Data Loggers & Thermocouples

Ellab all-in-one Solutions for Qualification, Validation, Monitoring and Batch Control

Validation & Calibration Solutions

Environmental Monitoring Solutions

Field Services & Consulting

GMP Forum 2022, Melbourne

May 19, 2022

by Roman V. Loretts

Speaker Profile

Speaker: **Roman Loretts**
Senior Sales Manager – Indirect Channel, ELLAB A/S (Denmark)

*I have radio engineering and consulting background. I joined **Ellab A/S** in 2011 **, a global leader in supplying validation & monitoring solutions.** In 11 years of product and commercial activities within thermal validation field, I have visited major pharmaceutical companies and vendors around Europe and Asia to exchange knowledge and gather feedback for further product development. I am responsible for customer training programs, product localization and registration within multiple markets, sales and support within our global distributor markets.*

Agenda

- Short ELLAB Company Profile
- Validation Hardware – Highlights and Trends
- Validation Software – Reporting and Data Integrity
- User Calibration – Time Savings
- Q&A

Company Details

Global Expertise with Local Reach

Established in Denmark in 1949

~ 550 employees (~160 in DK)

Combined with our hardware and software engineering and research office in Denmark, our 27 sales and service centers, and over 50 distributors around the globe, and our world-wide presence allows us to provide outstanding validation, monitoring, calibration and consulting solutions and services - no matter where you are!

Ellab performs direct sales and service in 22 countries and is represented by a dedicated Distribution Network in +50 countries

ECE Fast
26 Business Park Drive,
Notting Hill VIC, Australia
Colin Davidson
Phone: +61 (0)418 872 485
E-mail: colin.davidson@ecefast.com.au

Ellab's Purpose

Purpose

"Together we build confidence in consumer safety"

Leading Supplier of Validation & Monitoring Solutions

Equipment

Data loggers

Thermocouple system

- Industry leading accuracy measurements of temperature, pressure, humidity, conductivity, CO^2 and vacuum
- Wide range of applications within Life Science and Food Manufacturing
- Qualify or re-qualify laboratory or manufacturing equipment, as well as validation of product quality
- Rental of validation equipment is also available

Monitoring

- Continuously monitoring of critical processes or environments
- Includes extensive measurement options, such as temperature, humidity, diff. pressure, CO2, flood and leak

Field Services & Consulting

CQV & Calibration

- Skilled field service engineers conducting CQV at the customer's facilities
- Long-term staffing assignments
- Field calibration of sensors in various equipment

Consulting

- GMP Consulting
- Process/ Equipment Engineering
- Various other consulting or project management within the V-model

ValSuite®

CalSuite

myellab

EMS

VMS

Customer References

We are proud to work with the top brands within life science and food manufacturing

Validating the Sterilization Process at Pfizer Manufacturing

"We are very satisfied with the flexibility and support we received from Ellab. The project was changed several times during the entire process, but we never experienced any issues. After the demo, we were blown away by the possibilities of the software and the user-friendliness of the hardware."

Pfizer Manufacturing,

Belgium NV

Pharma & biotech

Food manufacturing

Healthcare

...and many more

8 Reasons Ellab Continues to Inspire Trust

With the satisfaction and well-being of our customers as our highest priority, we continue to provide top quality services and products in the best ways possible. Our dedication and growth can be traced through various figures across all fields.

9.000+

Active systems worldwide

60+

Offices and distributors worldwide

20+

Calibration centers and partners

500+

Great employees, of which 180+ are field service engineers

90%

Of customers are satisfied or very satisfied with using Ellab

90%

Of employees are satisfied or very satisfied with working at Ellab

40/40

Top global pharma companies use Ellab

60.000+

Calibrations performed annually

Validation Equipment

Durable, smart and immensely precise validation equipment

Examples of Life Science Applications

Ellab provides ideal validation solutions for the Pharmaceutical, Biotech and Healthcare Industries in applications like:

- CTUs
- Sterilization
- Environment chambers
- Lyophilization
- Warehouses
- Depyrogenation
- Pasteurization
- SIP and CIP
- Washer Disinfectors
- EtO Sterilization
- H2O2 Sterilization
- + many more

TrackSense® Pro - Wireless Data Loggers

Durable, smart and immensely precise validation equipment

TrackSense® Pro – Features & Benefits

- A **Wireless System** means saving time
- **Highly versatile** product line– a system for every need
  - Micro, Mini, Compact, Frigo & TrackSense Pro
- **Interchangeable Sensors** for Temperature, Pressure, Vacuum, Relative Humidity, CO2 and Conductivity
  - Adds versatility and flexibility
  - Cost efficient
- **Small Sized** Loggers
  - Minimizing the thermal impact on a product
  - Smallest logger on the market
- Reader Stations can be **expanded** to program 16 loggers simultaneously up to a total of 160 in same study using 4 reader stations
  - Save time during programming and download
- [Watch the TrackSense Video]

