Thermal Validation & Mapping Systems

LIVES INTERNATIONAL®

Accuracy & Reliability in Thermal Mapping - Lives International
**The reference in Thermal Validation and Mapping**

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

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

Wireless thermal mapping & validation systems **XpertLog®**
- 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 its Headquarters and distributors.

- **Hot Line 24h / 7**

- **Metrology** laboratories for calibration using traceable to COFRAC / NIST equipment

- **Calibration**:
  - **European** users: accredited calibration laboratory
  - **American** users: accredited calibration laboratory in **PA – USA** for both **XpertVal** & **XpertLog** systems
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:

<table>
<thead>
<tr>
<th>Loggers</th>
<th>PT-100, 4 wires</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure &amp; temperature</td>
<td>High accuracy: 0 à 5 bar abs</td>
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<tr>
<td>Humidity &amp; temperature</td>
<td>Capacity sensor</td>
</tr>
</tbody>
</table>

Range & accuracy:

- Temperature:
  - -60 to +140°C (continuous) ± 0.1°C
  - -80 to +100°C (continuous) ± 0.1°C

Extremes: no shield:
- 175°C
- 340°C

(limited time) with shield:
- -110°C
- +340°C

- Pressure: 0 to 5 bar absolute ± 8 mbar
- Humidity: 20 to 90%RH ± 2%RH

Material: Ketron Peek – FDA compliant

Battery: Lithium, user replaceable

Leak free: IP-68

Data collection interval: 1 second to 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 several days cycles - **no thermal shield needed**

2°: sterilisation tunnels: standard operation at up to 340°C for 15 minutes – requires **thermal shield** and standard cooling zone – not appropriate in depyrogenation 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 dryers
- Ovens / Stability chambers
- Freezers, Refrigerators
- Cold rooms
- Sterilization tunnels…

North American Head Quarter : Lives International Group Inc
1819, Boulevard Rene-Levesque Ouest, Suite 202 Montreal, PQ H3H 1Z5
Tel: +1 514 281 0197
Fax: +1 514 289 95 94
lives@lives-international.com

European Head Quarter : Lives International
3 rue Jules Quade - F-92300 Levallois Perret
Tel: +33 141 708 589
Fax: +33 141 708 744
www.lives-international.com
**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 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.

## Technical Specifications:

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

## Advantages:
- Reduced dimensions
- User friendly software
- Automated reports
- Automatic calibration

## Applications:
- Autoclaves
- Freeze dryers
- Ovens / stability chambers
- Freezers / refrigerators
- Cold rooms
- Sterilization tunnels...
**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 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 ± 1.5 %RH

**Accessories**

- Validation replaceable insert for block
- Adapter for autoclaves Fedegari…
- Leek free feedthru
- 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
  - performed 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

**Applications**

**Autoclaves**

**Freeze dryers**

**Comply with all Regulations:**

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

- Software validation manual
- IQ & OQ SOP
User friendly interface...

**XpertLog**

Loggers programming:

- Icon - loggers status
- Alert battery change date & calibration date
- Simultaneously loggers programming

**XpertVal**

Templates configuration:

- User’s custom calculations channels
- Universal sensors connection
- Automatic control of equipments

**XpertVal & XpertLog**

- Multiple points calibration / verification
- F Value configuration
Advanced Temperature Calibrators

ATC-125 ultra cooler

The coolest dry-block in the world!

Wide temperature range
ATC-125 ultra cooler:
-90°C to 125°C / -130°F to 257°F

Portable calibration at low temperature
State of the art cooling technology ensures energy efficiency, environmental friendliness and portable calibration

High accuracy
Using the internal reference or the external reference probe. 4-wire True-Ohm-Measurement technology is used

Improved temperature homogeneity
Unique dual-zone block ensures good temperature homogeneity in the critical calibration zone

Cost effective calibration system
Stand-alone operation eliminates the need for secondary equipment and PC. Universal inputs handle multiple type temperature sensors

Timesaving features
Up- and download complete calibration tasks. Auto-stepping, switch testing and many more features make the daily use smooth and fast

Documentation made easy
RS232 communication and JOFRACAL calibration software are included in the standard delivery

The ATC-125 ultra cooler is the first dry-block calibrator on the market offering the widest temperature range ever for cooling dry-blocks from 125°C down to -90°C!
The unique technology sets new standards for optimum temperature calibrations in frozen and deep frozen applications.

The ATC-125 ultra cooler features a unique technology for optimum performance and superior temperature homogeneity throughout the block at very low temperatures. The ATC-125 has a performance equivalent to a liquid temperature bath and features the widest temperature range for any cooling dry-block on the market today.

The ATC-125 ultra calibrator may be used to perform fully automatic calibration routines without using an external computer. It is also possible to use the computer for full upload and download capabilities. The ATC-125 may also be supplied with inputs for external reference sensors and for sensors-under-test. All ATC calibrators feature RS232 serial communication and the standard delivery also includes the JOFRACAL calibration PC software.

The ATC-125 ultra cooler is part of a series of calibrators, that includes the ATC-140 (-20 to 140°C) and the ATC-250 (28 to 250°C) available as liquid bath or large diameter dry-block calibrators, and the ATC-156, ATC-157, ATC-320 and ATC-650 dry-block calibrators covering temperature ranges between -45°C and 650°C.

