

Lives International®
XpertLog®

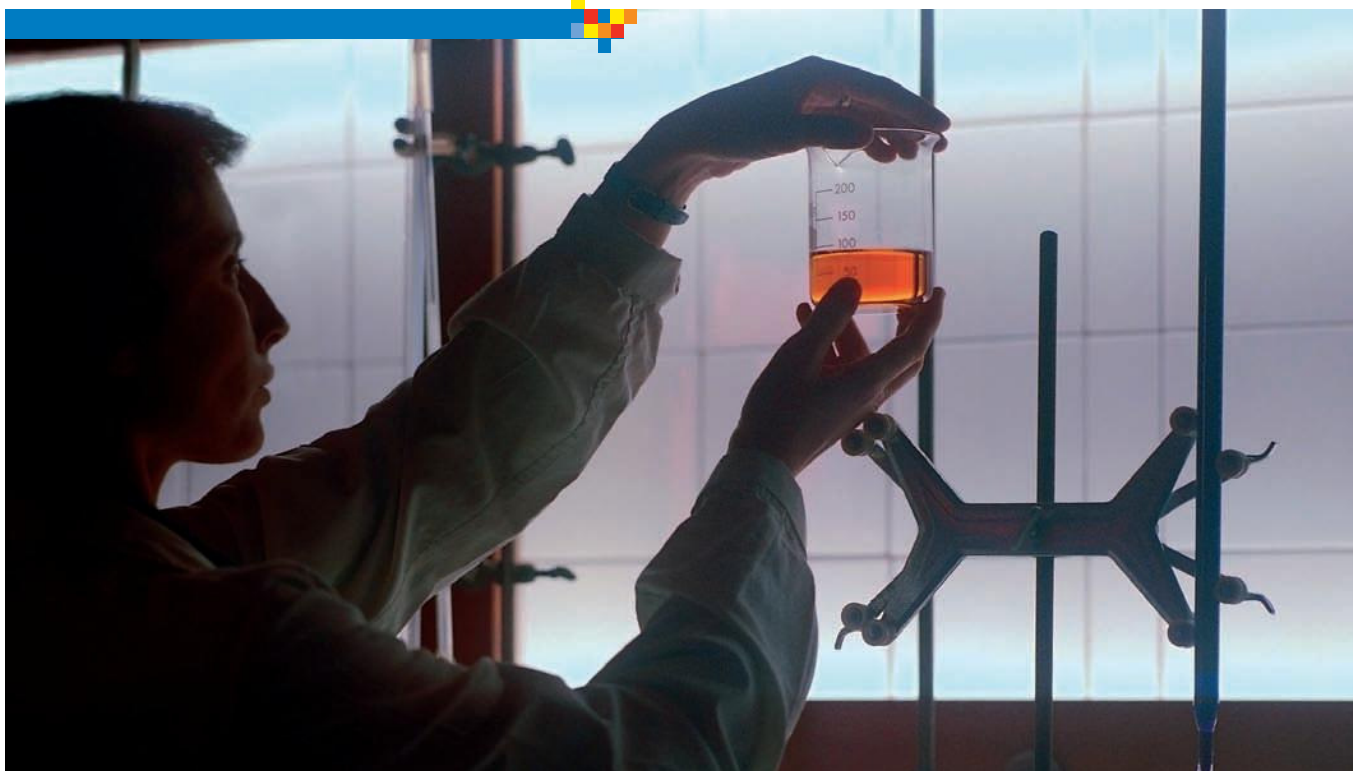
WIRELESS THERMAL VALIDATION
& MAPPING SYSTEM



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)

