

TrackSense® Pro



*The
ultimate
wireless
data logger*

The Ultimate Wireless Data Logger



Ellab has incorporated the latest in electronic technology and innovation to deliver a wireless multi channel data logger unmatched in accuracy, performance, and versatility.

Accuracy

The incorporation of state of the art technology and extensive testing has resulted in outstanding performance*:

- Temperature: ± 0.05 °C
- Humidity: $\pm 2\%$
- Pressure: $\pm 0.25\%$ full scale
- Time: ± 5 sec. per 24 hours
- Conductivity: ± 1 $\mu\text{S}/\text{cm}$
- Rotation: $\pm 1\%$

* For individual product performance please see specifications on www.ellab.com

TrackSense® Pro is the most accurate data logger available on the market today

Performance

The TrackSense® Pro X loggers are designed to operate under extreme conditions without ever losing valuable data. They operate in temperatures from -80 °C to $+150$ °C and withstand pressures up to 10 Bar fully immersed. When used with a thermal barrier, the measuring range is extended from -196 to $+400$ °C. The non volatile memory stores up to 60,000 data points and it is possible to have up to 128 data loggers in one validation study.

Versatility

With the unique feature of interchangeable sensors it is possible to configure the logger for any specific application by mounting different interchangeable sensors and if required an RF module for online data collection. This unique benefit is outstanding and highly appreciated for two main reasons – flexibility and cost of operation.



The TrackSense® Pro Multi Reader Station can be combined with modules for Micro, Mini, Compact, Frigo or Pro loggers allowing start up of 16 loggers simultaneously

	Time	Temperature	Pressure	Relative Humidity	Conductivity	Rotation	Sky
TSP Pro X	•	•	•	•	•		•
TSP Pro	•	•	•	•	•		•
TSP Basic	•	•	•	•	•		•
TSP Compact	•	•	•				
TS Frigo	•	•					
TS Lab	•	•		•			•
TSP Mini	•	•					
TSP Micro	•	•	•			•	

TrackSense® Pro parameter overview

Multi Reader Station

Starting up and reading loggers can now be performed in seconds. 16 loggers can be started or read simultaneously, saving time, especially when 128 data loggers have to be started for one study.

Introducing RF Data Transmission

Enjoy all the benefits of having real time process information available on your computer and a reduced setup time with self-contained wireless data loggers. Once the logger including a Sky module has been started in the reader station it can be read and restarted remotely by the Sky Access Point. At the end of a test cycle the logger is placed in the reader station to go offline for safety and backup purposes and to save battery life by turning the Sky module off.

Sky Module

The Sky module contains all the necessary components for wireless online communication between the logger and the Sky Access Point. The standard Sky module comes with an internal antenna. Should communication stop, data is stored in the logger for transmission once communication has been restored or the logger has been returned to the reader station. No data will ever be lost or corrupted due to loss of wireless communication. ATEX certified for use in environments such as EtO processes.

Sky Access Point

The Sky Access Point offers many advantages over standard wireless Access Points. The proprietary wireless protocol significantly reduces battery consumption in the data logger. All other wireless equipment is rejected by the Sky Access Point, greatly improving transmission success and security. A channel test function is available to eliminate data interference. The Sky Access Point comes with a standard antenna, but optional remote antennas are available for more difficult transmission environments. To cover larger areas or longer distances multiple Access Points can be operated simultaneously.



Enjoy all the benefits of having real time process information available on your computer

TrackSense® Pro Interchangeable Sensors

Ellab offers the largest range of different sensors with 1, 2 or 4 channels. Sensors are interchangeable, enabling the user to choose sensors for different applications. This reduces costs as one set of TrackSense® Pro loggers can be used for temperature, humidity, pressure and conductivity studies. All sensors (except quad sensors) are compatible with a Sky option to provide live data. The temperature sensors can be delivered in rigid, semi flexible and flexible material for ease of use. Rigid sensors are available with or without LED that shows the status of the logger. An active logger is identified by a green blink. This feature makes it much easier to start larger groups of loggers and helps avoid using non programmed loggers. In the case of an LED sensor being used in combination with a Sky module, the LED will also confirm communication status.

Sensors are compatible with a Sky option to provide live data.

Extreme Temperature Sensors

The standard temperature range goes up to +150 °C, but it is possible to order sensors which can measure down to -196 °C or up to +400 °C. The logger has to be placed outside of the environment when measuring at -80 °C to -196 °C. When measuring from +150 °C up to +400 °C, a thermal barrier is required to protect the battery. The principle is to insulate the logger for a specific amount of time keeping the battery temperature below +150 °C.

