E-Val Flex

ellab
Validation Solutions

The flexible solution in real-time thermal validation

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 and final compliance reports.

Flexibility for different validation applications

E-Val Flex is designed as a single solution for all thermal validation applications. It can be run as a stand alone unit or networked with your PC.
The software which can handle 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.

The E-Val Flex module has many expansion possibilities

Pharmaceutical:	Food:
• Autoclave Validation	• Retorts
• Lyophilization	• Pilot Vessels
• Depyrogenation	• Freezers
• Freezers	• Alarm Monitoring
• Stability Chambers	• Smoke Houses
• Incubators	• Ovens
• Alarm Monitoring	• Roasters
• Warehousing	• Aseptic

Quality

The highest quality electronics are incorporated into the design greatly improving quality and accuracy. With 8MB 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
4, 8 or 16 Channel Modules	Expandable up to 128 channels logging every second
Ethernet Network	Fast and reliable data transmission. Available on most PC's
Smart Thermocouple	High accuracy ±0.05 ºC, NIST traceability
ID on Thermocouple	Calibration offsets travel with thermocouple. Dramatic time savings during setup. Compliance tracking and reduces errors
8 MB Memory	Enough to store 8 hours of data, logging every second
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 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 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

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 ºC in an operating environment of +20 ºC to +30 ºC.

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

Total System accuracy using Ellab type T smart thermo-couples is ±0.10 ºC before system calibration.

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

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.

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 thermo-couples fails during a validation study.

E-Val Flex System Description

The E-Val Flex modules are available with 4, 8 or 16 type T thermocouple channels, and the master modules have additional inputs for digital pressure and deflection.

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

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

The sampling rate can be set from 1 second to 24 hours independent of the number of channels. The very fast sample rate is made possible by the modular design of the E-Val Flex system.

E-Val Flex 16 temperature channel master module

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 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 impractical.

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 where it is possible to see parameter values on the LCD display. At the end of a test cycle the module is reconnected to the PC to download the data for analysis and reporting.

For more than 65 years Ellab has been combining hardware, software, probes and fittings in order to provide customers with customized "turn-key" thermal validation solutions. The ValSuite™ Software is working with E-Val Flex, TrackSense® Pro loggers, temperature standard and reference.

Fittings & Accessories
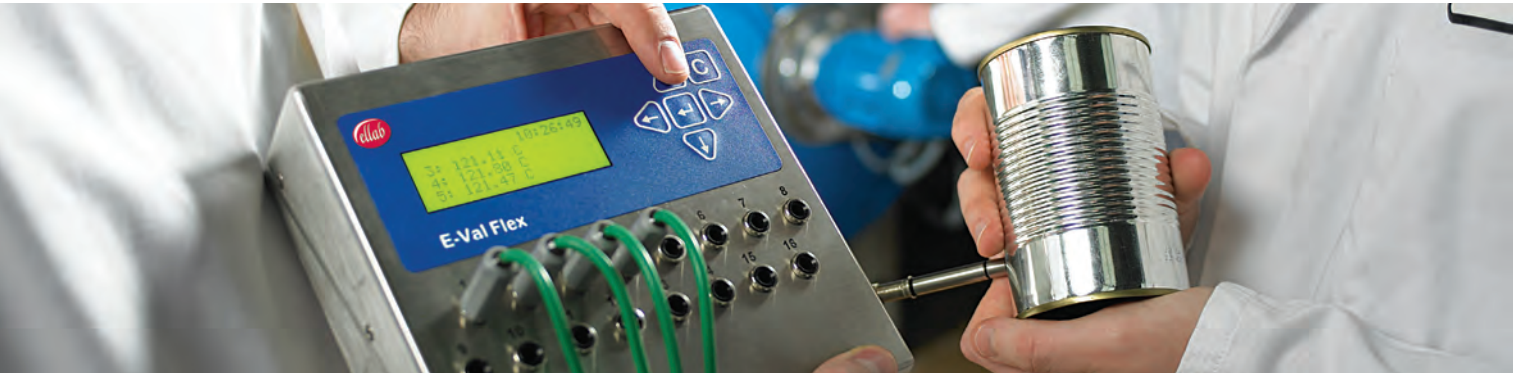
Fittings and accessories for placing probes and inserting tips

Custom Fittings
Packing glands and other fittings are available for placing probes and inserting the tips into any variety of packaging material. 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 label in set of 1-16 pieces for easy identification when placing the probes inside the application.

