

Libero. New dimensions.

The independent PDF Data Logger.



Libero makes the evaluation of temperature data **worldwide** possible – and this **without any software!**

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The independent PDF Data Logger.



Technical Specifications

Feature / Specifications	Libero Ti1	Libero Ti1-S
Type	Mobile Temperature Data Logger	
Record options	Multiple use	Single use
Record mode	<ul style="list-style-type: none"> Start/stop mode Loop mode 	<ul style="list-style-type: none"> Start/stop mode
Temperature Measurement Range	-35°C to +70°C	
Temperature Accuracy	<ul style="list-style-type: none"> +/- 0.2°C for the -10° to 25°C +/- 0.5°C for the ranges -35 to -10°C and 25° to 70°C 	
Memory Capacity	16'000 measuring data points	
Programmable measurement interval and display renewal	1 minute or more, programmable	
Programmable Temperature Alarms	a) 2 alarm limits or b) 5 multiple alarm ranges, conform with PDA Technical Report No 39 (Cold Chain Guidance for Medical Products: Maintaining the Quality of Temperature-sensitive Medicinal Products through the Transportation Environment)	
Start-Up Delay	0 minutes to 1 day	
Battery Life	3.6 V Lithium Battery 400 operating days during 3 years (on/off functionality)	3.0V Lithium Battery 100 days
Display	Multifunction LCD, size: 23.5 x 23.5 mm	
PDF Data Logger	Built-in PDF file generator that automatically establishes an evaluation file including chart.	
Evaluation Report (Adobe® PDF/A)	<ul style="list-style-type: none"> Includes a text area, a chart visualizing the temperature curve of the current transport section and the raw data of all transport sections. See sample report: The colored areas can be defined by the sender and are configured at set-up. There are additional 8 lines at 80 characters available for sender-specific information. 	
Display Functionality	<ul style="list-style-type: none"> Start & End marking functionality with TRANSIT & ARRIVED buttons Current temperature measurement (last stored value) Status OK or ALARM at exposure Indicator whether limit value has been exposed Remaining battery life in days 	
Interface	USB – PC Universal Serial Bus	
Case	ABS plastic material	
Protection Class	IP 65	
Dimensions	95 x 40 x 12 mm	
Weight	40 g	

Libero Sample Analysis Report

Libero PDF Report No 56952

Bio Pharmaceuticals Logistics Inc., Buchs, Switzerland



OK

Sender Information

1	Shipping No: 345	AWB-No. 65-LHX-9470-5005-06
2	Departure: 01/10/06	Origin: U.S.A.
3	Destination:	Bio Pharmaceuticals Logistics Inc., Buenos Aires, Argentina
4	Order No: 401.128040	
5	Instruction for user:	E-mail PDF report to quality@bppli.com and andrea.meier@elpro.com
6	Logger location:	Store file onto global network directory:
7		M:\quality\subsidiaries\Argentina\2006 shipments
8		Buchs, Switzerland - send Libero back with weekly return shipment

Libero Configuration

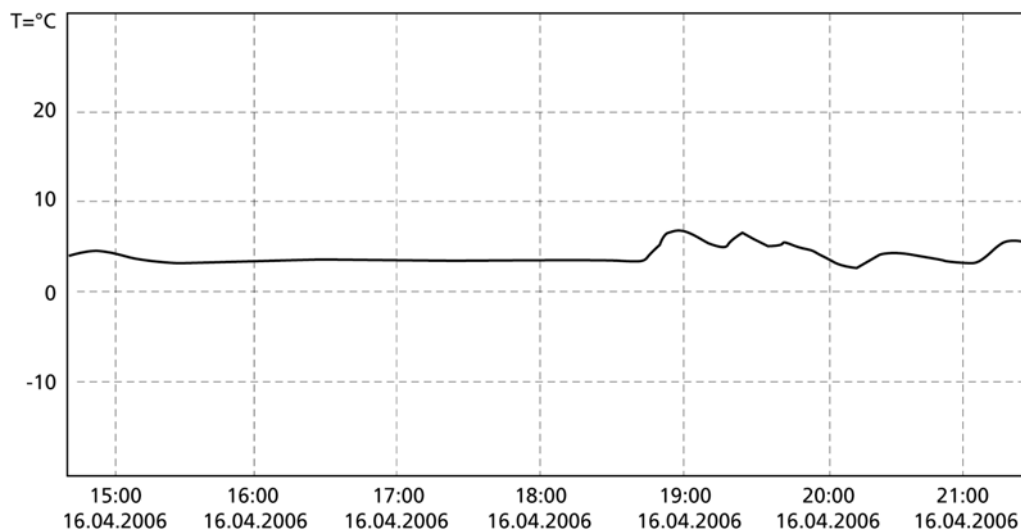
Logger ID:	000-325-634	Inspection Range:	LaNST Transit/Arrived
Log Interval / Duration:	10 min / 55d	Current State:	Logging / Transit
Run Mode:	Loop	Remaining Battery:	280 days
Time Base:	GMT +2	Logger Start:	14.04.2006 13:45:51
Configured by:	Login name, Host, 01.01.2006 14:15		

