



North American Head Quarters: Lives International Groupe Inc.  
1819, Boul Rene-Levesque Ouest, Suite 202 Montreal, PQ H3H 2P5  
Tel : + 1 514 281 0197 Fax : + 1 514 289 9594

European Head Quarters : Lives International  
3, rue Jules Guesde, F - 92300 Levallois Perret ; France  
Tel : + 33 142 708 589 Fax : + 33 142 708 744

[www.lives-international.com](http://www.lives-international.com)

[lives@lives-international.com](mailto:lives@lives-international.com)

## ***Thermal Validation & Mapping Systems***

# ***LIVES INTERNATIONAL®***



***Accuracy & Reliability in Thermal Mapping - Lives International***

## ***The reference in Thermal Validation and Mapping***

- **7 years experience** in thermal validation systems conception and manufacturing.

- Thermal Validation System **XpertVal**<sup>®</sup>
- thermocouple based system
- data protection (21 CFR part 11).



- Wireless thermal mapping & validation systems **XpertLog**<sup>®</sup>
- data protection (21 CFR part 11).



- **Using the most recent technology** wireless thermal mapping systems are used by major players in pharmaceutical area
- **Lives International** covers Europe and North America through it's Headquarters and distributors.
- **Hot Line 24 / 7**
- **Metrology** laboratories for calibration using traceable to **COFRAC / NIST** equipment
- **Calibration :**
  - European users :** accredited calibration laboratory in **France**
  - American users :** accredited calibration laboratory in **PA – USA**
 for both **XpertVal** & **XpertLog** systems

**Temperature, Pressure & Temperature, Humidity & Temperature**



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:**

Loggers :	Temperature Pressure Humidity	RTD PT-100, 4 wires High accuracy : 0 to 5 bar abs Capacity
Range : & accuracy	- Temperature	-60 à +150°C (continuous) ± 0.1°C -80 à +100 °C (continuous) ± 0.1°C
	Extremes: (limited time)	no shield: + 175°C with shield - 110 °C + 340 °C
	- Pressure	0 à 5 bar absolute ± 5 mbar
	- Humidity	20 à 90 %RH ± 2 %RH
Material :	Ketron Peek – FDA compliant	
Battery	Lithium, user replaceable	
Leak free	IP-68	
Data collection interval	1 second à 24 hours	
Memory	16 000 data points	
Internal watch accuracy	< 1 second / month	
Weight	35, 40 or 70 g (battery included)	
Calibration	COFRAC / NIST traceable ITS-90 coefficients included	

**Specific applications :**

- 1°: **-80°C** freezers : continuous operation @ -80°C for one week cycles - **no thermal shield needed**
- 2°: sterilisation tunnels: standard operation at up to **340°C for 10 minutes** – requires **thermal shield** and standard cooling zone – does not apply to heat ovens (250°C for several hours)

**USB Docking Station :**

- High speed communication
- Customizable : 4, 8, 12, 20
- Reduced dimensions
- Simultaneously programming of unlimited number of loggers



**Applications :**

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

## Fixed logger



Diameter : 40 mm  
Height (except sensitive element) : 31 mm  
Sensitive element : customizable

Ref. : DL\_Xlog\_TR

## Flexible logger



Diameter : 40 mm  
Height (except sensitive element): 31 mm

Cable length : max 50 mm  
Ref. : DL\_Xlog\_TF

*Shelf Contact Device* for freeze dryer  
Ref. : SL\_Xlog\_TF

## Humidity and Temperature logger (fixed & flexible)



Diameter : 40 mm  
Height : 72 mm  
Cable length : max 50 mm

Ref : DL\_Xlog\_HR  
Ref : DL\_Xlog\_HF

## Pressure and Temperature logger



Diameter : 40 mm  
Max height : 67 mm

Ref. : DL\_Xlog\_PF



XpertVal 21 channels

XpertVal was designed for simplifying validation jobs versus the existing validation systems; In compliance with FDA and European regulation, this system uses the most recent technology and the most powerful software enhancements. Reports are generated automatically and data integrity complies with FDA 21 CFR Part 11



XpertVal 60 channels



## Technical Specifications :

Regulations	- FDA - EN285 - EN 554 - NFX 15 140 - FDA 21 CFR part 11
Total system accuracy	Better then 0,20°C (after thermocouples calibration) - close loop calibration
Number of channels	- XpertVal FI                      21 channels - XpertVal HP                      60 channels
Standalone mode	The loggers can be programmed for working with or without computer
Reports	- Generated automatically - Customizable
Sensors	- Thermocouples (T, K, J ...) - RTD (PT 100) - 4-20 mA - 0-10 VDC ...
Memory	- XpertVal FI                      PCMCIA memory card up to 4 Mo - XpertVal HP                      10 000 internal data points