Feed Through
Support for up to 16 temperature probes and pressure sensor.
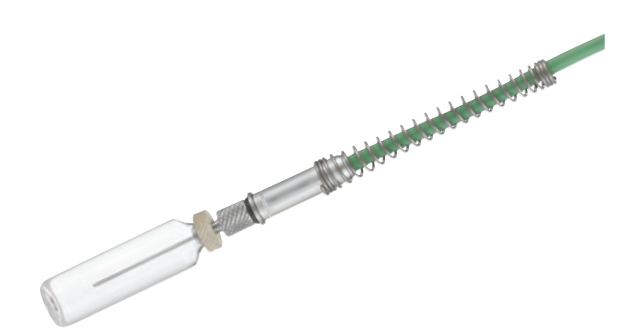
GVJ
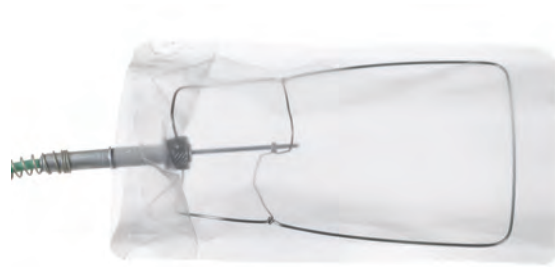packing gland for measuring inside ampoules or vials.

GNK
probe mounted on ampoules in moist heat sterilization applications.

GLK
Probe mounted in plastic ampoules in moist heat sterilization applications.

TPJ
probe mounted in pouch for sterilization application.

High Temperature
probe mounted in vial for depyrogenation application.

GPK
probe mounted in vial for terminal sterilization.

GEJ
fitting for very small plastic containers.

GVK
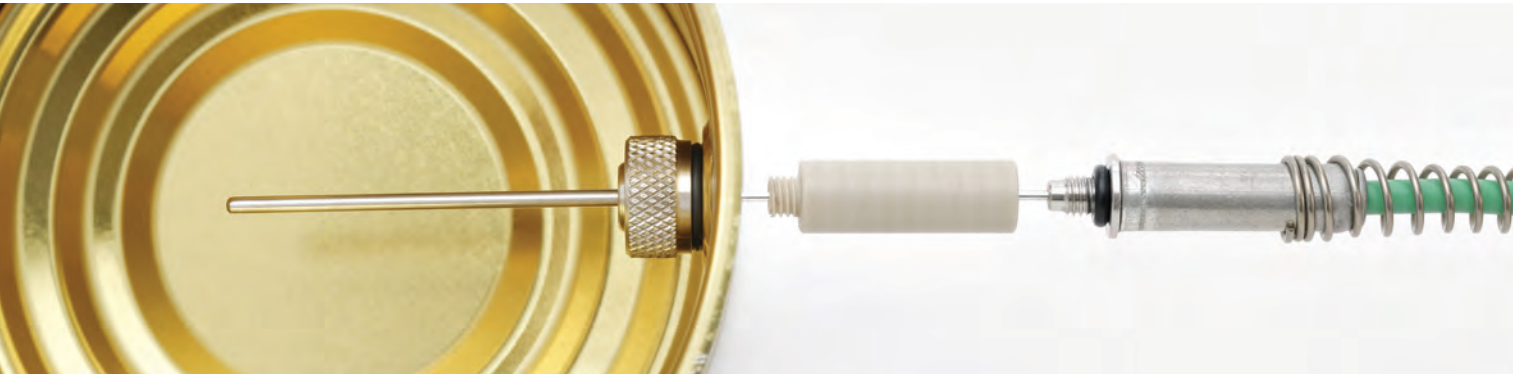on bottle neck using GVK packing gland for pasteurization application.

