

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 that is unmatched in accuracy, performance, and versatility.

Accuracy

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

- Temperature: ± 0.05 °C
- Humidity: $\pm 2\%$
- Pressure: $\pm 0.25\%$ full scale
- Time: ± 5 sec. per 24 hours
- Conductivity: ± 1 $\mu\text{S}/\text{cm}$
- CO₂: $\pm 0.2\%$
- Vacuum: ± 10 -50% of reading

* 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/XL loggers are designed to operate under extreme conditions without ever losing valuable data. They operate in temperatures from -80 to +150°C and can withstand pressure up to 10 Bar fully immersed. When keeping the Pro X/XL logger outside and using a flexible sensor inside the process you can extend the measuring range down to -196°C. When using at thermal barrier and a logger with high temperature sensor the measuring range is extended up to +400°C. The non-volatile memory stores up to 120,000 data points and it is possible to have up to 160 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 feature is highly beneficial when it comes to flexibility and lowered operation costs.



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	Vacuum	Relative Humidity	Conductivity	CO ₂	Sky
TSP Pro XL	•	•	•	•	•	•	•	•
TSP Pro X	•	•	•	•	•	•		•
TSP Pro	•	•	•	•	•	•		•
TSP Basic	•	•	•	•	•	•		•
TSP Basic L	•	•	•	•	•	•	•	•
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 within seconds. 16 loggers can be started or read simultaneously, saving time, especially when 160 data loggers have to be started for one study.

Single Reader Station

When only a few loggers are needed, a single reader station can be used. Available for all types of loggers.

Introducing RF Data Transmission

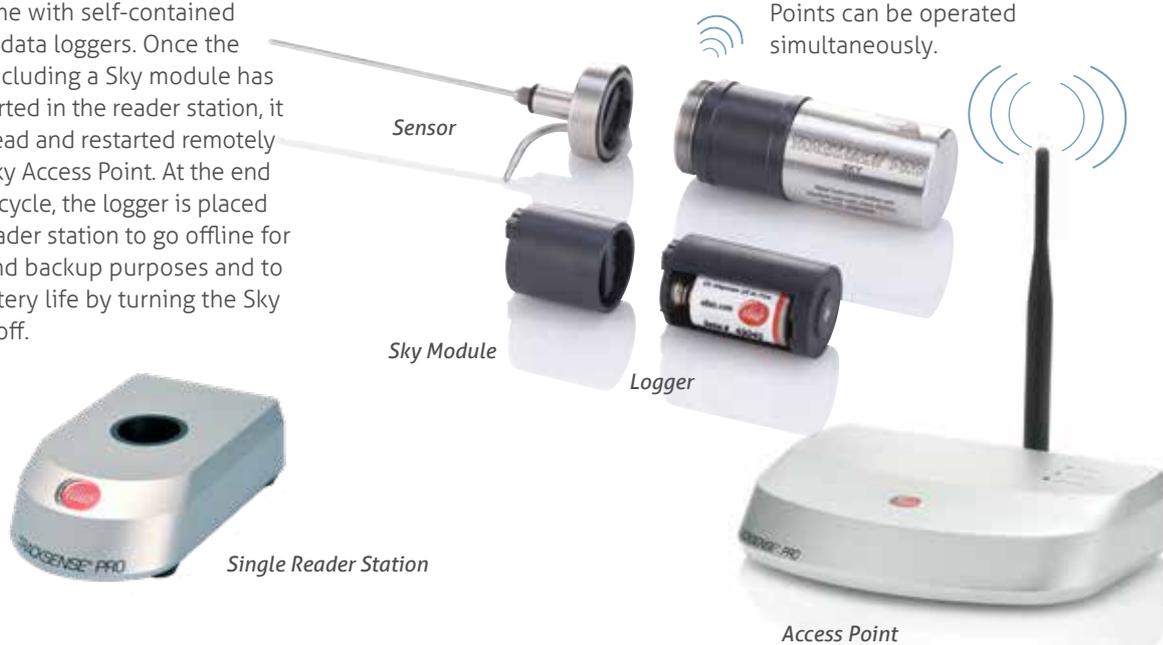
Enjoy all the benefits of having real time process information available on your computer and a reduced setup time with self-contained wireless data loggers. Once the logger including a Sky module has been started in the reader station, it can be read and restarted remotely by the Sky Access Point. At 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 will be 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. The sky module is 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. The 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, CO₂, 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 the light flashing green. This feature makes it easier to start larger groups of loggers and helps to avoid the use of 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.

