

Lives International®

Xpert Log®

WIRELESS THERMAL VALIDATION
& MAPPING SYSTEM



XpertLog® is a stand-alone thermal validation system that simplifies the entire validation process by significantly reducing setup, minimizing sensor handling, and presenting critical study data in easily customized report formats. This advanced system is specifically designed to conform with new FDA electronic records guidelines (21 CFR Part 11) and meet international and European regulations for validation of pharmaceutical, biotechnology and medical device (EN 285, EN 554, HTM 2010), manufacturing plants.

XpertLog® is a portable instrument intended to be used throughout the facility on a routine basis. XpertLog® is the latest generation in Lives International's line of thermal validation systems. It is composed by wireless data loggers, easy and quick to program and to use for validation purpose or for day by day routine testing. The loggers were designed specifically by Lives International to meet current thermal validation needs and regulations. XpertLog® can accommodate unlimited number of wireless data loggers; the sensor used for temperature measurements is a 4-wire class B 1/10 DIN RTD.

XpertLog® System was designed to easily use for verification or calibration a temperature block or oil bath manufactured by Lives International or Hart Scientific. This modular design allows for fully automatic sensor verification or calibration, as well as multiple calibration or qualification equipment configurations. Based on the use of high accurate RTD, the system does not require calibration before running validation studies but can use verification of specifications by the customer.





- **XpertLog®** systems represent the newest technology in wireless data loggers
- **XpertLog®** is the most reliable data logger for high accuracy measurements
- Very rugged systems, **XpertLog®** have been developed for working in unfriendly environment in pharmaceutical industry

TECHNICAL SPECIFICATIONS



Magnitudes

| | |
|---------------------|---------------------|
| Temperature: | RTD PT-100, 4 wires |
| Pressure: | 0 to 5 bar abs |
| Humidity: | Capacitive |

| Ranges | | Accuracy | Mode |
|------------------------------|---------------------|-----------------|-------------|
| Temperature: | | | |
| Nominal: | -60°C — +150°C | ±0,1°C | continuous |
| Ultra low temperature: | -80°C — +100°C | ±0,1°C | continuous |
| Extreme no thermal shield: | -80°C — +175°C | ±0,1°C | punctual |
| Extreme with thermal shield: | -110°C — +340°C | ±0,1°C | punctual |
| Pressure: | 0 to 5 bar absolute | ±5 mbar | |
| Humidity: | 20% - 90% RH | ±2% RH | |

General characteristics

| | |
|----------------------------|--|
| Material: | Ketron Peek – FDA compliant |
| Seal: | Leak free, IP-68 |
| Autonomy: | Lithium battery, user replaceable |
| Data sampling rate: | 1 second to 24 hours |
| Memory: | 16 000 data points |
| Watch drift: | < 1 second / month |
| Mass: | 35, 40 or 70 g (battery included) |
| Calibration: | COFRAC / NIST traceable (ITS-90 coefficients included) |
| Warranty: | 1 year |

Applications

- Autoclaves
- Cold rooms
- Freeze dryers
- Freezers, Refrigerators
- Ovens / Stability chambers
- Sterilization tunnels

Specific applications

- **Freezers -80°C**
Continuous operation at -80°C for 10 days. Thermal shield NOT needed
- **Sterilization tunnels**
Operation up to 340°C during 10 minutes requires thermal shield and cooling room
Ovens with continued operation higher than 250°C, not applicable