TrackSense® Pro - Wireless Data Loggers

Durable, smart and immensely precise validation equipment

TrackSense® Pro – Features & Benefits

- **Stainless Steel** ANSI 316 L housing
  - Fully immersible in steam, water and oil that is up to +150°C
  - Sealed electronics protection
- **Large Logger Memory**: 120,000 data points non-volatile
- SKY Option for **Live Data**
  - Sends information to a Networkable Access Point
- **Superior Temperature Specifications**
  - Logger body (-90°C to 150°C)
  - Sensors (-196°C to 400°C)
  - Rigid & Flexible options
  - High accuracy: +/- 0.05°C
- 20+ years of **experience** with Wireless Technology
- Transmission by Induction
  - Fast and reliable over time

TrackSense® LyoPro

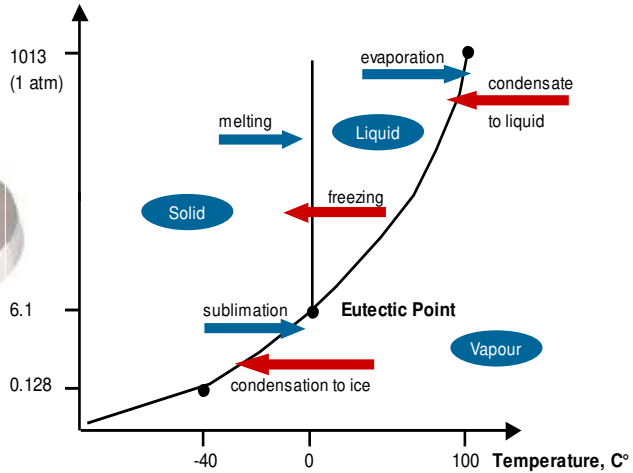
The ultimate solution for lyophilization temperature mapping and batch control

Winning features

- **No data gaps** from start to finish
- **Pinpoint accuracy** with fast response time
- **Live** data logging
- More than **100 data loggers** in one study
- **Most compact** LYO logger on the market
- **Minimal impact** on product temperature
- Industry leading software with **high data integrity**
- Watch the LyoPro Video

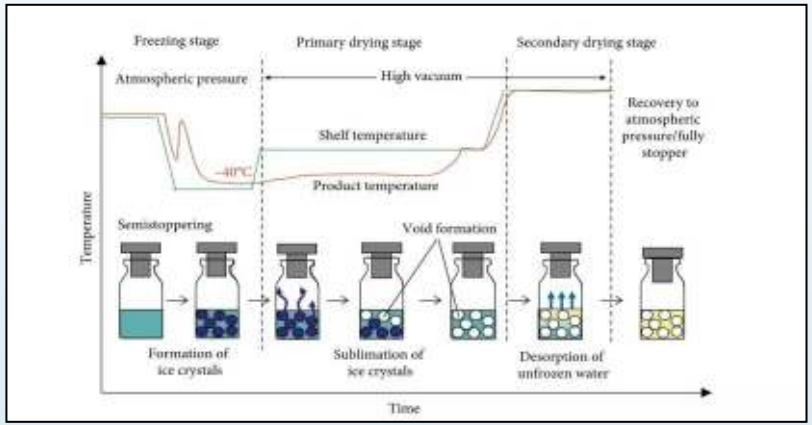
Pre LyoPro-Offering

The TrackSense® Pro Solution – already more than 15 years of experience with Freeze Drying



Reasons why TrackSense ® LyoPro was developed

- General reasons – application related:
  - In order to optimize the freeze-drying process and to protect the batch, it is beneficial **to know the temperature of the product inside selected vials** as this data can avoid failures and determine when to stop the primary drying phase, which can save a lot of energy & time (costs)
  - All new pharmaceutical freeze dryers use automatic loading systems (ALUS), which means they prefer to be able to **add the sensors before the vials are loaded onto the freeze dryer**
  - All freeze dryers need to be validated regularly according to **ISO 13408-3 norm** which involves tests at various temperatures and pressures / vacuum simulating the actual process involving **lots of measuring points** (as high as 5 per shelf on ALL shelves)



- Specific reasons - what we found missing:
  - Market needs sensors that **do not affect the product temperature** (much!) why they need to be tiny - and it should be able for clients to **calibrate the sensors on site** pre- and post to actual process.
  - Market needs **simultaneous on-line measurements from +100 measurement points** to cover even large production units in one take
  - Market requires **data transmission BUT ALSO logging to battery operated memory** to be fully FDA compliant (validation requirement)
  - Market needs **one single datalogger system fitting all vial sizes**
  - Market requires **advanced Validation and Monitoring Software** offering all sorts of analytical tools and reports without having to export data