TrackSense® Pro Logger

Each logger has multiple channels for recording data with a memory capacity of up to 60,000 data points. The state of the art technology allows for variable sample rates. A logger can be programmed to auto start or increase the sample rate at a specific time or temperature. The logger is made of AISI 316 stainless steel and the electronics are sealed in heat and moisture resistant material. The Pro logger is designed for adaptation of interchangeable sensors and all loggers have user replaceable batteries and are ATEX certified. The ATEX temperature range for each logger can be found on the certificate.



Basic Logger

TrackSense® Pro Basic is specially designed for the many applications below 100° C such as pasteurization or EtO sterilization.

-30 °C to +105 °C
60,000 Data Points
Diameter: 25 mm
Height: 44 mm



Pro Logger

TrackSense® Pro Logger is designed to be accurate and durable in the harshest conditions. All components have been selected and tested to withstand the high temperatures and pressures associated with steam sterilization and other demanding processes.

-50 °C to +150 °C
(-196 °C to +400 °C)
60,000 Data Points
Diameter: 25 mm
Height: 44 mm



Pro X Logger

TrackSense® Pro X is the most versatile logger in the range and specially designed for low temperature applications such as lyophilization or ultra low temperature storage but at the same time covering all other applications at higher temperatures including sterilization.

-80 °C to +150 °C
(-196 °C to +400 °C)
60,000 Data Points
Diameter: 25 mm
Height: 44 mm



Rigid Sensors ø 2 mm

Single or double rigid stainless steel sensors with round, conical or sharp tip. Straight design with an optional 90° or 180° bend. All temperature sensors are made with PT1000 elements.



Semi Flexible Sensor ø 1.5 mm

Single or double semi flexible stainless steel sensors with small sensor diameter for increased flexibility and usage for very narrow lumen e.g endoscopes.



Semi Flexible Sensor ø 2 mm

Single or double semi flexible stainless steel sensors with round, conical or sharp tip.



Multipoint Sensor ø 2.5 mm

The multipoint rigid stainless steel sensor is used to determine temperature differences in containers to locate the cold spot. A total of 4 PT1000 elements at specified positions measure simultaneously.



Low Temperature Sensor ø 1.2 mm

Single, double, or quad flexible sensors with small diameter. Ideal for low temperature applications such as lyophilization.



SmartFlex ø 1.8 mm

Single or double fully flexible color coded sensors. SmartFlex secures the intended position of the sensor and is ideal for applications where the measuring point is hard to reach e.g within a container where logger body mass should not influence the measured product.



Pressure Sensor

The pressure sensor is configured to measure one pressure or one pressure and one temperature. The pressure sensor is a strain gauge and the temperature sensor is a PT1000 element.



Relative Humidity Sensor for EtO

The sensor is developed for EtO processes. The sensor has a capacitance element and is optimized for a very humid and aggressive process and measures both humidity and temperature.



Relative Humidity Stability Sensor

The standard humidity sensor has a fast response to determine humidity level during the validation of a warehouse or stability chambers.



High Temperature Sensor

Single or double semi flexible stainless steel sensors specifically designed for high temperature applications such as dry ovens or depyrogenation.



AutoMarker Sensor

Sensor offers automatic setting of time markers on-the-fly as process events occur.



Conductivity Sensor

The Conductivity sensor with integrated temperature sensor for measurements applying to the control/monitoring of industrial processes and, for example to validate the washer disinfection processes in hospitals.

TrackSense® Pro Integrated Sensors



A large range of loggers with integrated sensors to fit a specific need.

A range of loggers with integrated sensors are available in temperature, pressure, rotation and humidity versions for various applications. The decision on which model to choose should be based on physical dimensions and process parameters.

Just like all other Ellab products these loggers are made of AISI 316 stainless steel.

Mini Temperature ø 2 mm

Length: 0, 10, 25, 50, 75, 100 mm

The small volume displacement makes this logger ideal for measuring inside packaging and due to its temperature range the logger is ideal for sterilization applications.

0 °C to +140 °C
30,000 Data Points
Diameter: 20 mm
Height: 12 mm



Frigo Temperature ø 2 mm

Length: 0 and 35 mm

The Frigo logger is designed specifically for ultra cold applications. Using a large battery in an extended housing this logger will be able to operate at ultra low temperatures for a very long time – up to 12 months.

