

# ELLAB Thermal Validation Systems - PHARMACEUTICAL APPLICATIONS

## 1. AUTOCLAVE VALIDATION

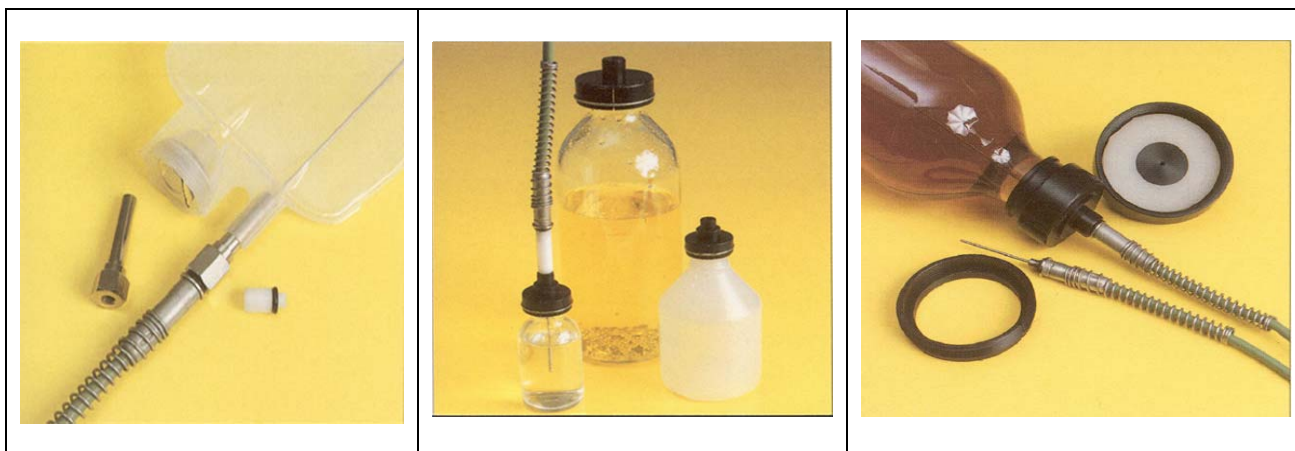
ELLAB EVal Flex Online Cable Based System and TS Pro Wireless Datalogger can be used for the validation of Autoclaves.

The EVal Flex system is supplied with Thermocouple Probes with concealed connectors provide high accuracy and reliability. The accuracy of the System with the probe is  $\pm 0.05$  deg C after calibration and 0.1 deg C before calibration.

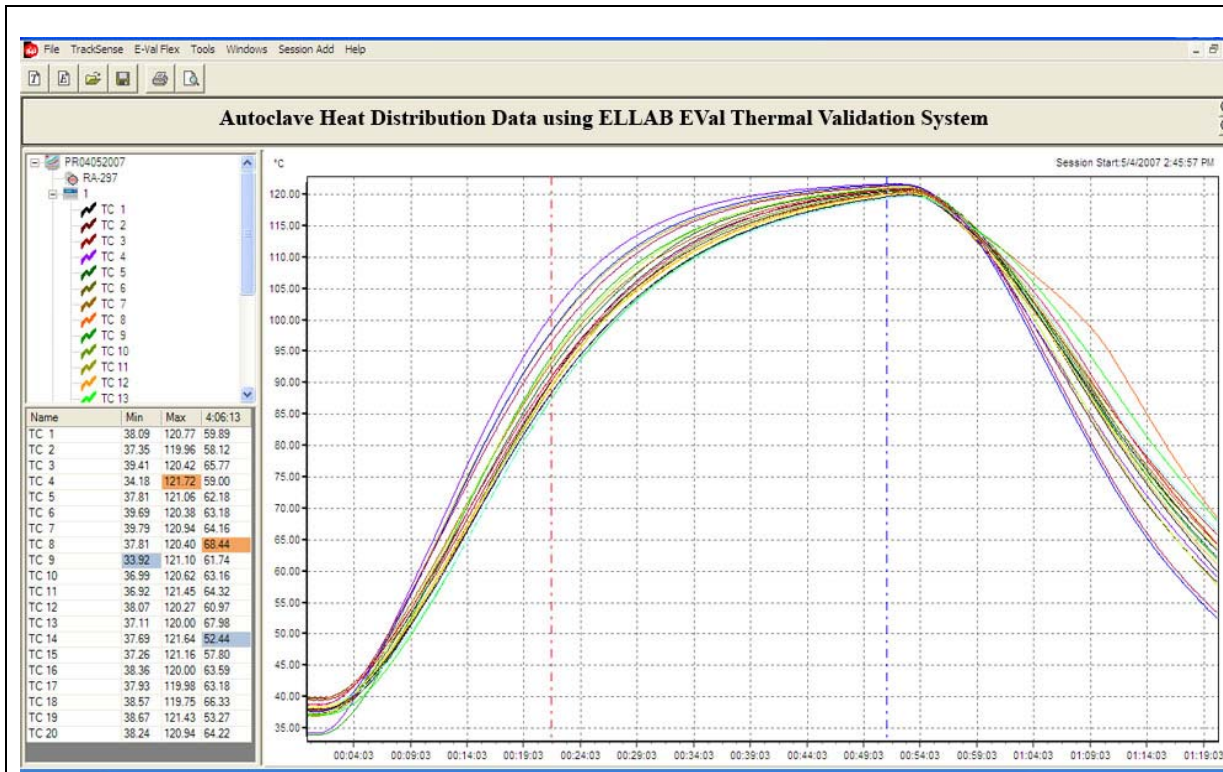
The Thermocouple probes are equipped with electronic ID and memory for calibration values which improves the accuracy to 0.05 deg C and ease of thermocouple identification. The identification number is engraved at the Jack Plug and at the tip of the measuring needle helps the operator to position the probes properly. The same ID is shown in the software for identification of the probes.

**Calibration** can be performed manually using the current metrology or completely automated with the reference standard data streamed into the calibration files as well as the ram control of the bath.

The Hardware, Software and Firmware are developed in accordance with guidelines set out in GAMP 4. The ValSuite Pro software has been validated and is fully compliance with FDA 21 CFR Part 11.