TrackSense® LyoPro

The ultimate solution for lyophilization temperature mapping and batch control

Features & main specifications

- PEEK dual housing with detachable thermocouple sensor
  - Shaped to fit all standard vials used in freeze dryers operating with automatic loading and unloading systems
  - Various accessories including VialClips, patent pending StopperClips and LyoStoppers to position sensor correctly and repeatedly in vials
- Large Logger Memory: 100,000 data points non-volatile and battery operated
- Using fast and reliable Radio Frequency (RF) communication
  - Logger is fitted with built-in RF transmitter communicating with 10-place Reader Station
  - Transmits LIVE data to a Networkable Access Point
- Superior Temperature Specifications
  - Measuring range -62 to +62°C
  - Ultrathin TC sensor calibrated between -60 and +60°C
  - High accuracy: +/- 0.3°C – can be user calibrated
- 20+ years of experience with Wireless Technology

LyoPro® Contact Puck

Shelf Mapping

Contact Puck

- For measuring the shelf temperature by
  - attaching the logger to the Contact Puck
  - Inserting the TC sensor in the bottom of the device that ensures the measuring tip is placed against the shelf in question
- Easily repeatable for consistent and accurate measurements
- Eliminates bulky and homemade alternatives
- Offers excellent performance at ambient conditions as well as during vacuum
- Made of PEEK material and Stainless Steel 316L

BAVARIAN NORDIC

LyoPro used to Qualify a Freeze Dryer with 15 Shelves

"The data loggers (LyoPro) proved ideal for shelf temperature mapping, without the need for feeding thermocouples through the chamber wall. Ellab went from proof of concept to delivering a system with 75 independent measuring points in less than 4 weeks. It has been a real pleasure working with Ellab on this project."

Rasmus Kirkegaard Stage

Technical Compliance Engineer at Bavarian Nordic A/S

Electronic Bowie Dick Test

Get peace of mind with SteriSense®

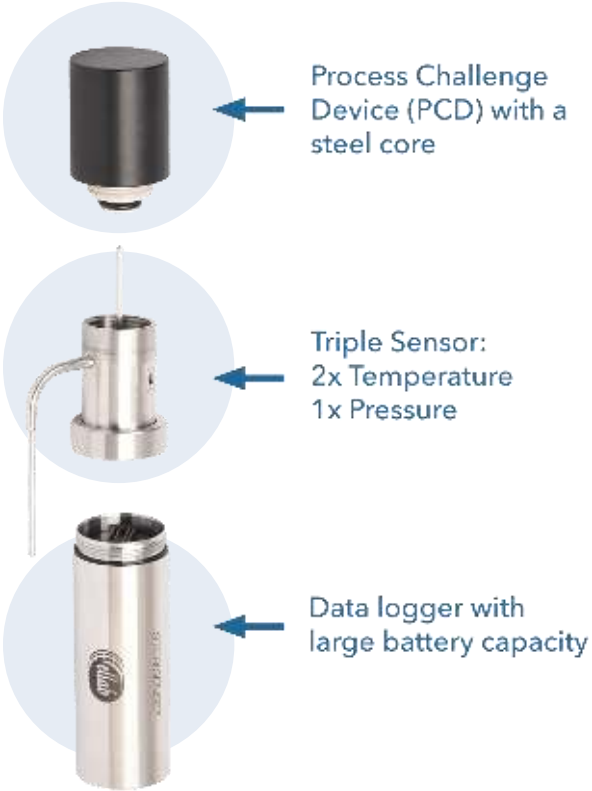
Features & Benefits

SteriSense is a new and innovative device for electronic Bowie Dick tests that is unmatched in accuracy, performance and reliability. SteriSense is by far the most compact electronic Bowie Dick test on the market and provides far more insight into critical sterilization parameters than previously possible

- Accurate Electronic Bowie Dick Test
- Reliable and cost efficient
- Very compact size
- User-friendly and intuitive software
- Eliminates guesswork and provides and objective result
- Replaceable PCD to run several cycles in a sequence
- Verification of critical sterilization parameters beyond traditional methods
- Up to 1,000 test cycles between each calibration
- Watch the SteriSense Video

How does TrackSense BD sensor work?

