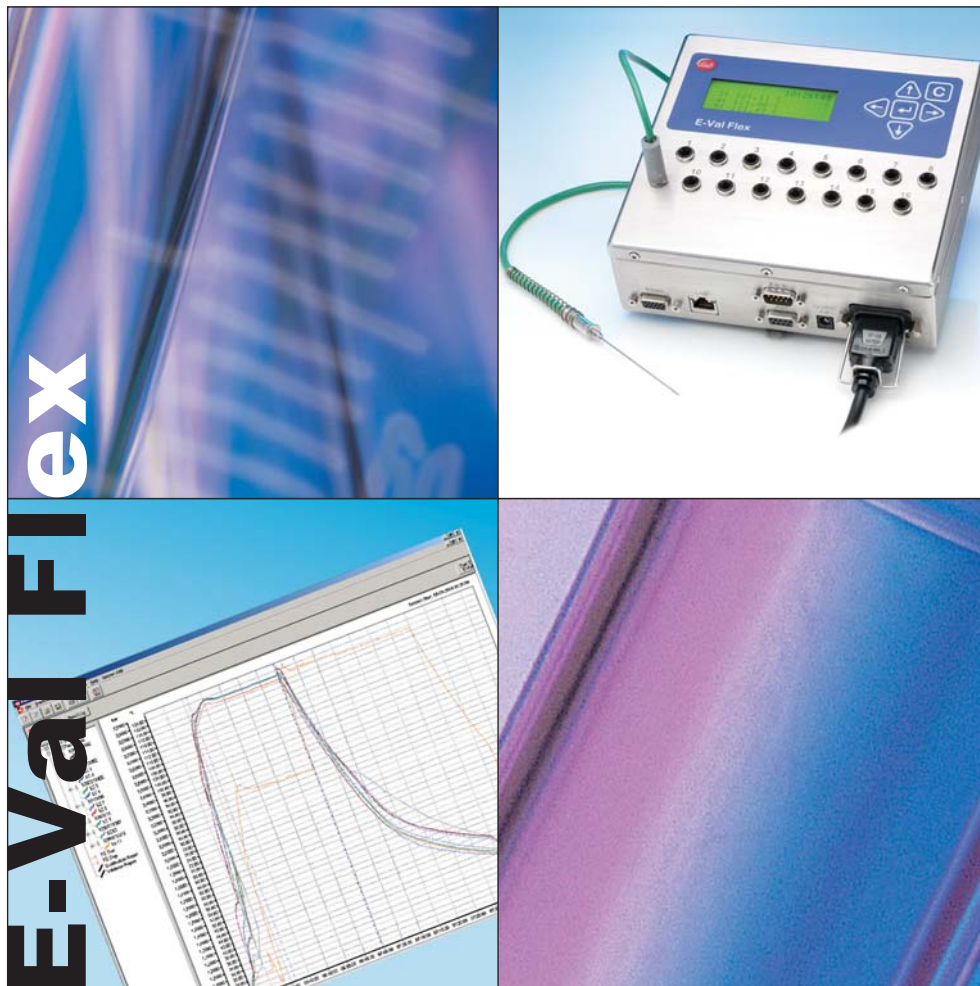


E-Val Flex



The flexible solution in
real-time thermal validation

E-Val Flex

E-Val Flex – Thermal Validation System

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

Flexibility for Different Validation Applications

E-Val Flex was designed as a single solution for all thermal validation applications. It can be run as a stand alone unit or network with your PC. The software which handles up to 128 channels documents and controls each step reducing errors and maintaining guidelines for more complex regulated applications that require tight compliance control. The easy expandability makes this a complete validation solution for a facility with a variety of applications.

Pharmaceutical:

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

Food:

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

Quality

The highest quality electronics were incorporated into the design greatly improving quality and accuracy. With 4MB of memory and a battery backup data will never be lost to a power outage. Pt1000 sensors are installed on each individual thermocouple channel eliminating gradient errors through the cold junction dramatically improving accuracy. The case is made in 316 stainless steel ensuring durability and reducing noise in the electronics which makes the unit ideal for the harsh environments on a factory floor.