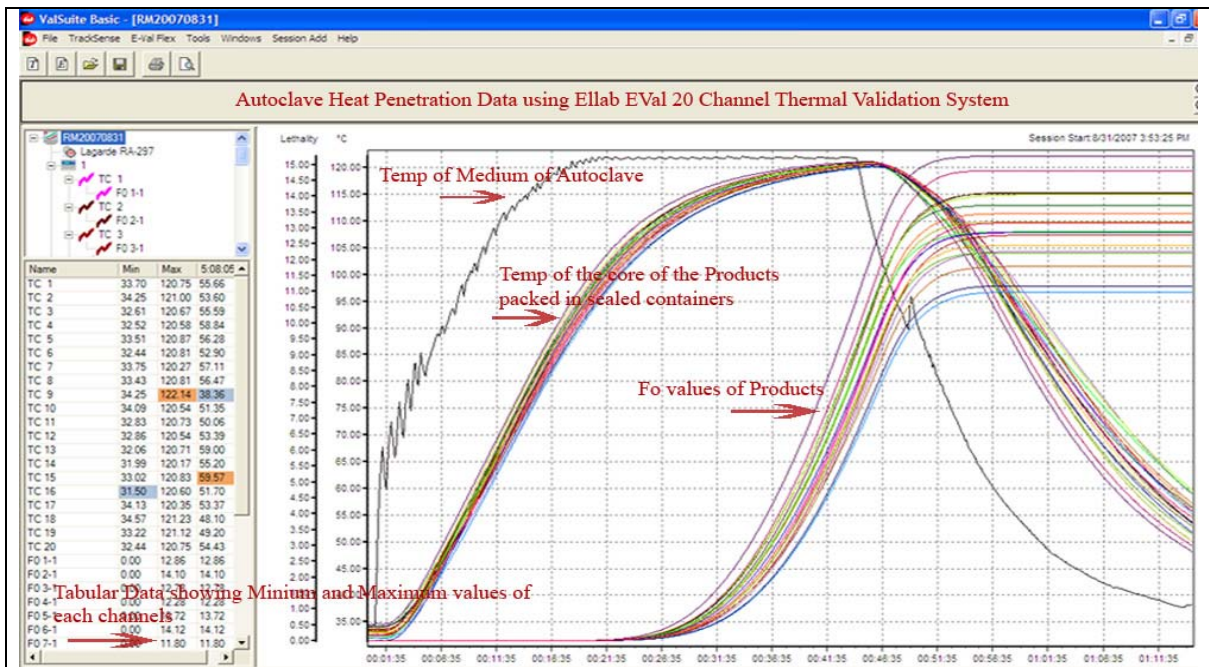


## Heat Distribution Data of Autoclave using Ellab EVal Flex 20 Channel System



## Heat Penetration Applications

Apart from standard Heat Distribution Studies, Ellab Eval Flex Systems can be used for the Heat Penetration Studies also. The needles of the probes are designed to be compatible to measure the core temperature of products packed in different types of containers.



## ELLAB WIRELESS DATA LOGGER FOR AUTOCLAVE VALIDATION



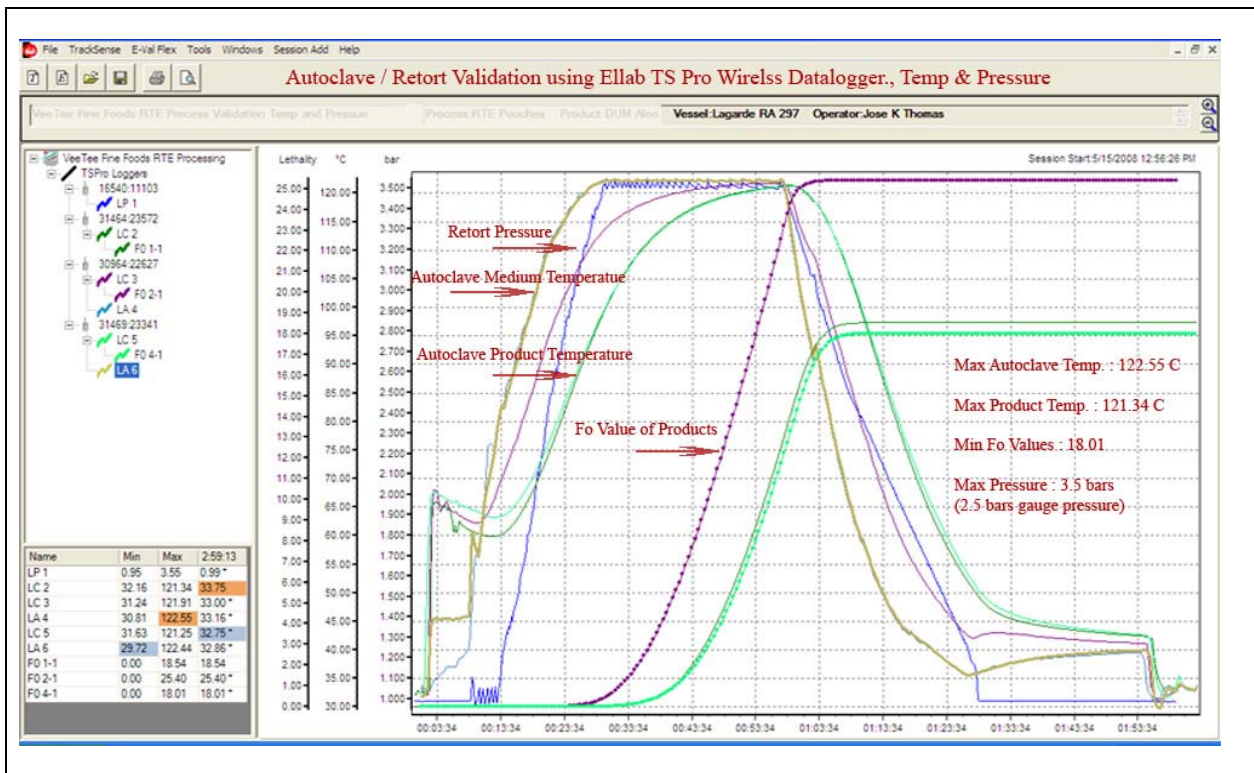
Ellab TS Pro Wireless Dataloggers can be used for the Validation of Autoclaves. It can be used for the Heat Distribution as well as Heat Penetration Applications. The needles of the probes are designed to be compatible with different types of containers. We offer fittings and fixtures to any type of containers

This equipment is CE-approved, ISO certified and manufactured according to international standards, the software packages are validated according to GAMP, and the measuring results are approved by EEC-Regulations, FDA/USDA and other regulatory authorities worldwide.



The TrackSense® Pro Wireless Datalogger is engineered with flexibility and speed. The station has 4 positions for loggers and is connected to the PC via USB, RS232 or Ethernet. By using the USB port power is supplied directly from your PC reducing the need for an external power source. Up to 3 additional expansion modules can be connected to the station allowing the capability to program or download 16 loggers at one time.