Smart Gasket
mounted with temperature probe in Tri Clamp for measuring inside pipes/hoses.

GKJ
packing gland for external mounting.

Probes & Sensors

High Precision Thermocouple Probes
High quality thermocouples are often overlooked when purchasing a temperature monitoring system. Using high quality probes dramatically improves accuracy, stability and leads to a successful study. Often money and time is wasted trying to calibrate or locate problems with inferior thermocouples. Why risk it when many of your maintenance problems can be solved with a quality probe?

Ellab develops and manufactures a wide range of type T thermocouples for all kinds of purposes, e.g. multipoint probes with 4 to 10 measuring points, probes for frozen applications, special probes for liquids and air, probes for hot air ovens and autoclaves, high temperature probes etc. Our standard probes are supplied with threads which fit into packing glands for a leak-free seal into packages or cans.

Rotating autoclaves
The slipring contact is used to facilitate temperature, pressure and deflection measurement in rotating autoclaves. The slipring also counts the rotations per minute (RPM). It is possible to measure up to 14 temperature, 1 RPM and 1 pressure channel.

Deflection
The deflection system, with a tray holding device and support for the deflection transducer, is used to measure the movements of a container during thermal processing.

Jack Plug
The plug consists of copper/constantan to minimize the source of errors. The jack plug is waterproof which means no liquid will enter the equipment. All plugs are fitted with an ID and calibration offsets.

Open ends
Open end probes have fewer benefits than jack plug probes but can be supplied to fit non-Ellab equipment.

Digital Pressure Sensor
Operating range:
0 to 4 bar (abs.)
Accuracy: 6 mbar

SSA-TS
Operating range: -20 °C to +135 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 0.8 sec.
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 °C to +135 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 0.8 sec.
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 °C to +135 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 0.8 sec.
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 °C to +135 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 1.8 sec.
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 °C to +135 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 1.8 sec.
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 °C to +135 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 5.1 sec.
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: -90 °C to +200 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 2.9 sec.
Electrode material: PTFE
Electrode Ø: 2.2 mm
Electrode end: Round
Cable material: PTFE
Cable dimensions: 2.0x1.2 mm

STC32-TF
Operating range: -90 °C to +200 °C
Accuracy: < 0.2 °C/calibrated ±0.05 °C
Response time: 4.5 sec.
Electrode material: PTFE
Electrode Ø: 3.2 mm
Electrode end: Round
Cable material: PTFE
Cable dimensions: 2.6x1.6 mm

SSU-MM
Operating range: -185 °C to +300 °C
(+400 °C short term)
Accuracy: 1.0% of measuring range
Response time: 0.35 sec.
Electrode and cable material:
Mineral insulated, Metal sheated
Electrode Ø: 1.5 mm
Electrode end: Round
Cable dimensions: Ø 1.5 mm

STC-AC
Operating range: -67 °C to +400 °C
Accuracy: <0.5 °C
Response time: 1.4 sec.
Electrode material: Fibre glass
Electrode Ø: 2.0 mm
Electrode end: Round
Cable material: Fibre glass
Cable dimensions: 1.8 x 1.1 mm

STC-KT
Operating range: 0 °C to +260 °C
(+350 °C short term)
Accuracy: ±0.5 °C
Response time: 1.9 sec.
Electrode material: Stainless steel
Electrode: 2.5 x 12 mm
Electrode end: Round
Cable material: Kapton
Cable dimensions: Ø1.7 mm

ValSuite™ Pro

Intuitive and user friendly software

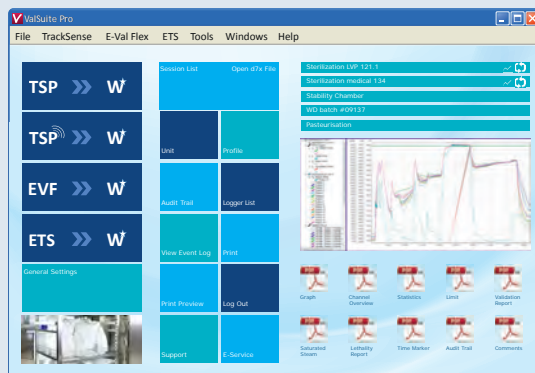The easy way to put the ValSuite™ Pro software to work:

1 Login, program and start the E-Val Flex 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.
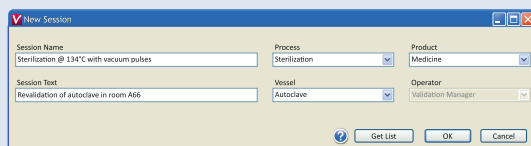
2 Record the data. Data analysis and reports are made automatically.
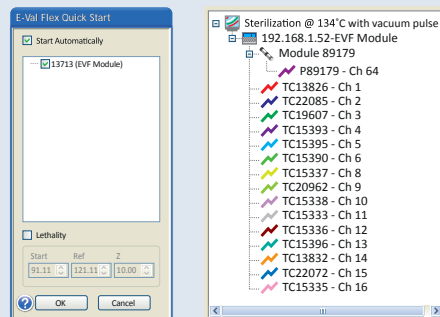
3 Print the reports and logout.

ValSuite™ Pro 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 7 and Windows 8, 64-Bit. The software is developed according to GAMP principles. ValSuite™ is available in three versions, ValSuite™, ValSuite™ Plus and ValSuite™ Pro. The ValSuite™ Pro version has all features and all reports and is 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 Chinese, English, French, German, Italian, Japanese, Polish, Portuguese, Russian, Spanish, Swedish and Turkish language.

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 probe 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 calculations such as min/max, standard deviation, average, deltaT and lethality can be calculated on any block of data displayed eliminating the need to export data thus improving data security.

ValSuite™ Pro collects and presents validation data from both E-Val Flex 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 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. It is also possible to merge individual sessions and run analysis for comparison purposes.

Samples of typical validation reports
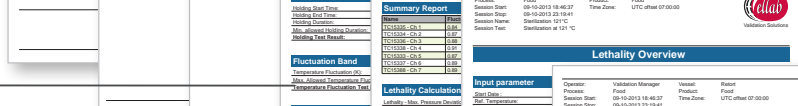
Sensor adjustment report
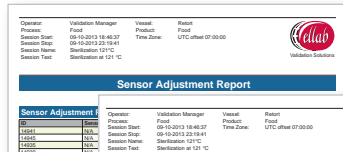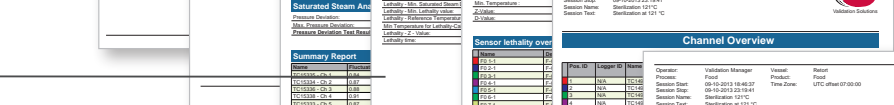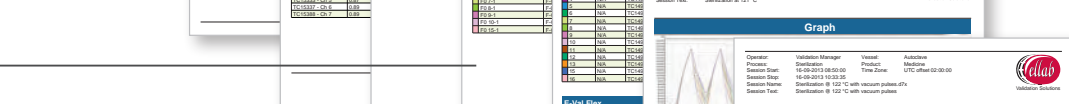
Limit report
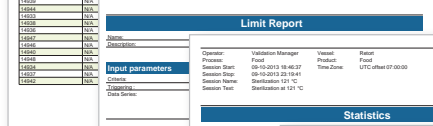
Statistics report
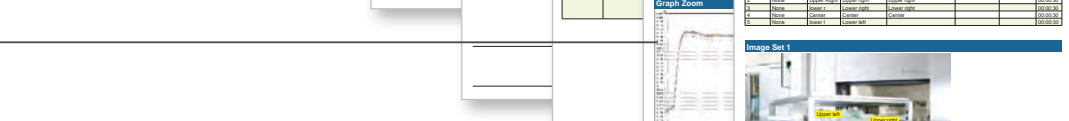
EN17665 report

Saturated steam report

Lethality report

Equipment used

Graph & Zoom

Unit

Monitoring Features

ValSuite™ Pro software also offers several monitoring type features such as on screen statistical calculations, limit alarms, alarms over internet and notification via e-mail services.