Features	Benefits
Stand Alone	Runs without PC on factory floor
8 or 16 Channel Modules	Expandable up to 128 channels logging every sec.
Ethernet Network	Fast and reliable data transmission Available on most PC's
Smart Thermocouple	High accuracy ± 0.05 °C, NIST traceability
ID on Thermocouple	Calibration offsets travel with thermocouple. Dramatic time savings during setup. Compliance tracking and reduces errors
4 MB Memory	Enough to store 8 hours of data, logging every sec.
LCD Display	Display real-time data without PC
Battery Power	Backup if power failure or electricity not available
Small only 1.9 kg.	Easy portability
Stainless Steel 316	Durable
Compliance Reports	Standard Fo-value reports, EN554, calibration report
Custom Reports	Ability to summarize and report key data as preferred
Print Reports	Print directly to pdf file format with print preview feature
Security	Encrypted data, user ID and passwords
Compliance	21 CFR, part 11, international GMP standards
Same Software Platform for E-Val Flex and Wireless Data Loggers	Less validation work Less training Advantages from both systems



E-Val Flex 16 temperature channel master module

Accuracy

Dramatic improvements in accuracy with improved engineering:

- Pt1000 sensors are installed on each individual thermocouple channel eliminating gradient errors through the cold junction.
- Implementation of ID chips enabling factory certification and storage of calibration offsets in each individual thermocouple.
- Use of high quality sealed thermocouples.

Accuracy of the E-Val Flex modules is ± 0.05 °C in an operating range of 20 °C to 30 °C.

Accuracy of Ellab type T smart thermocouples is ± 0.05 °C from -50 °C to +150 °C.

Total System accuracy using Ellab type T smart thermocouples is ± 0.10 °C before system calibration.

The real time clock accuracy is better than 3 sec. per 24 hours over the operating temperature range.

The E-Val Flex system reduces the need for frequent calibration saving a tremendous amount of time. Competitive systems require calibrations before every study. We recommend running a one point verification test to find any damaged or degraded thermocouples. If you need to replace a damaged thermocouple a system calibration is not required. Since the Ellab type T thermocouples are pre-calibrated and hold the offsets in the ID chip the ± 0.05 °C accuracy is held.

Saving Time

Using E-Val Flex saves valuable time in a variety of situations. Setup time is minimized by using jack plugs. These plugs quickly snap into the module saving time with placing or replacing thermocouples. Furthermore, there are no small screw terminals which require wiring. The software automatically identifies the channel because of the ID chip in the plug, eliminating the need to label each thermocouple manually.

The administrator can set up a profile for each user. This can greatly simplify the operation for less trained users. Functions such as calibration, creating reports and general settings can be "greyed" out by the administrator. This dramatically reduces the risk of errors during operation and maintains a high degree of quality control over your studies.

Automated calibration or pre- and post-verification is the greatest time saving feature. Once the calibration template is setup the software can ramp the bath, stream data from the temperature standard directly into the calibration file and automatically calibrate and save offsets into the thermocouples ID chip. Additional thermocouples can be pre-calibrated alleviating the need to run a system calibration, if one of the thermocouples fail during a validation study.

E-Val Flex

E-Val Flex System Description

The E-Val Flex modules are available with 8 or 16 type T thermocouple channels, and the master modules have additional channels for digital pressure and for Ellab temperature standard.

The four line illuminated LCD display automatically scrolls through all active channels updating every 2 sec. showing time, temperature, pressure and Fo for each channel.

Measuring range from -200 °C to +400 °C.
Operating range from 5 °C to 50 °C.
Resolution 0.01 °C.

The master module works as stand alone or as network master. When the module has been setup and started, the PC can be disconnected and removed from the production area. Later when the process is complete, the module is reconnected and the data downloaded to the PC.