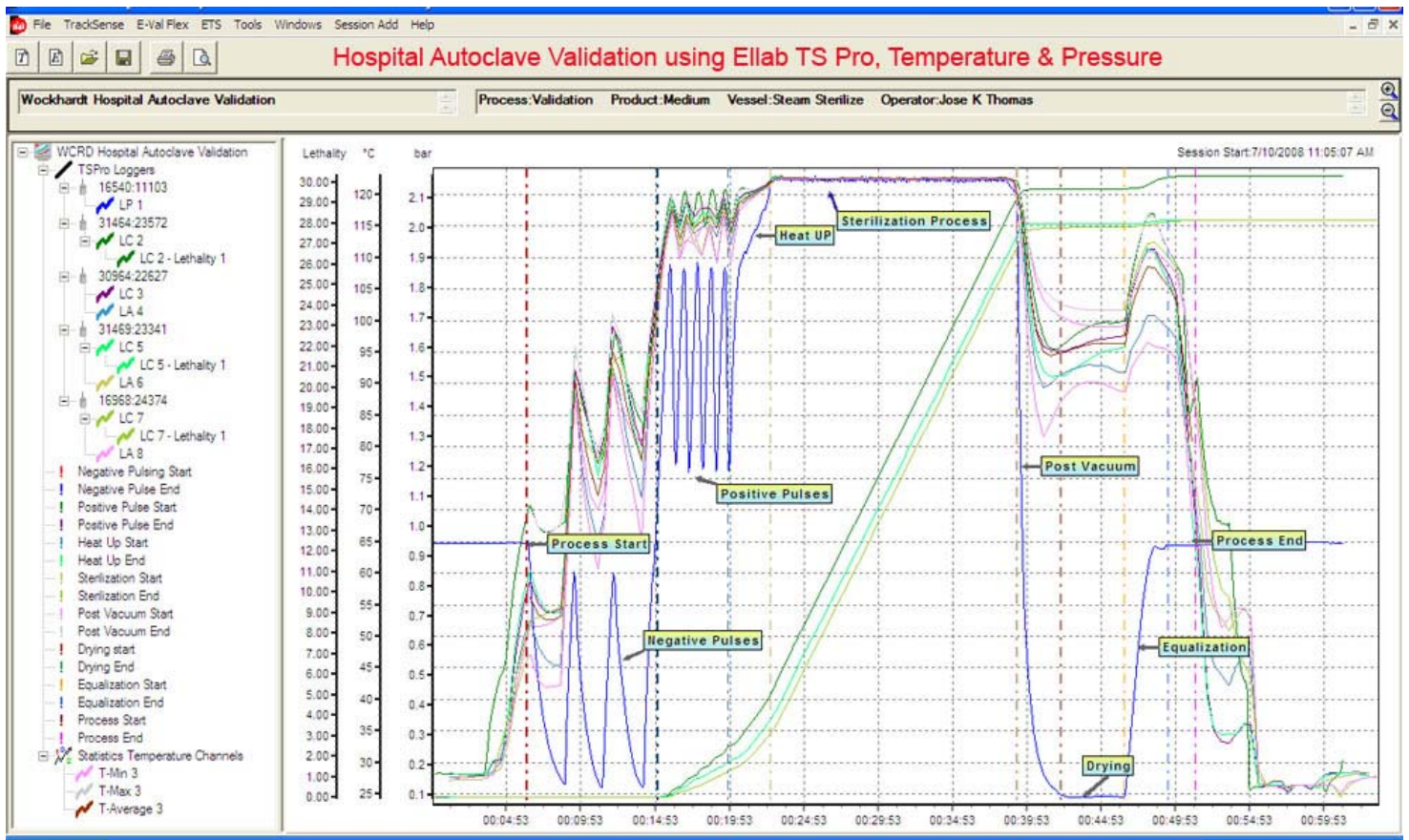
The TrackSense® Pro loggers communicate via induction greatly improving the speed and reliability of data transfer. Thousands of data points from multiple loggers can be downloaded in less than ten minutes. The software will automatically cycle through each logger it finds in the station enabling the operator to walk away during data transfer



Autoclave Validation Data using Ellab TS Pro Wireless Datalogger is shown above. The temperature of the medium of autoclave (Heat Distribution), the temperature of the core of the products packed in sealed containers (Heat Penetration), Sterilization values (Fo values) of the products, Autoclave pressure etc are shown in the above graph.

The Hardware, Software and Firmware are developed in accordance with guidelines set out in GAMP 4. The ValSuite Pro software has been validated and is fully compliance with FDA 21 CFR Part 11.

# MEDICAL AUTOCLAVE VALIDATION



The above picture shows the Medical Autoclave Validation using Ellab TS Pro System. The positive and negative pressure pulses (in order to apply vacuum), Heat up phase, Sterilization phase, Post vacuum phase, drying phase, equilibration phase etc can be very well estimated and documented in the graph.

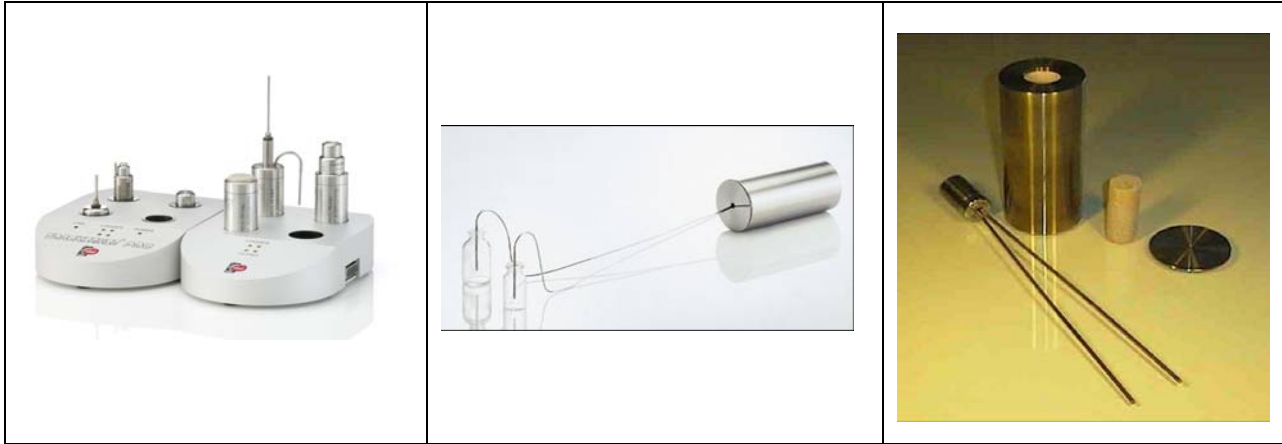
It is possible to analyze each section and to make sure that all the sections are working well within the limits.