Humidity & Temperature logger Ref. DLTH



Temperature with extended RTD probe Ref. DLT-Ext



Pressure & Temperature logger Ref. DLTP

WIRELESS DATALOGGERS



| Loggers | Diameter | Height | Cable length | Sensitive element |
|---|-----------------|-----------------------------------|---------------------|--------------------------|
| Temperature logger with fixed RTD probe | | | | |
| Ref. DLT | 40 mm | 31 mm (without sensitive element) | — | Customizable |
| Ref. DLT-ULT (ultra low temperature) | 40 mm | 31 mm (without sensitive element) | — | Customizable |
| Temperature logger with extended RTD probe | | | | |
| Ref. DLT-Ext | 40 mm | 31 mm | 500 mm | — |
| Ref. DLT-ULT-Ext (ultra low temperature) | 40 mm | 31 mm | 500 mm | — |
| Temperature and humidity logger | | | | |
| Ref. DLTH (fixed) (-60 to +150°C, 20%-90% HR if T=0 to 65°C) | 40 mm | 72 mm | — | — |
| Ref: DLTH-Ext (flexible) (-60 to +150°C, 20%-90% HR if T=0 to 65°C) | 40 mm | 72 mm | 500 mm | — |
| Temperature and pressure logger | | | | |
| Ref. DLTP (-60 to +150°C, 0 - 5 bar abs) | 40 mm | 67 mm | — | — |



Characteristics

- Professional design
- Intuitive operation
- Secured access
- Probe automatic identification
- Traceability
- Electronic signatures
- Automatic verification / calibration of probes
 - After and pre-validation test
 - Guided by software
 - Configurable by the user
 - Up to 7 calibration points
- Data protection
- Automatic report generation
- Ability to customize reports and calculations
- Support for an unlimited number of probes
- Multilanguage: English, French, Spanish, etc...

DATALOGGER PROGRAMMING

The programming and reading the dataloggers is fast and easy with the modular Docking Station.

The standard Docking Station has 4 loggers input channels. The temperature measurement range of wireless data loggers is -60°C to 150°C . The system will be validated based on the temperature range available on customer's site (could be from -80 to 100°C), with a total system measurement accuracy of 0.1°C for all range of measurement.

Regulations

Compliant to standards and regulations

- EN-554
- EN-285
- HTM-2010
- CGMP
- 21 CFR part 11

Validation manual

Operational Qualification Document (OQ)

Installation Qualification Document (IQ)

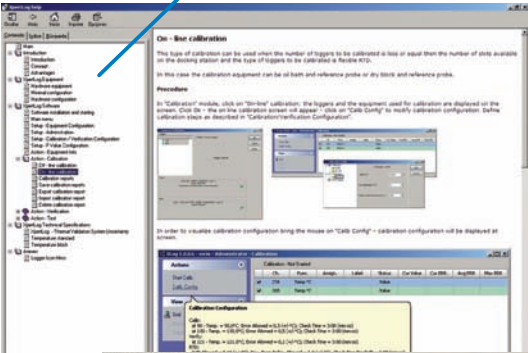
Standard Operational Procedure (SOP)



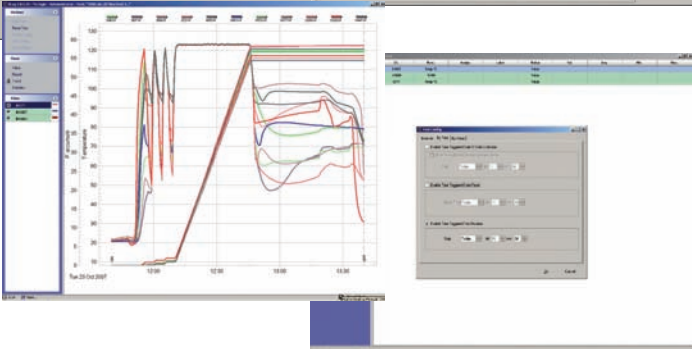
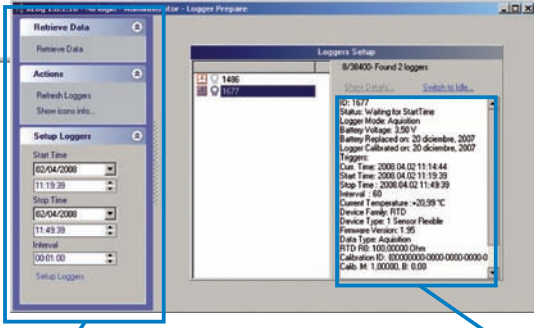
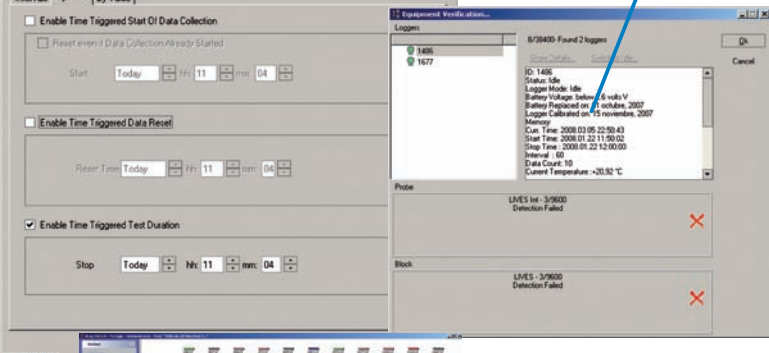
XpertLog® software is designed to run on Windows 95, 98, 2000, NT, XP or Vista and provides everything needed to perform validation testing. Using XpertLog® software, a system administrator can create user accounts by

