

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.

*E-Val™ Pro
40 channel
module*

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 ± 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 ± 0.05 °C between -100 and +400 °C and ± 0.1 °C between -200 °C and <-100 °C in an operating environment of $+23$ °C ± 3 °C.

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

Total system accuracy using Ellab type T smart thermocouples is ± 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.

*The E-Val™ Pro
module
has many
expansion
possibilities*





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.

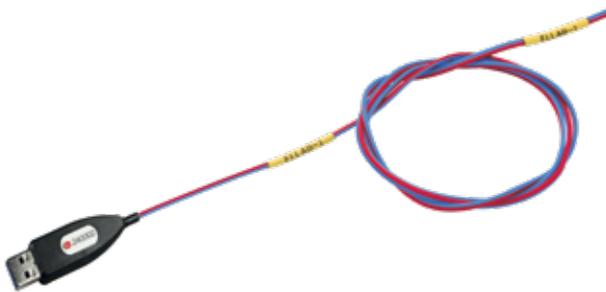
Fittings & Accessories



Fittings and accessories for placing probes and inserting tips

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.

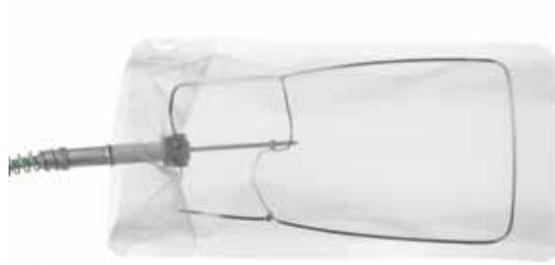


Feed Through for STC Thermocouples

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.



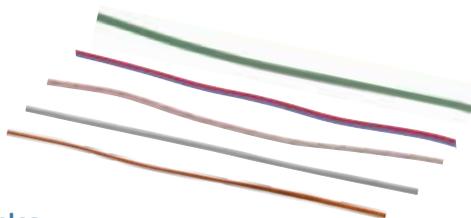
Smart USB Connectors

The USB connectors consist of copper/constantan to minimize the source of errors. The connector is water-proof 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: 0 to 4 bar (abs.)
 Accuracy: ±6 mbar



SSA-TS

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



SSA-TF

Operating range: -50 to +135 °C
 Accuracy: < 0.2 °C/calibrated ±0.05 °C
 Response time: 1.0 sec (T63)/1.8 sec (T90)
 Electrode material: Stainless steel
 Electrode Ø: 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 ±0.05 °C
 Response time: 1.8 sec (T63)/5.9 sec (T90)
 Electrode material: Stainless steel
 Electrode Ø: 2.0 mm
 Electrode end: Round/sharp/conic
 Cable material: Silicone
 Cable dimensions: Ø 4.0 mm



SSS

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



SSR

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



SD4

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



STC22-TF

Operating range: -196 to +200 °C
 Accuracy: < 0.2 °C/calibrated ±0.05 °C
 Response time: 3.4 sec (T63)/6.6 sec (T90)
 Electrode material: PTFE
 Electrode Ø: 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 ±0.05 °C
 Response time: 4.2 sec (T63)/9.3 sec (T90)
 Electrode material: PTFE
 Electrode Ø: 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 ±0.5 °C
 Response time: 0.20 sec (T63)/0.25 sec (T90)
 Electrode and cable material:
 Mineral insulated, Metal sheathed
 Electrode Ø: 1.0 mm
 Electrode end: Round
 Cable dimensions: Ø 4.0 mm



STC-AC

Operating range: -67 to +400 °C
 Accuracy: ±2 °C/calibrated ±0.5 °C
 Response time: 1.4 sec (T63)/2.7 sec (T90)
 Electrode material: Stainless steel
 Electrode Ø: 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: ±2 °C/calibrated ±0.5 °C
 Response time: 2.5 sec (T63)/5.2 sec (T90)
 Electrode material: Stainless steel
 Electrode: 2.5 x 12 mm/3.0 x 12 mm
 Electrode end: Round
 Cable material: Kapton
 Cable dimensions: 1.2 x 1.9 mm /
 1.4 x 2,4 mm