## DEPYROGENATION / DRY HEAT STERILIZERS

Depyrogenation is normally performed in a batch-wise manner or using tunnels in a continuous process.

Ellab offers complete solutions for the validation of Depyrogenation / Dry Heat Sterilization applications. For stationary Batch Hot Air Ovens, we offer EVal Flex with High Temperature Probes which can go upto +400 deg C.

For Tunnel types of Depyrogenators, we offer TS Pro Wireless Dataloggers with special Loggers and Sensors with protectors which can be used upto + 400 deg C. Special Insulation Packs (Thermal Barriers) are being used to insulate the logger when it is being used at extreme temperatures.



The Sensors of the loggers are supplied with flexible metal insulated wires which can be positioned exactly at the cold spot of the containers. The thin profile of the sensors does not block the flow of the hot air into the bottom surface of the vials and bottles which helps to simulate the actual process conditions. Please refer the above mentioned picture showing the positing of the tip of the measuring sensor inside the vials and the parts of the Thermal Barrier to protect the electronic parts of the logger from extreme temperatures.

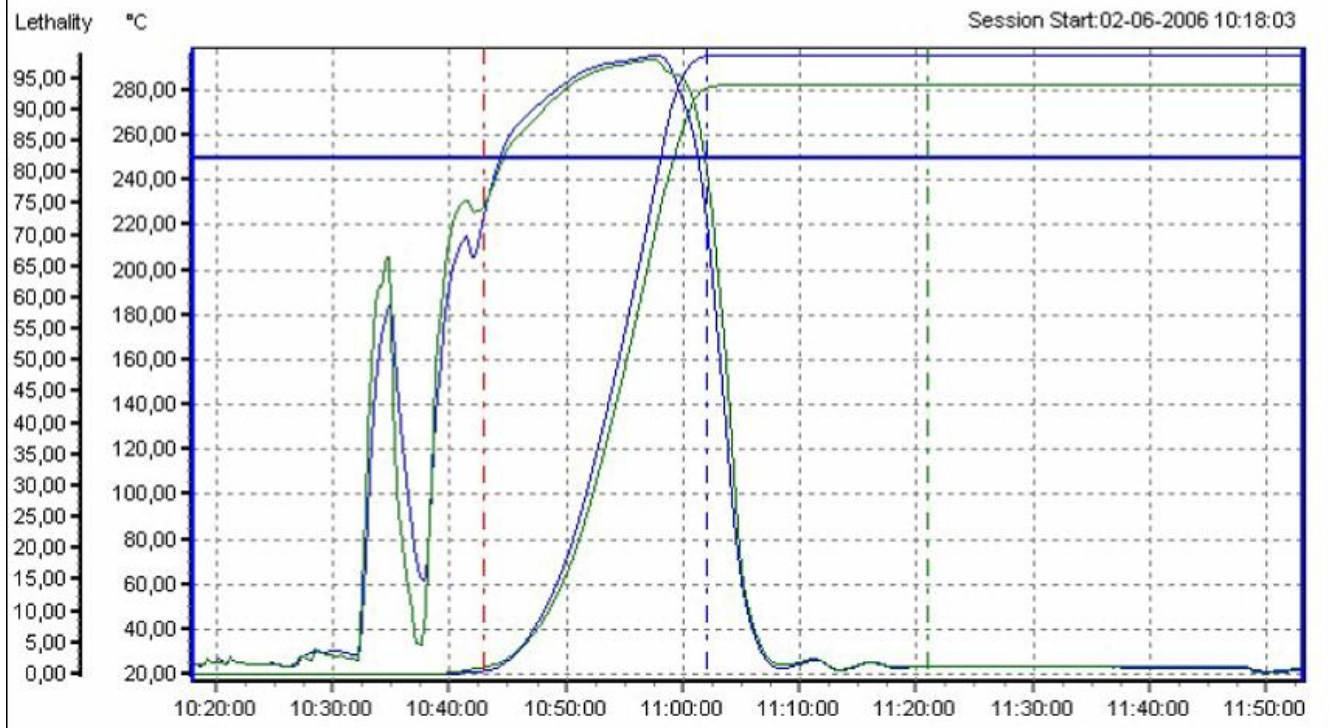


The Ellab EVal Flex Cable Based system also can be used for the validation of the Depyrogenators / Dry Heat Sterilizers using the special High Temperature Thermocouple Probes. The High temperature probes can be used to measure temperatures upto + 400 deg C.

The Hardware, Software and Firmware are developed in accordance with guidelines set out in GAMP 4. The ValSuite Pro software has been validated and is fully compliance with FDA 21 CFR Part 11.

Operator: Enrique Riis Vessel: tunnel M22/23  
Process: Depyrogenation Product:  
Session Start: 02-06-2006 10:18:03 Time Zone: Rom, normaltid (UTC offset 02:00:00)  
Session Stop: 02-06-2006 11:53:06  
Session Name: C:\Documents and Settings\cmu\Skivebord\Depyrogenation 1.d7x  
Session Text:

### Graph



Data from Ellab system showing the validation of tunnel Depyrogenation applications. The temperature range was about 300 deg C.

Ellab systems can measure upto 400 deg C .

## EtO (Ethylene Oxide) Sterilization and H2O2 (Hydrogen Peroxide) Sterilization

These compounds are strong oxidizing agents which are used to sterilize products that can not withstand heat. These agents are used in the gaseous phase and penetrate the products over a period of hours.

EtO Sterilization Standard Procedure.

