

TrackSense® Pro



The ultimate solution
in wireless thermal validation

The Ultimate Solution in Wireless Thermal Validation

TrackSense® Pro

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

The flexible system is easily adapted to your requirements and provides an elegant solution to the most demanding validation applications.

Accuracy

The incorporation of state of the art technology and extensive testing have resulted in:

- Temperature: ± 0.05 °C
- Humidity: $\pm 2\%$
- Pressure: $\pm 0.25\%$ full scale
- Time: ± 5 sec. per 24 hours
- Rotation: $\pm 1\%$

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

Performance

The new TrackSense® Pro 2nd generation loggers are designed to operate under extreme conditions without ever losing valuable data. They can tolerate temperatures from -80 °C to +150 °C and withstand pressures up to 10 Bar fully immersed. The non volatile memory stores up to 60,000 data points. Recent improvements in battery technology have dramatically improved performance and lifetime even at high temperatures.

The small size and convenience of wireless data loggers make them exceptionally easy to use in countless validation applications such as;

► Pharmaceutical

- Steam Sterilization
- Depyrogenation
- Lyophilization
- Stability Chambers
- Cold Storage
- EtO Sterilization
- H₂O₂ Sterilization
- Warehouse Validation
- Incubation

► Food

- Retorts
- Pasteurization
- Spiral Cooker/Coolers
- Hydrostats
- Conveyorized Ovens
- Spiral Freezers
- Blast Freezers
- Cold Storage Chain
- Smoke Houses



The TrackSense® Pro Master Reader Station can be combined of TS Pro and modules for Micro, Mini or standard loggers allowing up to 16 loggers at a time.



TrackSense® Pro Reader Stations, Sky Access Point and Sky Loggers.

Introducing RF Data Transmission

Enjoy all benefits of having real time process information available on your computer and the reduced setup time with self contained wireless data loggers.

TrackSense® Pro 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.

The Sky Access Point comes with a standard antenna, but optional remote antennas are available for more difficult transmission environments.

TrackSense® Pro Sky Module

The Sky module contains all the necessary components for wireless communication between the logger and the Sky Access Point. The standard Sky module comes with an internal antenna. An external antenna is also available for more difficult transmission environments. No data will ever be lost or corrupted due to loss of wireless communication. In case of loss of wireless communication data is stored in the logger and it will be transmitted once communication has been restored or the logger has been returned to the TrackSense® Pro reader station. Operating Temperature: -80 °C to +140 °C.



TrackSense® Pro Reader Station

The new TrackSense® Pro 2nd generation logger and the Sky concept are fully compatible with existing reader stations. The reader station is used to start loggers the first time and to read any data that cannot be downloaded through the Sky Access Point.

Once the logger and the Sky module have been started in the reader station they can be read and restarted remotely by the Sky Access Point until they are stopped again. The purpose of the reader station besides safety and backup is to save battery life by being able to turn the Sky module off during standby.



TrackSense® Pro Logger

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 autostart 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.

A variety of loggers to fit your application

The standard Pro logger is designed with interchangeable sensors and user replaceable batteries whereas the Mini and Micro are working with mounted sensors and user replaceable button cell batteries.

TrackSense® Pro

TrackSense® Pro Loggers are 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.

TrackSense® Pro X

TrackSense® Pro X is specially designed for -80 °C applications such as lyophilization with low temperature and vacuum.



TrackSense® Pro Sensors

Ellab offers the largest range of different sensors with 1, 2 or 4 channels. Sensors are interchangeable, enabling the user to change sensors for different applications. This reduces costs because one set of TrackSense® Pro loggers can be used for temperature, humidity and pressure studies.

The temperature sensors can be delivered in rigid, semi flexible and flexible material for ease of use. New 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 unprogrammed loggers. In the case of an LED sensor being used in combination with a Sky module, the LED will confirm communication status.

► Pharmaceutical

- Infusion Pouches
- Vials and Ampoules
- Syringes and Tubes
- Bottles
- EtO and H₂O₂
- Environmental
- Chambers

► Food

- Cans
- Glass Jars
- Bottles
- Trays
- Pouches

Extreme Temperature Sensors

The standard temperature range is -50 °C 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 -196 °C. When measuring from +150 °C up to +400 °C, an Insulation Pack (thermal barrier) is required. The principle is to insulate the logger for a limited amount of time keeping the logger below +150 °C. Please consult your local Ellab representative for specific time and temperature limits.