ValSuite™ Pro

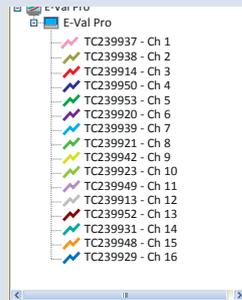
Intuitive and user friendly software

The easy way to put the ValSuite Pro software to work:

- 1 Login, program and start the E-Val Pro using a Repeat function, which includes a unit configuration and a selection of reports. Place the probes in the load or process and run the cycle.



- 2 Record the data. Data analysis and reports are made automatically.



- 3 Print the reports and logout.



ValSuite Pro Data Integrity is approved by Quality Compliance Partners Inc.

ValSuite™ Pro Software

ValSuite Pro is an intuitive validation software which collects and presents validation data from all Ellab measuring devices. The software package is designed for Windows 10, 64-Bit. The software is developed according to GAMP principles. ValSuite is available in four versions, ValSuite, ValSuite Medical, ValSuite Plus and ValSuite Pro. The ValSuite Pro version has all features and all reports all while being fully validated and compliant with 21 CFR, part 11.

Full IQ/OQ documentation and validation services are available from Ellab. The software is currently available in the following languages: Chinese, Dutch, English, French, German, Italian, Japanese, Polish, Portuguese, Russian, Spanish, Swedish and Turkish.

Detailed Control of Validation Studies

The ValSuite Pro 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

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

Software Data Analysis Features

Data analysis tools greatly reduce the time needed to find critical data. The ability to zoom graphically and display multiple windows at once simplifies identifying important data. Multiple calculation such as min/max, standard deviation, average, delta T and lethality can be calculated using any ValSuite™ Pro data, eliminating the need to export data thus improving data security.

ValSuite Pro collects and presents validation data from both E-Val Pro and TrackSense Pro data logging systems. The data from both systems can be presented and analyzed in the same session. The system can run up to 160 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. It is also possible to merge individual sessions and run analysis for comparison purposes.



Sensor adjustment report



Limit report



Statistics report



Adv. phase statistics report



EN17665 report



Saturated steam report



Lethality report



Equipment used



Graph & Zoom



Unit



Monitoring Features

ValSuite Pro software also offers several monitoring features such as real-time statistical calculations and alarm limits (via software and email).

ValSuite™ Pro Main Feature List

- One software for both TrackSense Pro loggers and E-Val Pro wired systems
- Can be run from a stand-alone PC or a server solution. Network security can be applied.
- Full synchronization of all data meaning no "phantom" values in reports
- Up to 160 channels in one session
- Switch between multiple languages
- Drivers for calibration equipment

Reporting

- Sample validation reports
 - Lethality report
 - Limit report
 - Statistics report
 - Adv. phase statistics report
 - Calibration report
 - Autoclave validation
 - Washer disinfection validation
 - Rotation report
 - MKT report
 - Combined uncertainty report
 - Leak test report
 - Advanced validation report
 - Dew Point Calculation
- Printed or PDF format
- Comment field and Word document attachment
- Heating Factors / Ball Simulation
- 3D Visualization