The non volatile memory in all modules stores data that has not been transferred to PC in case of power failure or loss of connection to PC. The 4 MB memory is sufficient for minimum 8 hours, 16 channels with sampling every sec. for each channel.

The RS485 port on the master module allows easy inexpensive pressure measurements. One or more pressure sensors can be connected to the same RS485 port.

The sampling rate can be set from 1 sec. to 24 hours, independent of number of channels. The fastest sampling rate is once every sec. for each channel. The modular design of the E-Val Flex enables this very fast sample rate independent of the number of channels in the system.

Ethernet or Wireless Network

The E-Val Flex modules are connected together and to the PC through a standard Ethernet network, and each module samples data independent from the other modules. The ValSuite software and the E-Val Flex hardware can handle up to 128 active channels. Ethernet is the world wide standard for local area networks (LAN), and it exists in many companies. Ethernet enables fast and reliable data transmission over long distances, and it is not affected by noise. If a cable to one module is broken, the rest of the modules will still be working.

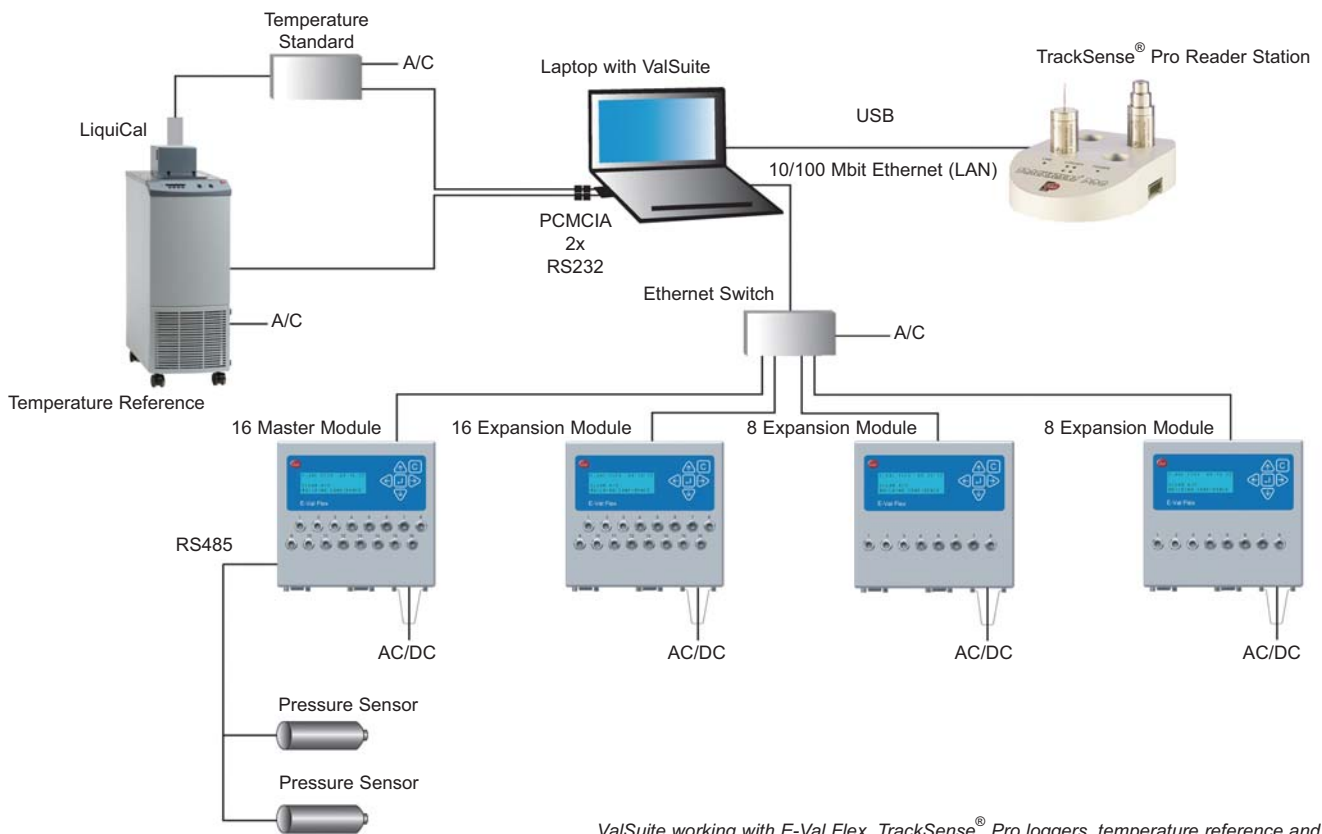
The modules can communicate through a standard Ethernet connection to your PC. If a wireless network is available, a standard transmitter can be placed on the module for wireless communication. The open network configuration is a tremendous advantage, because it can run on currently installed networks or via wireless where running wiring is troublesome.