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 120,000 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 316L 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 Long Logger

TrackSense® Pro Basic L is designed for the many applications below 100°C where there is a need for extended battery capacity such as operating with the CO₂ sensor for incubation purposes.

-30 to +85 °C
120,000 Data Points
Diameter: 25 mm
Height: 68.8 mm

Basic Logger

TrackSense® Pro Basic is specially designed for the many applications below 100 °C such as pasteurization or EtO sterilization where there is no need for additional battery capacity or extended sampling periods.

-30 to +105 °C
120,000 Data Points
Diameter: 25 mm
Height: 44 mm

Pro Logger

TrackSense® Pro 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 to +150 °C
120,000 Data Points
Diameter: 25 mm
Height: 44 mm

Pro X Logger

TrackSense® Pro X is the most versatile logger in the range. It is specially designed for low temperature applications such as lyophilization or ultra low temperature storage while also being able to handle higher temperatures, including sterilization.

-80 to +150 °C
120,000 Data Points
Diameter: 25 mm
Height: 44 mm

Pro X Long Logger

TrackSense® Pro XL is an enlarged logger with an extended battery capacity. Due to the larger capacity, the battery stability is particularly increased in applications where temperatures change from being very high to very low.

-80 to +150 °C
120,000 Data Points
Diameter: 25 mm
Height: 68.8 mm

Internal Temperature Sensor

With Pt1000 element positioned internally, this sensor is ideal for applications where space is limited and/or maximum protection of the sensor is required.

-80 to +150 °C



Rigid Temperature Sensor ø 2 mm

Single rigid stainless steel sensor with round, conical or sharp tip. All temperature sensors are made with Pt1000 elements.

-196* to +150 °C



Double Rigid Temperature Sensors ø 2 mm

Double rigid stainless steel sensor with round, conical or sharp tip. Straight design with an optional 90° or 180° bend.

-196* to +150 °C



Semi Flexible Temperature 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.

-196* to +150 °C



Semi Flexible Temperature Sensor ø 2 mm

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

-196* to +150 °C



Rigid Multipoint Temperature Sensor ø 2.5 mm

The stainless steel sensor is used to determine temperature differences in containers to locate the cold spot with a total of four Pt1000 elements measuring simultaneously.

-80 to +150 °C



Rugged Temperature Sensor ø 2.5 mm

The rugged sensor is extremely robust, but still allows access to hard to reach areas.

-196* to 140 °C



SmartFlex Temperature Sensor ø 1.8 mm

Single or double fully flexible color coded sensors. SmartFlex secures the intended position of the sensor.

-196* to +140 °C



Semi Flexible High Temperature Sensor

Single or double semi flexible stainless steel sensors, specifically designed for high temperature applications.

0 to +400 °C



Vacuum Sensor

The sensor is configured to measure Vacuum and is ideal for lyophilization applications.

0.0001 to 1,000 mBar
-80 to +140 °C



Pressure Sensors

These sensors are configured to measure pressure. Two versions available.
10 mBar to 6 Bar ABS
20 mBar to 8 Bar ABS



Pressure and Rigid Temperature Sensor

The sensor is configured to measure pressure together with temperature.

10 mBar to 6 bar ABS
0 to +150 °C



Relative Humidity and Temperature Sensor

The sensor has a fast response to determine humidity levels during the validation of warehouses, stability chambers and ETO sterilization.

0 to +90 °C
0 to 100% RH



CO₂ Sensors

The sensors provides measurements of CO₂ concentration used for the validation or monitoring of incubators.

Requires Basic L or Pro XL logger
0 to 50 °C
0 to 10% CO₂
0 to 20% CO₂



Automarker Sensor

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



High Range Conductivity and Temperature Sensor

The Conductivity sensor with integrated temperature sensor for measurements applying to the control of mainly WD processes.