A wide range of sensors.

TrackSense® Lab for Stability Studies

This logger is designed with an active LED light to indicate when a pre programmed alarm situation has been achieved. The LED blinks green when the logger is running within the pre programmed temperature band. If the measured temperature reach outside of this band the LED blinks red indicating an alarm situation. The TrackSense® Lab logger is ideal for monitoring temperature or RH in long term stability applications.

TrackSense® Pro Mini and Micro

The Mini and Micro loggers are designed for applications where size is an issue. Each logger has a memory capacity of up to 14,500 data points. The low volume displacement makes these small loggers ideal for monitoring inside packaging. The TrackSense® Pro Mini offers temperature only. The TrackSense® Pro Micro can be configured with temperature, pressure or rotation sensors.

Custom Fittings

Packing glands are available for inserting sensors into any variety of packaging. The glands are threaded to accept sensors and will maintain the seal when pressurized.



Steam sterilization.

Logger	Dimension D x H (mm)	Data storage	Battery life hours	Temperature range °C
TrackSense® Pro X	25 x 43.5	60,000	1,000	-80 to +150
TrackSense® Pro	25 x 43.5	60,000	1,000	-30 to +150
Tracksense® Pro Basic	25 x 43.5	60,000	1,000	-30 to +105
TrackSense® Pro Mini	20 x 16	14,500	100	0 to +140
TrackSense® Pro Micro (Temperature)	15 x 22	14,500	75	-20 to +140
TrackSense® Pro Micro (Pressure)	15 x 40	7,200	50	-20 to +140
TrackSense® Pro Micro (Rotation)	15 x 24	14,500	40	-20 to +140
TrackSense® Lab	25 x 43.5	60,000	1,000	-30 to +100
TrackSense® Lab Mini	20 x 16	14,500	100	0 to +100

ValSuite™ Pro

Detailed Control of Validation Studies

The ValSuite™ 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 pre set 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 set and saved. This ensures accurate documentation and correct implementation of required procedures for consistent repeatable tests.



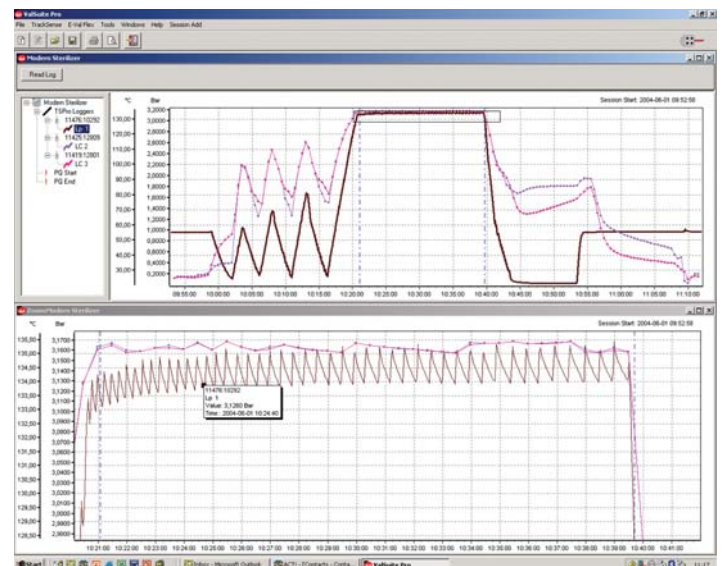
Validation system with 64 temperature channels and 2 pressure channels.

Pre identifying sensor positions greatly reduces setup time and errors. A test setup sheet indicates where each sensor should be placed. Later during analysis this information is easily displayed and tracked.

Software Data Analysis Features

Data analysis tools greatly reduce the time needed to find critical data. The ability to zoom graphically and display up to 8 tiled 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™ collects and presents validation data from both E-Val Flex and TrackSense® Pro wireless realtime 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.



Typical test of hospital autoclave with 4 pre vacs.

Producing Reports

A complete thermal validation report 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™ also maintains templates for reports designed to meet the specific requirements of tests such as EN17665 (EN554). Possibly the templates can be customized to organize the data and perform calculations to your exact criteria. Offering this 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 document.