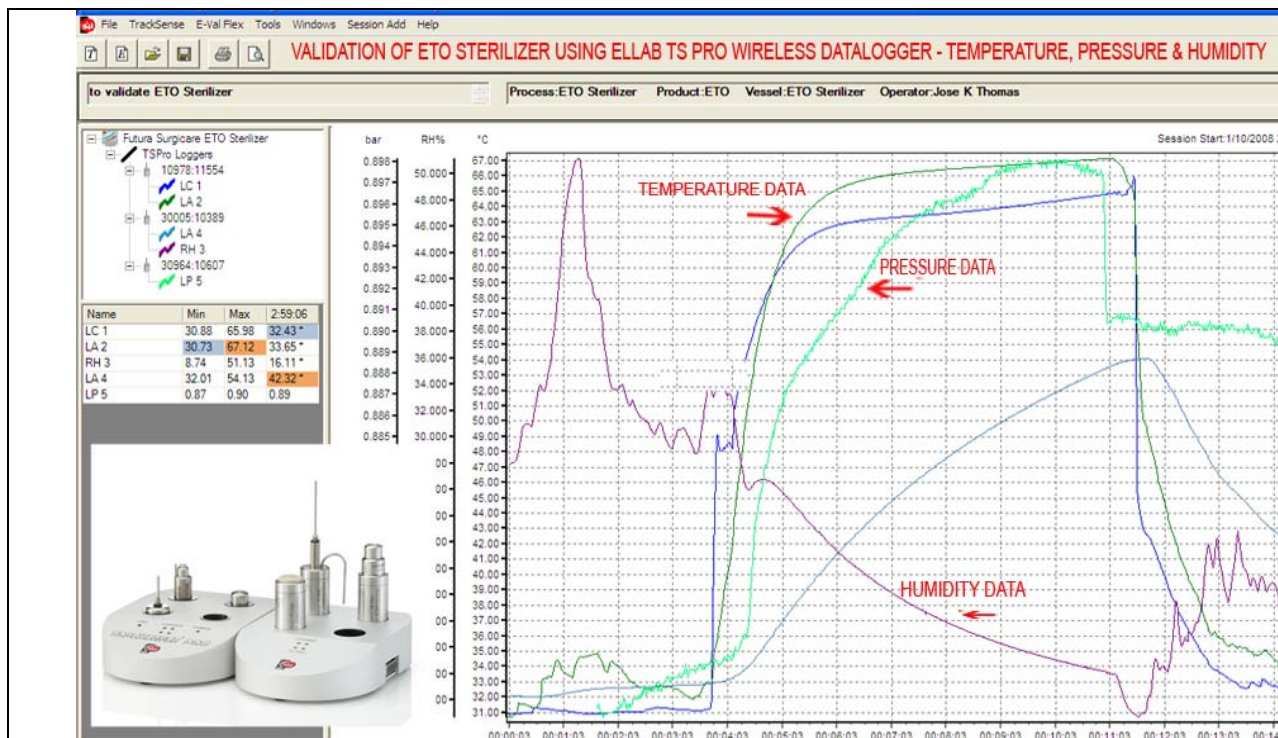
- ▶ Pre conditioning – expose product to tropical environment for at least 12 hours - 55°C/70% RH.
- ▶ Exposure – pull vacuum and expose to gas usually for 4 to 8 hours (varies per product and must be validated).
- ▶ Post conditioning – air out all the EtO gas. 8-12 hours
- ▶ Temperature and RH% are critical in pre-conditioning to induce microbial activity EtO will not kill many microbes in their dormant or (spore) stage.
- ▶ Moisture is critical as a transfer agent for EtO – it helps to permeate through plastic, paper, cardboard, packaging etc.
- ▶ Pulling a vacuum dramatically dries out the product. Therefore steam (RH) is increased to replace lost moisture in the product.
- ▶ The influence of pressure is also a factor in helping EtO permeate a product. Pulling a vacuum pulls EtO into product.

Ellab TS Pro Wireless Datalogger offers total solution for the validation of EtO and H2O2 Sterilization.

The Temperature, Pressure and Humidity can be measured using TS Pro Loggers.

Ellab offers special **PRO Ex Logger for EtO Sterilization** having the temp range of **-50 to +150 C**.

The Ex Logger is designed for use in explosive environments i.e. where aggressive gases such as EtO are used for sterilization. The temperature range of Pro Ex Logger is from -50 to +150 C and is **Ex approved**, which is incorporated in the Atex Directive 94/9/EC. The certificate for Ex is mandatory when using loggers for EtO applications. Similarly Special Loggers are designed for measuring Humidity inside EtO sterilizers.



The Data from Ellab TS Pro Logger showing the Temperature, Pressure and Humidity inside EtO Sterilizer.

## FREEZE DRYING ( LYOPHILISATION )

Freeze Drying ( Lyophilisation) is the process of removing water from a frozen solution by Sublimation. The product is frozen to very low temperature (-40 C and below) and then slowly heated in the presence of vacuum. The result is the water sublimates and is captured on condensers at extremely low temperature (-80 C and below).

Freeze Drying consists of 3 stages: Freezing, Primary Drying (removal of water present as ice crystals) and Secondary Drying (removal of water bound to the product). The critical factors in a freeze drying process are the shelf temperature, chamber pressure and product temperature.

Ellab Offers complete solutions for the Freeze Drying Validation and Monitoring.

**PRO X Logger ( -80 to +150 C)** is designed for difficult low temperature applications. The data logger can run studies in excess of 250 hours at -80 °C degrees. This data logger is appropriate for a range of applications such as **mapping -80 °C freezers and lyophilizers** with low temperature and vacuum. The thin ( 1.2 mm diameter) sensors are perfect for monitoring temperatures in vials.

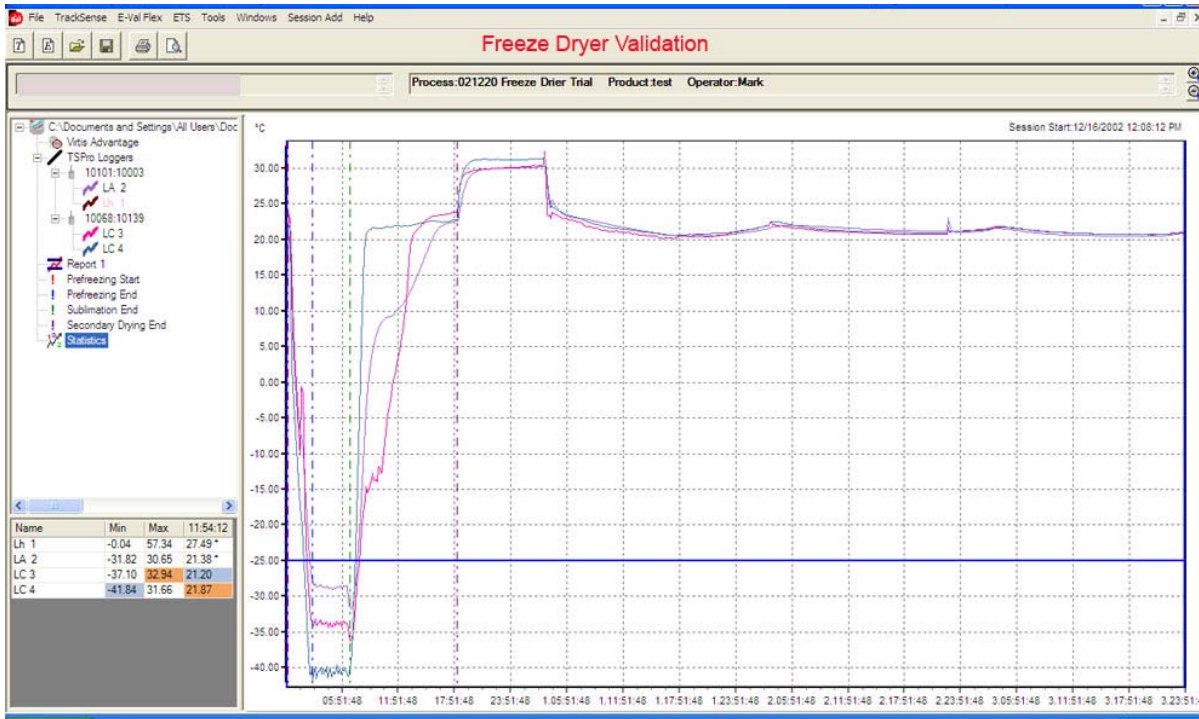
The Pressure Loggers can measure the pressure from 10mBar to 6 Bars absolute. The Pressure sensors can be supplied with special sensors which can measure the chamber pressure as well as pressure inside the containers.

