TrackSense® Pro

Validation Solutions

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

* 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.

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

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

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

TrackSense® Pro parameter overview

Multi Reader Station

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

Introducing RF Data Transmission

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

Sky Module

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

Sky Access Point

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

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

TrackSense® Pro Interchangeable Sensors

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

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 ºC to +105 ºC
60,000 Data Points
Diameter: 25 mm
Height: 44 mm

Pro Logger

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

-50 ºC to +150 ºC
60,000 Data Points
Diameter: 25 mm
Height: 44 mm

Pro X Logger

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

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

Rigid Sensors ø 2 mm

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

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.

Semi Flexible Sensor ø 1.5 mm

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

Semi Flexible Sensor ø 2 mm

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

Multipoint Sensor ø 2.5 mm

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

Rugged Sensor ø 2.5 mm

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

Low Temperature Sensor ø 1.2 mm

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

SmartFlex ø 1.8 mm

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

Vacuum Sensor

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

Pressure Sensor

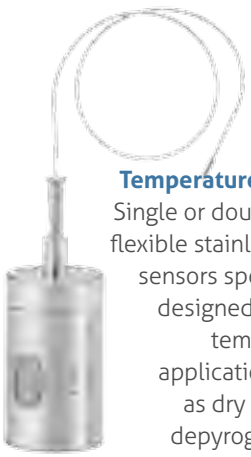
The sensor is configured to measure pressure.

Pressure/Temperature Sensor

The sensor is configured to measure pressure together with temperature.

Conductivity Sensor

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



High Temperature Sensor

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

Relative Humidity Sensor for EtO

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

Relative Humidity Sensor for Stability

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

AutoMarker Sensor

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

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 ºC to +85 ºC
60,000 Data Points

Diameter: 25 mm
Height: 60 mm

Frigo SmartFlex ø 1.8 mm
Length:
30 and 50 cm

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

-90 ºC to +85 ºC
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 ºC to +85 ºC
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 ºC to +140 ºC
14,500 Data Points

Diameter: 25 mm
Height: 60 mm

Compact X ø 2 mm

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

-50 ºC to +140 ºC
14,500 Data Points

Diameter: 25 mm
Height: 35 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 ºC to +140 ºC
14,500 Data Points

Diameter: 25 mm
Height: 35 mm

Compact SemiFlex

Length: 30, 50 cm

The material is semi flexible stainless steel ø 1.5 mm.

-30 ºC to +140 ºC
14,500 Data Point

Diameter: 25 mm

Compact SmartFlex

Length: 30, 50 cm

The material is PTFE ø 1.8 mm.

-30 ºC to +140 ºC
14,500 Data Points

Diameter: 25 mm

Compact Combi

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

-30 ºC to +140 ºC
0 to 6 bar

Combi: 10,000 Data Points

Diameter: 25 mm
Height: 55 mm

Compact Pressure

The Compact logger is configured to measure one pressure.

-30 ºC to +140 ºC
0 to 6 bar

Pressure: 7,200 Data Points

Diameter: 25 mm
Height: 55 mm

Lab ø 2 mm

Length: 0 and 35 mm

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

-30 ºC to +100 ºC

60,000 Data Points
LED Sky optional

Diameter: 25 mm
Height: 44 mm

Lab Relative Humidity

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

-30 ºC to +100 ºC
0 to 100% RH

30,000 Data Points
LED Sky optional

Diameter: 25 mm
Height: 46 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 ºC to +100 ºC
15,000 Data Points

Diameter: 25 mm

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 ºC to +140 ºC
30,000 Data Points

Diameter: 20 mm
Height: 12 mm

Micro ø 2 mm

Length: 10 mm

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

-20 ºC to +140 ºC
14,500 Data Points

Diameter: 15 mm
Height: 22 mm

Micro Combi

The Micro logger is configured to measure temperature/pressure.

-20 ºC to +140 ºC
0 to 6 bar

Combi: 10,000 Data Points

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 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.

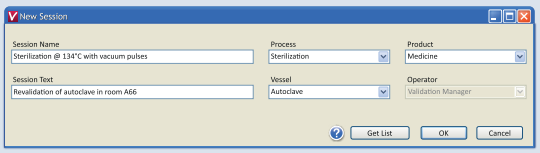
TTB Thermal Barrier
logger with high temperature sensor mounted in TTB Thermal Barrier for depyrogenation application.