Statistics

EN17665 report

Saturated steam report

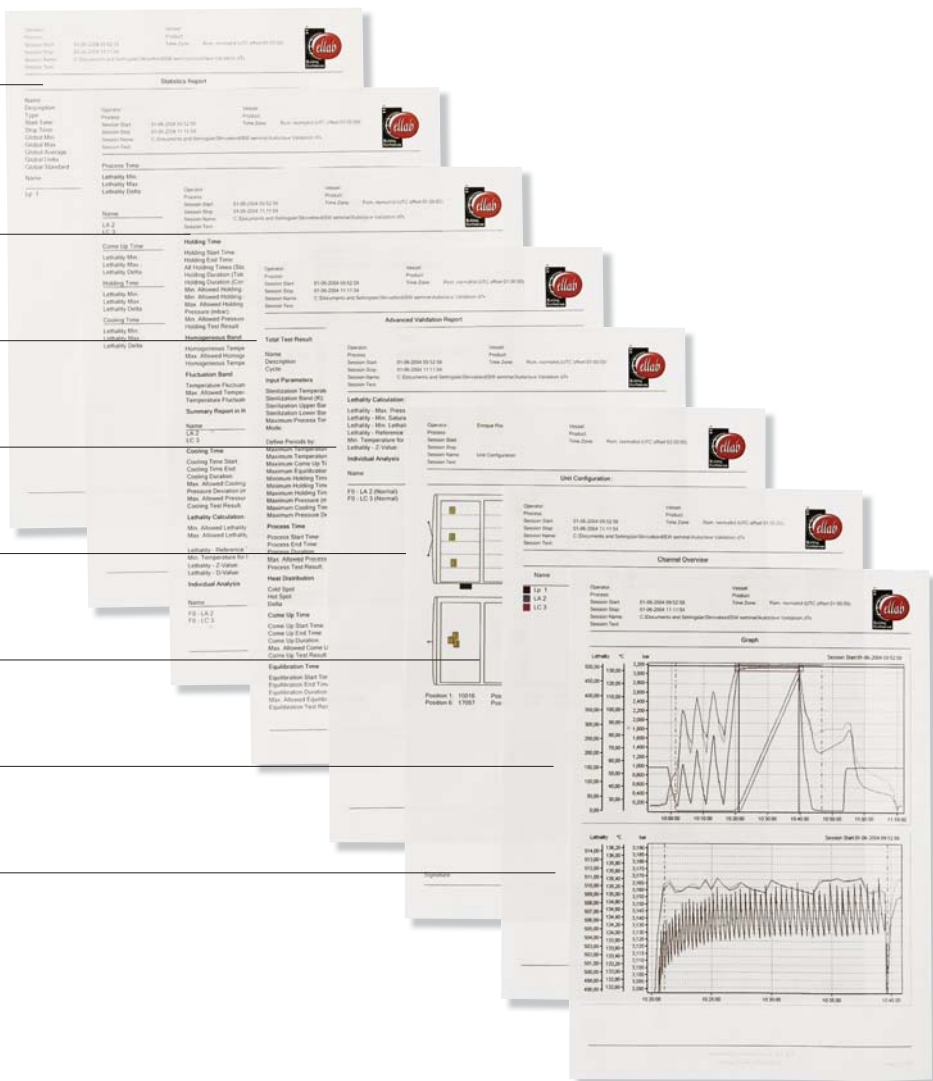
Lethality report

Unit

Equipment used

Graph

Zoom window print

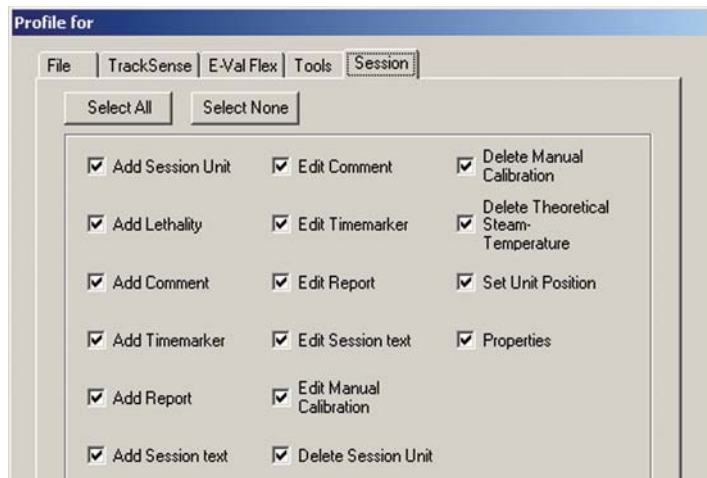


Sample of a validation report

Maintain Security

ValSuite™ Pro operating software is designed to maintain the highest level of security for compliance to 21 CFR Part 11. The software administrator controls and assigns user ID and access privileges. Any user function can be deactivated, removing the software feature from view and access of specified users. This significantly reduces the risk of mistakes giving tight control of usage by the administrator.

Raw data cannot be changed and user actions are recorded in the audit trail. Any analysis of data such as time markers, limits or comments will be recorded in the audit trail. Analysis reports can be produced with an electronic signature ID'ed to the user generating the report. Accessing information from the audit trail is simplified with the ability to search by date, study ID, user ID and vessel ID.



Profile, Session.

Compliant to FDA Guidelines

- Raw data is built into a database structure and cannot be modified or erased.
- Complete audit trail with easy search engine to find data by date, session, user and module.
- User ID and passwords with detailed user access control.
- Sensor ID provides complete NIST traceability.
- Customized report generator eliminating need to export data.
- Specific compliance reports (e.g. EN17665).
- Automated pre and post calibration reports.
- Print preview feature with report output in pdf file format.

GAMP guidelines and DS/EN ISO 9001

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 DS/EN ISO 9001.

Ellab

TrackSense® Pro

Ellab