Samples of typical validation reports

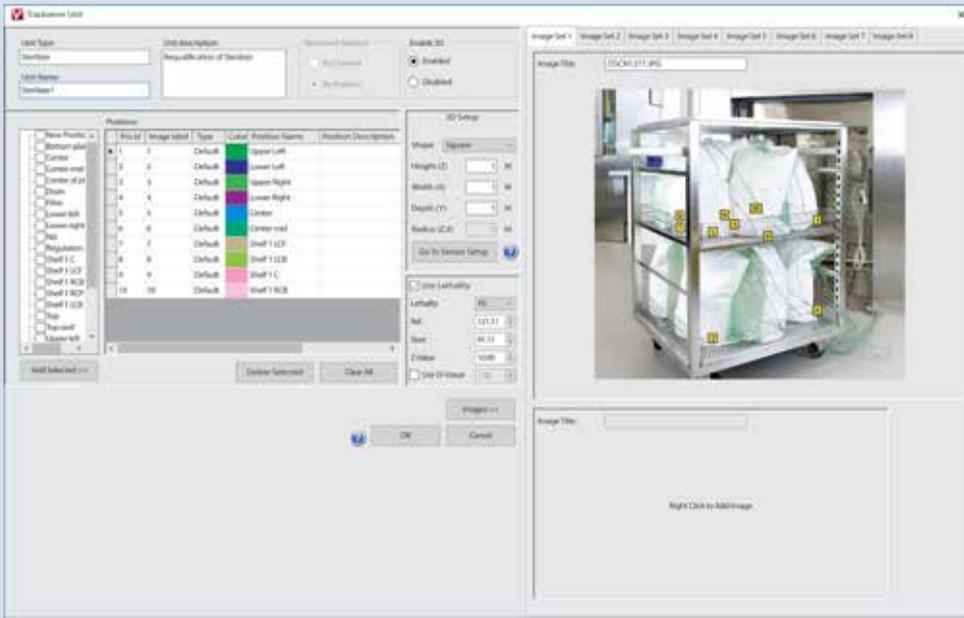
Producing Reports

A complete set of reports can be produced with Pass/Fail criteria, detail on mapping positions, operator and vessel ID, calibration offsets for probes, data list and statistical summaries on the data.

ValSuite Pro also maintains templates for reports designed to meet the specific requirements of tests such as EN17665 for moist heat autoclaves or

EN15883 for washer disinfectors and NFX 15-140 for stability chambers. The templates can be customized to organize the data and perform calculations to exact criteria.

This feature greatly reduces the time needed for the data analysis process. Reports can be reviewed with the print preview feature and saved in a PDF file format.



Unit configuration with drag and drop

Operator: Validation Manager Vessel: Steam with vacuum pulses
 Process: Pharma Product: Pharma
 Session Start: 02-03-2017 11:56:23 AM Time Zone: UTC offset 02:00:00
 Session Stop: 02-03-2017 12:23:58 PM
 Session Name: Sterilization 134 °C, 07s
 Session Text: Sterilization 134 °C

Validation Report

Name: Validation Report
 Description: 134.00 °C
 Total Test Result: **Failed**

Input parameters

Process Temperature: 134.00 °C
 Process Temperature Band (K): 2.00
 Max. Allowed Temperature Fluctuation (K): 1.00
 Max. Allowed Difference Temperature (K): 2.00
 Maximum Equilibration Time: 00:00:15
 Minimum Holding Time: 00:03:00
 Maximum Pressure Deviation: 0.1000 bar

Equilibration Time

Equilibration Start Time: 02-03-2017 12:08:48 PM
 Equilibration End Time: 02-03-2017 12:11:24 PM
 Equilibration Duration: 00:02:38
 Max. Allowed Equilibration Duration: 00:03:00
 Equilibration Test Result: **Failed**

Process band

Holding Start Time: 02-03-2017 12:11:24 PM
 Holding End Time: 02-03-2017 12:23:58 PM
 Holding Duration: 00:12:02
 Max. Allowed Holding Duration: 00:15:00
 Holding Test Result: **Failed**

Difference Band

Difference Temperature (K): 1.52
 Max. Allowed Difference Temperature (K): 2.00
 Selected data series: TC15835 - Ch 1, TC15834 - Ch 2, TC15838 - Ch 3, Ch 6, TC15837 - Ch 8, TC15838 - Ch 7, TC15836 - Ch 10, TC15894 - Ch 16, TC15891 - Ch 11, TC15882 - Ch 1, TC15898 - Ch 14, TC15893 - Ch 15, TC15889 - Ch 1