ValSuite™ Pro

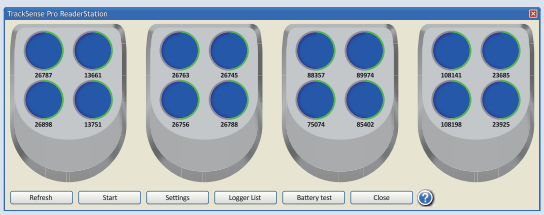
Intuitive and user friendly software

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

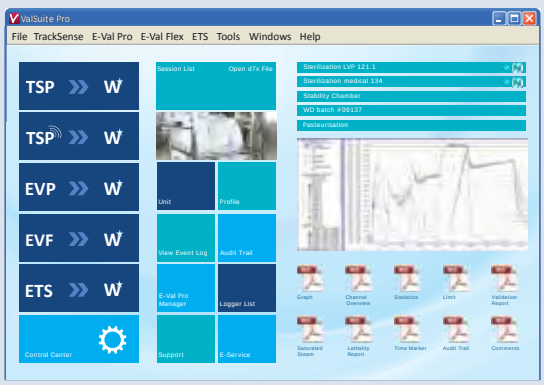
1 Login, program and start the loggers using a Repeat function, which includes a unit configuration and a selection of reports. Place the loggers in the load or process and run the cycle.



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



3 Print the reports and logout.



ValSuite™ Pro 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 three versions, ValSuite™, ValSuite™ Plus and ValSuite™ Pro. The ValSuite™ Pro version has all features and all reports and is fully validated and compliant with 21 CFR, part 11. Full IQ/OQ documentation and validation services are available from Ellab.

The software is currently available in Chinese, English, French, German, Italian, Japanese, Polish, Portuguese, Russian, Spanish, Swedish and Turkish language.

Detailed Control of Validation Studies

The ValSuite™ Pro software documents and guides you through the complete thermal validation process. The database structure in the software enables complete documentation and procedural control for the operators.

Test Setup

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™ 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.