0 to 200 µS/cm
200 to 2000 µS/cm



Thermocouple Temperature Sensor

The TC sensor with it's very thin thermocouple wire is ideal for monitoring sample temperatures during freeze drying.

-80 to +62 °C
-200 to +400 °C when logger at ambient



Sensors are compatible with a Sky option to provide real time data.

*The sensor can measure down to -196 °C when the logger is placed outside the process.

TrackSense® Pro Integrated Sensors



*A large range
of loggers with
integrated
sensors to fit
specific needs*

A range of loggers with integrated sensors are available in temperature, pressure 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 316L stainless steel.

Rigid Temperature Sensor

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 up to 12 months.

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



SmartFlex Temperature Sensor

Ø 1.8 mm
Length:
30 and 50 cm

Due to the design, this Frigo logger is ideal for low temperature applications such as lyophilization.

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



Semi Flexible Temperature Sensor

Ø 1.5 mm
Length: 30 and 50 cm

Due to the design, this Frigo logger is ideal for monitoring freezing processes over extended time periods such as biological sample storage.

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



Rigid Temperature Sensor

The Compact Ultra X uses a larger battery and can go down to -80 °C.

-80 to +140 °C
60,000 Data Points
Diameter: 25 mm
Height: 60 mm



Rigid Temperature Sensor
 ø 2 mm

The Compact X logger is configured to measure temperature with a rigid or flexible sensor.



-50 to +140 °C
 30,000 Data Points
 30,000 Samples
 Diameter: 25 mm
 Height: 35 mm

Rigid Temperature Sensor
 ø 2 mm
 Length: 35, 50, 75, 100 mm

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



-30 to +140 °C
 30,000 Data Points
 30,000 Samples
 Diameter: 25 mm
 Height: 35 mm

Semi Flexible Temperature Sensor
 Length: 30, 50 cm

Compact logger where the material is semi flexible stainless steel ø 1.5 mm.



-30 to +140 °C
 30,000 Data Points
 30,000 Samples
 Diameter: 25 mm

SmartFlex Temperature Sensor
 Length: 30, 50 cm

Compact logger where the material is PTFE ø 1.8 mm.



-30 to +140 °C
 30,000 Data Points
 30,000 Samples
 Diameter: 25 mm

Pressure and Rigid Temperature Sensor

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



-30 to +140 °C
 0 to 6 bar
 30,000 Data Points
 10,000 Samples
 Diameter: 25 mm
 Height: 55 mm

6 Bar Pressure Sensor
 The Compact logger is configured to measure pressure.



-30 to +140 °C
 0 to 6 bar
 30,000 Data Points
 15,000 Samples
 Diameter: 25 mm
 Height: 55 mm

Internal Temperature Sensor
 ø 2 mm
 Length: 0 and 35 mm

The Lab logger is designed for stability studies. Ideal for monitoring temperature. Can be fitted with a SKY module.



-30 to +100 °C
 120,000 Data Points
 120,000 Samples
 Sky optional
 LED included
 Diameter: 25 mm
 Height: 44 mm

Relative Humidity and Temperature Sensor

Lab logger ideal for monitoring humidity and temperature in long term stability applications. Can be fitted with a SKY module.



0 to +90 °C
 0 to 100% RH
 120,000 Data Points
 60,000 Samples
 Sky optional
 Diameter: 25 mm
 Height: 74 mm

Quad Flexible Temperature Sensor
 ø 1.8 mm
 Length: 50 cm

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



-30 to +100 °C
 120,000 Data Points
 30,000 Samples
 Diameter: 25 mm

Rigid Temperature Sensor
 ø 2 mm

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

The small volume displacement makes the Mini logger ideal for measuring inside packaging. Due to its temperature range it is ideal for sterilization applications.



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

Rigid Temperature Sensor
 ø 2 mm
 Length: 10 mm

The small diameter makes these Micro loggers ideal for measuring inside bottles during pasteurization cycles.