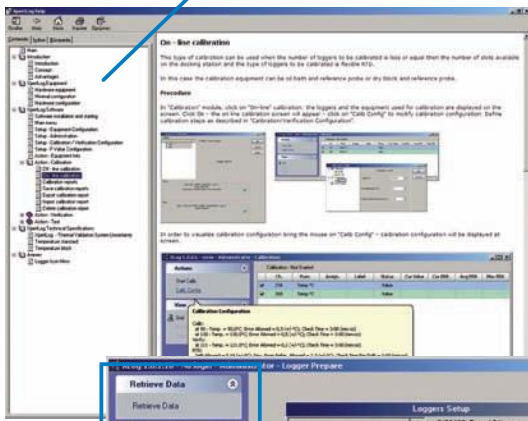


SOFTWARE INSTALLATION AND SECURITY

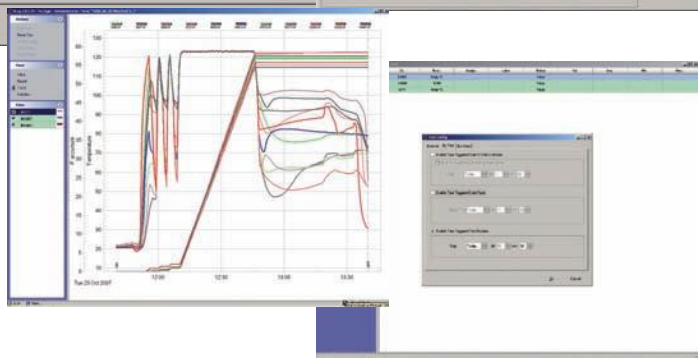
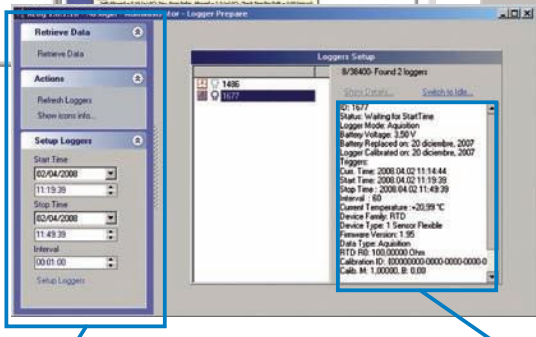
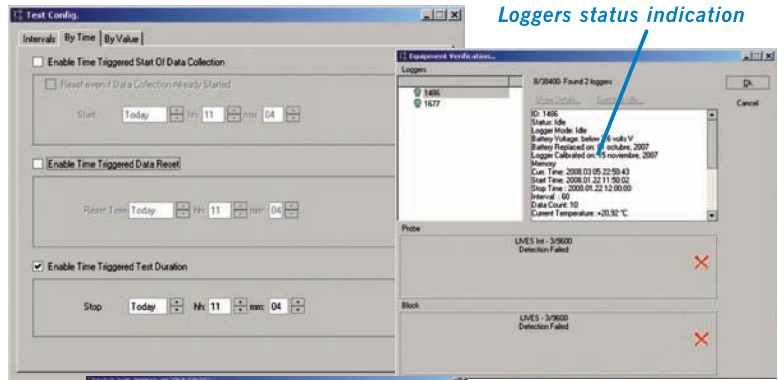
XpertLog® software is designed to run on Windows 95, 98, 2000, NT, XP or Vista and provides everything needed to perform validation testing. Using XpertLog® software, a system administrator can create user accounts by