- The PCD has been specially designed to reflect the **reference method** originally developed by Dr. J. Bowie and J. Dick in the 1960's (also including temperature sensors)
- The function of the PCD is to "challenge" the **steam penetration** of a steam sterilizer in accordance with ISO 11140-4 & EN 17665, 121˚C and 134°C
- The two temperature sensors measures the **temperature inside the PCD** and the **ambient temperature** in the sterilization chamber, of which the values have to follow each other (e.g. reach min. 121˚C and max. 124˚C)
- The pressure sensor measures the ambient pressure value within the chamber, which is used for detecting **vacuum pulses**, calculating the **theoretical ambient temperature** and detecting super-heated steam
- TrackSense BD sensor is also able to indirectly check for the **presence of non-condensable gases (NCG)** by analyzing the steam's capability to heat the steel core inside the PCD
- The checks performed are referring to **ISO 17665**



E-Val™ Pro - Wired Thermocouple System

Compact, precise and extremely efficient

E-Val™ Pro – Features & Benefits

- Compact and Light Design
  - Only 3 Kg / 5.9lbs
  - No Fans
  - Up to 40 sensors
- Large Memory
  - 11.5 million samples
  - 10 independent studies
- Integrated and Rechargeable Battery Backup
  - Up to 8 hours
- 8” Touch Screen Display with Full Operator Interface and Graphical Data
- Standalone or Networkable through USB or LAN
  - Up to three E-Val Pros can be used together to have 120 sensors in one continuous study
  - Reporting takes place on PC or tablet
- [Watch the E-Val Pro Video]

E-Val™ Pro - Wired Thermocouple System

Compact, precise and extremely efficient

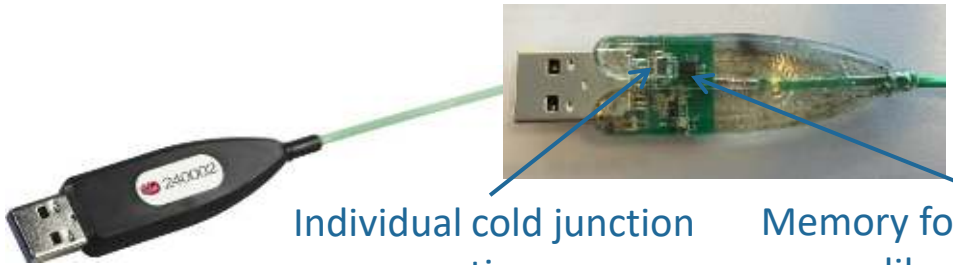
E-Val™ Pro – Features & Benefits

- Accurate, Stable and Reliable Measurements
  - Works with solid state components
- Wide Measuring Range: -200°C to +1300°C
- Operating Range within 5°C to 50°C
- Traceable Smart Thermocouples
  - Calibration offsets stored in each USB plug
  - Temperature compensation in each USB plug
  - Plug and Play interchangeability
- High Accuracy
  - E-Val Pro Sensor Array: +/-0.05°C (Type T)
  - Ellab type T smart T/C: +/-0.05°C
  - Total system accuracy with calibrated Ellab type T smart T/C: +/-0.10°C
- A Sensor Interface that connects TrackSense Sensors for more parameters
  - CO2, RH, Conductivity, etc.
  - Cost efficient expansion
- 0-10V and 4-20mA Array for non-Ellab sensors
- [Watch the E-Val Pro Video]

E-Val™ Pro - Wired Thermocouple System

Sources of error in the measurement chain

- Sensor design & position (mass, position)
- Creation of secondary junctions / sharp kinks in the wire / autoclave feed through
- Corrosion / aging of the wire / moisture tracking
- Cold junction errors (draughts, thermal lag in cold junction compensation, measurement error in the cold junction (CJ) temp)
- Electrical interference / noise (long runs)
- A/D conversion errors / CPU (linearization errors)