The E-Val Flex module has many expansion possibilities

Stand Alone or Control via PC

Once the module has been started, it can be disconnected from the PC and moved out to the production floor. It is possible to see parameter values on the LCD display.



Smart Thermocouples

The E-Val Flex modules are designed for Ellab premium grade type T, 7 strand thermocouples. As a new feature the Ellab thermocouples are now equipped with an electronic ID and memory for calibration values.

The fact that Ellab has incorporated an identification chip in the jack plug of each thermocouple dramatically improves the specified accuracy ($\pm 0.05\text{ }^{\circ}\text{C}$) and ease of thermocouple identification. The internal chip identifies specific thermocouples with a serial number and contains calibration offsets which can now travel with the thermocouple. This enables easy management of thermocouple locations, historical calibration data and easy replacement during process runs.



Jack plug with ID chip

The software database keeps a complete record of usage which is a tremendous advantage in keeping track of NIST traceability and calibration history for compliance. The serial number is displayed on the jack plug and probe tip making it extremely easy to identify where each thermocouple is positioned resulting in tremendous time savings during setup.

Reduce Replacement Frequency and Maintenance Costs

Ellab thermocouples are either teflon sealed wires for distribution tests or silicone with a variety of stainless steel probe tips for penetration studies. The superior quality results in longer and more stable performance reducing replacement frequency, saving time and maintenance costs. Ellab thermocouples use jack plugs which stop moisture regression into electronics improving accuracy and durability. Jack plugs are very simple to plug into the module and do not require the setup time of screw terminal systems.

Automated Calibration

Flexibility was designed into the calibration procedure and included in the ValSuite Pro software. Calibrations can be performed manually using your current metrology standard and equipment, or completely automated with the reference standard data streamed into the calibration file as well as the ramp control of the bath. The ValSuite software enables the user to choose between standard Ellab recommended calibration points or setup a custom calibration procedure to better fit application requirements.

The reference data is logged directly into the data calibration file ensuring a high level of security. Criteria for temperature set points and stability are set in the software controlling the automatic bath ramp freeing valuable operator time. At completion, a calibration report is produced, and the offsets are saved in the thermocouple ID chip.

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Detail Control of Real-time Validation Studies

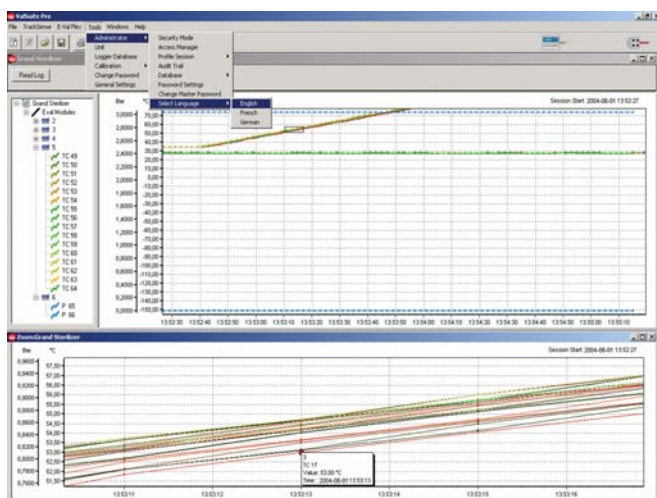
The ValSuite software documents and guides you through the complete thermal validation process. The database structure in the software enables complete documentation and procedural control for the operators.

