Advanced Calibration

- IFTPS 1th European Conference 30-31 October 2007
  - Grande Hotel do Porto, Porto, Portugal

  - Product Manager Jan Eriksen, Ellab A/S Denmark

Ellab A/S - who are we?

- Founded in 1949
- Headquarter in Denmark close to Copenhagen
- Subsidiaries in France, UK, Germany, USA and Philippines
- Number of employees ~ 80 (~ 55 in Denmark)
- Main products E-Val Flex online data acquisition system and TrackSense® Pro wireless data loggers

- Mission Statement

  Ellab improves quality of life by building confidence in food and health products, by providing solutions for measuring, recording, monitoring and validating critical parameters of thermal processing.

Scope

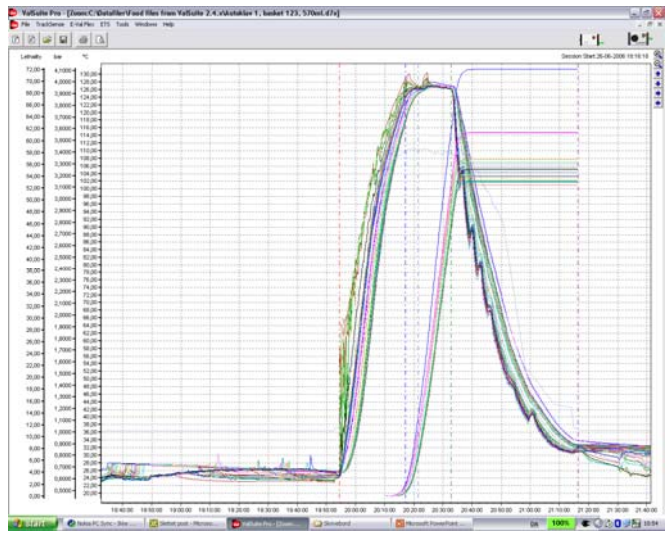
- The scope of this presentation is to introduce advanced calibration on wireless and cabled systems.At the same time show advances in instrumentation, procedures and software tools that can contribute to the improvement of process validation

Process Validation

- Specific processes must be validated because:
  - Critical to product safety
  - Critical to product quality
  - Contributes to process optimization
- Process Validation:
  - Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its pre-determined specifications and quality characteristics (FDA definition)

Critical Parameters

- When validating a sterilization process the critical parameters are:
  - Temperature, pressure, time and lethality (F_0)
  - Rotation
- These parameters form the basis for:
  - The validation results
  - The final assessment of the process
- It is critical that the process validation is based on reliable data

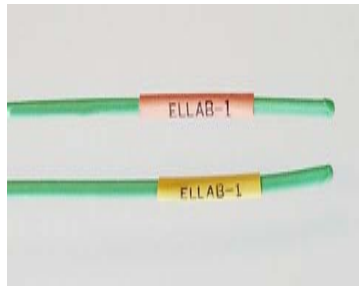


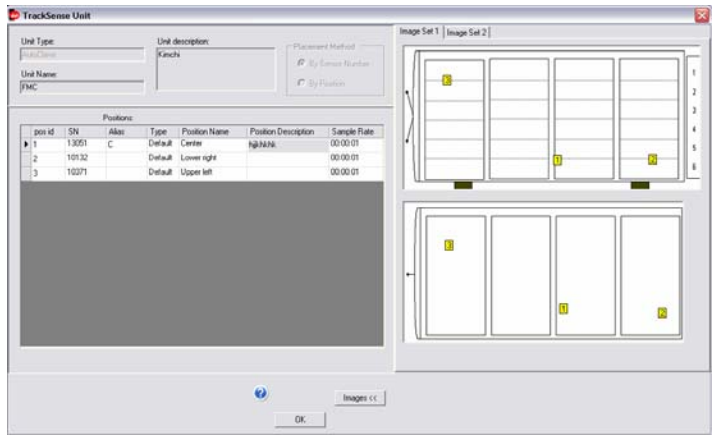
Reliability - Set Up & Handling

- The reliability of the data acquisition system can be improved in these steps:
  - Well-documented installation of software and hardware
  - Simple configuration and operation of the data acquisition system
  - Ensure data integrity
  - Automatic validation procedure according to templates
  - Automatic assessment of validation results according to predefined criteria (Pass/Fail criteria)
  - Automatic calibration procedure