ValSuite™ Pro Main Feature List

- One software for both TrackSense® Pro loggers and E-Val Flex 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 128 channels in one session
- Switch between multiple languages
- Drivers for calibration equipment

Reporting

- Sample validation reports
  - Lethality report
  - Limit report
  - Statistics Report
  - Calibration report
  - Autoclave validation
  - Washer disinfection validation
  - Rotation report
  - MKT report
  - Combined uncertainty report
  - Leak test report
  - Advanced validation report
- Printed or PDF format
- Comment field and Word document attachment
- Heating Factors / Ball Simulation

*Fully compliant with 21 CFR, Part 11*

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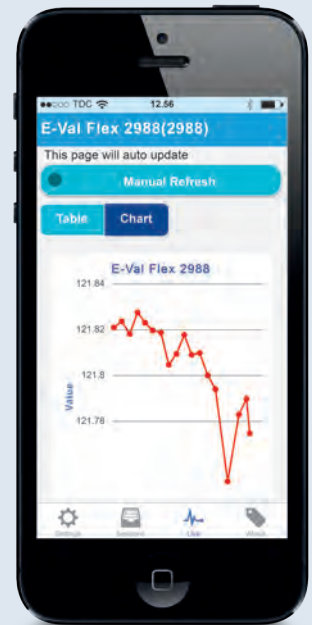
This feature greatly reduces the time needed for the data analysis process. Reports can be reviewed with the print preview feature and saved in a PDF file format.
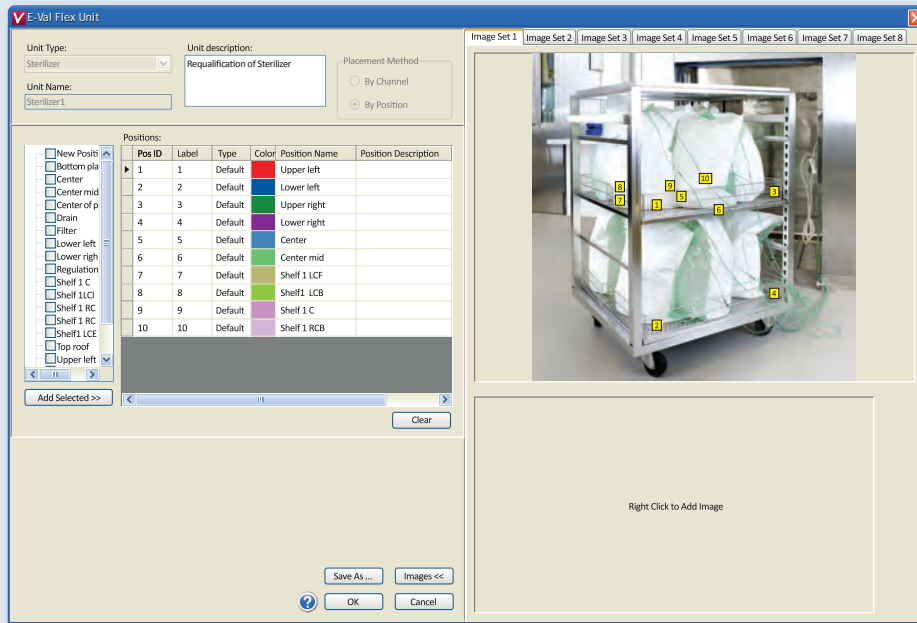
Unit configuration with drag and drop
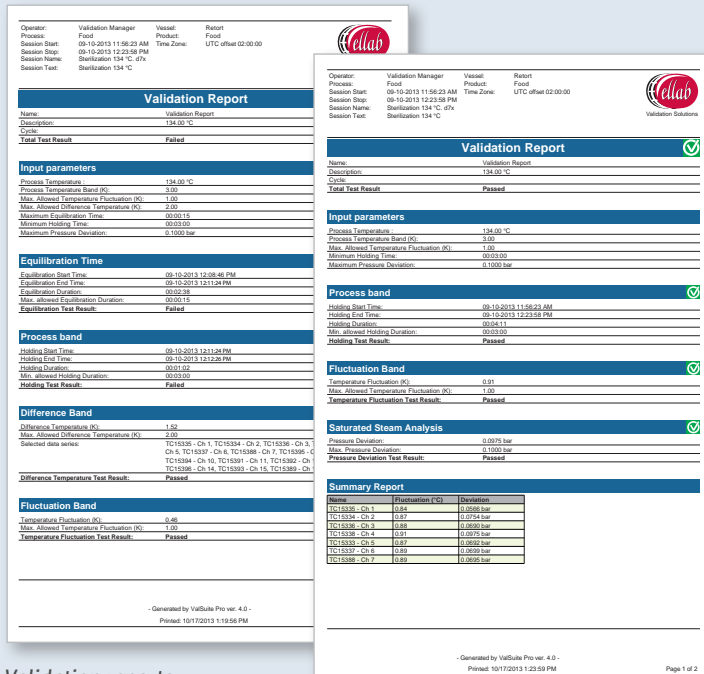
Validation reports