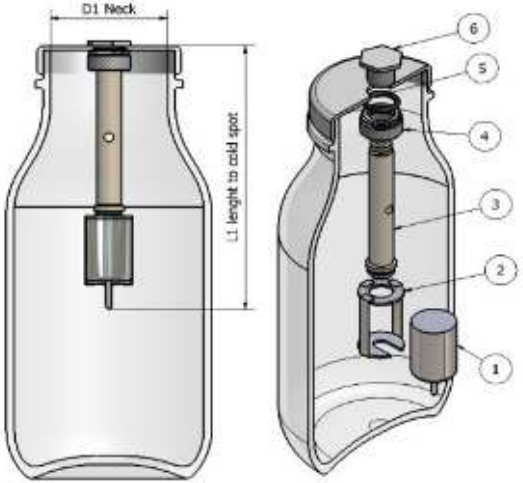


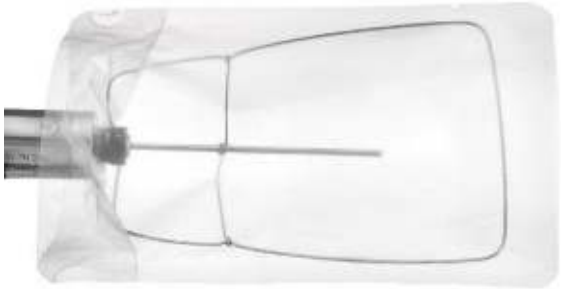
Individual cold junction compensation

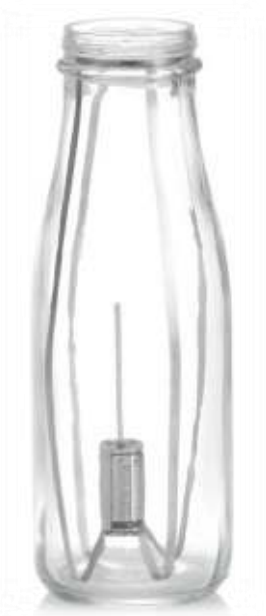
Memory for factory and user calibration

Container Temperature Mapping

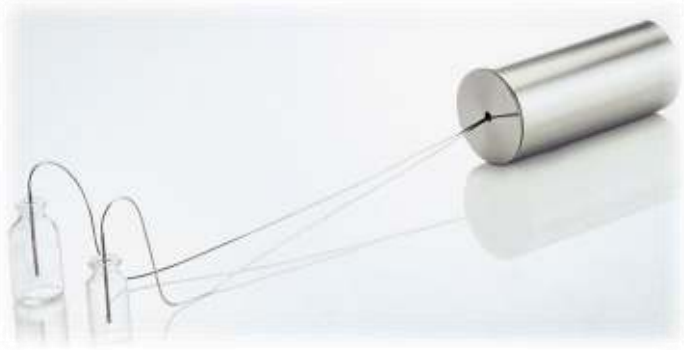
- Precise positioning in the “cold spot”
- Systematic error of 1ºC would give inaccuracy of 26% in F0 calculation at 121,1ºC







Container Temperature Mapping



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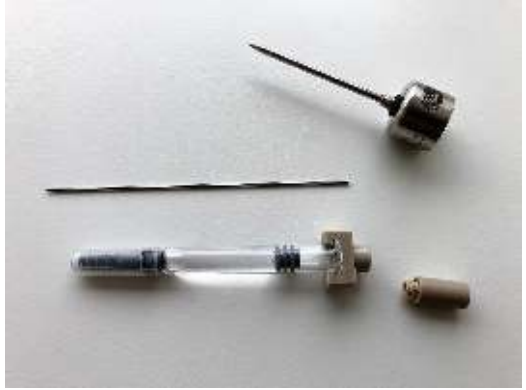
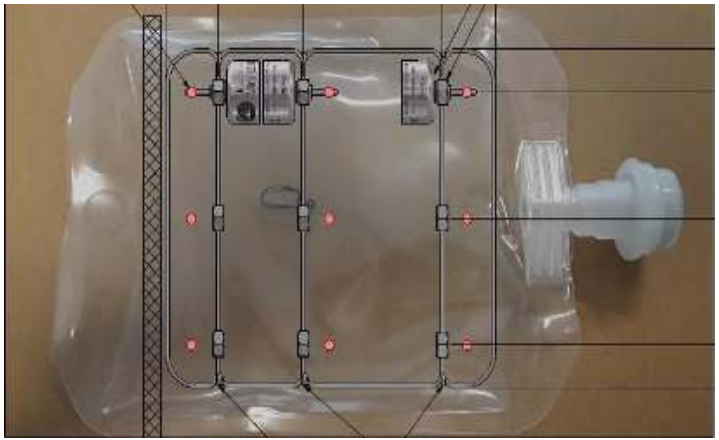




Validation Software

Time-saving and user-friendly with the highest data integrity

ValSuite® - Validation & Calibration Software

The ideal solution for any thermal validation process

ValSuite® – Features & Benefits

- Intuitive & User-Friendly Software
- Data Acquisition to Database
  - Same Software used for Data Loggers & Thermocouple System
  - Data Integrity - stores data in Secure SQL Database
  - Search Engine Option
- Validated Software
  - The Software has been validated and allows for 21 CFR Part 11 compliance
- Excellent Documentation Features
  - Numerous Reports with Pass/Fail criteria
  - Templates that make Reporting Easy
  - Output to PDF and Excel
- Useful Monitoring Features
  - Real-time Statistical Calculations and Display
  - Limit Alarms
  - Online Notifications
- Watch the ValSuite Video