Reliability - Procedures

- Validation procedure according to predefined templates
  - ID number of each measuring point
  - Position of each measuring point
  - Create relation between data session and template
- Reports generated in PDF format
  - Validation results can be distributed in a secure and locked format

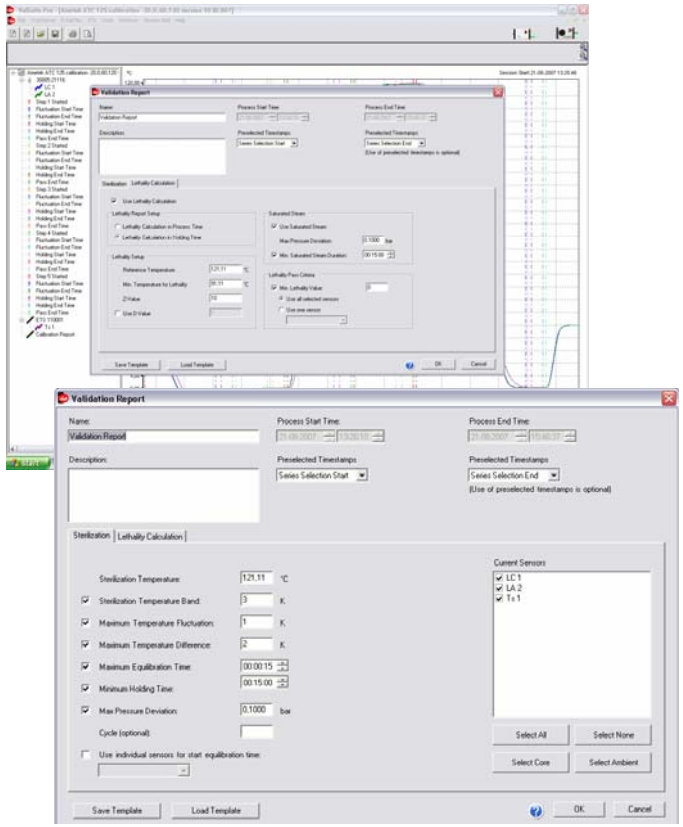




Reliability - Deviations & Errors

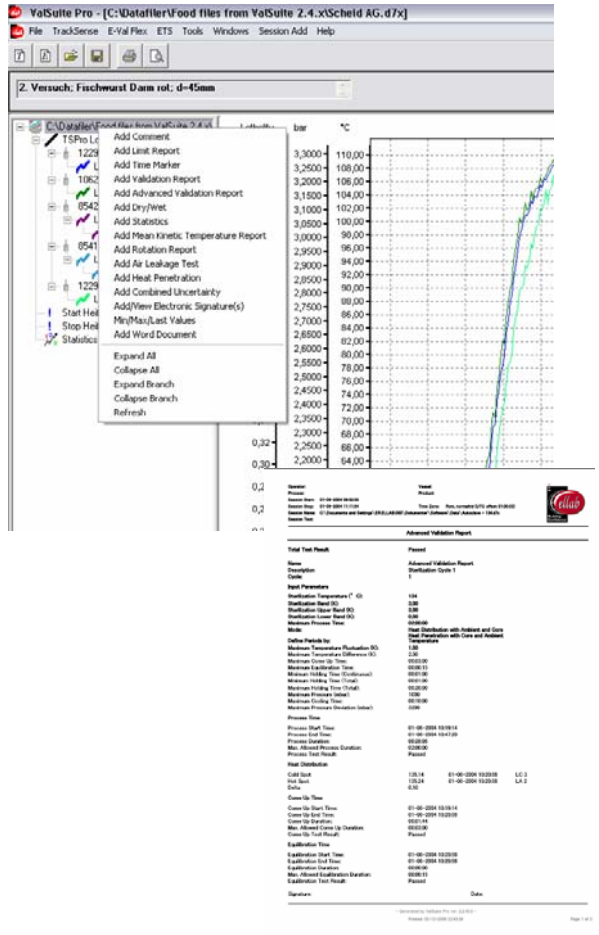
- Why reliability of the data acquisition system is important:
  - Even small temperature deviations cause large errors in the calculated lethality (F_0)
  - The final measuring error is the sum of all errors