-90 °C to +85 °C
60,000 Data Points
Diameter: 25 mm
Height: 60 mm



Frigo Temperature

Length: 30 and 50 cm

Due to the design, this logger is ideal for monitoring freezing processes over extended time periods such as biological sample storage. The material is either semi flexible stainless steel ø 1.5 mm or SmartFlex PTFE ø 1.8 mm.

-90 °C to +85 °C
60,000 Data Points
Diameter: 25 mm

Micro Temperature ø 2 mm

Length: 10 mm

Micro loggers are designed for applications where size and in particular diameter is an issue. The small diameter makes these loggers ideal for measuring inside bottles during pasteurization cycles.



-20 °C to +140 °C
14,500 Data Points

Diameter: 15 mm
Height: 22 mm

Micro Pressure

The Micro logger is configured to measure pressure or temperature/pressure.

-20 °C to +140 °C
0 to 6 bar

Pressure: 7,200
Data Points

Combi: 4,800
Data Points
Diameter: 15 mm
Height: 40 mm



Micro Rotation

The small diameter makes these loggers ideal for measuring inside cans in a spiral cooker cooler.

-20 °C to +140 °C
14,500 Data Points

Diameter: 15 mm
Height: 24 mm



Compact Temperature ø 2 mm

Length: 35, 50, 75, 100 mm

The Compact logger is configured to measure one temperature with a rigid temperature sensor.



-30 °C to +140 °C
14,500 Data Points

Diameter: 25 mm
Height: 35 mm

Compact Temperature

Length: 30 and
50 cm

The material is either semi flexible stainless steel ø 1.5 mm or SmartFlex PTFE ø 1.8 mm.



-30 °C to +140 °C
14,500 Data Points
Diameter: 25 mm

Compact Pressure

The Compact logger is configured to measure one pressure or one pressure combined with temperature.

-30 °C to +140 °C
0 to 6 bar

Pressure: 7,200
Data Points

Combi: 10,000
Data Points

Diameter: 25 mm
Height: 55 mm



Lab Temperature

Length: 0 and 35 mm

The Lab logger is designed for stability studies. Ideal for monitoring temperature and can be fitted with SKY option.



-30 °C to +100 °C
60,000 Data Points
LED Sky optional

Diameter: 25 mm
Height: 44 mm

Lab Relative Humidity

Ideal for monitoring humidity in long term stability applications - and can be fitted with SKY option.

-30 °C to +100 °C
0 to 100% RH
30,000 Data Points
LED Sky optional

Diameter: 25 mm
Height: 46 mm



Lab Temperature

Length: 50 mm

The Lab logger is designed with four temperature channels. The cables have different colors for easy identification.

-30 °C to +100 °C
15,000 Data Points
Diameter: 25 mm



Fittings & Accessories



Custom Fittings

Packing glands and other fittings are available for placing loggers and inserting sensors into any variety of packaging material. The glands are threaded to accept sensors and will maintain the seal when

pressurized. It is very important that sensors are placed correctly in the "cold/hot zone" to obtain true lethality values. See examples of typical applications and configurations below.

It is very important that sensors are placed correctly in the "cold/hot zone"



TSS/FixPro

sleeves for protection during movement and silicone case holder for secure positioning.



LYO

with contact puck and LYO13/22 rubber stopper for lyophilization application.



TBJ/TSJ

fitting for internal mounting inside bottles.



TBJ/TSK/TSJ and GKJ

fitting for internal mounting and packing gland for external mounting.

**GVK**

on bottle neck using GVK packing gland for pasteurization application.

**Smart Gasket**

mounted with logger in Tri Clamp for measuring inside pipes/hoses.

**TDJ**

logger mounted inside pouch for sterilization application.

**TIK**

Internal fixture for measuring inside IV-bags.

**GNK**

logger mounted on ampoules in moist heat sterilization applications.

**GVJ**

Packing gland for measuring inside ampoules or vials.

**PTFE Thermal barrier**

logger protected in special PTFE Thermal barrier for liquid boiling applications.

**TTB Thermal Barrier**

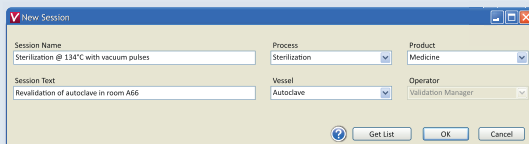
logger with high temperature sensor mounted in TTB Thermal Barrier for depyrogenation application.