ValSuite® - Validation & Calibration Software

Facts & Figures

+30 software engineers at Ellab's R&D department working full-time

All software code lines made in-house

More than 5.000 installations worldwide

New releases every 6-12 months

Regular developments and change control

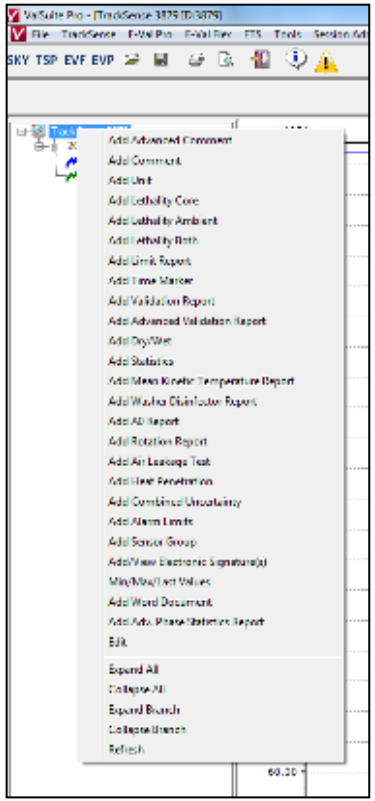
Software Support Team

ValSuite® Pro

ValSuite Pro has all built in functionalities

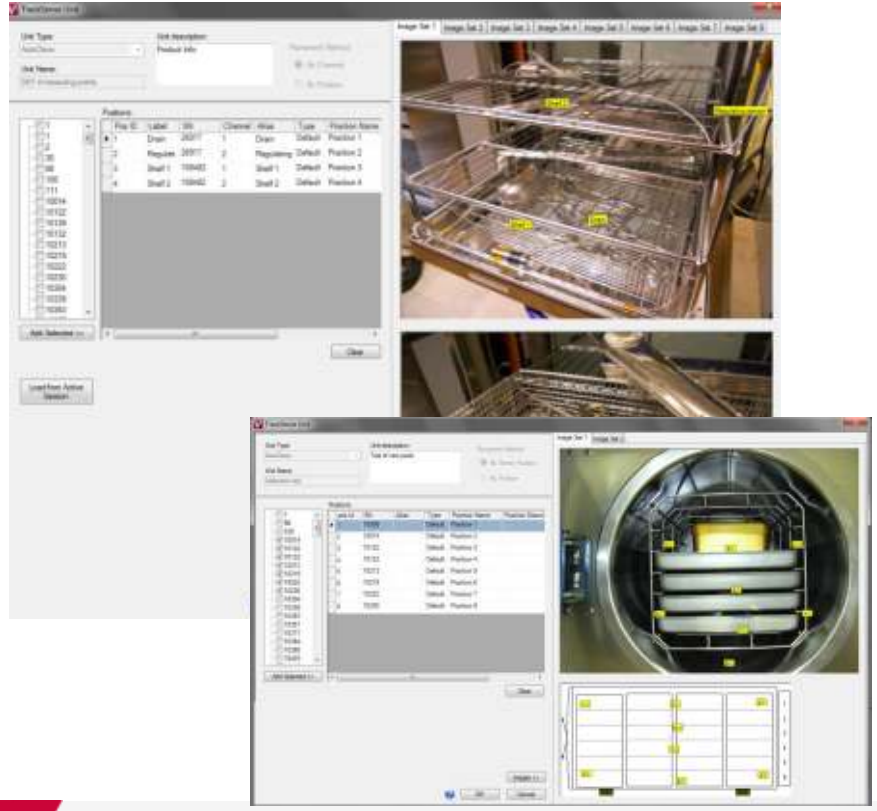
- Complete set of analytical tools and reports including optional 3D visualization
- Automatic calibration including optional OEM configuration
- MSQL Database back-up and restore
- Client-Server solution
- MS Citrix Support
- KNEAT Support (work in progress)
- Fulfils all FDA 21 CFR Part 11 requirements
- Fulfils Annex 11, Volume 4, Part 2 requirements
- Fully Validated

Main clients are pharmaceutical industries



ValSuite® - Validation & Calibration Software

The ideal solution for any thermal validation process



Integration into Big Pharma IT systems

– New generation of FDA Inspectors with focus on IT Integration, data integrity and security

ValSuite® Pro

- 2016-2017: 26 big pharmaceutical customers with Citrix / Client-Server installations
- New user requirements for software:
  - SQL Server Technology
  - Client/Server Solution
  - MS Citrix Support
  - Windows security
  - Windows Active Directory Groups
  - Server Based Audit Trail
  - Dual Dynamic Database
  - Electronic Signature (Workflow approvals)
  - Handle calibration certificates/instruments in Cloud
  - E-Val Pro Instrument mode/Windows security