We offer special sensors with fittings and fixtures to fix to any type of containers in order to measure the temperatures of the products as well as the chamber temperature.



We offer Wireless Real Time RF Dataloggers which transmits the data on real time which help the customer to validate and control the Freeze Drying applications.





Freeze Dryer Validation data using Ellab TS Pro System

## Bio Media Sterilization

Ellab TS Pro Systems can be used to validate the sterilization of Bio Media. The loggers can be immersed into the media and the autoclave temp and media temperature with Fo values can be validated.

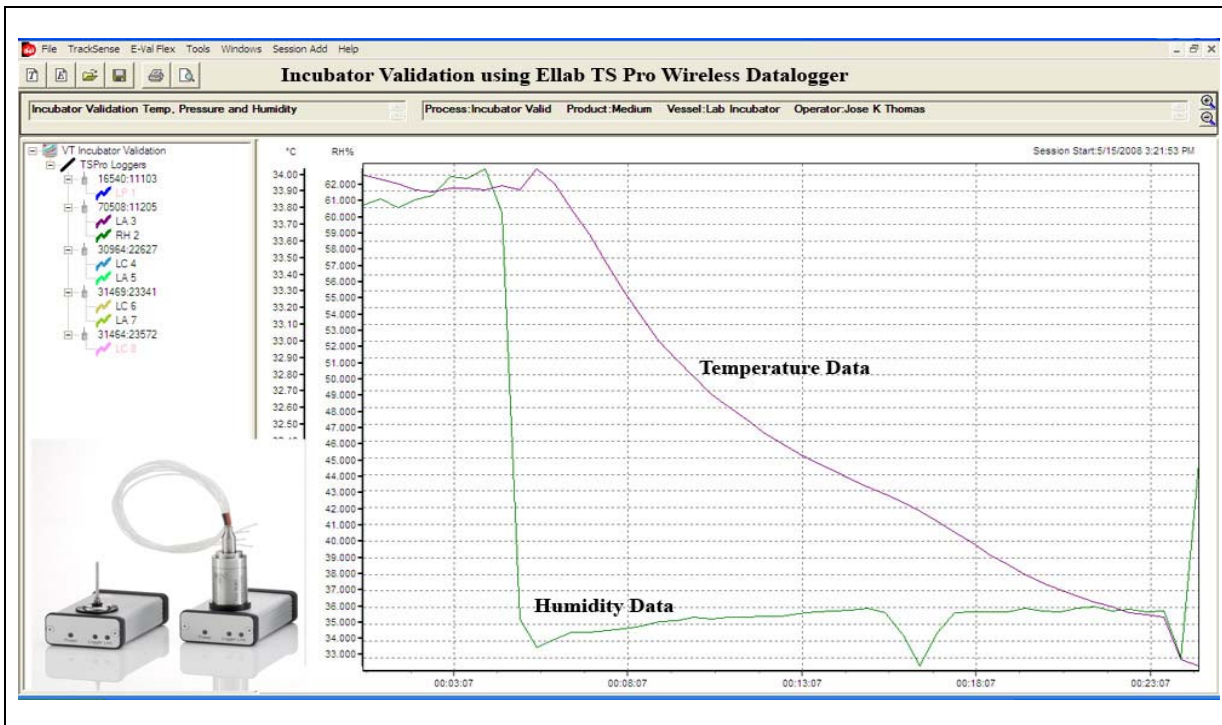


Bio Media Sterilization Validation Data using Ellab TS Pro System

**INCUBATOR / STABILITY CHAMBER VALIDATION – Temperature & Humidity  
WASHER DISINFECTORS, REFRIGERATOR, COLD STORES, HUMIDITY CHAMBERS,  
HEATING CHAMBERS, ENVIRONMENTAL CHAMBERS ETC.**

The TrackSense Lab Logger has been designed to meet the temperature monitoring and validation requirements for freezers, refrigerators, stability chambers, incubators etc. The logger monitors the temperature between -30 to + 100 deg C with an accuracy of +/-0.1 C and +/-2 % RH. To simplify the operation, a three color LED will assist the operator with instant information about the status of the logger.

The TS PRO SKY Logger transmits the data online which helps the customer to monitor the processing online.



## WAREHOUSE MONITORING & VALIDATION SYSTEMS

ELLAB Offers 3 different types of Equipments for Warehouse Validation.

### 1. EVal Flex Thermal Validation System

EVal Flex Thermal Validation system can be used for the Online Thermal Monitoring Applications.

About 100 Thermocouple Probes can be integrated into the same system which can be distributed across different chambers. The data can be monitored throughout the day and this equipment does not need any frequent calibration.