ValSuite™ Pro

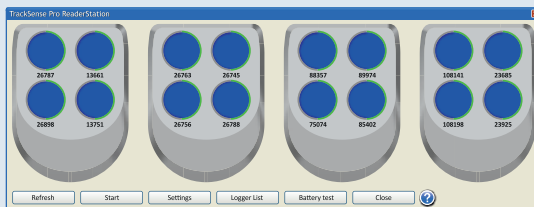
Intuitive and user friendly software

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

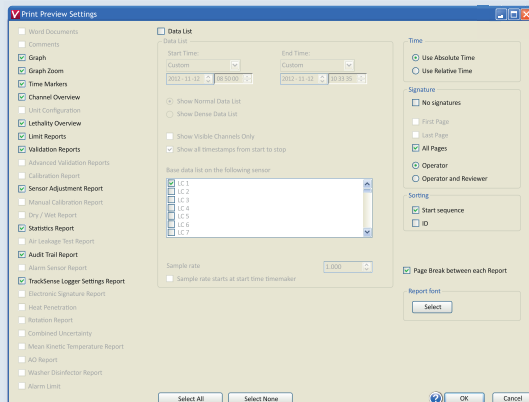
- 1 Login, program and start the loggers using a Profile, which includes a unit configuration and a selection of reports. Place the loggers in the load or process and run the process.



- 2 Read the loggers. 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, 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

Templates allow detailed test criteria to be programmed in the software by the assigned administrator. Information on sensor placement, operator, test, vessel, required temperature limits, start and stop time, monitoring interval and specific calculations can all be pre-defined and saved. 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.

Statistics

EN17665 report

Saturated steam report

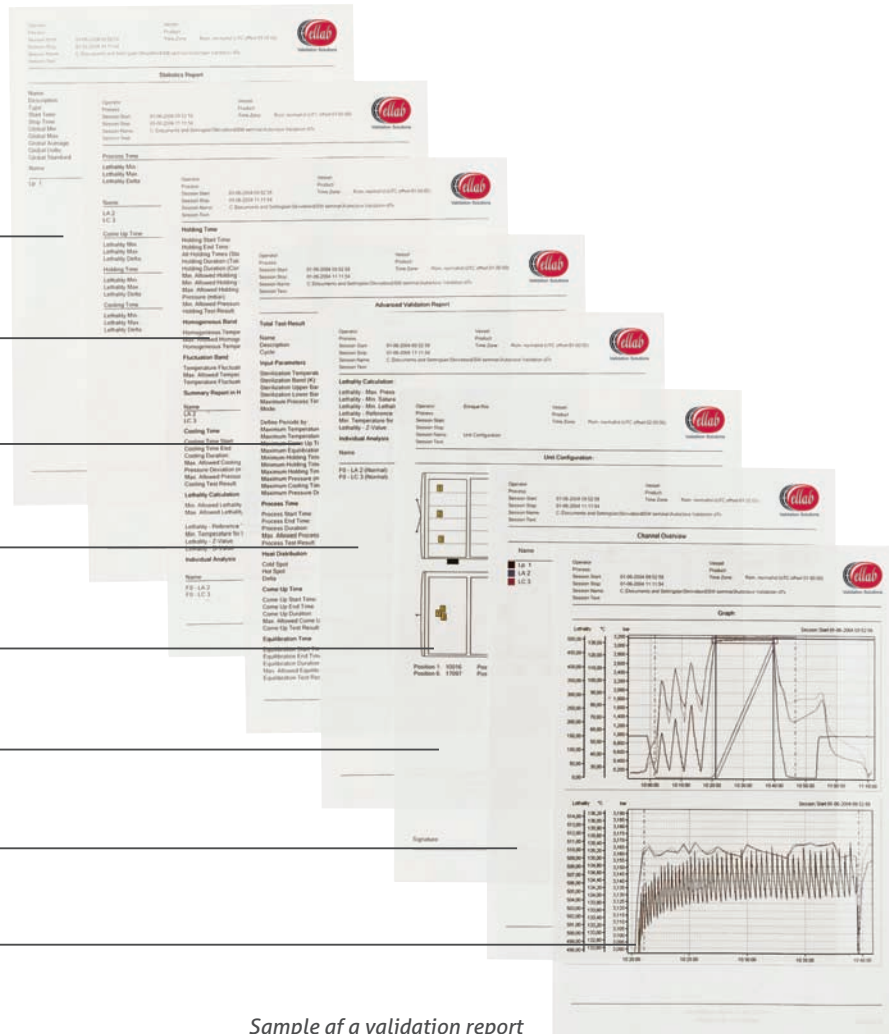
Lethality report

Unit

Equipment used

Graph

Zoom window print



Sample of a validation report

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. Further to this, a “transport logger” function makes it possible to start and read the logger from two different databases / PC’s thus allowing the logger to be used to monitor parameters during transportation over long distances.