- Mistakes are often induced by human error
  - Predefined and automatic procedures can reduce the risk of human errors

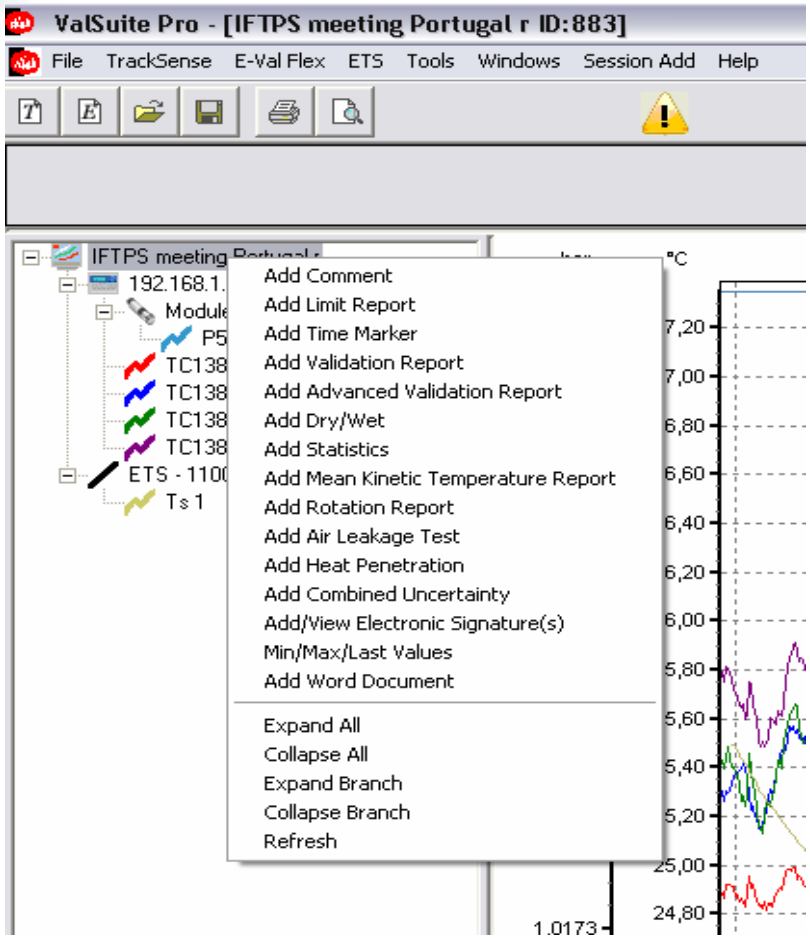


Reliability - Data & Reports

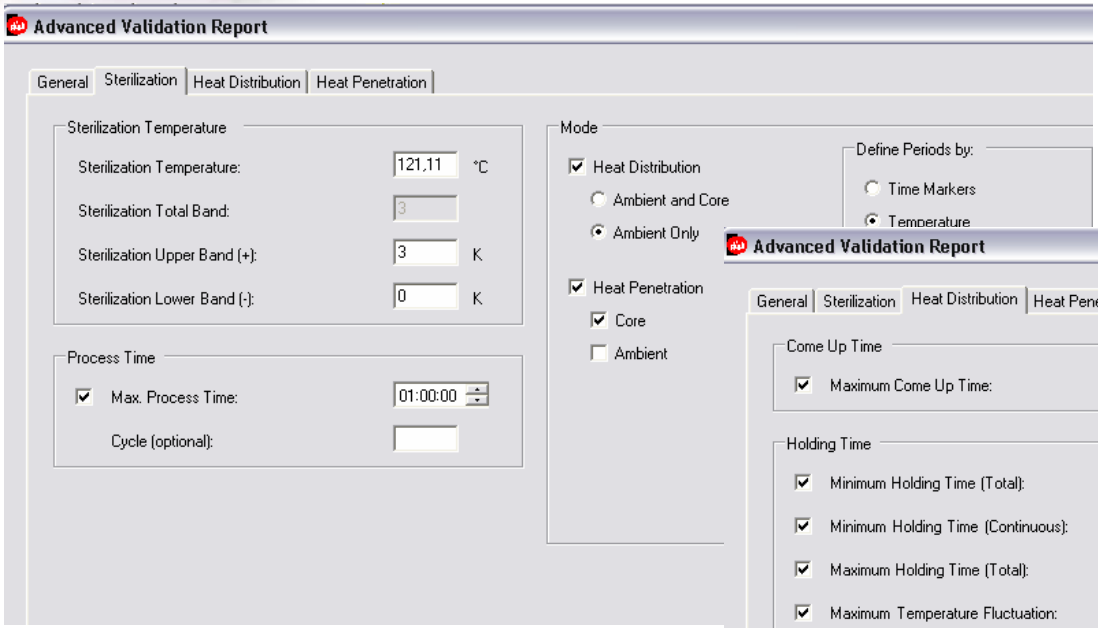
- Processing of raw data in a secure environment
  - View data and graphs and make analyses without having to export data to other platforms e.g. Excel
- Automatic storage to a database
  - Sessions in a database cannot be modified or deleted
  - Improved data integrity compared to common file structure
- Automatic generation of reports with pass/fail outputs
  - The assessment is based on raw data and predefined validation criteria