Calibration Solutions

Calibrate, adjust, continue…

Calibration Solutions - In House

Calibrate, adjust, continue…

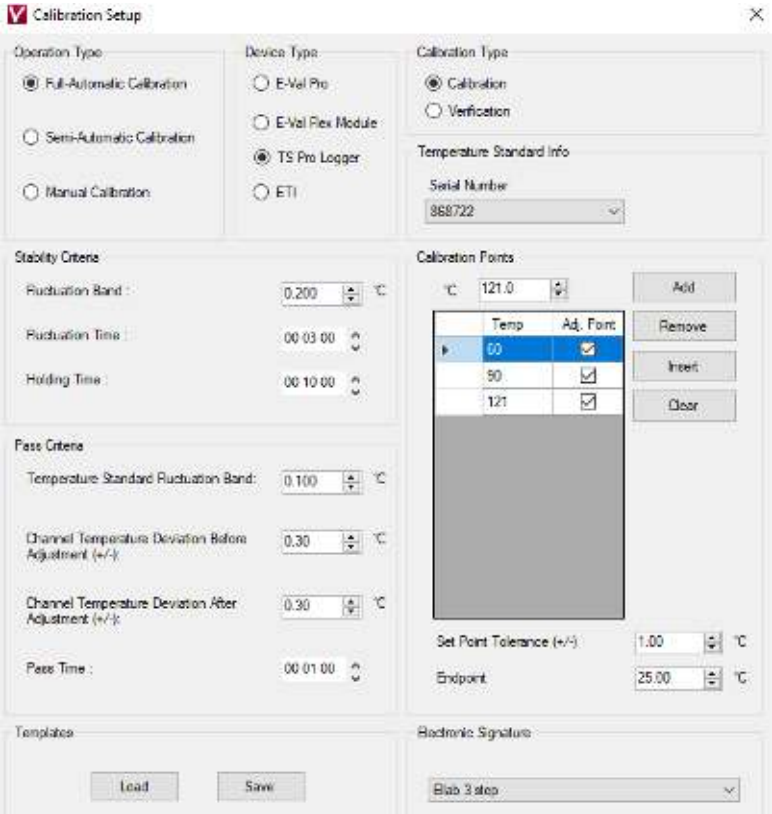
Features & Benefits

- Same ValSuite® Software Package for Validation and Calibration
  - Manual, Semi or Fully-Automatic Mode
  - Calibration Certificates available through V-Lims
- LiquiCal™ using high Quality Baths
  - Temperatures covering -80°C to +300°C
  - Stability +/- 0.005°C
  - High Performance Liquids
  - Internal Fixtures
- Reliable & Fast Dry Block Solutions
  - Temperatures covering -100 to +750°C
  - Accuracy +/- .04°C Stability +/- 0.005°C
  - Inserts for every need
- ETS Ellab Temperature Standards
  - Temperature Accuracy up to +/- 0.015°C
  - -196°C to 420°C range available