-20 to +140 °C
 14,500 Data Points
 14,500 Samples
 Diameter: 15 mm
 Height: 22 mm

Pressure and Temperature Sensor
 The Micro logger is configured to measure temperature/pressure.



-20 to +140 °C
 0 to 6 bar
 30,000 Data Points
 10,000 Samples
 Diameter: 15 mm
 Height: 30 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 SHUTTLE

Vial holder with contact puck and rubber stopper for lyophilization applications.



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 necks use the GVK packing gland for pasteurization applications.

**Luer lock**

Positioned on the syringe with pressure sensor mounted on logger for pressure measurement in pharmaceutical processes.

**TDJ**

Logger mounted inside pouch for sterilization applications.

**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 applications.

ValSuite® Pro

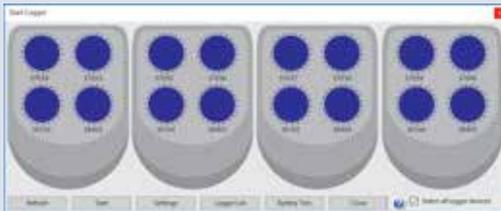
Intuitive and user friendly software

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

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



- 2 Read the loggers. 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 FDA 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 calculations such as min/max, standard deviation, average, deltaT and lethality can be calculated using 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 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.

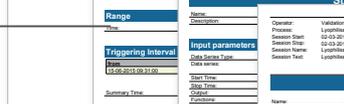
Sensor adjustment report



Limit report



Statistics report



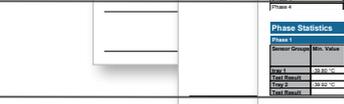
Adv. phase statistics report



EN17665 report



Saturated steam report



Lethality report



Equipment used



Graph & Zoom



Unit



Monitoring Features

ValSuite Pro software also offers several monitoring 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 Pro wired systems
- Can be run from a stand alone PC or a server/Citrix 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
- MKT report
- Combined uncertainty report
- Leak test report
- Advanced validation report
- Dew Point Calculation

- Printed or PDF format
- Comment field and Word document attachment
- Heat Factors/Ball Simulation
- 3D Visualization



Samples of typical validation reports

Fully compliant with 21 CFR, Part 11

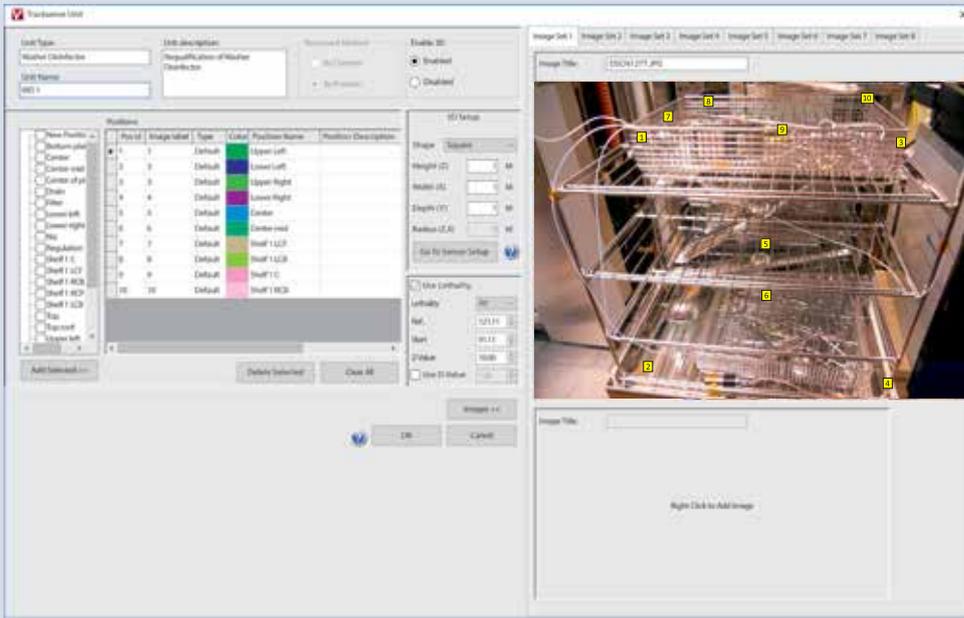
Producing Reports

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.