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
- Heat Factors / Ball Simulation

Fully compliant with 21 CFR, Part 11

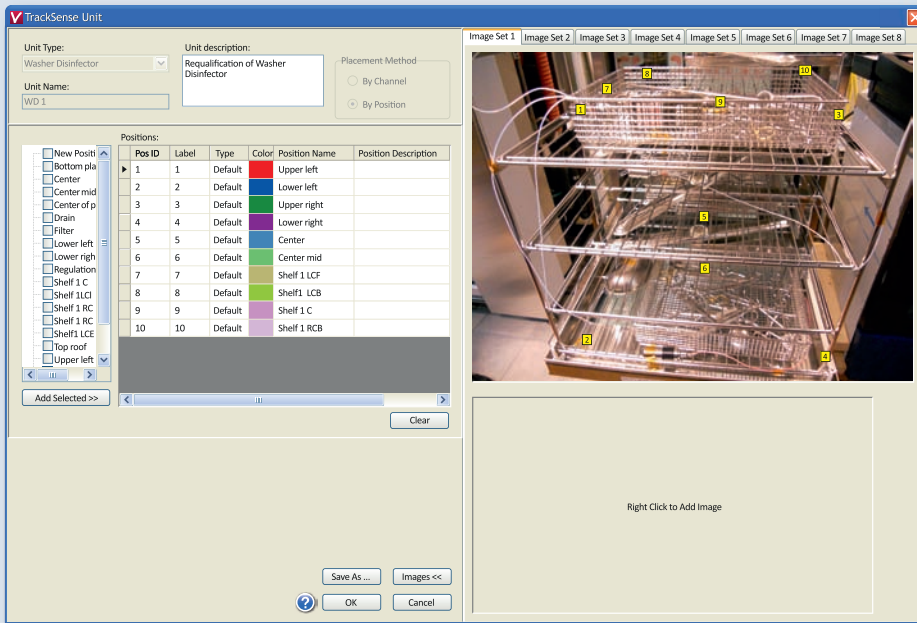
Producing Reports

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

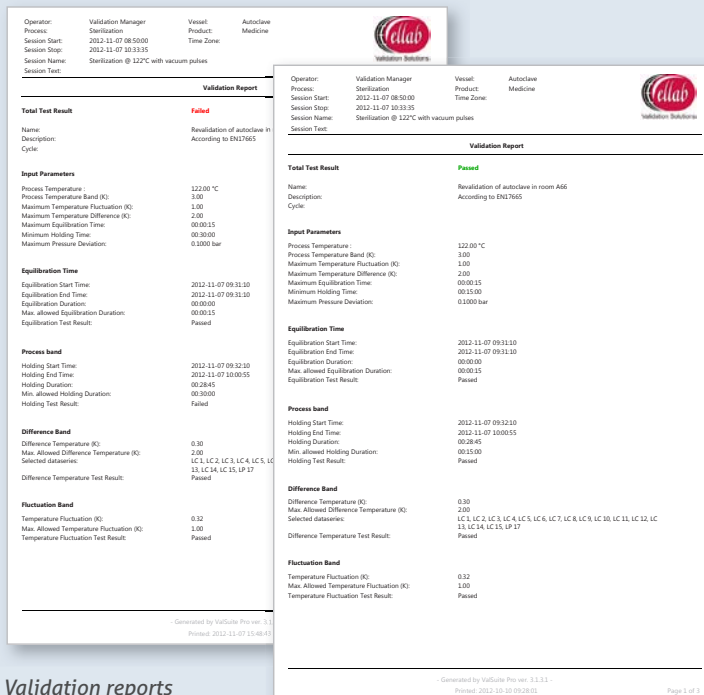
ValSuite™ Pro also maintains templates for reports designed to meet the specific requirements of tests such as EN17665 (EN554) for moist heat autoclaves

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

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 (sensors) 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 sensors can be user calibrated at defined intervals and store offset values.

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 sensor and will be taken into account whenever the sensor is used in future measurements.