Difference Temperature Test Result: **Passed**

Fluctuation Band

Temperature Fluctuation (K): 0.48
 Max. Allowed Temperature Fluctuation (K): 1.00
 Temperature Fluctuation Test Result: **Passed**

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Operator: Validation Manager Vessel: Steam with vacuum pulses
 Process: Pharma Product: Pharma
 Session Start: 02-03-2017 11:56:23 AM Time Zone: UTC offset 02:00:00
 Session Stop: 02-03-2017 12:23:58 PM
 Session Name: Sterilization 134 °C, 07s
 Session Text: Sterilization 134 °C

Validation Report

Name: Validation Report
 Description: 134.00 °C
 Cycle: **Passed**

Input parameters

Process Temperature: 134.00 °C
 Process Temperature Band (K): 2.00
 Max. Allowed Temperature Fluctuation (K): 1.00
 Minimum Holding Time: 00:03:00
 Maximum Pressure Deviation: 0.1000 bar

Process band

Holding Start Time: 02-03-2017 12:08:48 PM
 Holding End Time: 02-03-2017 12:23:58 PM
 Holding Duration: 00:14:11
 Max. Allowed Holding Duration: 00:15:00
 Holding Test Result: **Passed**

Fluctuation Band

Temperature Fluctuation (K): 0.50
 Max. Allowed Temperature Fluctuation (K): 1.00
 Temperature Fluctuation Test Result: **Passed**

Saturated Steam Analysis

Pressure Deviation: 0.0975 bar
 Max. Pressure Deviation: 0.1000 bar
 Pressure Deviation Test Result: **Passed**

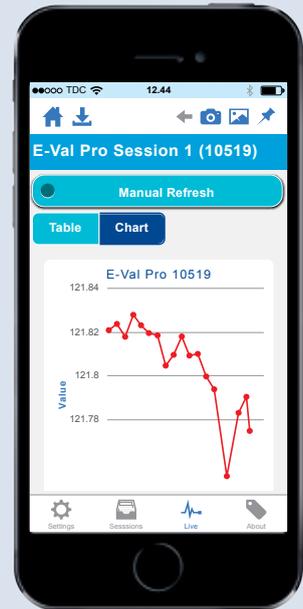
Summary Report

Name	Fluctuation (K)	Deviation
TC15835 - Ch 1	0.48	0.0595 bar
TC15834 - Ch 2	0.87	0.0754 bar
TC15838 - Ch 3	0.68	0.0595 bar
TC15838 - Ch 4	0.81	0.0975 bar
TC15833 - Ch 6	0.87	0.0692 bar
TC15837 - Ch 8	0.69	0.0692 bar
TC15838 - Ch 7	0.89	0.0895 bar

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Validation reports



Use ValSuite app to survey active processes and validation reports

Validation Report

Report header: **1**
Validation Report

Process Start Time: **2**
10-05-2017 13 23 53

Process End Time: **3**
10-05-2017 15 01 56

Name:
Revalidation of autoclave in room 66

Preselected Timestamps
First possible start

Preselected Timestamps
Last possible end

Description:
According to EN 17665

(Use of preselected timestamps is optional)

Process Lethality Calculation

Process Temperature: **4**
134.00 °C

Process Temperature Band: 3.00 K

Maximum Temperature Fluctuation: 1.00 K

Maximum Temperature Difference First 60 Sec.: 5.00 K

Maximum Temperature Difference: 2.00 K

Maximum Equilibration Time: 00 00 15

Use individual sensor for start equilibration time:
LC 04

Holding Time:

Minimum Holding Time: 00 03 00

Maximum Holding Time: 00 35 00

Use 24 hours as minimum holding time

Automatic by temperature

Manual by time markers

Max Pressure Deviation: 0.1000 bar

Cycle (optional): **5**

Dynamic Pressure Test

Max 10 bar/min. Calculated in 3 sec. interval

Max 10 bar/min. Calculated in 2 sec. interval

Current Sensors

LC 01

LA 02

LC 03

LC 04

LC 05

LC 06

LC 07

LC 08

LC 09

LC 10

LC 11

LC 12

LC 13

Select All Select None

Select Core Select Ambient

Save template Load template **7** ? OK Cancel

Report Setup

The example shows the layout of the Validation Report. All reports are designed with the concept in mind to provide maximum flexibility and easy input of data.