assigning different user IDs, passwords and rights that identify the person using the instrument in a manner that prevents unauthorized operation of the system.

Electronic manual of help integrated



Loggers status indication



Simultaneous programming of loggers

Change notice of battery and date of calibration

AUTOMATIC REPORT GENERATION

XpertLog® provides data files that prevent the modification of the original data, and includes data printing options, either in paper or electronic files compatible with

spreadsheets. This process of safe treatment of the data has been designed to meet the requirements of 21 CFR Part 11 (Records and Electronic Signatures).

Test Data Report

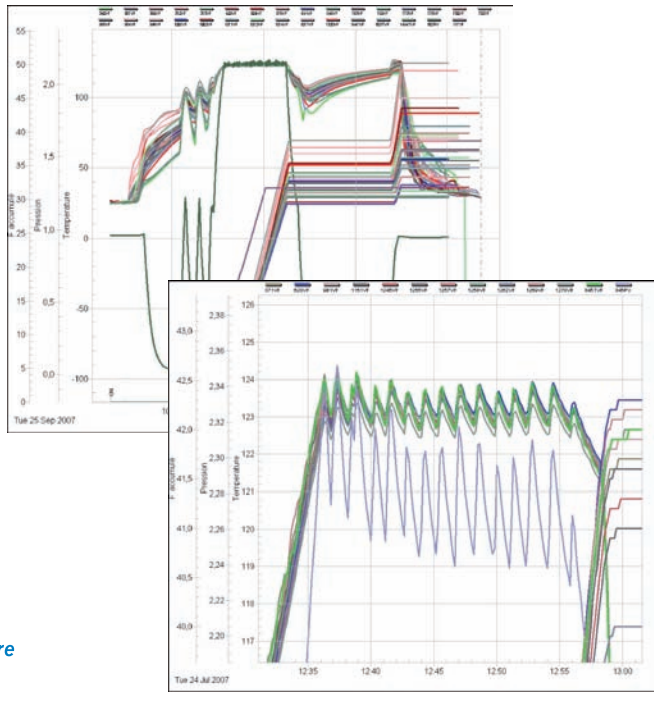
Test: BA00 1

XLog 1.0.1.19 - SN: 47095-07062-83569-0006 - Licensed to Geomatics

| Date & Time | Action | #1071 | #1090 | #1090 | #1091 | #1092 | #1098 | #1099 |
|----------------------|--------|---------|---------|---------|---------|---------|---------|---------|
| (odometry histogram) | Funct. | Temp °C | Temp °C | Temp °C | Temp °C | Temp °C | Temp °C | Temp °C |
| Set As | | Value | Value | Value | Value | Value | Value | Value |
| M-Val | | 1.00000 | 1.00000 | 1.00000 | 1.00000 | 1.00000 | 1.00000 | 1.00000 |
| B-Val | | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Assign. | | - | - | - | - | - | - | - |
| Label | | - | - | - | - | - | - | - |
| 28:02:00 10:45:00 | ON | - | - | +18.73 | +18.81 | +18.60 | - | - |
| 28:02:00 10:45:15 | | - | - | +18.73 | +18.81 | +18.60 | - | - |
| 28:02:00 10:45:30 | | - | - | +18.75 | +18.84 | +18.03 | - | - |
| 28:02:00 10:45:45 | | - | - | +18.73 | +18.91 | +18.60 | - | - |
| 28:02:00 10:46:00 | | - | - | +18.72 | +18.90 | +18.66 | - | - |
| 28:02:00 10:46:15 | | - | - | +18.75 | +18.97 | +18.70 | - | - |
| 28:02:00 10:46:30 | | - | - | +18.67 | +18.89 | +18.62 | - | - |
| 28:02:00 10:46:45 | | - | - | +18.48 | +18.72 | +18.51 | - | - |
| 28:02:00 10:47:00 | | -21.97 | +18.61 | +18.66 | +18.78 | +18.59 | - | - |
| 28:02:00 10:47:15 | | -24.10 | +19.09 | +18.67 | +18.61 | +18.59 | - | - |
| 28:02:00 10:47:30 | | -22.78 | +19.04 | +18.70 | +18.81 | +18.58 | - | - |