## Advantages :

- Reduced dimensions
- User friendly software
- Automated reports
- Automatic calibration

## Applications :

- Autoclaves
- Freeze dryers
- Ovens / stability chambers
- Freezers / refrigerators
- Cold rooms
- Sterilization tunnels ...
- Dry heat ovens

**Temperature blocks & oil bath**



Lives temperature block :

- ATC 156 : -25 to 155°C
- ATC 157 : -45 to 155°C
- ATC 320 : 30 to 320°C
- ATC 650 : 30 to 650°C
- **ATC 125: -90 to 125 °C**

Oil bath :

- -40 to 140°C
- -80 to 100°C

**Reference Probe**



Hart Scientific



Ametek

Hart probe :  
With external display, accuracy 0.027°C

Lives/ Ametek probe :  
To be connected on the front panel of the block – correction coefficients introduced in the block

**Pressure / Humidity**



Sensitive pressure surface  
Clamp connection, 0 to 5 bar absolute.

Humidity transducer  
Capacity 0 to 100 % , accuracy  $\pm 1,5$  %RH



**Accessories**



- Validation replaceable insert for block
- Adapter for autoclaves Fedegari ...
- Leak free feed-through
- Bundle of thermocouples T, J, K...

**Lives Software: total validation solution, yet user friendly...**



**CARACTERISTICS**

**XpertLog & XpertVal Software Advantages**

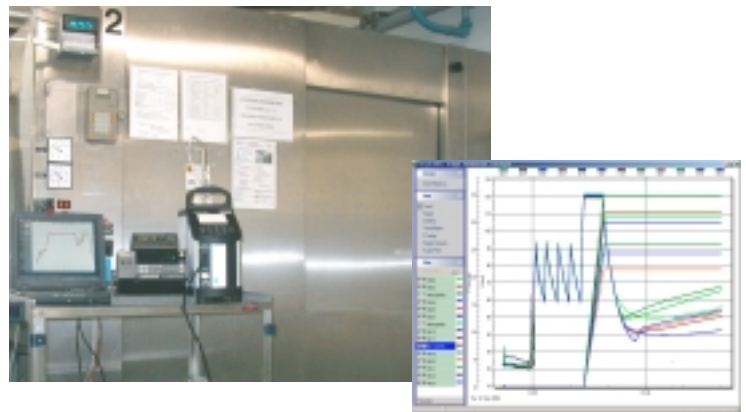
- Intuitive and user friendly – cut half training time
- Secured access, Id of equipment, traceable
- Electronic signatures
- Close loop Verification / Calibration (several points) automatically
  - driven by the software
  - configured by the user
- Protected raw data and test reports
- Report :
  - Customized
  - Generated automatically
  - Different programming possible for the same cycle
  - **Unlimited number of loggers (XpertLog)**
- Calculations : user customizable
- Languages : Multilanguage

Comply with all Regulations :

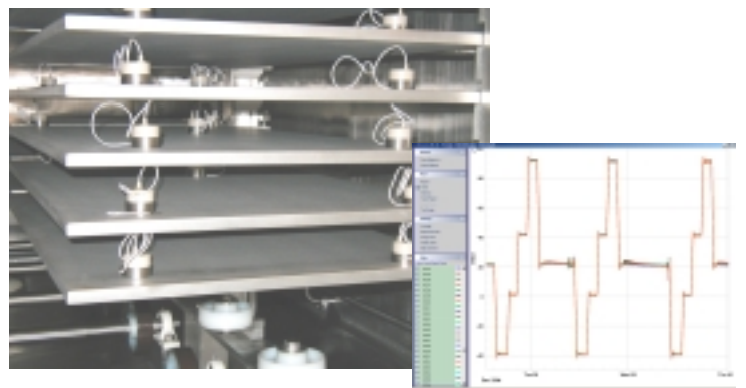
- EN - 554
- EN - 285
- HTM - 2010
- CGMP
- 21 CFR part 11...

**Applications**

**Autoclaves**



**Freeze dryers**

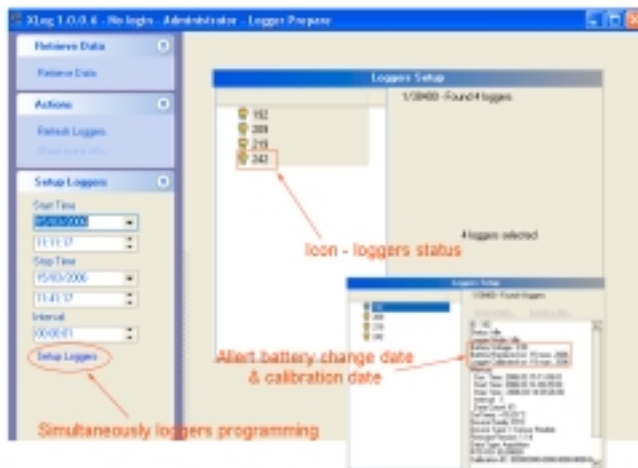


- Software validation manual
- IQ & OQ SOP

User friendly interface...