- 1** Input for report header, name of report as well as a more detailed description.
- 2** Input for process start time and optional time marker setting.
- 3** Input for process end time and optional time marker setting.
- 4** Input fields and selection of process parameters according to appropriate standard.
- 5** Further input fields and selection of process parameters according to appropriate standard.

- 6** Definition of which measuring points (probes) should be included in the reporting.

- 7** Saving and uploading of pre-configured report templates.

The result of the analysis is presented in a clear format ready for printing, saving or distributing electronically.

A non-successful validation process will not only show "Failed", but will also indicate which part of the process failed, making it easier to diagnose and correct.

This feature greatly reduces the time needed for the data analysis process

ValSuite™ Pro Calibration

ValSuite Pro is not only a validation software but also a calibration software. This means that all probes can be user calibrated at defined intervals and offset values are stored.

Using the ETS temperature standard and appropriate baths/dry blocks, a fully automated calibration can be executed eliminating operator error. This is a safe and time saving feature.

A report is automatically generated that shows the overall calibration results. When using the Calibration Set-up, users can choose Manual, Semi-Automatic, or Full-Automatic Calibration. At the same time, various templates can be stored and uploaded whenever required. The found offset values are linked directly to the ID number of the probe and will be taken into account whenever the probe is used in future measurements.

Operator:	Validation Manager	Vessel:	LiquiCal HM
Process:	Calibration	Product:	Pharma
Session Start:	02-03-2017 08:29:49	Time Zone:	UTC offset 01:00:00
Session Stop:	02-03-2017 10:03:13		
Session Name:	Post calibration of sensors.d7x		
Session Text:	Post calibration of sensors		



Calibration

Name:	Calibration Report
Description:	
Total Calibration Result:	Passed

Temperature Standard

Manufacturer:	Ellab A/S
	ETS20
Serial Number:	110001
Certificate Number:	18255
Calibration Date:	01-01-2016
Calibration Expiry Date:	01-01-2017

Stability Criteria

Fluctuation Band:	0.15°C
Fluctuation Time:	00:03:00
Holding Time:	00:03:00

Pass Criteria

Temperature Standard Fluctuation Band:	0.10°C
Sensor Temperature Deviation +/-:	0.25°C
Pass Time:	00:01:00

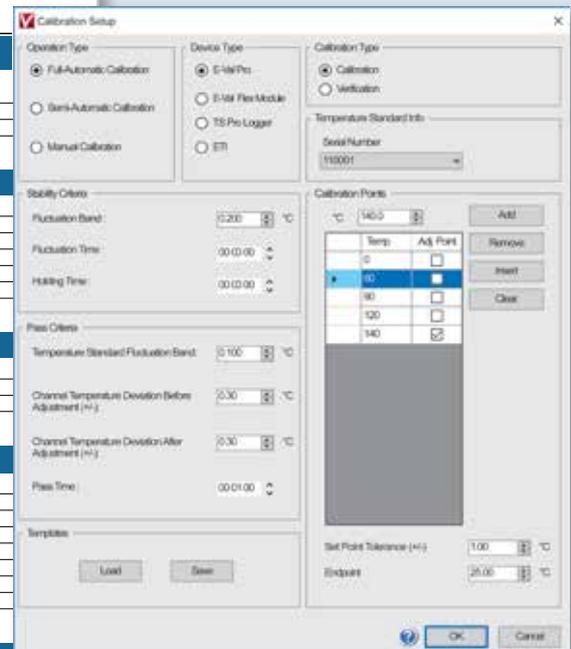
Status for Temperature Standard:	Temperature	Result
	40.00°C	Passed
	60.00°C	Passed
	90.00°C	Passed
	120.00°C	Passed
	140.00°C	Passed