Alarm Conditions

Upper threshold:	28 °C	Time above threshold:	1 h
Lower threshold:	2 °C	Time below threshold:	2 h
Alarm Delay:	5 min		

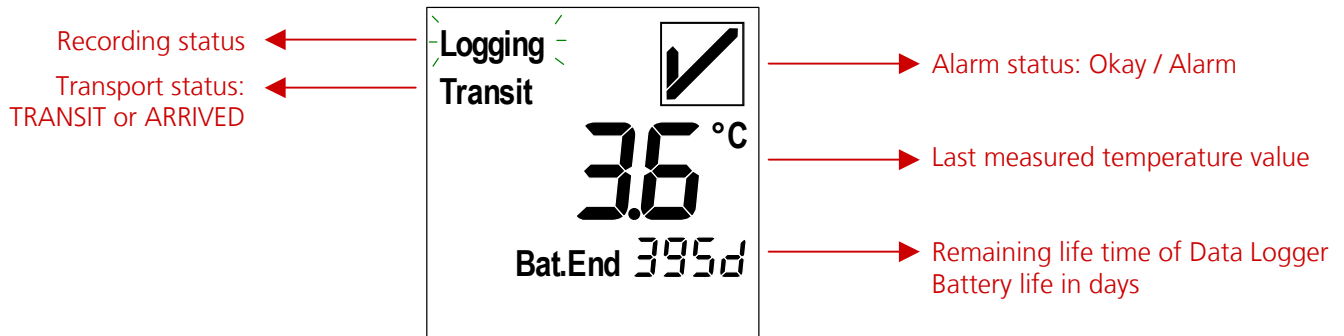
Logging Results

Highest Temperature:	7.2 °C	Transit Start at:	14.04.2006 13:56
Lowest Temperature:	4.5 °C	Arrived at:	17.04.2006 09:10
Average Temperature:	6.3 °C	File created:	03.08.2006 16:54



Report created by Libero – the PDF Data Logger

Libero Display – Explanations:



How do you work with Libero?

1. Configuration / Set-up

- Elpro sends new equipment in "OFF" mode (turned off). This allows storing Libero without any loss of battery power.



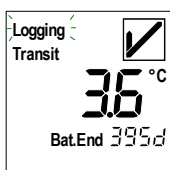
- With the first time use, the equipment is activated over the USB interface of the PC. The user enters the specific data (company name, memory mode, measurement interval, password protection, etc.) by means of a configuration program (downloadable from the Internet – free of charge).



- As soon as the Data Logger is activated, temperature logging starts. (Exception: delayed start)

2. At departure

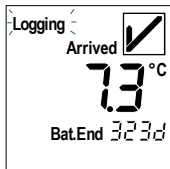
- Libero is ready in the warehouse.
- Press the "TRANSIT" key to mark the start of this transport section.
- From now on, all measured values are constantly stored.



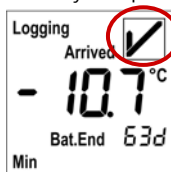
Pack Libero together with your products and dispatch the shipment.

3. At destination

- Take Libero out of the shipment.
- Press the ARRIVED key to mark the end of this transport section.



- Libero shows the transport status:
 - OK = your product has well traveled.

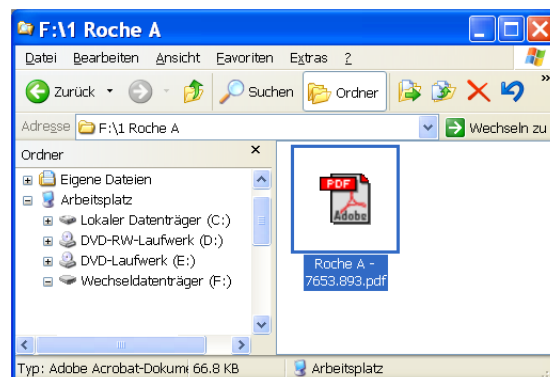
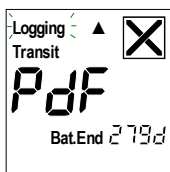


- ALARM = your product has been out of specifications during transportation. The lower limits have been violated.



4. Data Evaluation

- Put Libero into the USB interface of your computer. The evaluation report (PDF file) will automatically be generated and directly be shown in the Explorer window.



- View the evaluation report with Acrobat® Reader (free of charge), print, archive or send it by e-mail.