Sensor adjustment report

Limit report

Statistics report

Adv. phase statistics report

EN17665 report

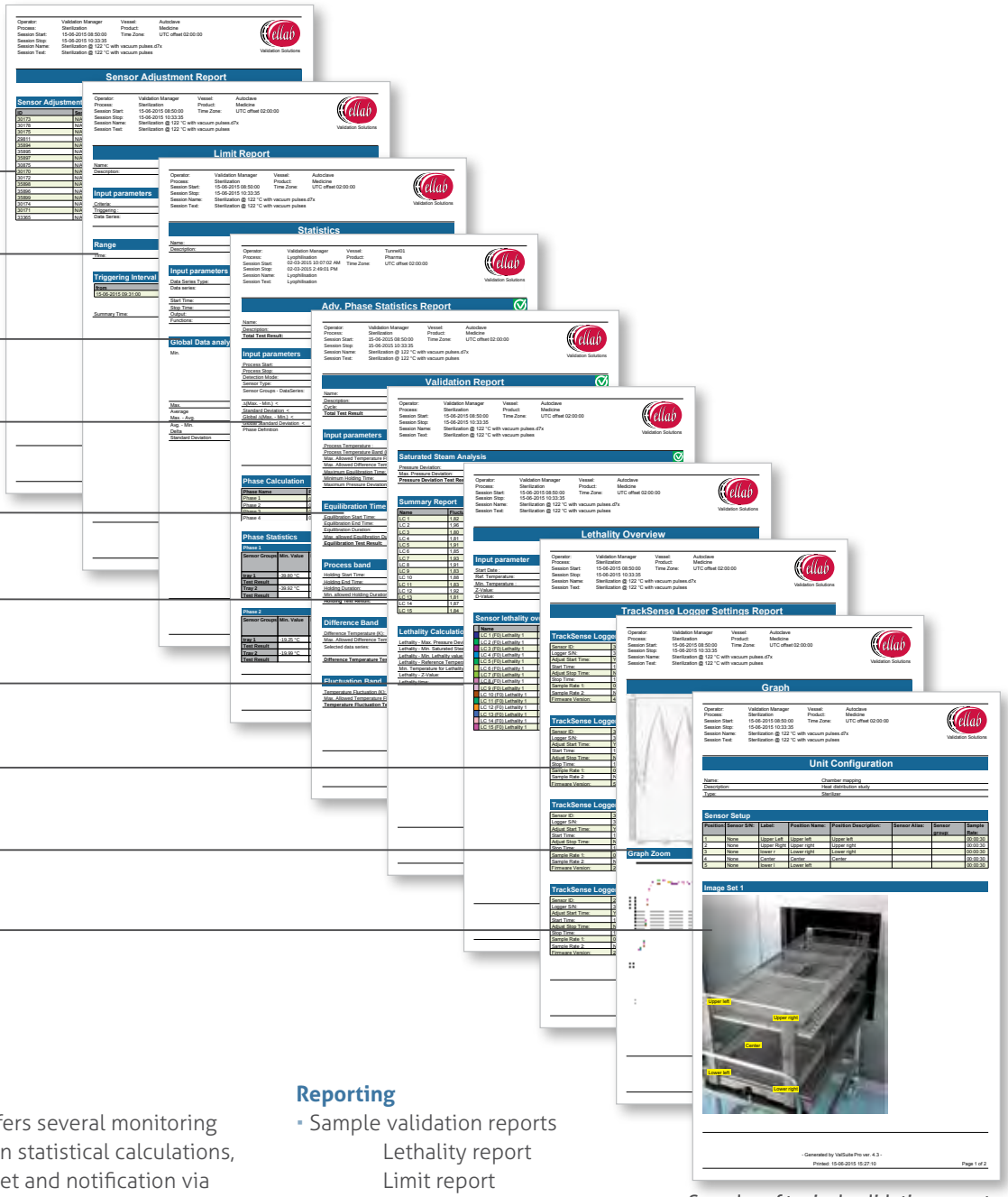
Saturated steam report

Lethality report

Equipment used

Graph & Zoom

Unit



Samples of typical validation reports

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 128 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
- Printed or PDF format
- Comment field and Word document attachment
- Heat Factors / Ball Simulation