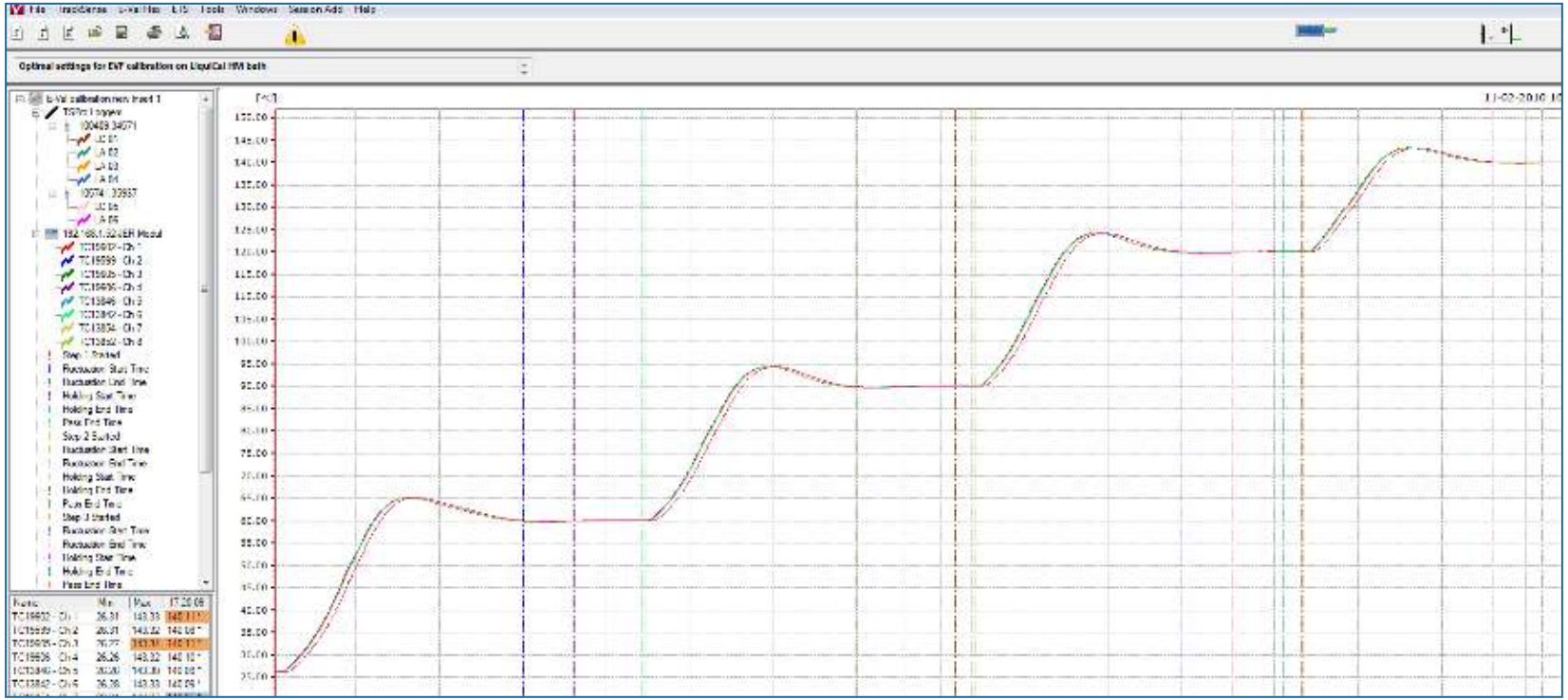
Full-Automatic User Calibration

Full-Automatic User Calibration

- automatic collection of data from the temperature standard (ETS) and ramp the temperature reference



Full-Automatic User Calibration

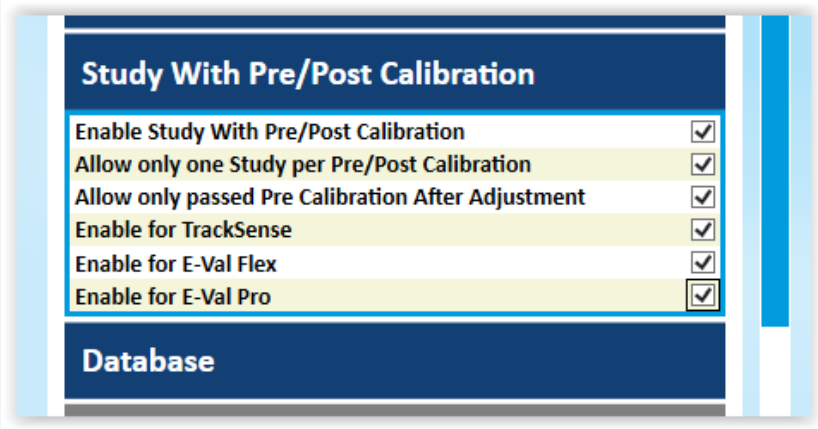


- Saves time (can be started and performed overnight)
- Eliminates human error factor and improves traceability of calibration

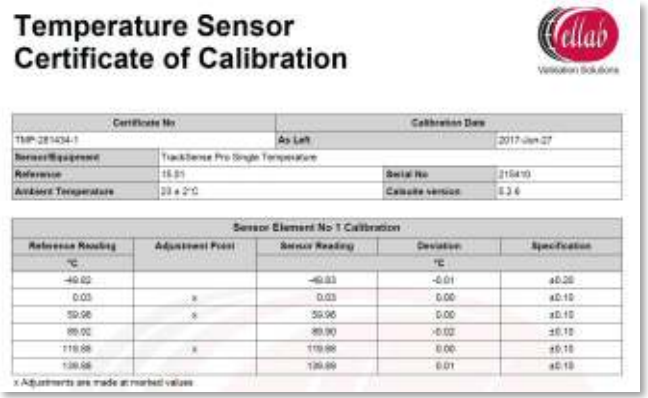
Merging Of Calibration Reports

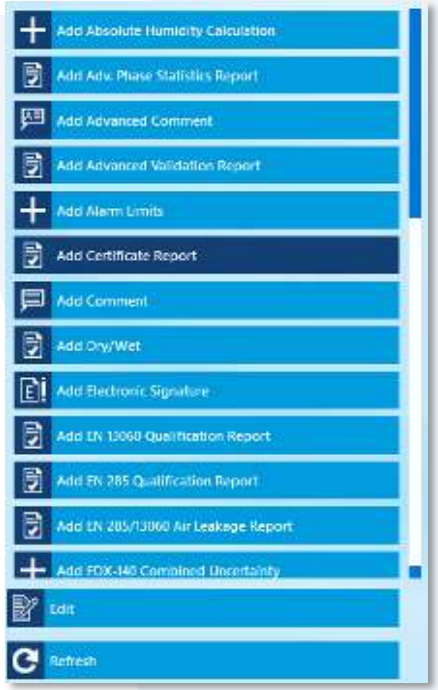
ValSuite is able to merge calibration reports (pre) from previous made user calibration into actual session according to the sensor ID used – and add post calibration data afterwards

- Option is activated in calibration setup
- A complete report is executed
- If user calibration is repeated later this report will automatically be updated in database
- Time limitation for using “old” calibration data



Calibration Certificate Report





Calibration Certificate Report

- Lists all available calibration certificates from this specific session
- Can be viewed or printed/included in complete PDF report

Thank you!

Do you have any questions?

Message us: contact form

E-mail us: contact@ellab.com

E-mail us: colin.davidson@ecefast.com.au

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