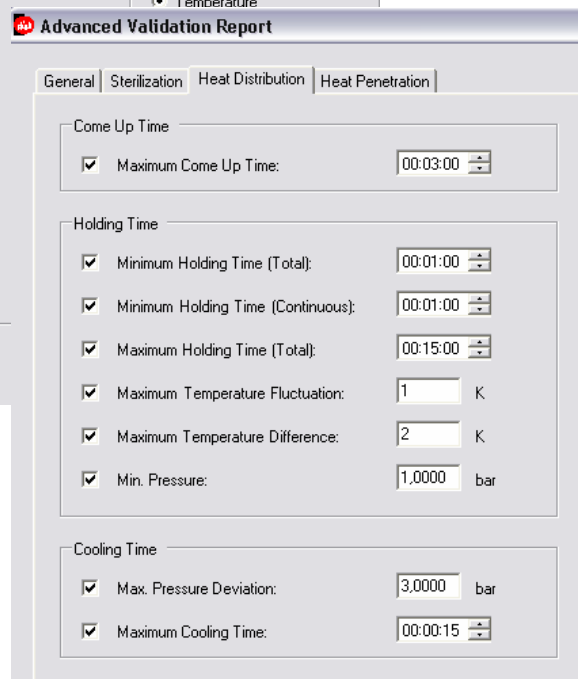


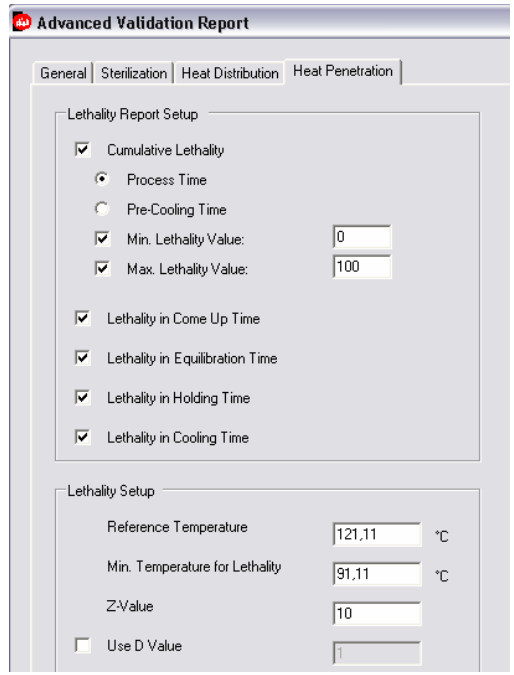
Reliability - Data & Reports



Reliability - Data & Reports







Reliability - Data & Reports

Heat Penetration

Mode
- Ball Method
- Sensor Pair

Ball Simluation
- Desired Process Time (Minutes)
- Retort Temperature: 121,00
- Ti (°C): 20,00

Graph
- View Series Separately

Sensors

	Core Sensors
☑	TC13833 - Ch 1
☑	TC13834 - Ch 2
☑	TC13839 - Ch 3
☑	TC13832 - Ch 4

Broken Heating

C.U.T.: 0,58

j Correction: 1,00

Heat Penetration Data - Heat Penetration

Process Time: 30,00 RT Sim: 121,00 Ti: 20,00

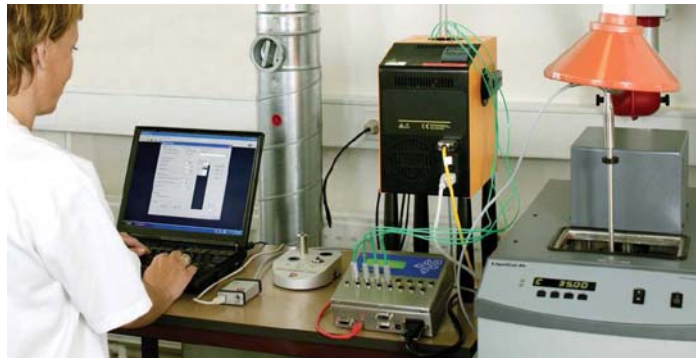
Name	RT	jh	fh	F0
C1 L4 product	121,73	1,57	27,68	0,25
C2 L4 product	121,73	1,58	18,54	2,60
C3 L3 product	121,73	1,47	20,37	1,90
C4 L4 product	121,73	1,49	22,79	1,04