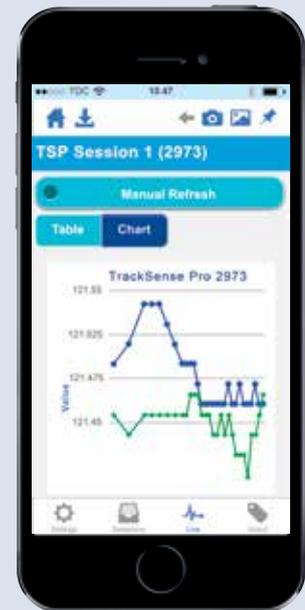


Unit configuration with drag and drop

Validation Report	
Operator:	Validation Manager
Process:	Sterilization
Session Start:	15-06-2017 09:50:00
Session Stop:	15-06-2017 10:33:35
Session Name:	Sterilization @ 122 °C with vacuum pulses.d7x
Session Text:	Sterilization @ 122 °C with vacuum pulses
Validation Report	
Name:	Validation Report
Description:	121.00 °C
Cycle:	Failed
Total Test Result: Failed	
Input parameters	
Process Temperature:	121.00 °C
Process Temperature Band (K):	3.00
Max. Allowed Temperature Fluctuation (K):	1.00
Max. Allowed Difference Temperature (K):	2.00
Minimum Equilibration Time:	00:00:15
Minimum Holding Time:	00:15:00
Minimum Pressure Duration:	3.0000 bar
Equilibration Time	
Equilibration Start Time:	15-06-2017 09:50:05
Equilibration End Time:	15-06-2017 09:51:00
Equilibration Duration:	00:00:55
Max. Allowed Equilibration Duration:	00:01:15
Equilibration Test Result: Passed	
Process band	
Holding Start Time:	15-06-2017 09:51:10
Holding End Time:	15-06-2017 10:33:30
Holding Duration:	00:39:40
Max. Allowed Holding Duration:	00:15:00
Holding Test Result: Passed	
Difference Band	
Difference Temperature (K):	0.63
Max. Allowed Difference Temperature (K):	2.00
Selected data series:	LC 1, LC 2, LC 3, LC 4, LC 5, LC 6, LC 7, LC 8, LC 9, LC 10, LC 11, LC 12, LC 13, LC 14, LC 15, LP 17
Difference Temperature Test Result: Passed	
Fluctuation Band	
Temperature Fluctuation (K):	1.96
Max. Allowed Temperature Fluctuation (K):	1.00
Temperature Fluctuation Test Result: Failed	

Validation reports

Validation Report	
Operator:	Validation Manager
Process:	Sterilization
Session Start:	15-06-2017 09:50:00
Session Stop:	15-06-2017 10:33:35
Session Name:	Sterilization @ 122 °C with vacuum pulses.d7x
Session Text:	Sterilization @ 122 °C with vacuum pulses
Validation Report	
Name:	Validation Report
Description:	122.00 °C
Cycle:	Passed
Total Test Result: Passed	
Input parameters	
Process Temperature:	122.00 °C
Process Temperature Band (K):	3.00
Max. Allowed Temperature Fluctuation (K):	1.00
Max. Allowed Difference Temperature (K):	2.00
Minimum Equilibration Time:	00:00:15
Minimum Holding Time:	00:15:00
Minimum Pressure Duration:	3.0000 bar
Equilibration Time	
Equilibration Start Time:	15-06-2017 09:51:05
Equilibration End Time:	15-06-2017 09:51:10
Equilibration Duration:	00:00:05
Max. Allowed Equilibration Duration:	00:00:15
Equilibration Test Result: Passed	
Process band	
Holding Start Time:	15-06-2017 09:51:10
Holding End Time:	15-06-2017 10:33:30
Holding Duration:	00:39:25
Max. Allowed Holding Duration:	00:15:00
Holding Test Result: Passed	
Difference Band	
Difference Temperature (K):	0.30
Max. Allowed Difference Temperature (K):	2.00
Selected data series:	LC 1, LC 3, LC 4, LC 5, LC 6, LC 7, LC 8, LC 9, LC 10, LC 11, LC 12, LC 13, LC 14, LC 15, LP 17
Difference Temperature Test Result: Passed	
Fluctuation Band	
Temperature Fluctuation (K):	1.00
Max. Allowed Temperature Fluctuation (K):	1.00
Temperature Fluctuation Test Result: Passed	



