# 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: ±2%
- Pressure: ±0.25% full scale
- Time: ±5 sec. per 24 hours
- Conductivity: ±1 µS/cm

TrackSense<sup>®</sup> Pro is the most accurate data logger available on the market today



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

#### 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 °C 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	<b>Relative Humidity</b>	Conductivity	Sky	
TSP Pro XL	٠	•	•	٠	•	•	
TSP Pro X	٠	•	•	٠	•	٠	
TSP Pro	٠	•	•	٠	•	٠	
TSP Basic	٠	•	•	٠	•	•	
TSP Compact	٠	•	•				
TS Frigo	٠	•					
TS Lab	٠	٠		٠		٠	
TSP Mini	٠	٠					
TSP Micro	٠	•	•				

TrackSense<sup>®</sup> 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* 

Access Point

Sky Module

Sensor



## 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.

#### **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 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.

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

#### **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



TrackSense<sup>®</sup> 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.



#### 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 tempertures including sterilization.

-80 °C to +150 °C 60,000 Data Points

Diameter: 25 mm Height: 44 mm

#### **Pro X Long Logger**

TrackSense® Pro XL is an enlarged logger with extended battery capacity. Due to larger capacity the battery stability is increased in particular in applications changing from

very high to very low temperatures.

-80 °C to +150 °C 60,000 Data Points Diameter: 25 mm Height: 68.8 mm



### TRACKSENSE® PRO I PAGE 5



double semi flexible stainless steelsensors with small sensor diameter for increased flexibility and usage for very narrow lumen.

### **Double rigid sensors** ø 2 mm

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

### **Rigid Sensors** ø 2 mm

Single rigid stainless steel sensors with round, conical or sharp tip. All temperature sensors are made with PT1000 elements.



### **SmartFlex** ø 1.8 mm Single or double fully flexible color coded sensors. SmartFlex secures the intended position of the sensor.

ø 2 mm

semi flexible

stainless steel

sensors with round,

conical or sharp tip.

#### Low Temperature Sensor ø 1.2 mm Single, double, or quad flexible sensors with small diameter. Ideal for low temperature

applications such as lyophilization.

**Pressure/Temperature** 

Sensor

The sensor is

configured to

together with

temperature.

measure pressure



### ø 2.5 mm The multipoint rigid stainless steel

**Multipoint Sensor** 

sensor is used to determine temperature differences in containers to locate the cold spot with a total of four PT1000 elements measuring simultaneously.



### **Conductivity Sen**sor

The Conductivity sensor with integrated temperature sensor for measurements applying to the control/monitoring of industrial processes.



### **Vacuum Sensor**

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

### **Pressure Sensor** The sensor is configured to measure pressure.

is extremely robust,

but still allows

access to hard to reach areas.





**Relative Humidity** 

developed for EtO-

has a capacitance

element and is

optimized for a

very humid and

aggressive process

processes. The sensor

**Sensor for EtO** 

The sensor is





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

## **Relative Humidity Sensor** for Stability





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



## High **Temperature Sensor**



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



## 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 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.

#### Frigo 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



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

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

### Frigo SemiFlex ø 1.5 mm 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.

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



#### **Compact Ultra X**

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



-80 °C to +140 °C 14,500 Data Points

Diameter: 25 mm Height: 60 mm



#### Compact 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 Combi**



#### Compact X ø 2 mm

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

> -50 °C to +140 °C 14,500 Data Points Diameter: 25 mm Height: 35 mm

> > Compact **SmartFlex**

Length: 30, 50 cm

The material is

PTFE ø 1.8 mm.

-30 °C to +140 °C 14,500 Data Points

Diameter: 25 mm



## The Compact logger is

configured to measure one pressure combined with temperature.

-30 °C to +140 °C 0 to 6 bar

Combi: 10.000 Data Points

Diameter: 25 mm Height: 55 mm

### Lab Relative Humidity

Ideal for monitoring humidity and temperature 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





### Micro ø 2 mm Length: 10 mm

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







Height: 44 mm

option.

#### Mini 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



#### **Micro Combi**

The Micro logger is configured to measure temperature/pressure.

> -20 °C to +140 °C 0 to 6 bar

Combi: 10,000 Data Points

Diameter: 15 mm Height: 30 mm



The Compact logger is configured to measure one pressure.

**Compact Pressure** 

ø 1.5 mm.

-30 °C to +140 °C 0 to 6 bar

Pressure: 7,200 Data Points

Diameter: 25 mm Height: 55 mm

#### Lab 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 °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 SHUTTLE** vial holder with contact puck and 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.



### 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 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:

 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.

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2 Read the loggers. Data analysis and reports are made automatically.



#### **3** Print the reports and logout.



#### ValSuite<sup>™</sup> Pro Software

ValSuite<sup>™</sup> 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<sup>™</sup> is available in three versions, ValSuite<sup>™</sup>, ValSuite<sup>™</sup> Plus and ValSuite<sup>™</sup> Pro. The ValSuite<sup>™</sup> 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<sup>™</sup> 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 on any block of data displayed eliminating the need to export data thus improving data security.

ValSuite<sup>™</sup> 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 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.



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

Fully compliant with 21 CFR, Part 11

• Up to 128 channels in one session

"phantom" values in reports

Switch between multiple languages

- 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

- Drivers for calibration equipment

## **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<sup>™</sup> 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.





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Use ValSuite<sup>™</sup> App to survey active processes and validation reports

Validation Report		X
Report header:     1       Validation Report       Name       Revalidation of autoclave in room A66       Description:       According to EN17665	Process Start Time: 2 2015-06-15 C 08 50 00 C Preselected Timestamps First possible start	Process End Time: 3 2015-06-15 10 25:10 1 Preselected Timestamps Last possible end (Use of preselected timestamps is optional)
Process Temperature:   Process Temperature Band:   Maximum Temperature Fluctuation:   Maximum Temperature Difference First 60 Sec.:   Maximum Temperature Difference:   Maximum Temperature Difference:   Maximum Temperature Difference:   Maximum Equilibration Time:   Use individual sensor for start equilibration time:   LC 4   Maximum Holding Time:   Automatic by temperature   Manual by timemarkers   Holding time start   Holding time stop   Max Pressure Deviation:   Cycle (optional):   5   Max 10 bar/min. Calculated in 3 sec. interval	134.00	Current Sensors   U C 1   U C 2   U C 3   U C 4   U C 5   U C 6   U C 7   O C 10   U C 10   U C 11   U C 12   U C 13     Select All   Select Annoient
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 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.



**Calibration Report** 

	Jext	Category	User	Timestamp	Im
94	Edit Extended Session Properties(ID:18)- Process to 'Sterilization'-Pro	Session	Validation Manager	2015-05-12 09:27:22	
93	Print Preview Session(ID:18)	Session	Validation Manager	2015-05-12 09:23:41	
92	Add to Session(ID:18)-Validation Report(Name:Revalidation of autoc	Session	Validation Manager	2015-05-12 09:21:19	
91	Add to Session(ID:18)-Time Marker(Name:Holding time stop)	Session	Validation Manager	2015-05-12 09:15:09	
90	Add to Session(ID:18)-Time Marker(Name:Holding time start)	Session	Validation Manager	2015-05-12 09:14:53	
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to m					
			4	10 (m) (m)	

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

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	Change passw	ord on next login	OK Cancel
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Select Security Mode
Security Enabled
Security
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O Access Points
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OK Cancel

Security Setup

Ellab ValSuite<sup>™</sup> 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.

#### **Building Confidence**

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



#### Ellab A/S

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