### 2. TS Pro SKY Wireless Online Data logger.

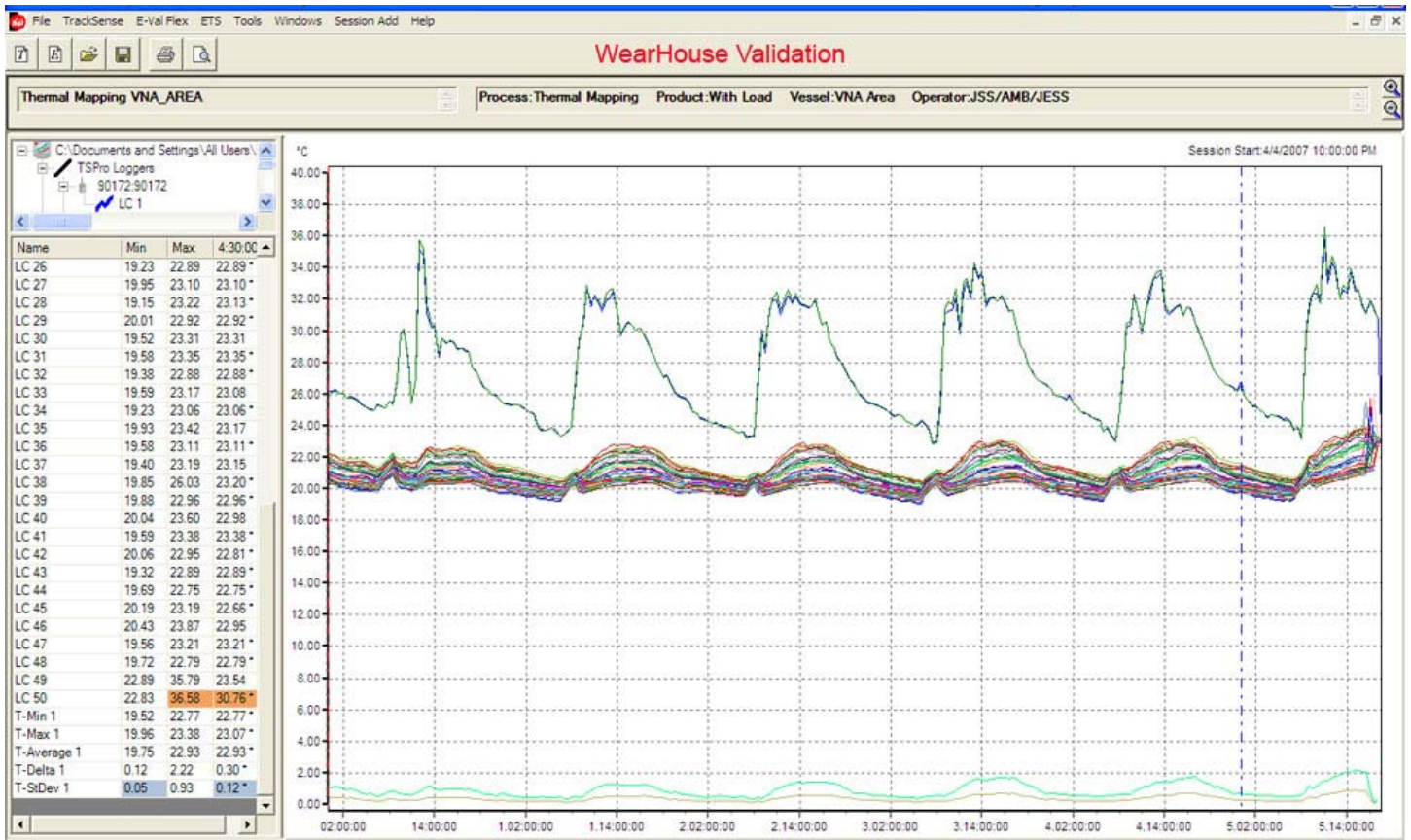
The Data loggers can be positioned at different parts of the Warehouses and the data can be monitored online at the computer. The Sky module transmits the data online and it is possible to use 32 loggers into the same logger, which means 64 sensors can be monitored online simultaneously.



### 3. EVal Thermal Validation System.

This system can integrate 8 different warehouses positioned at different locations and can monitor the data in the same computer as 8 different files simultaneously. About 100 thermocouple probes can be integrated together into the same system which can be used to monitor the processing for a very long time. .





Wear House Validation data using Ellab System.

Apart from the validation applications, Ellab systems can be used for the regular monitoring applications in the wear house. The temperature and humidity inside the wear house can be monitored for months together without doing any recalibration of the system. More than 100 measuring probes can be integrated into the system for the regular monitoring applications.

### S I P ( Steam In Place )

<p><b>Ellab Thermocouple Probes</b></p>	<p>We offer special Package for the validation and Monitoring of SIP ( Steam In Place).</p> <p>The Thermocouple Probe with 4 measuring points can Be inserted into the module to measure the heat Penetration and distribution inside the module.</p> <p>It occupies minimum space and so it simulates the Actual processing conditions.</p> <p>Also we offer micro loggers which can be placed inside the modules to download the data.</p>
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## E-MON - CENTRALIZED PROCESS MONITORING SOLUTIONS.

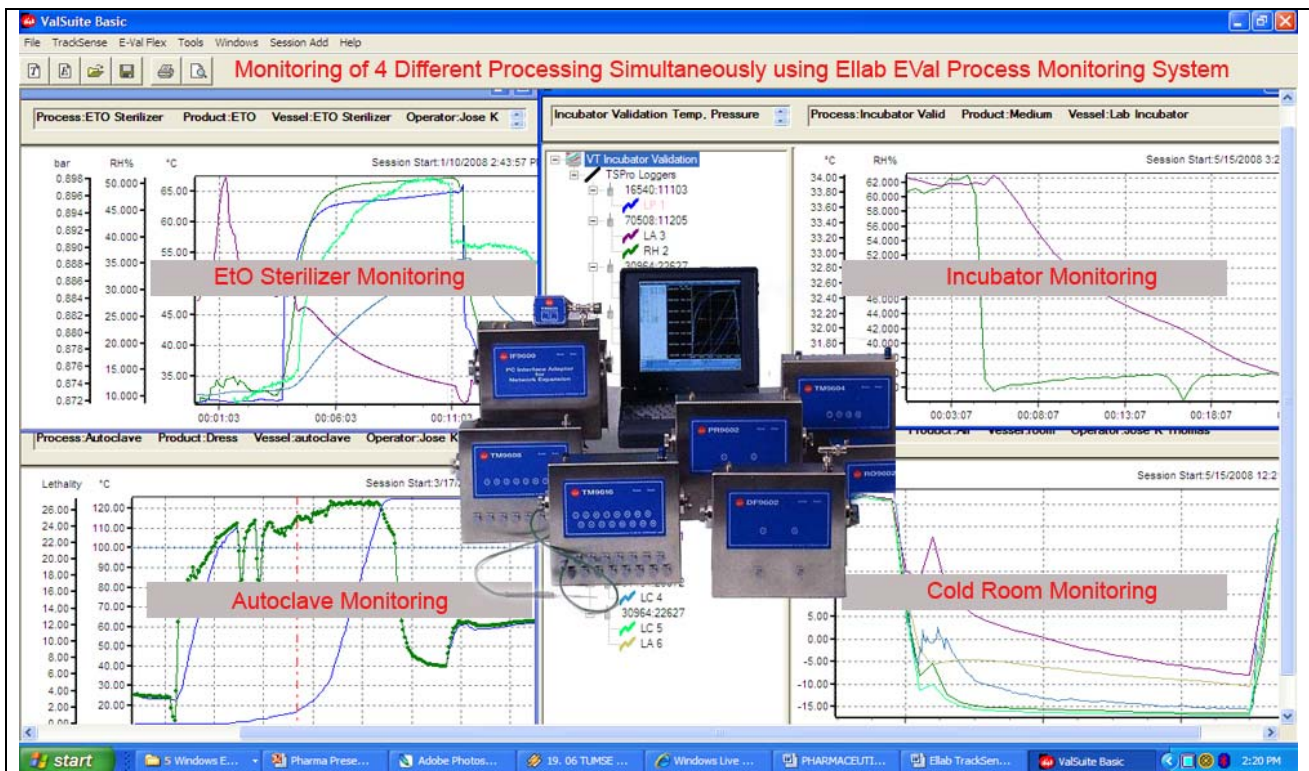
Ellab Offers Total Thermal Monitoring Solutions to the Pharmaceutical Industries, where in it is possible to do the centralized monitoring of different processing located at different places. The temperature, pressure and humidity of different process chambers can be monitored simultaneously.

