual User Profiles
- + Server Solution

## ValSuite® Pro

- targeted the Pharmaceutical industry

- ✓ All **ValSuite Plus** features
- + Complete set of analytical tools and reports including Advanced Phase Statistics
- + FDA 21 CFR Part 11 Compliant (Audit Trail/Electronic Signature/Access Point)
- + Validated according to GAMP 5



Get more detailed  
information in our  
ValSuite® brochure



### Validated Software - Documentation

The structure of the validation documentation behind the software complies with guidelines set by the following authorities:

- Good Automated Manufacturing Practice (GAMP 5), which is written by the International Society for Pharmaceutical Engineering (ISPE)
- FDA 21 CFR Part 11, subpart B & C, which is written by the U.S. Food & Drug Administration (FDA)

These documents are either included or available upon request:

- User Requirement Specification (URS)
- Project Master Plan (PMP)
- Project Plan (CC) (RD system On-track)
- Critical Parameters (CP)
- Change Control (CC)
- Risk Based Code Review (RBCR)
- FDA 21 CFR Part 11 Compliance (21 CFR Part 11)
- Installation Qualification (IQP/IQR)
- Operational Qualification (OQP/OQR)

### GAMP Guidelines and ISO 9001:2015

All documentation and development of the ValSuite software is in accordance with the guidelines specified in GAMP and includes all the appropriate documentation. Ellab's quality system is in compliance with ISO 9001:2015.

### User Calibration

ValSuite is not only a validation software, but also a calibration software. This means that all sensors and probes can be user calibrated at predefined intervals and their offset values stored either in software and/or hardware.

A report is automatically generated with the overall calibration results. When using the Calibration Setup, users can, depending on the ValSuite version, choose Manual, Semi-Automatic or Full-Automatic Calibration. Various templates can be stored and uploaded at any given time. The identified offset values are linked directly to the ID number of the sensors, and will be taken into account whenever the sensor is used in future measurements.



# Ellab



Ellab has been your validation and monitoring partner since 1949, offering wireless data loggers and thermocouple systems for thermal validation processes 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 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 is ISO 9001 & ATEX IEC 80079-34 certified. Our calibration laboratories in DK are accredited according to ISO/IEC 17025:2005 by DANAK under registration no. 520 and our German laboratory has a DAkkS ISO/IEC 17025:2005 accreditation. We also have a UKAS ISO/IEC 17025:2005 accreditation at our monitoring manufacturing site in UK.



Validation & Monitoring  
Solutions

## Ellab A/S

Trollesmindealle 25  
3400 Hilleroed  
Denmark  
+45 4452 0500

contact@ellab.com  
www.ellab.com