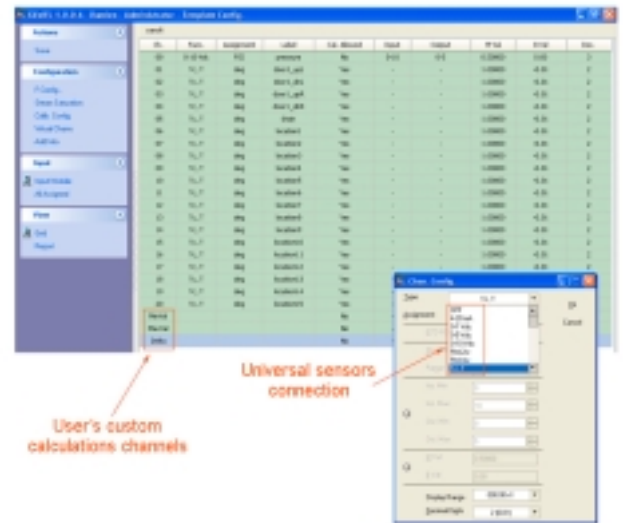
XpertLog

Loggers programming :

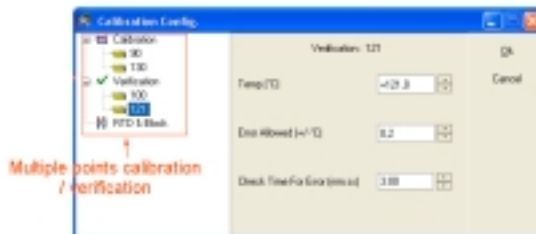


XpertVal

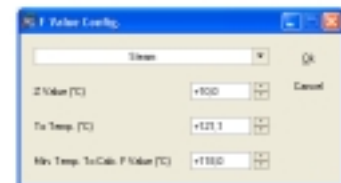
Templates configuration :



XpertVal & XpertLog



F Value configuration



XpertVal & XpertLog

Test Report

Test Data Report

Test: autoclave cycle à vide

Xlog 1.0.0.0 - SR: 1219-1202-0200-0017 - Generated by: Lives International
F Config.: Beam: 2 Value: +10.0 °C; To Temp: +121.0 °C; Min. Temp. To Calc.: F Value: +10.0 °C

Table with 17 columns: Date & Time, Action, #F01, #F02, #F03, #F04, #F05, #F06, #F07, #F08, #F09, #F10, #F11, #F12, #F13, #F14, #F15. Rows show temperature data for various time intervals from 10:58:30 to 12:00:00.

Electrical signature

Completed: 02/08/08 14:11:03 by: Domagoj (Damian)

Created: \_\_\_\_\_

Reviewed: \_\_\_\_\_

Verification Report

Verification Report

Verification: Verification Index 1

Xlog 1.0.0.0 - SR: 1219-1202-0200-0017 - Generated by: Lives International
Imprimé le 02/08/08 10:44:02 C:\LIVES\Log 0\_1\_0\_155400.xls (15002008 122038)

Verify:
T1: Temp = 121.0°C, Error Allowed = 0.2 (ΔT/°C), Check Time = 0.00 (min:sec)
R12:

Delta Allowed = 0.00 (ΔT/°C), Dev. from Ref. Allowed = 1.0 (ΔT/°C), Check Time For Delta = 1.00 (min:sec)