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

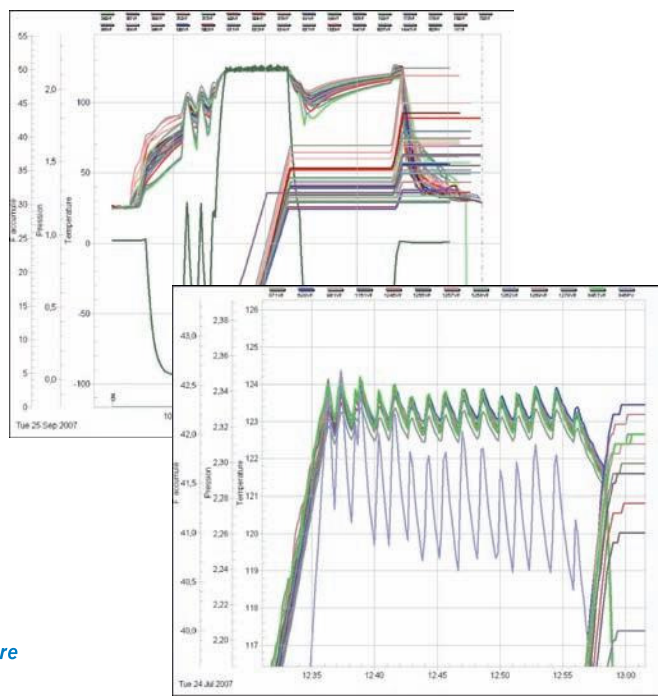
Test: BAÑO 1

XLog 1.0.1.19 - SN: 47095-07002-83559-02008 - Licensed to Genetec

Date & Time	Action	#1671	#1680	#1690	#1691	#1692	#1693	#1694	#1695
(ddmmyy hh:mm:ss)	Func.	Temp °C	Temp °C	Temp °C	Temp °C	Temp °C	Temp °C	Temp °C	Temp °C
Set As		Value	Value	Value	Value	Value	Value	Value	Value
M-Val		1.00000	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	0.00
Assign		-	-	-	-	-	-	-	-
Label		-	-	-	-	-	-	-	-
28/02/08 10:45:00	ON	-	-	+18.75	+18.81	+18.60	-	-	-
28/02/08 10:45:15	-	-	-	+18.75	+18.81	+18.60	-	-	-
28/02/08 10:45:30	-	-	-	+18.75	+18.84	+18.63	-	-	-
28/02/08 10:45:45	-	-	-	+18.75	+18.91	+18.60	-	-	-
28/02/08 10:46:00	-	-	-	+18.72	+18.92	+18.66	-	-	-
28/02/08 10:46:15	-	-	-	+18.75	+18.97	+18.70	-	-	-
28/02/08 10:46:30	-	-	-	+18.67	+18.88	+18.62	-	-	-
28/02/08 10:46:45	-	-	-	+18.63	+18.72	+18.51	-	-	-
28/02/08 10:47:00	-	-21.97	+18.61	+18.66	+18.78	+18.39	-	-	-
28/02/08 10:47:15	-	-22.10	+18.09	+18.07	+18.81	+18.59	-	-	-
28/02/08 10:47:30	-	-22.78	+19.04	+18.70	+18.81	+18.56	-	-	-
28/02/08 10:47:45	-	-21.71	+18.94	+18.92	+20.38	+18.93	-	-	-
28/02/08 10:48:00	-	-22.11	+19.26	+21.33	+20.19	+21.63	-	-	-
28/02/08 10:48:15	-	-21.90	+19.18	+20.25	+20.19	+22.47	-	-	-
28/02/08 10:48:30	-	-22.18	+19.29	+27.63	+21.14	+27.88	-	-	-
28/02/08 10:48:45	-	-22.50	+19.48	+29.17	+20.50	+30.52	-	-	-
28/02/08 10:49:00	-	-21.99	+19.43	+27.94	+19.91	+29.75	-	-	-
28/02/08 10:49:15	-	-21.94	+19.56	+27.29	+19.39	+29.59	-	-	-
28/02/08 10:49:30	-	-21.49	+19.48	+26.19	+18.92	+29.11	-	-	-
28/02/08 10:49:45	-	-21.25	+19.42	+25.52	+18.56	+28.8	-	-	-
28/02/08 10:50:00	-	-20.86	+19.26	+24.51	+18.27	+27.7	-	-	-
28/02/08 10:50:15	-	-20.90	+19.36	+24.25	+18.04	+28	-	-	-
28/02/08 10:50:30	-	-21.12	+19.48	+24.46	+17.88	+27	-	-	-
28/02/08 10:50:45	-	-20.75	+19.40	+24.11	+17.76	+26	-	-	-
28/02/08 10:51:00	-	-20.28	+18.18	+23.00	+17.66	+22	-	-	-
28/02/08 10:51:15	-	-20.56	+19.31	+23.27	+17.59	+25	-	-	-
28/02/08 10:51:30	-	-20.75	+19.56	+23.89	+17.50	+26	-	-	-
28/02/08 10:51:45	-	-21.26	+20.12	+24.98	+17.45	+26	-	-	-
28/02/08 10:52:00	-	-21.03	+20.50	+26.16	+17.42	+27	-	-	-
28/02/08 10:52:15	-	-21.25	+20.24	+25.49	+17.40	+26	-	-	-
28/02/08 10:52:30	-	-20.92	+20.10	+24.95	+17.42	+25.6	-	-	-

Electronic signature

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





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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