C5 L3 product	121,73	1,41	23,20	1,06

Reliability - Validity of data

- Measurements at pre-defined positions
  - Cold spot determination
  - Use of appropriate accessory
  - Reproducible data
- Pre calibrated sensors & probes
  - Full traceability
  - Optimal accuracy

Calibration - Definitions

- Calibration (ISO definition):
  - Determines the performance characteristics of an instrument
  - Calibration is achieved by means of a direct comparison against measurement standard
- Verification (ISO definition):
  - Confirmation through examination of a given item and provision of objective evidence that it fulfils specified requirements
  - Demonstrates that the stated performance properties of a measuring system are achieved



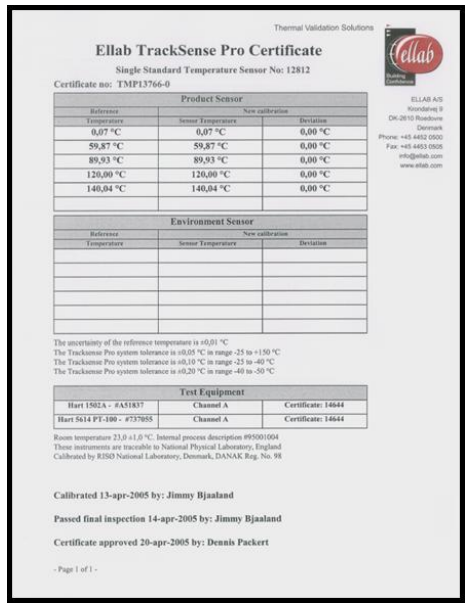
Calibration - Why ?

