TrackSense® Pro





The ultimate wireless data logging system

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 °CHumidity: ±2%

Pressure: ±0.25% full scale
Time: ±5 sec. per 24 hours

Conductivity: ±1 μS/cmCO₂: ±0.2%

Vacuum: ±10-50% of reading

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.



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

| | 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 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.



120,000 Data Points

Diameter: 25 mm

Height: 68.8 mm

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



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.





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.





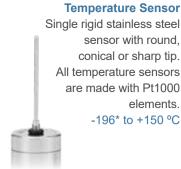
Pro X Long Logger

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



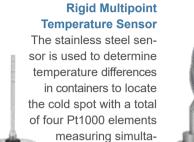
Double Rigid Temperature Sensor Double rigid stainless steel sensor with round, conical or sharp tip. Straight design with an optional 90° or 180° bend. -196* to +150 °C

Semi Flexible **Temperature Sensor** 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

Single or double semi flexible stainless steel sensors with round, conical or sharp tip. -196* to +150 °C



Rigid

elements.





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



-80 to +150 °C

neously.

The sensor is configured to measure Vacuum and is ideal for lyophilization applications. 0.0001 to 1.000 mBar



Pressure Sensors

These sensors are configured to measure pressure. Two versions available. 10 mBar to 4 Bar ABS 15 mBar to 6 Bar ABS 20 mBar to 8 Bar ABS



measure pressure together with temperature. 15 mBar to 6 bar ABS 0 to +150 °C



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



-80 to +140 °C

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.



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



-200 to +400 °C when logger at ambient



Designed for daily routine control of air removal (vacuum) sterilizers. Ideal with a Pro XL logger. 0 to +140 °C 10 mBar to 6 Bar



TrackSense® Pro Integrated Sensors



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 Length: 0 and 35 mm Ø 2 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 Length: 30 and 50 cm Ø 1.8 mm 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

Length: 30 and 50 cm Ø 1.5 mm

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

Semi Flexible

Temperature Sensor

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

Rigid Temperature Sensor

Length. 35, 50, 75 and 100 cm Ø 2 mm

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

Temperature Sensor

Length: 30, 50 cm

Compact logger where the material is

PTFE ø 1.8 mm.

30,000 Data Points 30,000 Samples

Diameter: 25 mm

Rigid Temperature Sensor

The Lab logger is designed

for stability studies. Ideal for

monitoring temperature. Can be fitted with a SKY module.

Length: 0 and 35 mm

Ø 2 mm

-30 to +100 °C

Sky optional

LED included

Height: 44 mm

120,000 Data Points

120,000 Samples

Diameter: 25 mm

-30 to +140 °C

SmartFlex

Ø 1.8 mm

Rigid Temperature Sensor

Length: 35, 50, 75, 100 mm Ø 2 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

Comp.

Length: 30, 50 cm
Ø 1.5 mm
Compact logger
where the material is
semi flexible stainless
steel.

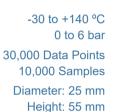
Semi Flexible

Temperature Sensor

-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.





6 Bar Pressure Sensor

The Compact logger is configured to measure pressure.

0 to 6 bar 30,000 Data Points 15,000 Samples

-30 to +140 °C

Diameter: 25 mm Height: 55 mm

Quad Flexible

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

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Temperature Sensor
Length: 50 cm
Ø 1.8 mm
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

Length: 0, 10, 25, 50, 75, 100 mm Ø 2 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

Length: 10 mm

Ø2mm

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.



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.



TDJ

Logger mounted inside pouch for sterilization applications.



GNK

Logger mounted on ampoules in moist heat sterilization applications.



Luer lock

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



Recart Packing Gland

For catron containers that need to be sterilized.



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® Software

The Ultimate Time-saving Software Solution

ValSuite is our reputable validation and calibration software. It combines all our equipment systems into a single platform, opening the door to a vast amount of new possibilities by allowing users to combine data loggers with the traditional thermocouple systems.

We offer multiple versions of ValSuite to meet different industry needs, most notably ValSuite Pro which is FDA 21 CFR Part 11 compliant and secures full data integrity.

ValSuite offers features like customized reports with clear pass/fail criteria, test templates, data analysis, monitoring, live data and much more.

ValSuite is available in multiple languages and can run with Windows 7, 8 and 10 32/64-Bit.

Detailed Control of Validation Studies

ValSuite guides you through the complete thermal validation process. The database structure within the software provides operators with complete documentation and procedural control.