Use ValSuite™ app to survey active processes and validation reports

Validation Report

Report header: [1]
Validation Report

Name
Revalidation of autoclave in room A66

Description:
According to EN17665

Process Start Time: [2]
2012-11-12   08 50 00

Preselected Timestamps
First possible start

Process End Time: [3]
2012-11-12   10 25 10

Preselected Timestamps
Last possible end

(Use of preselected timestamps is optional)

Process | Lethality Calculation

[4]
Process Temperature: 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:
   TC 4
☑ Minimum Holding Time: 00 03 00
   ◯ Automatic by temperature
   ◉ Manual by timemarkers
      Holding time start
      Holding time stop
☑ 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
☑ TC 1
☑ TC 2
☑ TC 3
☑ TC 4
☑ TC 5
☑ TC 6
☑ TC 7   [6]
☑ TC 8
☑ TC 9
☑ TC 10
☑ TC 11
☑ TC 12
☑ TC 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 preconfigured 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 also indicate in which part of the process it failed making it easier to diagnose and correct.

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

ValSuite™ Pro

Calibration

Ellab 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 stored.

Using the ETS temperature standard and appropriate reference instruments connected to the PC, a fully automatic calibration can be executed without any interference of operator – a very safe and time saving feature.

A report is automatically generated which shows overall calibration results. When using the Calibration Setup, 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
Process:	Calibration
Session Start:	08-10-2013 08:29:49
Session Stop:	08-10-2013 10:03:13
Session Name:	Post calibration of sensors.d7x
Session Text:	Post calibration of sensors

Vessel:	LiquiCal HM
Product:	Pharma
Time Zone:	UTC offset 01:00:00

Calibration

Name:	Calibration Report
Description:	
Total Calibration Result:	**Passed**

Temperature Standard

Manufacturer:	Ellab A/S
	ETS20
Serial Number:	110001
Certificate Number:	18255
Calibration Date:	01-01-2013
Calibration Expiry Date:	01-01-2014

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:	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