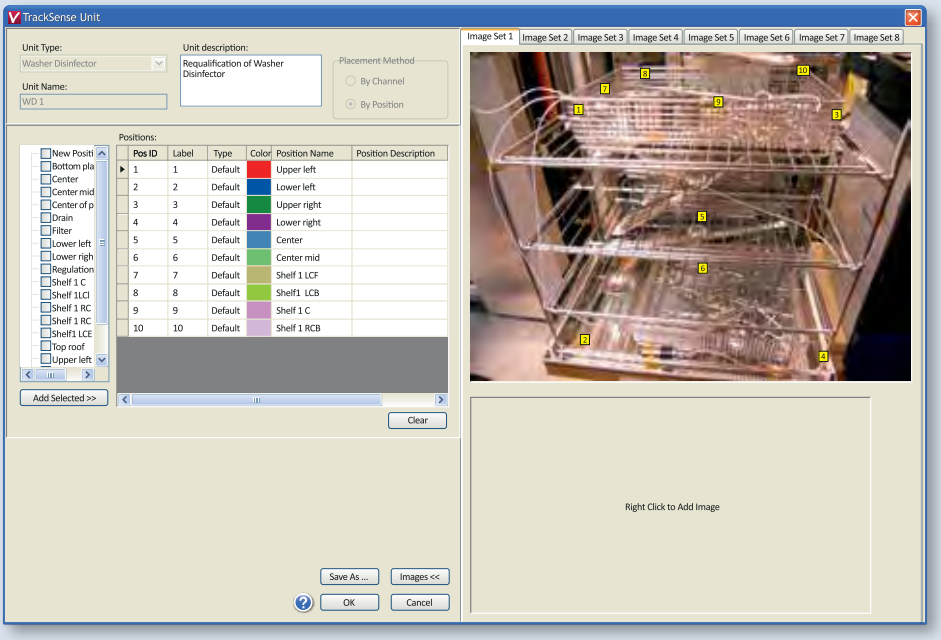
Fully compliant with 21 CFR, Part 11

Producing Reports

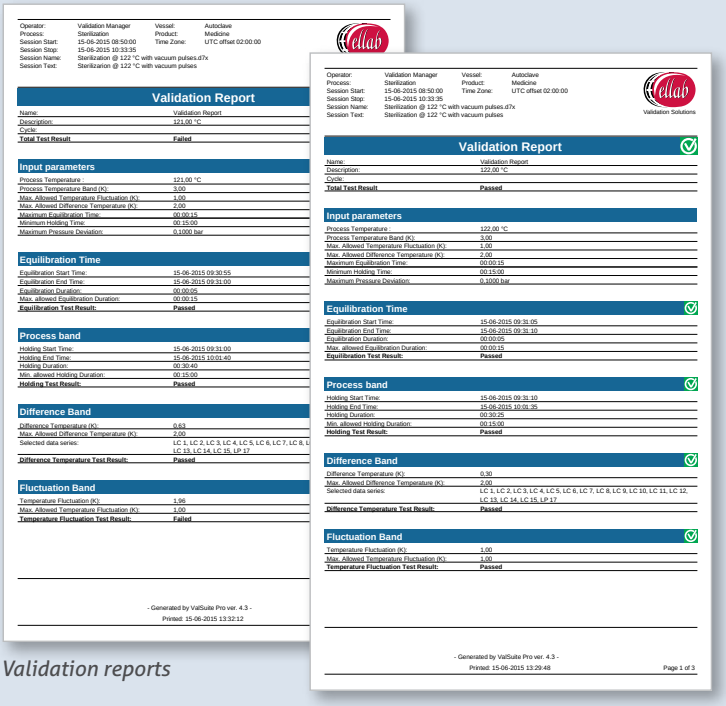
A complete set of reports can be produced with Pass / Fail criteria, detail on mapping positions, operator and vessel ID, calibration offsets for sensors, real data and statistical summaries on the data.

ValSuite™ Pro also maintains templates for reports designed to meet the specific requirements of tests such as EN17665 (EN554) for moist heat autoclaves or EN15883 for washer disinfectors and NFX 15-140 for stability chambers. The templates can be customized to organize the data and perform calculations to exact criteria.

This feature greatly reduces the time needed for the data analysis process. Reports can be reviewed with the print preview feature and saved in a PDF file format.