For over 50 years Ellab A/S has been a leading manufacturer of Process Validation and Monitoring Systems used in the food, medical device and pharmaceutical industries.

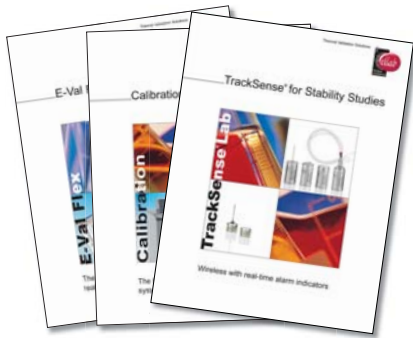


QUALITY SYSTEM
DS/EN
ISO 9001



GAMP5 guidelines and DS/EN ISO 9001

All Ellab software packages include full documentation developed in accordance with the guidelines set out in GAMP5. Ellab quality system is compliant with DS/EN ISO 9001.



Calibration Certifications and Service

Ellab maintains a complete calibration facility for annual certifications and service. All certifications are traceable to NPL and NIST Standards. 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

Training and equipment installation are available through Ellab. Validation consultants experienced with Ellab equipment are available to assist with IQ, OQ and PQ procedures.

Building Confidence

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

ELLAB A/S
Kronalvej 9
DK-2610 Roedovre
Denmark
Phone: +45 4452 0500
Fax: +45 4453 0505
E-mail: info@ellab.com

Thermal Validation Solutions



www.ellab.com

ELLAB Inc.
6551 South Revere Parkway,
Suite 145,
Centennial, CO 80111
USA
Phone: 303 425 3370
Fax: 303 425 3384
E-mail: usa@ellab.com

ELLAB GmbH
An der Autobahn 5
D-27404 Bockel
Germany
Phone: 04286 92662-0
Fax: 04286 92662-66
E-mail: germany@ellab.com

ELLAB UK Ltd.
3 Lodge Farm Barns
New Road, Bawburgh
Norwich
Norfolk NR9 3LZ
United Kingdom
Phone: 01603 743724
Fax: 01603 740118
E-mail: uk@ellab.com

ELLAB S.A.R.L.
ZAC de Mercières
5 Ter, rue Clément Ader
2e étage
60200 Compiègne
France
Phone: 0344 2302 57
Fax: 0344 2308 94
E-mail: france@ellab.com

ELLAB Philippines Corp.
4810-B Sampaguita St.
Marimar I, Bicutan,
Parañaque City,
1700 Philippines
Phone: 02787 8258
Fax: 02824 7924
E-mail: ph@ellab.com