- Obvious reasons
  - Ensure that a specific process is within specification – every time / every day
  - Avoid overheating
    - change / loss of product
  - Avoid insufficient heating
    - risk of invalid Fo value
  - Ensure that control system is working according to optimal performance

Calibration - Reasons

- General reasons for calibrating
  - Determine the accuracy of the instrument readings
  - Ensure that readings from the instrument are consistent with other measurements
  - Establish the reliability of the instrument i.e. that it can be trusted
  - Document that the measuring device is fully functional
  - Document that both instrument and measuring device(s) are within the required accuracy

”Because all sensors drift”



Thermal Validation Solutions

Ellab TrackSense Pro Certificate

Single Standard Temperature Sensor No: 12812

Certificate no: TMP13766-0

Product Sensor

Reference Temperature	New calibration Sensor Temperature	Deviation
0,07 °C	0,07 °C	0,00 °C
59,87 °C	59,87 °C	0,00 °C
89,93 °C	89,93 °C	0,00 °C
120,00 °C	120,00 °C	0,00 °C
140,04 °C	140,04 °C	0,00 °C

Environment Sensor

Reference Temperature	New calibration Sensor Temperature	Deviation

The uncertainty of the reference temperature is ±0,01 °C
The Tracksense Pro system tolerance is ±0,05 °C in range -25 to +150 °C
The Tracksense Pro system tolerance is ±0,10 °C in range -25 to -40 °C
The Tracksense Pro system tolerance is ±0,20 °C in range -40 to -50 °C

Test Equipment

Hart 1502A - #A51837	Channel A	Certificate: 14644
Hart 5614 PT-100 - #737055	Channel A	Certificate: 14644

Room temperature 23,0 ±1,0 °C. Internal process description #95001004
These instruments are traceable to National Physical Laboratory, England
Calibrated by R250 National Laboratory, Denmark, DANAK Reg. No. 98

Calibrated 13-apr-2005 by: Jimmy Bjaaland

Passed final inspection 14-apr-2005 by: Jimmy Bjaaland

Certificate approved 20-apr-2005 by: Dennis Packert

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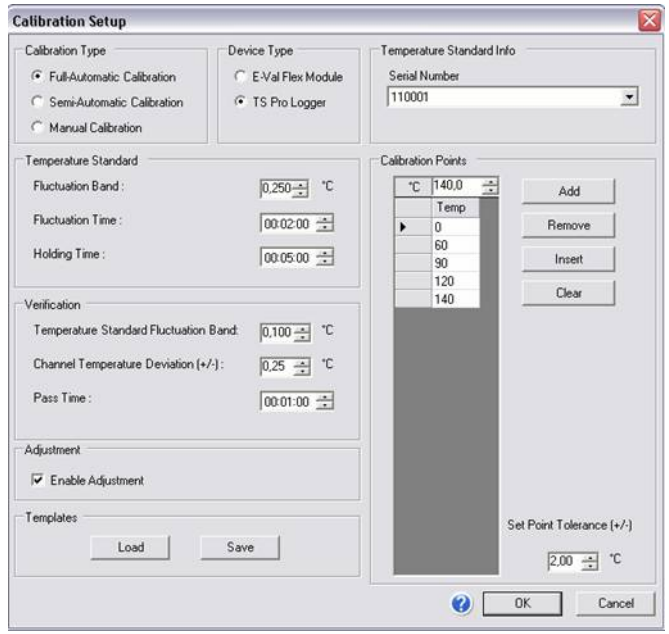
Calibration - Reliability

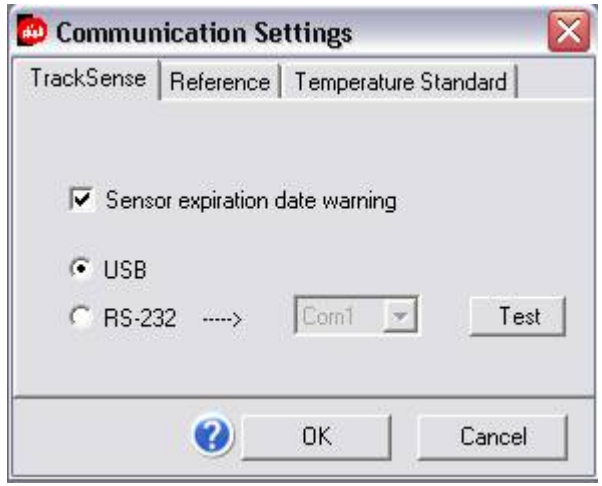
- Ways to improve the reliability of the calibration procedure:
  - Perform calibrations according to predefined templates
  - Ensure that the measurements from the instrument and the standard are logged automatically
  - Use systems that document standard values and deviations in a report automatically



Calibration - How often?