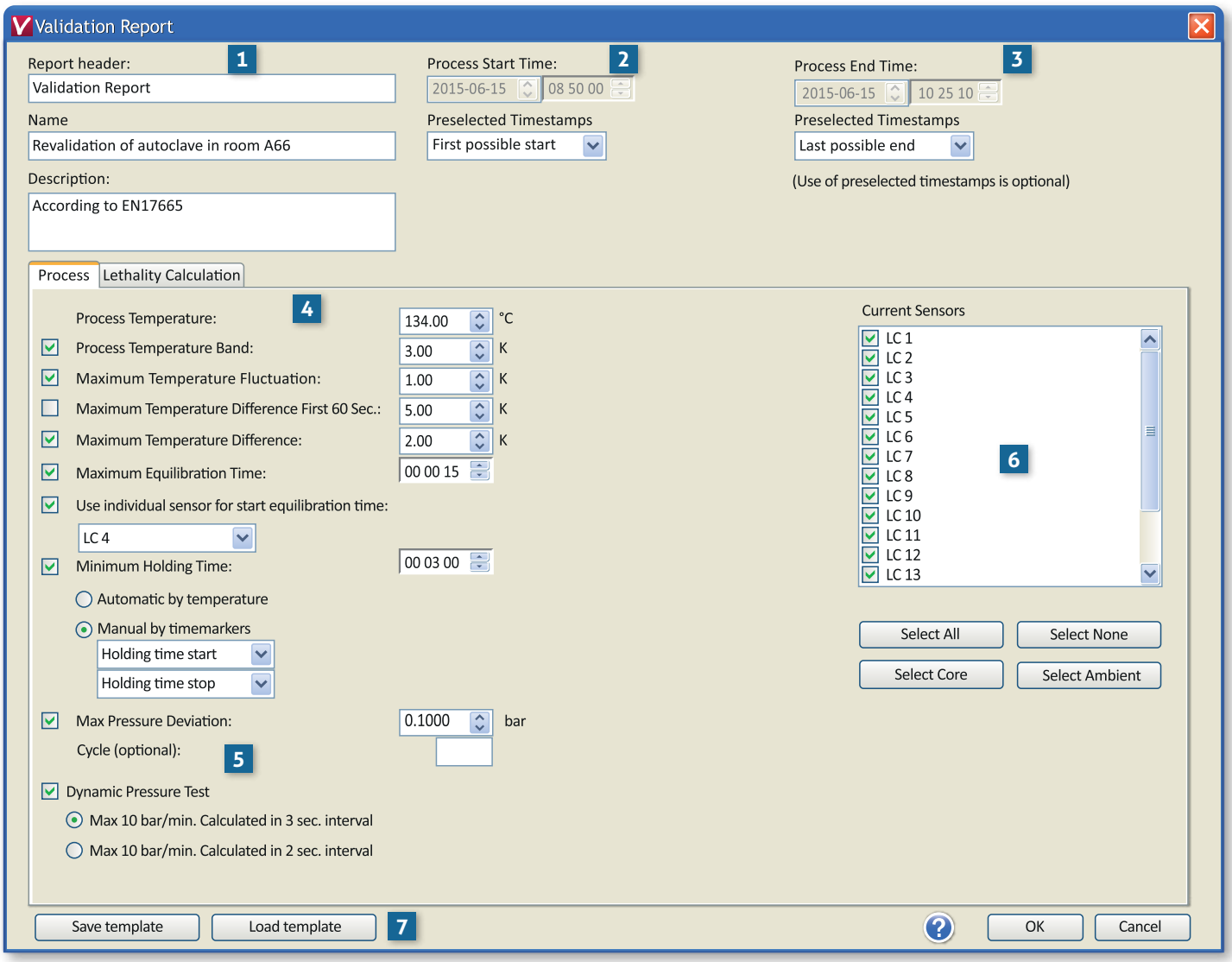


Unit configuration with drag and drop



Validation reports

Use ValSuite™ App to survey active processes and validation reports



Report Setup

The example shows the layout of the Validation report. All reports are designed with the concept in mind to provide maximum flexibility and easy input of data.

1 Input for report header, name of report as well as a more detailed description.

2 Input for process start time and optional time marker setting.

3 Input for process end time and optional time marker setting.

4 Input fields and selection of process parameters according to appropriate standard.