Upto 100 thermocouple probes can be integrated together which can be shared between 8 different types of processing. For example, Autoclave Sterilizers, Stability Chambers, Warehouses, Incubators, Freezers, Refrigerators, EtO / H2O2 sterilization Chambers, Lyophilizers etc can be integrated into a centralized unit and can monitor all these processing simultaneously in the same centralized unit.

This helps the processor to do the Continuous monitoring which allows the preventive maintenance as well as it make sure that all the processing are done perfectly within the tolerance limits. The Q.C. manager can watch the processing conditions of different process chambers which are located at different places of the production facility, by sitting in a centralized unit. The system offers documentation which complies with FDA/USDA regulations and norms.

The Q.C. manager can write the comments and reports online about each processing conditions and it will be recorded as safe document in the file. He can call for the maintenance department if any unforeseen problems are visible in the online data.

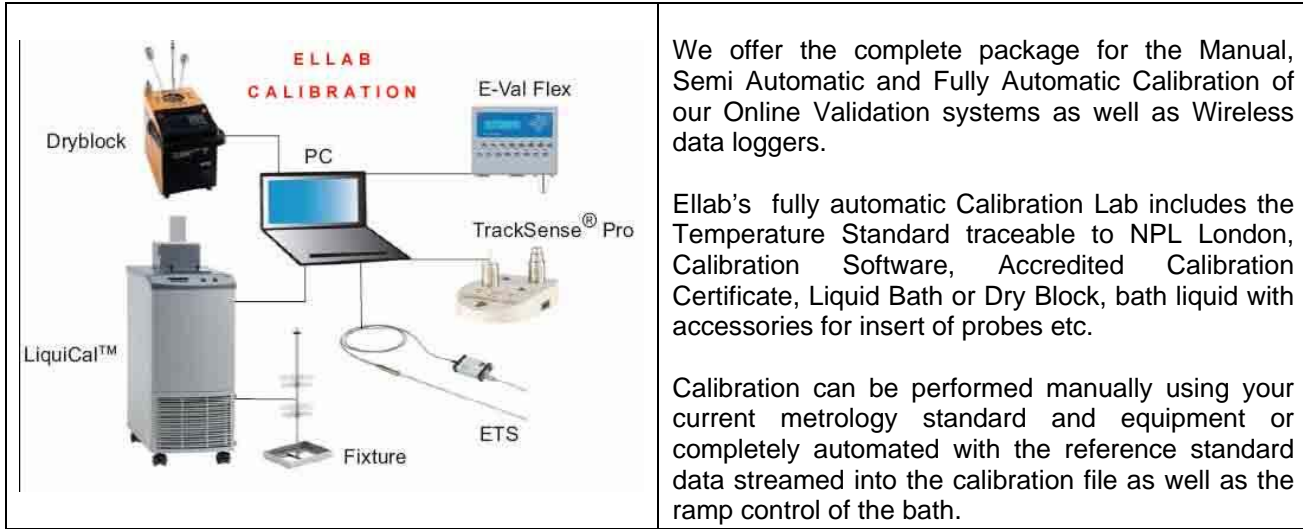
For example, if there is problem at the supply lines of the autoclave (steam, air or water lines) then it would be easily identified at the centralized monitoring unit and the concerned person can alert the maintenance department immediately. The data will be permanently stored in the database. The valuable products processed in the autoclave can be safely recovered.



The centralized monitoring system make sure that all the processing chambers are working fine within its limits and daily reports can be generated for each chambers. Any mistakes or repair work on any of the connected chambers can be easily identified and preventive maintenance can be done immediately which saves the valuable products .

The data is fully compliance with FDA / USDA and other international regulatory agencies.

## CALIBRATION



We offer the complete package for the Manual, Semi Automatic and Fully Automatic Calibration of our Online Validation systems as well as Wireless data loggers.

Ellab's fully automatic Calibration Lab includes the Temperature Standard traceable to NPL London, Calibration Software, Accredited Calibration Certificate, Liquid Bath or Dry Block, bath liquid with accessories for insert of probes etc.

Calibration can be performed manually using your current metrology standard and equipment or completely automated with the reference standard data streamed into the calibration file as well as the ramp control of the bath.

The LiquiCAL baths can be integrated with Ellab Temperature Standards ( ETS) and ValSuite Pro Calibration Software for complete automated calibration and control. The software controls the ramp, stability time and automatically calibrate Ellab's Data logging equipment.

### Thermocouple Probes

The EVal Flex modules are designed for Ellab premium grade type T, 7 strand thermocouple probes equipped with an electronic ID and memory for calibration values. The accuracy of the thermocouple probes will be **0.05 deg c** after calibration. An identification chip in the probes helps the user to identify each probes during the validation process.

The software database keeps a complete record of usage which is a tremendous advantage in keeping track of NIST traceability and calibration history for compliance. The serial number is displayed on the jack plugs and probe tip making it extremely easy to identify where each thermocouple is positioned resulting in tremendous time saving during set up.



Ellab Thermocouple Probes are equipped with an electronic ID and memory for calibration values.

The internal chip identifies specific thermocouples with a serial number and contains calibration offsets which travels with the thermocouples. This enables easy management of thermocouple locations, historical calibration data and easy replacement during process runs.

The serial number is displayed on the jackplug and the probe tip making it extremely easy to identify where each thermocouple is positioned, resulting in tremendous time savings during setup.

ELLAB uses **Gold / Platinum** coated jack plugs with **Copper / Constantan technology** with special compounding material for its thermocouple probes to make it most superior for accuracy and durability.