Calibration Summary Before Adjustment

Deviation: Difference between Temperature Standard and Sensor in calibration point (middle point of pass time)
Max Deviation: Max difference between Temperature Standard and Sensor in pass time

Sensor	ID	Set point	Before Adjustment	Deviation	Max. Deviation
TC15393 - Ch 1	14469	40.00°C	Passed	0.05°C	0.07°C
TC15393 - Ch 1	14469	60.00°C	Passed	0.05°C	0.09°C
TC15393 - Ch 1	14469	90.00°C	Passed	0.00°C	0.03°C
TC15393 - Ch 1	14469	120.00°C	Passed	-0.08°C	-0.11°C
TC15393 - Ch 1	14469	140.00°C	Passed	-0.16°C	-0.18°C
TC15395 - Ch 2	14469	40.00°C	Passed	0.07°C	0.09°C
TC15395 - Ch 2	14469	60.00°C	Passed	0.06°C	0.08°C
TC15395 - Ch 2	14469	90.00°C	Passed	0.03°C	0.04°C
TC15395 - Ch 2	14469	120.00°C	Passed	-0.10°C	-0.10°C
TC15395 - Ch 2	14469	140.00°C	Passed	-0.17°C	-0.18°C
TC15337 - Ch 3	14469	40.00°C	Passed	0.08°C	0.09°C
TC15337 - Ch 3	14469	60.00°C	Passed	0.09°C	0.10°C
TC15337 - Ch 3	14469	90.00°C	Passed	0.01°C	0.04°C
TC15337 - Ch 3	14469	120.00°C	Passed	-0.09°C	-0.10°C
TC15337 - Ch 3	14469	140.00°C	Passed	-0.14°C	-0.17°C

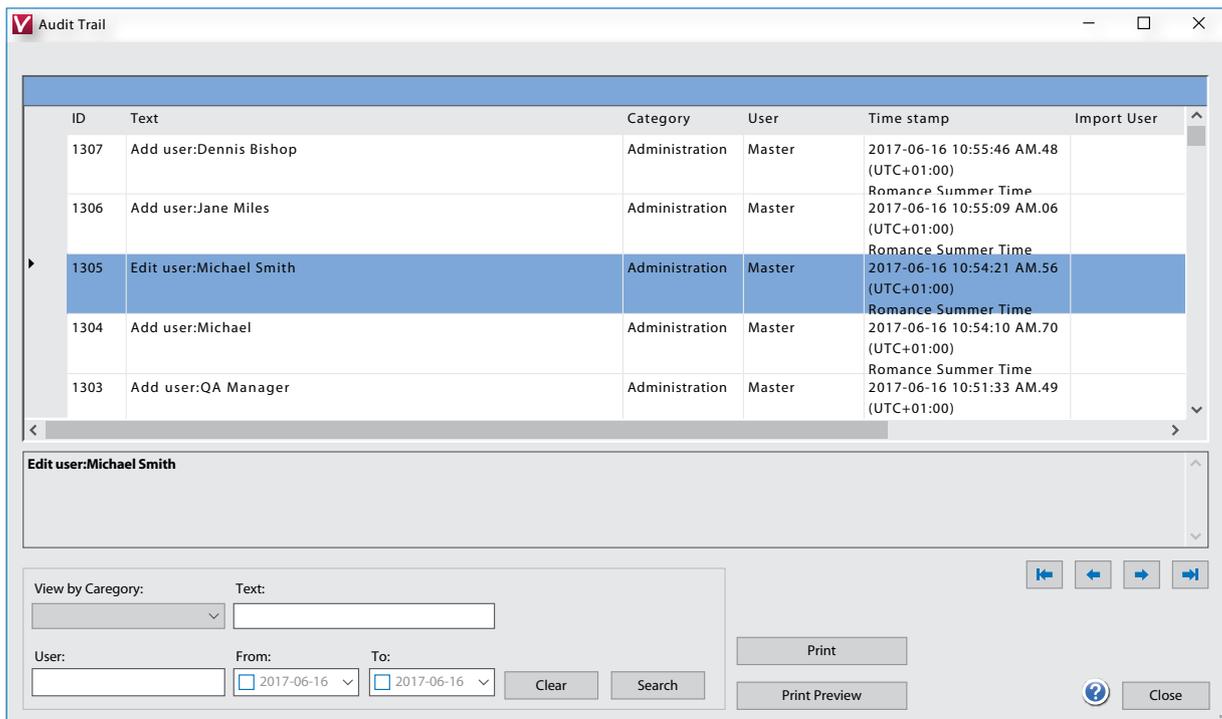
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Calibration Set-up