| 28:02:00 10:47:45 | | -21.71 | +18.94 | +18.92 | +20.38 | +18.90 | - | - |
| 28:02:00 10:48:00 | | -22.11 | +19.26 | +21.58 | +20.19 | +21.88 | - | - |
| 28:02:00 10:48:15 | | -21.90 | +19.18 | +20.25 | +21.79 | +22.47 | - | - |
| 28:02:00 10:48:30 | | -22.18 | +19.29 | +22.48 | +21.14 | +27.88 | - | - |
| 28:02:00 10:48:45 | | -22.50 | +19.48 | +20.17 | +20.50 | +30.52 | - | - |
| 28:02:00 10:49:00 | | -21.99 | +19.43 | +22.94 | +19.91 | +29.75 | - | - |
| 28:02:00 10:49:15 | | -21.94 | +19.56 | +22.29 | +19.39 | +29.59 | - | - |
| 28:02:00 10:49:30 | | -21.49 | +19.48 | +26.19 | +18.92 | +29.11 | - | - |
| 28:02:00 10:49:45 | | -21.23 | +19.42 | +25.52 | +18.56 | +29.19 | - | - |
| 28:02:00 10:50:00 | | -20.86 | +19.26 | +24.51 | +18.27 | +27.77 | - | - |
| 28:02:00 10:50:15 | | +20.00 | +19.56 | +24.25 | +18.04 | +26.26 | - | - |
| 28:02:00 10:50:30 | | +21.12 | +19.48 | +24.46 | +17.88 | +26.26 | - | - |
| 28:02:00 10:50:45 | | +20.75 | +19.40 | +24.11 | +17.76 | +26.26 | - | - |
| 28:02:00 10:51:00 | | +20.28 | +19.18 | +26.00 | +17.66 | +24.24 | - | - |
| 28:02:00 10:51:15 | | +20.56 | +19.31 | +26.27 | +17.59 | +24.24 | - | - |
| 28:02:00 10:51:30 | | +20.73 | +19.56 | +26.89 | +17.53 | +26.19 | - | - |
| 28:02:00 10:51:45 | | +21.26 | +20.12 | +24.88 | +17.43 | +26.19 | - | - |
| 28:02:00 10:52:00 | | +21.63 | +20.50 | +26.16 | +17.42 | +27.17 | - | - |
| 28:02:00 10:52:15 | | +21.29 | +20.21 | +25.49 | +17.40 | +26.19 | - | - |
| 28:02:00 10:52:30 | | +20.92 | +20.10 | +24.96 | +17.42 | +25.85 | - | - |

Performed 28:02:08 13:20:19 WILLIAM by: (WCL)

Electronic signature





| | | | |
|----------------------|---------------|-----------------|-----------------|
| Axcell Biotech | GSK | Pfizer | Soredab |
| Baxter Belgique | Hikma | Pharma Frontier | Techniserv |
| Biomérieux | Human Genome | Pierre Fabre | Thissen |
| Confarma | Innothera | Qualitech | Transgene |
| Dar-El-Dawa Jordan | Lilly | Sanofi Aventis | Trinity Biotech |
| Delpharm | Merck | Sanofi Pasteur | Usifroid |
| Est Coast Validation | MSD | Schering Plough | ValidaPro |
| Famar | Organogenesis | Septodont | Weleda |
| Genzyme | Organon | Serono | |

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