5 Further input fields and selection of process parameters according to appropriate standard.

6 Definition of which measuring points (sensors) should be included in the reporting.

7 Saving and uploading of preconfigured report templates.

The result of the analysis is presented in a clear format ready for printing, saving or distributing electronically.

A non-successful validation process will not only show Failed, but also indicate in which part of the process it failed making it easier to diagnose and correct.

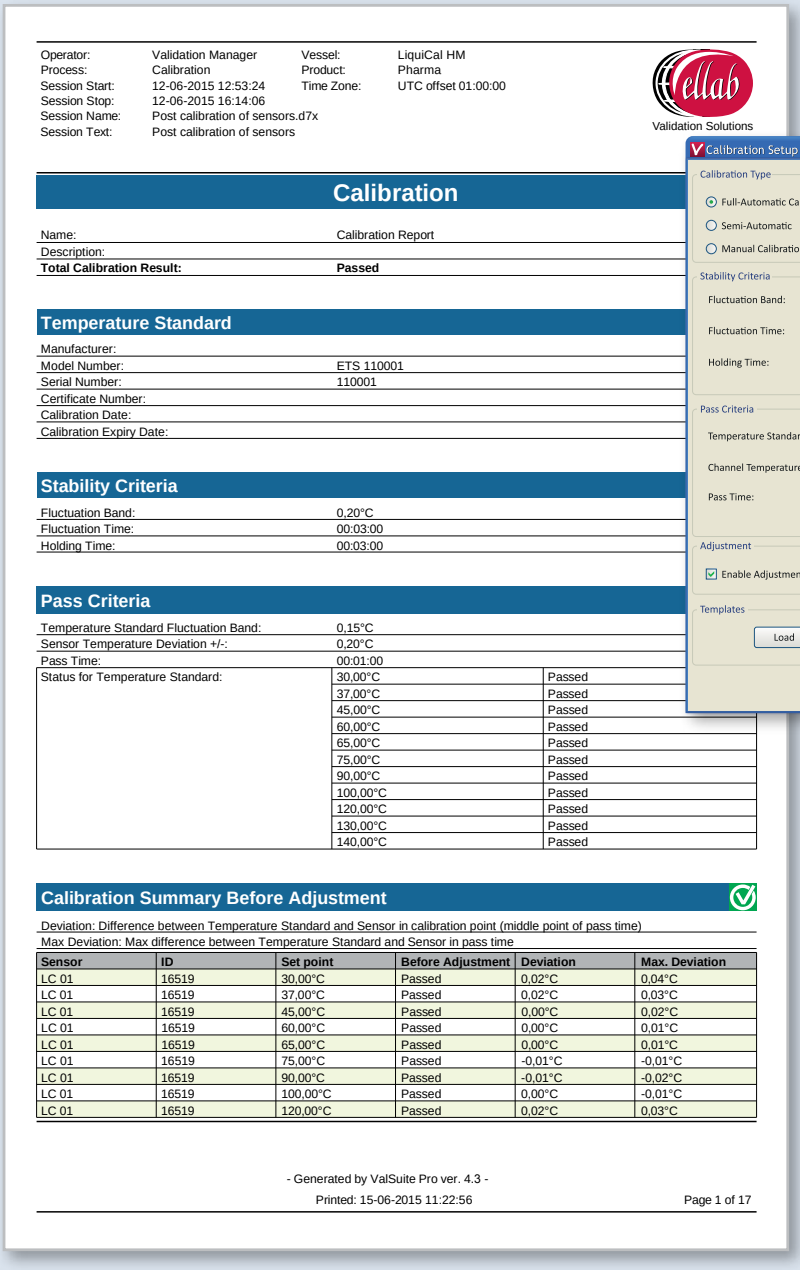
This feature greatly reduces the time needed for the data analysis process