Test Setup

Templates allow detailed test criteria to be pre-set in the software by the assigned administrator. Information on thermocouple placement, operator, test, vessel, required temperature limits, start and stop time, monitoring interval and specific calculations can all be pre-set and saved. This ensures accurate documentation and correct implementation of required procedures for consistent repeatable tests.

Pre-identifying thermocouple positions greatly reduce setup time and errors. A test setup sheet is output indicating where each thermocouple should be placed. Later during analysis this information is easily displayed and tracked.

Real-time data can be viewed on the PC or via the LCD screen on the module. Input keys on the module allow you to scroll through different channels or historical readings. These keys can also be used to manually start or stop a study on the production floor if running without the PC.

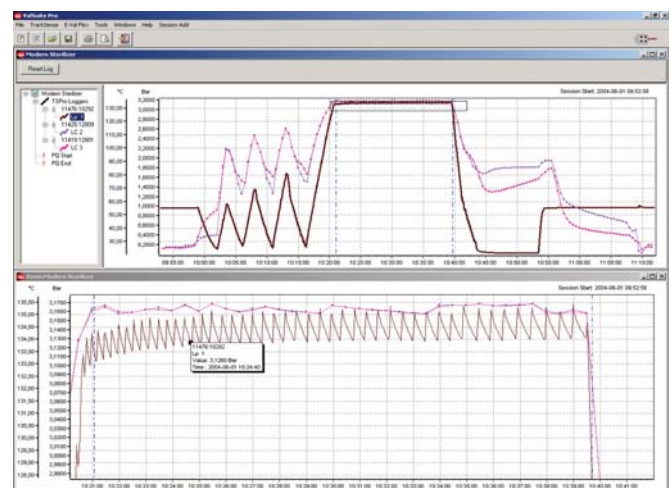


One E-Val Flex system with 64 temperature channels and 2 pressure channels

Software Data Analysis Features

Data analysis tools greatly reduce the time needed to find critical data. The ability to zoom graphically and display up to 8 tiled windows at once greatly simplifies identifying important data. Multiple calculations such as min/max, deltaT and Fo can be calculated on any block of data displayed removing the need to export data and improving data security.

ValSuite collects and presents validation data from both realtime E-Val Flex and TrackSense[®] Pro wireless data logging systems. The data from both systems can be presented and analyzed in the same session. The system can run up to 128 channels which can be identified and displayed in different groups such as penetration and distribution. Any grouping or specific channels can be displayed in a separate data block and analyzed.



Typical test of hospital autoclave with 4 pre-vacs

Outputting Reports

A complete thermal validation report can be produced with pass/fail criteria, detail on mapping positions, operator and vessel ID, calibration offsets for thermocouples, raw and statistical summaries on the data. ValSuite also maintains templates for reports designed to meet the specific requirements of tests such as EN554. The templates can be customized to organize the data and perform calculations to your exact criteria. This saves tremendous time reducing the data analysis process. Reports can be reviewed with the print preview feature and output in a pdf file document.