- Intervals to be defined according to :
  - Potential failure of instrument device
  - Impact to product quality
  - Past history
  - Manufactors recommendations
  - Instrument reliability and accuracy
  - Danger of too long intervals (safety)

- Calibration secures product integrity
  - Measurements are taken throughout the life cycle of the instrument device to avoid changes in performance (drift) over time



Calibration - Drift

- How much do they drift?
  - Good quality type T thermocouples typically show drift of < +/-0.5°C over time (12 months)
  - RTD sensors have significant less drift over time

TrackSense recalibration offset values after 12 months

	0 C	60 C	90 C	120 C	140 C
Avr.	-0,007	-0,019	-0,020	-0,018	-0,022
Sd.	0,027	0,032	0,034	0,038	0,046
Min.	-0,107	-0,126	-0,114	-0,124	-0,187
Max.	0,108	0,135	0,172	0,191	0,200

Calibration - Measuring Device

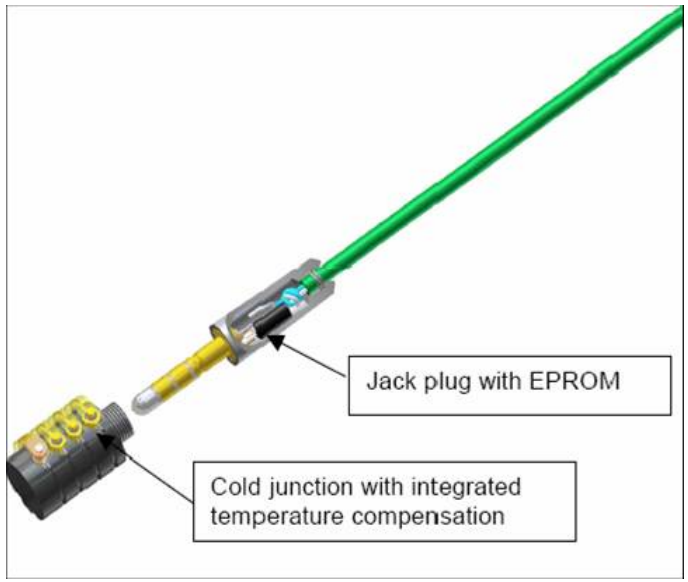
- Usually, in the pharmaceutical industry thermocouples (and wireless data loggers) are calibrated pre- and post every process validation according to SOP:
  - Handled with less care
  - Subject to transportation
  - High risk for damage and shocks during use (moisture,pressure,temperature)

Calibration - Instrument & Standard

- Usually, an ETS temperature standard is calibrated every 12 months
  - RTD technology – low drift over time
  - Linear temperature/resistance characteristic
  - Protected during transportation
  - Handled with great care

Calibration - Results

- Ways to improve the calibration results :
  - Choose RTD sensors with low drift and excellent linearity
  - When using thermo couples look for cold junction compensation for each individual temperature probe to secure better accuracy and flexibility
  - Protect the measuring device
  - Store calibration data in each individual measuring device



Conclusion

- Factors that improve the reliability of the validation results:
  - Use of data acquisition systems that ensure data integrity ✓
  - Automatic validation procedure according to templates ✓
  - Automatic assessment of validation results according to predefined criteria ✓
  - Use automatic calibration procedures if possible ✓

Ellab Update

- Hardware news
  - Micro logger TMP/PRS/Rotation
  - Teflon Flex Sensors
  - Pro-X logger
- Software news
  - New release 2.5.x
  - New reports
  - Multi language
  - Client / server

Thank you for your attention !