ValSuite™ Pro Calibration

Ellab ValSuite™ Pro is not only a validation software but also a calibration software. This means that all sensors can be user calibrated at defined intervals and store offset values.

Using the ETS temperature standard and appropriate reference instruments connected to the PC, a fully automatic calibration can be executed without any interference of operator – a very safe and time saving feature.

A report is automatically generated which shows overall calibration results. When using the Calibration Setup, users can choose Manual, Semi-Automatic, or Full-Automatic Calibration. At the same time various templates can be stored and uploaded whenever required. The found offset values are linked directly to the ID number of sensor and will be taken into account whenever the sensor is used in future measurements.



Operator:	Validation Manager	Vessel:	LiquiCal HM
Process:	Calibration	Product:	Pharma
Session Start:	12-06-2015 12:53:24	Time Zone:	UTC offset 01:00:00
Session Stop:	12-06-2015 16:14:06		
Session Name:	Post calibration of sensors.d7x		
Session Text:	Post calibration of sensors		

Validation Solutions

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:	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

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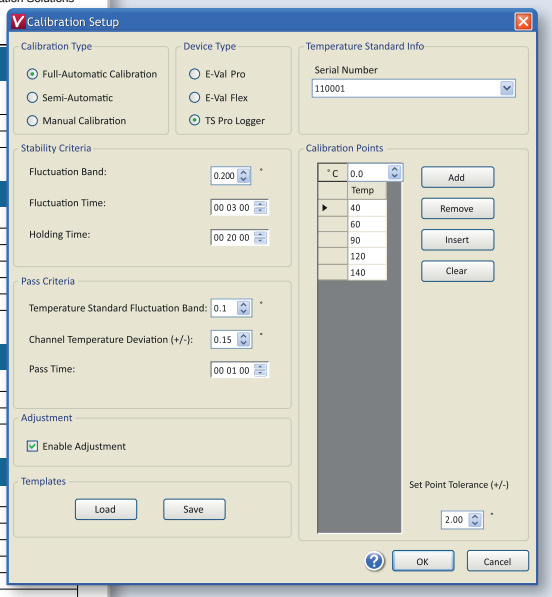
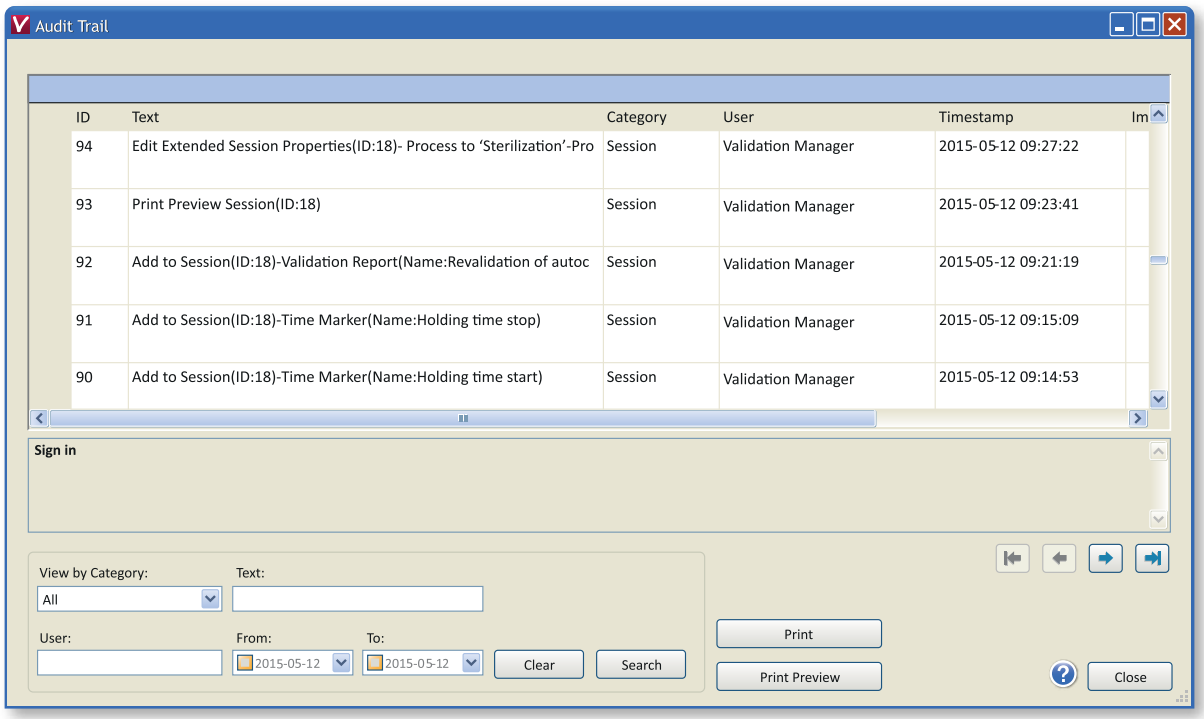
Calibration Report



Calibration Setup

Calibration Equipment



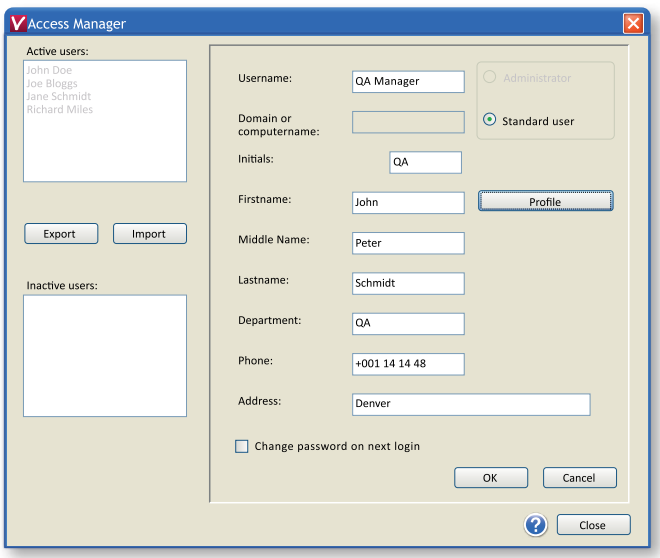
Audit Trail

Compliant to FDA Guidelines

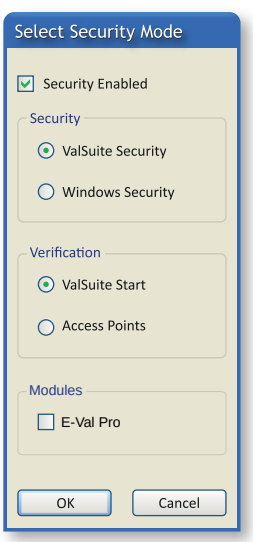
- SQL database where complete sessions or individual data cannot be deleted or manipulated
- Audit trail report
- Electronic signature
- Access manager with user ID and passwords
- Sensor ID provides complete traceability
- Customized report generator eliminating export of data

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

Ellab ValSuite™ 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.

Validation Solutions

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