Calibration Equipment



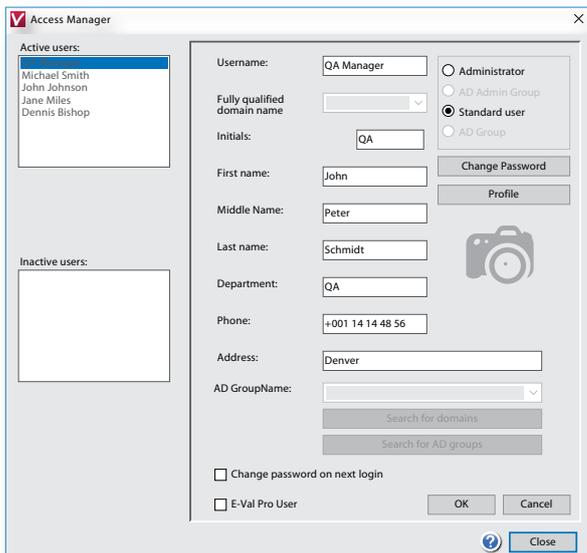
Audit Trail

Compliant to FDA Guidelines

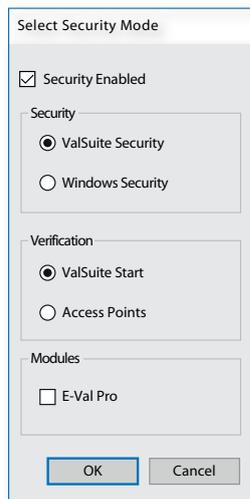
- SQL database where complete sessions or individual data cannot be deleted or manipulated
- Audit trail report
- Electronic signature
- Access manager with user ID and passwords
- Probe ID provides complete traceability
- Customized report generator eliminating export of data

GAMP Guidelines and ISO 9001:2008

All documentation for development of ValSuite Pro software is in accordance with the guidelines set out in GAMP. Software package includes appropriate documentation. The Ellab quality system is compliant with ISO 9001:2008



Access Manager



Security Setup

ValSuite™ Pro is not only a validation software but also a calibration software

Ellab



Since the late 1940's Ellab A/S has been a leading manufacturer of process validation and monitoring systems used in the food, medical device and pharmaceutical industries.

Calibration Certifications and Service

Ellab maintains a complete calibration facility for annual certifications and service. Ellab A/S temperature, resistance, pressure and humidity calibration laboratory is accredited according to ISO 17025 by DANAK under registration no. 520. Service and maintenance contracts are available.

Rental & Demos

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

Training

Ellab Academy offers regular training courses for end-users. On-site individual training and equipment installations are also available through Ellab. Our Validation Consultants are available to assist you with IQ, OQ, and PQ procedures.



Validation Solutions

Ellab A/S

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