Use ValSuite App to survey active processes and validation reports

Validation Report

Report header: 1
Validation Report

Name:
Revalidation of autoclave in room 66

Description:
According to EN 17665

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

Preselected Timestamps
First possible start

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

Preselected Timestamps
Last possible end

(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 (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 that shows the 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:	12-06-2017 12:53:24	Time Zone:	UTC offset 01:00:00
Session Stop:	12-06-2017 16:14:06		
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: _____

Model Number: _____ ETS 110001

Serial Number: _____ 110001

Certificate Number: _____

Calibration Date: _____

Calibration Expiry Date: _____

Stability Criteria

Fluctuation Band: _____ 0.20°C

Fluctuation Time: _____ 00:03:00

Holding Time: _____ 00:03:00

Pass Criteria

Temperature Standard Fluctuation Band: _____ 0.15°C

Sensor Temperature Deviation +/-: _____ 0.20°C

Pass Time: _____ 00:01:00

Status for Temperature Standard:	Temperature	Result
	30.00°C	Passed
	37.00°C	Passed
	45.00°C	Passed
	60.00°C	Passed
	65.00°C	Passed
	75.00°C	Passed
	90.00°C	Passed
	100.00°C	Passed
	120.00°C	Passed
	130.00°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
LC 01	16519	30.00°C	Passed	0.02°C	0.04°C
LC 01	16519	37.00°C	Passed	0.02°C	0.03°C
LC 01	16519	45.00°C	Passed	0.00°C	0.02°C
LC 01	16519	60.00°C	Passed	0.00°C	0.01°C
LC 01	16519	65.00°C	Passed	0.00°C	0.01°C
LC 01	16519	75.00°C	Passed	-0.01°C	-0.01°C
LC 01	16519	90.00°C	Passed	-0.01°C	-0.02°C
LC 01	16519	100.00°C	Passed	0.00°C	-0.01°C
LC 01	16519	120.00°C	Passed	0.02°C	0.03°C

- Generated by ValSuite Pro -
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Calibration Setup

Operation Type

Full-Automatic Calibration

Semi-Automatic Calibration

Manual Calibration

Device Type

E-Val Pro

E-Val FlexModule

TS Pro Logger

ETI

Calibration Type

Calibration

Verification

Temperature Standard Info

Serial Number:

Stability Criteria

Fluctuation Band: °C

Fluctuation Time:

Holding Time:

Pass Criteria

Temperature Standard Fluctuation Band: °C

Channel Temperature Deviation Before Adjustment (+/-): °C

Channel Temperature Deviation After Adjustment (+/-): °C

Pass Time:

Calibration Points

Temp	Adj. Point
0	<input type="checkbox"/>
60	<input checked="" type="checkbox"/>
90	<input type="checkbox"/>
120	<input type="checkbox"/>
140	<input checked="" type="checkbox"/>