Operator: Validation Manager Vessel: LiquiCal HM
 Process: Calibration Product: Pharma
 Session Start: 2012-11-08 08:29:49 Time Zone:
 Session Stop: 2012-11-08 10:03:13
 Session Name:
 Session Text: Post calibration of sensors

Calibration

Name: Calibration Report
 Description:

Temperature Standard
 Manufacturer: Ellab A/S
 Model Number: ETS20
 Serial Number: 110001
 Certificate Number: 18255
 Calibration Date: 2012-01-01
 Calibration Expiry Date: 2013-01-01

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 +/-: 0.20°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

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	After Adjustment
TC15393 - Ch 1	14469	40.00°C	Passed	0.05°C	0.07°C	Passed
		60.00°C	Passed	0.05°C	0.09°C	Passed
		90.00°C	Passed	0.00°C	0.03°C	Passed
		120.00°C	Passed	-0.08°C	-0.11°C	Passed
		140.00°C	Passed	-0.16°C	-0.18°C	Passed
TC15395 - Ch 2	14469	40.00°C	Passed	0.07°C	0.09°C	Passed
		60.00°C	Passed	0.06°C	0.08°C	Passed
		90.00°C	Passed	0.03°C	0.04°C	Passed
		120.00°C	Passed	-0.10°C	-0.10°C	Passed
		140.00°C	Passed	-0.17°C	-0.18°C	Passed
TC15337 - Ch 3	14469	40.00°C	Passed	0.08°C	0.09°C	Passed
		60.00°C	Passed	0.09°C	0.10°C	Passed
		90.00°C	Passed	0.01°C	0.04°C	Passed
		120.00°C	Passed	-0.09°C	-0.10°C	Passed
		140.00°C	Passed	-0.14°C	-0.17°C	Passed
TC15338 - Ch 4	14469	40.00°C	Passed	0.05°C	0.09°C	Passed
		60.00°C	Passed	0.07°C	0.09°C	Passed
		90.00°C	Passed	0.02°C	0.03°C	Passed
		120.00°C	Passed	-0.08°C	-0.10°C	Passed

Calibration Setup

Calibration Type: Full-Automatic Calibration E-Val Flex
 Semi-Automatic TS Pro Logger
 Manual Calibration

Device Type: Temperature Standard Info: Serial Number: 110001

Stability Criteria: Fluctuation Band: 0.200 Fluctuation Time: 00 03 00 Holding Time: 00 20 00

Pass Criteria: Temperature Standard Fluctuation Band: 0.1 Channel Temperature Deviation (+/-): 0.15 Pass Time: 00 01 00

Adjustment: Enable Adjustment


Templates: Load Save

Calibration Points: 0.0, 40, 60, 90, 120, 140 (Add, Remove, Insert, Clear buttons)

Set Point Tolerance (+/-): 2.00

OK Cancel

Calibration Setup



Calibration Equipment

- Generated by ValSuite Pro ver. 3.1.3.1 -
 Printed: 2012-11-09 13:32:52 Page 1 of 75

ID	Text	Category	User	Timestamp	Im
94	Edit Extended Session Properties(ID:18)- Process to 'Sterilization'-Pro	Session	Validation Manager	2012-10-10 09:27:22	
93	Print Preview Session(ID:18)	Session	Validation Manager	2012-10-10 09:23:41	
92	Add to Session(ID:18)-Validation Report(Name:Revalidation of autoc	Session	Validation Manager	2012-10-10 09:21:19	
91	Add to Session(ID:18)-Time Marker(Name:Holding time stop)	Session	Validation Manager	2012-10-10 09:15:09	
90	Add to Session(ID:18)-Time Marker(Name:Holding time start)	Session	Validation Manager	2012-10-10 09:14:53	

Sign in

View by Category: All | Text: | User: | From: 2012-10-10 | To: 2012-10-10 | Clear | Search | Print | Print Preview | Close

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
- Sensor 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. Ellab quality system is compliant with ISO 9001:2008

Active users: John Doe, Joe Bloggs, Jane Schmidt, Richard Miles

Inactive users:

Username: QA Manager | Administrator | Standard user

Domain or computername: | Initials: QA | Profile

Firstname: John | Middle Name: Peter | Lastname: Schmidt | Department: QA | Phone: +001 14 14 48 | Address: Denver

Change password on next login | OK | Cancel | Close

Access Manager

Select Security Mode

Security Enabled

Security

ValSuite Security | Windows Security

Verification

ValSuite Start | Access Points

OK | Cancel

Security Setup

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

Ellab



For over 60 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 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 semi-annual 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.

Building Confidence

Industry leading 2 year warranty on loggers, non-flexible sensors, Sky components and reader stations.



Validation Solutions

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