Test Setup

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

Software Data Analysis Features

- The data analysis tools, reduces the time required to locate critical data
- The ability to zoom in the graphs and display multiple windows at a time
- Multiple calculations, such as min/max, standard deviation, average, delta T and lethality can be calculated using any block of the displayed data eliminating the need to export data and compromise data security

Compliant to FDA Guidelines

- SQL database where complete sessions and individual data cannot be deleted or manipulated
- · Serialized sensor ID, providing complete traceability
- Customized report generator that eliminates the need to export data into a different program

ValSuite® Basic

- targeted small or midsized food companies
- ✓ Basic set of analytical tools and reports including Lethality Calculations
- ✓ Manual Calibration
- ✓ Database back-up and Restore

ValSuite® Medical

- targeted hospitals and medical companies
- All ValSuite Basic features
- Unit report with pictures
- + Bowie Dick Test for routine control of autoclaves

ValSuite® Plus

- targeted larger food companies and hospitals
- ✓ All ValSuite Medical features
- + Automatic calibration including optional OEM configuration
- Moderate set of analytical tools and reports including Heat Factors/Ball Simulation
- + Access Manager/Individual User Profiles
- + Server Solution

ValSuite® Pro

- targeted the Pharmaceutical industry

- ✓ All ValSuite Plus features
- Complete set of analytical tools and reports including Advanced Phase Statistics
- FDA 21 CFR Part 11 Compliant
 (Audit Trail/Electronic Signature/Access Point)
- Validated according to GAMP 5





Validated Software - Documentation

The structure of the validation documentation behind the software complies with guidelines set by the following authorities:

- Good Automated Manufacturing Practice (GAMP 5), which is written by the International Society for Pharmaceutical Engineering (ISPE)
- FDA 21 CFR Part 11, subpart B & C, which is written by the U.S. Food & Drug Administration (FDA)

These documents are either included or available upon request:

- User Requirement Specification (URS)
- Project Master Plan (PMP)
- · Project Plan (CC) (RD system On-track)
- Critical Parameters (CP)
- Change Control (CC)
- Risk Based Code Review (RBCR)
- FDA 21 CFR Part 11 Compliance (21 CFR Part 11)
- Installation Qualification (IQP/IQR)
- Operational Qualification (OQP/OQR)

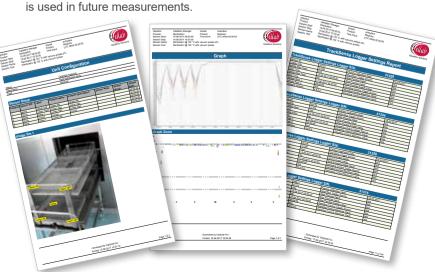
GAMP Guidelines and ISO 9001:2015

All documentation and development of the ValSuite software is in accordance with the guidelines specified in GAMP and includes all the appropriate documentation. Ellab's quality system is in compliance with ISO 9001:2015.

User Calibration

ValSuite is not only a validation software, but also a calibration software. This means that all sensors and probes can be user calibrated at predefined intervals and their offset values stored either in softwae and/or hardware.

A report is automatically generated with the overall calibration results. When using the Calibration Setup, users can, depending on the Valsuite version, choose Manual, Semi-Automatic or Full-Automatic Calibration. Various templates can be stored and uploaded at any given time. The identified offset values are linked directly to the ID number of the sensors, and will be taken into account whenever the sensor



Ellab





Ellab has been your validation and monitoring partner since 1949, offering wireless data loggers and thermocouple systems for thermal validation processes as well as wireless environmental monitoring solutions.

We serve both small and large companies within the Life Science and Food industries and have solutions for almost all applications such as sterilization, freeze drying, environmental chamber testing, depyrogenation, warehouse mapping, pasteurization and many more.

Ellab develops unique and innovative solutions based on input from close interactions and dialogues with our customers. Our goal is to help our customers overcome challenges and increase their productivity by providing reliable and efficient solutions.

Ellab also offers complete turn-key or supplemental rental solutions, equipment qualification and validation services and our specialized training courses within Ellab Academy.

Ellab has a long tradition and dedication for delivering the highest performance and quality in our industry. Our user friendly and flexible validation and monitoring solutions are recognized and used by thousands of customers worldwide.

Ellab A/S is ISO 9001 & ATEX IEC 80079-34 certified. Our calibration laboratories in DK are accredited according to ISO/IEC 17025:2005 by DANAK under registration no. 520 and our German laboratory has a DAkkS ISO/IEC 17025:2005 accreditation. We also have a UKAS ISO/IEC 17025:2005 accreditation at our monitoring manufacturing site in UK.



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