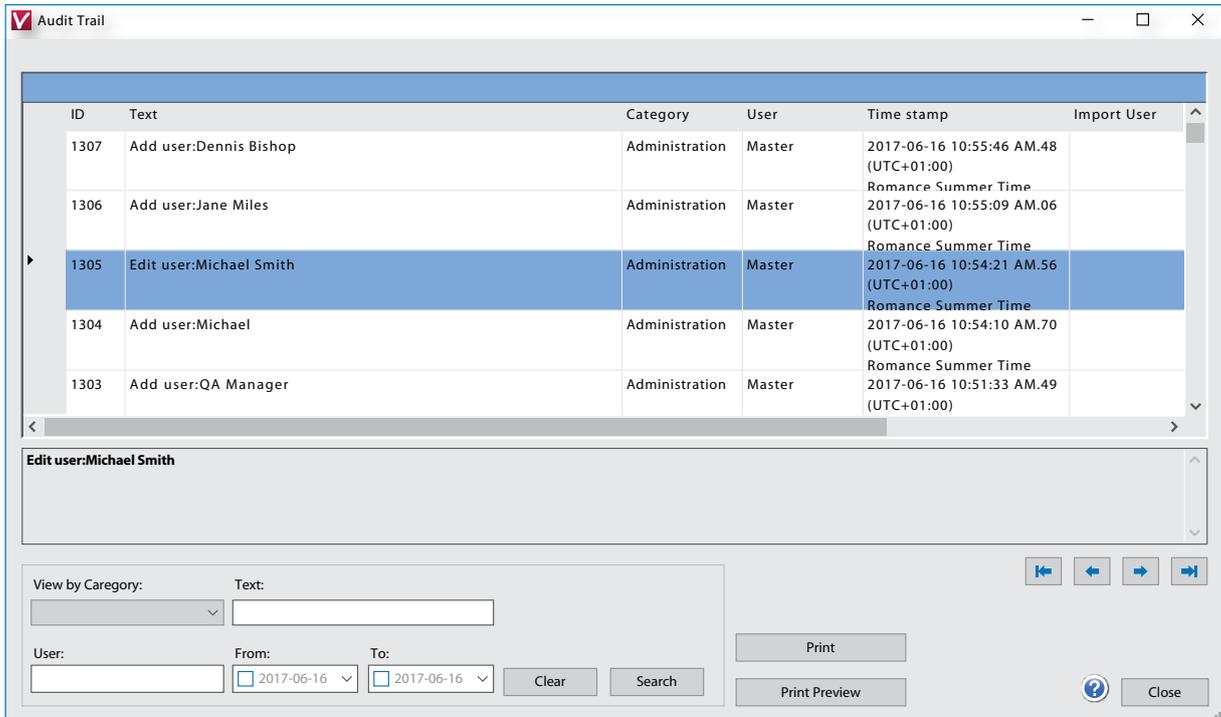
Set Point Tolerance (+/-): °C

Endpoint: °C

Calibration Setup



Calibration Equipment



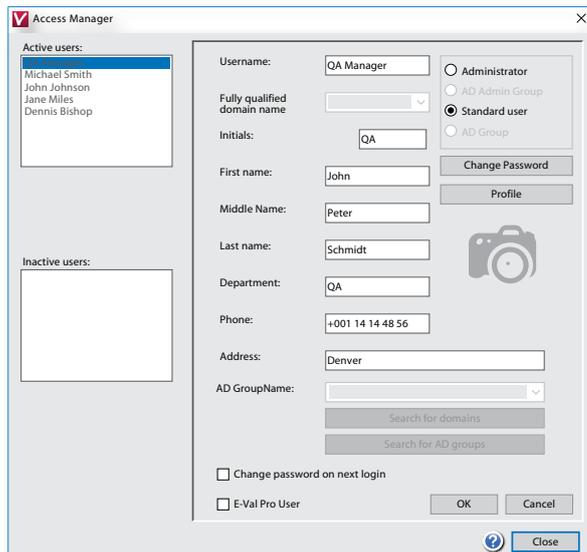
Audit Trail

Compliant to FDA Guidelines

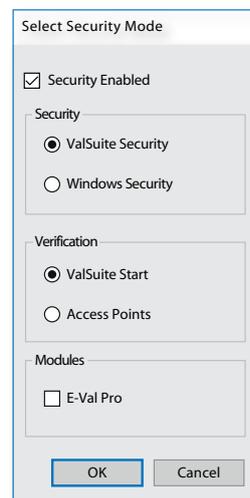
- SQL database where complete sessions or individual data cannot be deleted or manipulated
- Audit trail report
- Electronic signature
- Access manager with user ID and passwords
- Sensor ID provides complete traceability
- Customized report generator eliminating export of data

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



Access Manager



Security Setup

ValSuite™ 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.

Building Confidence

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



Validation Solutions

Ellab A/S

Trollesmindeallé 25
DK-3400 Hilleroed
Denmark

P: +45 4452 0500
info@ellab.com
www.ellab.com