Sample of a validation report

Maintain Security

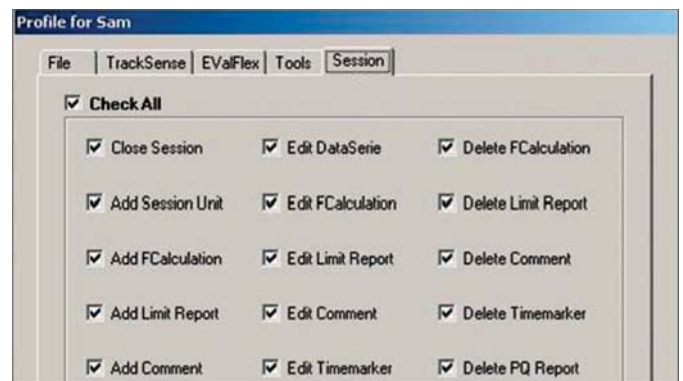
ValSuite operating software is designed to maintain the highest level of security for compliance to 21 CFR Part 11. The software administrator controls and assigns user ID and access privileges. Any user function can be deactivated, removing the software feature from view and access of specified users. This reduces the risk of mistakes significantly giving tight control of usage by the administrator.

All user actions affecting the raw data are logged in the audit trail. Raw data cannot be changed. Any manipulation of data such as time markers, limits or comments will be recorded in the audit trail. Analysis reports can be produced with an electronic signature ID'ed to the user generating the report. Accessing information from the audit trail is simplified with the ability to search by date, study ID, user ID and vessel ID.

Compliant to FDA Guidelines

- Raw data is built into a database structure and cannot be modified or erased.
- Complete audit trail with easy search engine to find data by date, session, user and module.
- User ID and passwords with detailed user access control.
- Thermocouple ID chips provide complete NIST traceability.
- Customized report generator eliminating need to export data.

- Specific compliance reports (e.g. EN554).
- Automated pre- and post-calibration reports.
- Print preview feature with report output in pdf file format.



Profile, Session

Compliant to GAMP4 Guidelines

The hardware, firmware and software have been developed in accordance with the guidelines set out in GAMP4. The ValSuite Pro software has been validated, and the cd includes all the documentation.

Ellab

Calibration Certifications and Service

Ellab maintains a complete calibration facility for annual certifications and service. All certifications are traceable to NPL and NIST standards. Service and maintenance contracts are available.

Training

Training and equipment installation are available through Ellab. Validation consultants are available experienced with Ellab equipment to assist with IQ, OQ and PQ qualifications.

Rental & Demos

Demo systems are available for trial and rental. Please contact your local Ellab representation for details.

Compliance Documentation

Complete software validation guide (IQ, OQ).
FDA 21 CFR part 11 Compliance Report.
Suggested SOP's for autoclave validation.
ISO 9001 Certified.



QUALITY SYSTEM
DS/EN ISO 9001
DS/EN ISO 13485



Building Confidence

Industry leading 2 year warranty.

Approvals

UL & CE listed.

ELLAB A/S

Krondalvej 9
DK-2610 Roedovre
Denmark
Phone: +45 4452 0500
Fax: +45 4453 0505
E-mail: info@ellab.com

ELLAB Inc.

6551 South Revere Parkway,
Suite 220,
Centennial, CO 80111
USA
Phone: 303 425 3370
Fax: 303 425 3384
E-mail: usa@ellab.com

ELLAB GmbH

An der Autobahn 5
D-27404 Bockel
Germany
Phone: 04286 925 020
Fax: 04286 925 818
E-mail: gmbh@ellab.com

ELLAB UK Ltd.

3, Dundee Court
Hamburg Way,
King's Lynn
Norfolk PE30 2ND
England
Phone: 01553 7691 43
Fax: 01553 7690 70
E-mail: uk@ellab.com

Thermal Validation Solutions



www.ellab.com

ELLAB S.A.R.L.

ZAC de Mercières
5 Ter, rue Clément Ader
2e étage
60200 Compiègne
France
Phone: 0344 2302 57
Fax: 0344 2308 94
E-mail: france@ellab.com

ELLAB Philippines Corp.

4810-B Sampaguita
St. Marimar I
Bicutan
Paranaque City
Philippines
Phone: 02787 8258
Fax: 02824 7924
E-mail: ph@ellab.com