See more about the other ATC-series calibrators at page 5 or at www.jofra.com
### FUNCTIONAL COMPARISON

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<td><strong>Accuracy with internal reference sensor</strong></td>
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<tr>
<td>180 mm</td>
<td>7.1 in</td>
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<tr>
<td>160 mm</td>
<td>6.3 in</td>
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<tr>
<td>150 mm</td>
<td>5.9 in</td>
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<tr>
<td><strong>Insertion tube diameter</strong></td>
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<tr>
<td>63.5 mm</td>
<td>2.5 in</td>
<td>X</td>
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<tr>
<td>30 mm</td>
<td>1.2 in</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
<td>20 mm</td>
<td>0.8 in</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Dual-zone heating/cooling block</th>
<th>Model A</th>
<th>Model B</th>
</tr>
</thead>
<tbody>
<tr>
<td>MVI - Mains Variance Immunity (or similar)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Stability indicator</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Automatic step function</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>JOFRACAL Calibration software included as standard</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>SYNC output (for external recording device)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Display resolution 0.01&quot;</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Graphical LCD display</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Programmable max. temperature</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Input for RTD, TC, V, mA</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>4-20 mA transmitter input incl. 24 VDC supply</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>All inputs scalable to temperature</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Automatic switch test (open, close and hysteresis)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>External precision reference probe input</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Download of calibration work orders from PC</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>Upload of calibration results (as found &amp; as left)</td>
<td>●</td>
<td>●</td>
</tr>
<tr>
<td>&quot;SET&quot; follows &quot;TRUE&quot;</td>
<td>●</td>
<td>●</td>
</tr>
</tbody>
</table>

### 140 and ATC-250

For a wider product description of the ATC-140 and ATC-250 please see specification sheet SS-CP-2284, which is to be found at www.jofra.com

X = Delivered as standard
S = Improved specifications (from October 01, 2006)

1 Using an external STS reference sensor connected to the reference probe input
2 Immersion depth for ATC-140 as dry-block
3 Immersion depth for ATC-140 as liquid bath
4 Immersion depth for ATC-250 as dry-block and as liquid bath

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### ATC-156/157/320/650

For a wider product description of the ATC-156, ATC-157, ATC-320 and ATC-650 please see specification sheet SS-CP-2285, which is to be found at www.jofra.com
### Mains specifications
- **ATC-125**: 115V(90-127) / 230V(180-254)
- Frequency, non US deliveries: 50 Hz ±5, 60 Hz ±5
- Frequency, US deliveries: 60 Hz ±5
- Power consumption (max.): ATC-125: 300 VA

### Temperature range
- **ATC-125 Maximum**: 125°C / 257°F
- Minimum @ ambient temp.: 0°C / 32°F to -90°C / -130°F
- Minimum @ ambient temp.: 23°C / 73°F to -90°C / -130°F
- Minimum @ ambient temp.: 40°C / 104°F to -73°C / -99°F

### Stability
- **ATC-125**: ±0.03°C / ±0.05°F
  Measured after the stability indicator has been on for 10 minutes. Measuring time is 30 minutes.

### Accuracy (model B) with external STS reference sensor
- **ATC-125 B**: ±0.06°C / ±0.11°F
  12 month period. Relative to reference standard. Specifications by use of the external JOFRA STS-100 reference sensor (see specification sheet SS-CP-2290, which can be found at www.jofra.com)

### Accuracy (model A+B) with internal reference sensor
- **ATC-125 A+B**: ±0.3°C / ±0.54°F

### Resolution (user-selectable)
- All temperatures: 1° or 0.1° or 0.01°

### Radial homogeneity (difference between holes)
- **ATC-125**: 0.01°C / 0.02°F

### Immersion depth
- **ATC-125**: 185 mm / 7.3 in

### Heating time
- -90 to 125°C / -130 to 257°F: 40 minutes
- 23 to 125°C / 73 to -257°F: 20 minutes

### Cooling time
- 125 to 23°C / 212 to 73°F: 25 minutes
- 23 to -80°C / 73 to -112°F: 70 minutes
- -80 to -90°C / -112 to -130°F: 30 minutes

### SYNC output (dry contact)
- Switching voltage: Maximum 30 VDC
- Switching current: Maximum 100 mA

### Transmitter supply
- **Output voltage**: 24VDC +10%
- **Output current**: Maximum 25 mA

### Transmitter input mA
- **Range**: 0 to 24 mA
- **Accuracy (12 months)**: ±(0.01% Rdg. ±0.015% F.S.)

### Voltage input VDC
- **Range**: 0 to 12 VDC
- **Accuracy (12 months)**: ±(0.005% Rdg. ±0.015% F.S.)

### Switch input
- **Switch dry contacts**
  - Test voltage: Maximum 5 VDC
  - Test current: Maximum 2.5 mA
Distributors:

- Canada: Lives Groupe International Inc.
- Ireland: ITL
- Portugal: Activeng
- Spain: Gometrics
- Italy: Delta Strumenti
- Switzerland: Techniserv
- Romania: Medisol
- Jordan, Syria: Startech
- Egypt: MYMSA

References:

- Pfizer - France
- Pfizer – Ireland
- MSD - France
- LFB
- Organogenesis - USA
- Innothera
- Usifroid
- Validapro - Canada
- Serono - France
- Transgene
- Lab Assistance
- Ciba Vision
- Hydrex
- Trinity Biotech - Ireland
- Merck – USA
- Merck Mexico
- Hikma - Jordan
- Validapro - France
- Weleda
- Assystem
- Techniserv
- Abbott
- Genzyme - USA
- Sanofi Pasteur
- Merck Santé
- Organon
- Septodont
- GSK
- Ingerop
- Serono Suisse
- Biomérieux
- Delpharm
- Axcell Technologies
- Sofresid
- Human Genome - USA
- Hikma Germany
- Hikma - Portugal
- Trust Pharma - Algeria
- Pierre Fabre
- Weleda
- Confarma
- Pharma Frontier - Korea