- Generated by ValSuite Pro ver. 4.0 -

Printed: 16-10-2013 11:18:54

Calibration Report

Calibration Setup



Calibration Equipment
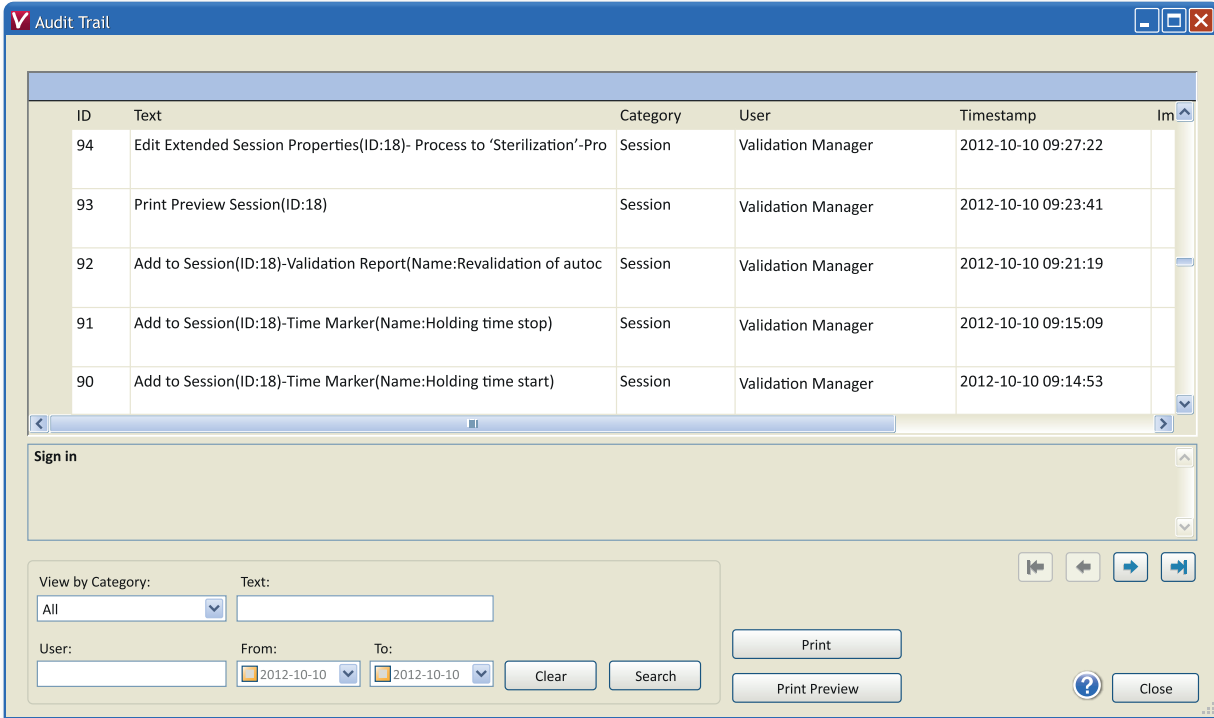
Audit Trail

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
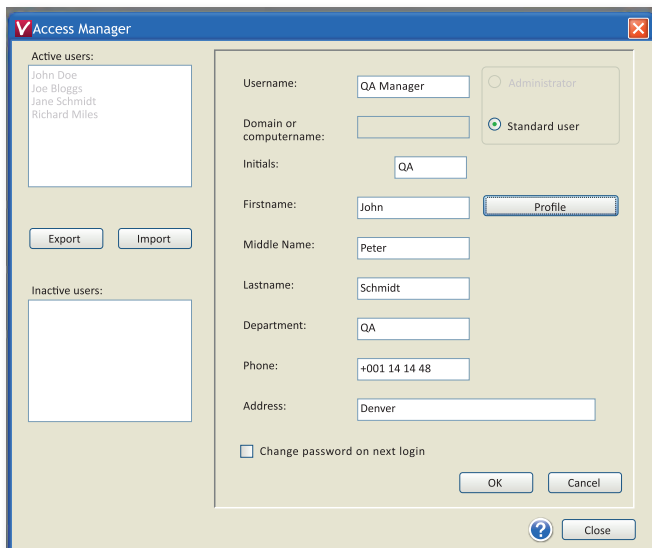
Access Manager
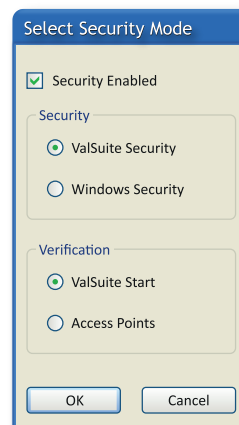
Security Setup

Ellab ValSuite™ is not only a validation software but also a Calibration software

Ellab

For over 65 years 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.

ellab
Validation Solutions

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