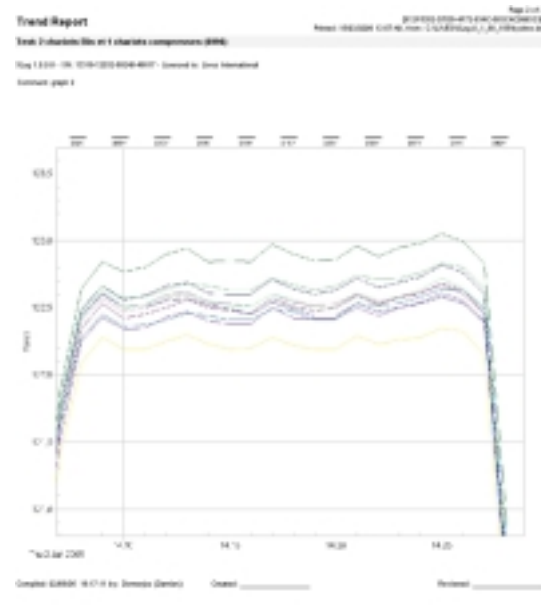
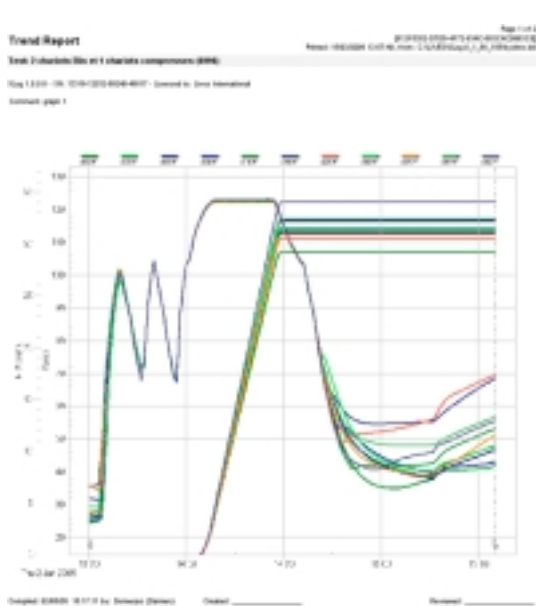
Table with 17 columns: Action, Date & Time, Probe, #R01, #R02, #R04, #R07, #R10, #R11, #R12, #R13, #R14, #R15, #R16, #R17, #R18. Rows show verification data for multiple probes (R01-R18) across various time intervals from 23:11:05 to 23:11:55.

Performed: 23/11/08 00:46:20 by: Domagoj (Damian)

Created: \_\_\_\_\_

Reviewed: \_\_\_\_\_

**Trend Report**



**Statistics Report :**

**Statistics Report** Page 1 of 1  
 Test: autoclave cycle 4 wide  
 File: 13119-1010-1010-4010-4010 - Locked to: Lives International  
 Print: 1561/0005 141018, Item: 030605/Log 0 1 00 000000000000

Date & Time	Axis	#307	#308	#309	#310	#311	#312	#313	#314	#315	#316	#317	#318	#319	#320	#321	#322	#323	#324
Set-As	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value	F Value
MVal	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000	1.00000
S-Val	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
AcqSp.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Label	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

**Statistical intervals**

Item: 030605 10:47:00  
 Det: 030605 11:07:00

F Config - Steam, Z Value = 98.6 °C; To Temp = 121.6 °C; Min. Temp. To Calc. F Value = 98.6 °C

Min.	#307	#308	#309	#310	#311	#312	#313	#314	#315	#316	#317	#318	#319	#320	#321	#322	#323	#324
Min	+102.07	+102.14	+102.13	+102.11	+101.77	+101.99	+101.99	+102.19	+102.12	+102.11	+102.17	+102.10	+102.17	+102.30	+101.99	+101.99	+101.90	+102.00
Max	+102.09	+102.09	+102.09	+102.09	+102.17	+102.51	+102.81	+102.52	+103.02	+102.82	+102.81	+102.82	+102.81	+102.43	+102.33	+102.28	+102.28	+102.19
Range	0.01	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Avg	102.388	102.484	102.384	102.387	102.308	102.204	102.388	102.488	102.331	102.378	102.496	102.387	102.388	102.383	102.387	102.387	102.387	102.309
F Avg.	27.6	27.7	27.6	27.6	26.4	27.2	27.4	27.7	28.2	27.2	27.6	27.7	27.6	28.6	28.3	28.3	28.3	27.6

**Dwell time calculation for each logger / channel**

Calc. Duration: Value for Every Channel  
 Item Condition: Value of Channel = 121.1  
 Stop Condition: Value of Channel = 121.1

Start	#307	#308	#309	#310	#311	#312	#313	#314	#315	#316	#317	#318	#319	#320	#321	#322	#323	#324
Start	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01
Stop	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01	03:04:01
Duration (Minutes)	21:40	21:38	21:38	21:38	20:45	21:40	21:40	21:40	21:40	21:40	21:40	21:40	21:40	21:40	21:38	20:45	21:38	21:38

Compiled: 030605 141118 by: Somogyi (Denise)    Created: \_\_\_\_\_    Reviewed: \_\_\_\_\_



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- Korea: Pharma Frontier
- Jordan & Syria: Startech
- Egypt : MYMSA

**References :**

- |                      |                         |
|----------------------|-------------------------|
| - Pfizer             | - Abbott                |
| - MSD                | - Sanofi Aventis        |
| - LFB                | - Merck Santé           |
| - BMS                | - Organon               |
| - Innothra           | - Septodont             |
| - Usifroid           | - GSK                   |
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