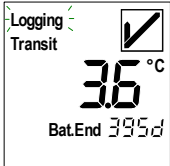
5. Back to the sender

- Send Libero back according to your internal SOP.

Libero Display – Some examples:

Recording modes

- Loop Mode:



There are always the last xs days (depending on the measurement interval) present in the memory. For example 55 days if a 5-minute measurement interval has been selected. (16'000 temperature measuring points available in total)

- Start / Stop Mode:



Recording time run off. For example after 55 days if a 5-minute measurement interval was been selected. 16'000 temperature measuring points available in total. Restart Libero by applying the configuration program again.

Specialities

- Password protection

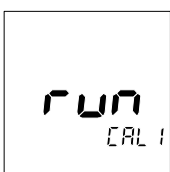
Libero can be password protected in order to avoid unauthorized re-configuring. If the PDF/A file is opened with the elproLOG analysis software, the user has access to the embedded raw data and can do detailed analysis. That only certified persons can do this, the PDF/A file can also be protected by a password.

- Delayed start:

The Data Logger starts recording with a delay, for example after the cool-down period in the warehouse or in case of transportation at a later time.



- Calibration mode:



Supports an easy calibration (documentation of rated and true values).

Alarm possibilities

a) 2 Alarm Limits (Minimum / Maximum):

- The lower and upper alarm limits can be set with the configuration program.
- With the function keys TRANSIT and ARRIVED, the transport section is marked.

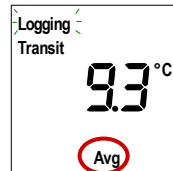
- In case of an exposure of the set limits within the current transport section, the sign changes to .
- In the submenu, the measured values can be displayed:



Lowest value (x)



Highest value (y)

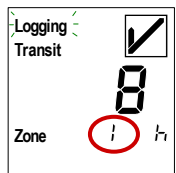


Average value (z)

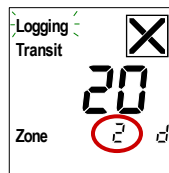
a) Multiple alarm (5 alarm ranges):

- The configuration program allows you to define 5 different temperature / time zones.
- With the function keys TRANSIT and ARRIVED, the transport section is marked.

- In case of an exposure of the set limits within the current transport section, the sign changes to .
- In the submenu, the measured values can be displayed:



Number of hours for zone 1



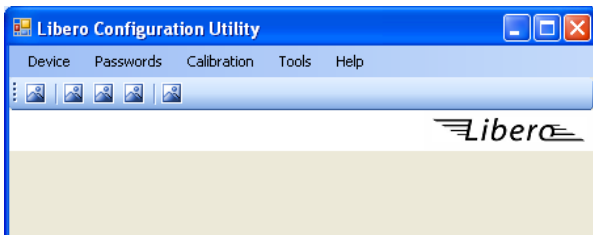
Number of days for Zone 2

- Example for a definition of permitted short excursions during transportation:

Temperature Range:	Time:
Over 40°C	Do not use
25 to 40°C	2 days
8 to 25°C	6 days
2 to 8°C	Until expiry
2 to -20°C	2 days
Below -20°C	Do not use

Libero Configuration Tool – Sample screens

Libero can be customized. With the free configuration tool available through the Internet, parameters can be programmed such as password, sender information, logging mode, alarms, etc. Certain configuration profiles can be stored, e.g. per product or per destination, so that initializing can efficiently be accomplished. After the program start, the main program screen shows a list of the plugged in Libero's. A newly plugged in Libero is automatically recognized:

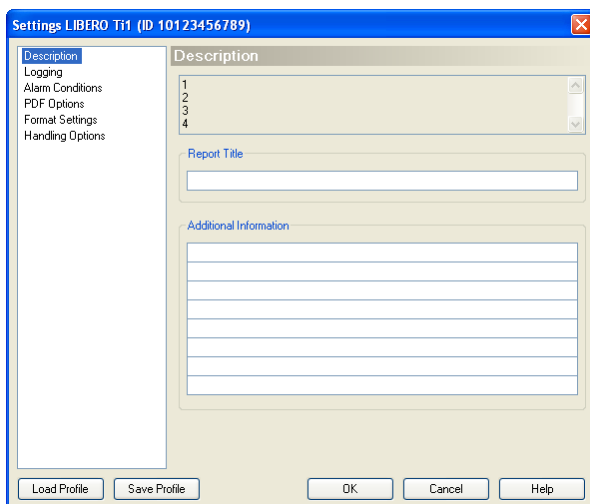


Prior to inserting Libero into the USB port, the configuration mode has to be activated by means of a key combination. The following screen appears:

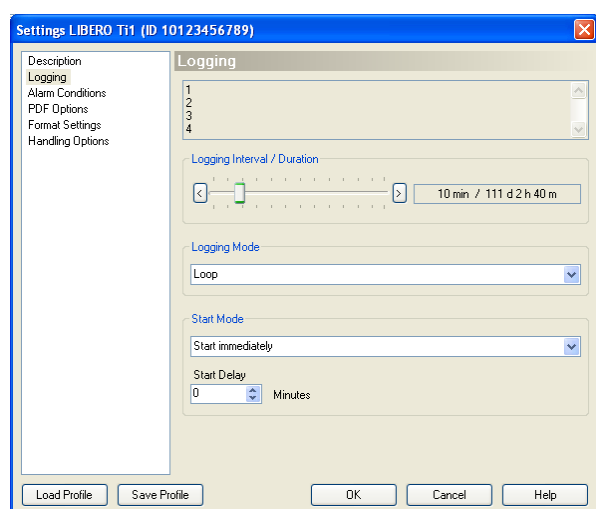


By the following screen shots you receive an impression on how the configuration tool looks like:

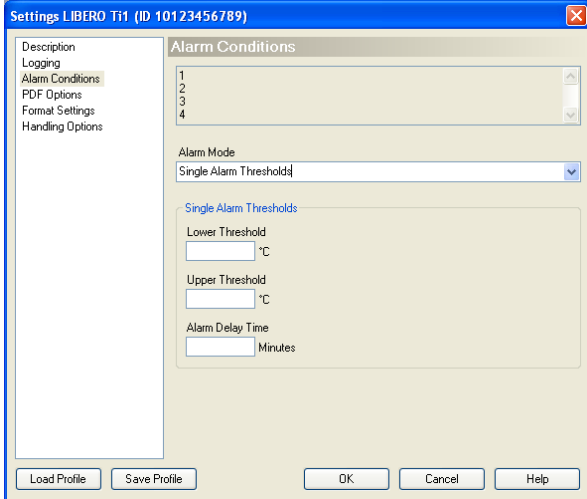
Input for the customer specific information:



Input for logging interval and logging mode:



Input of the 2 alarm limits:



Settings LIBERO T11 (ID 10123456789)

Alarm Conditions

Alarm Mode: Single Alarm Thresholds

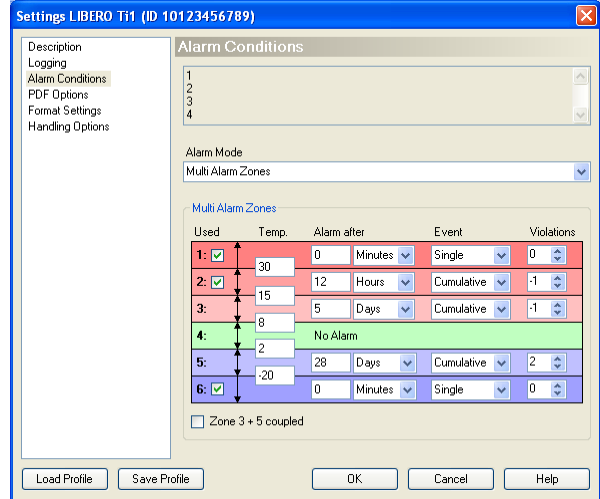
Single Alarm Thresholds

Lower Threshold: °C

Upper Threshold: °C

Alarm Delay Time: Minutes

Input of the 5 alarm / time ranges:



Settings LIBERO T11 (ID 10123456789)

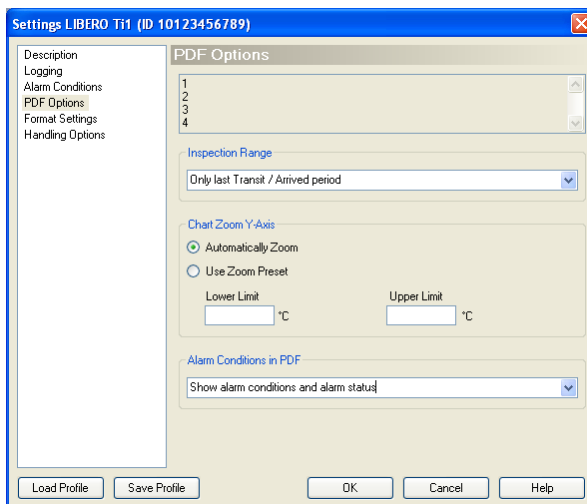
Alarm Conditions

Alarm Mode: Multi Alarm Zones

Used	Temp.	Alarm after	Event	Violations
<input checked="" type="checkbox"/>	30	0 Minutes	Single	0
<input checked="" type="checkbox"/>	15	12 Hours	Cumulative	-1
<input checked="" type="checkbox"/>	0	5 Days	Cumulative	-1
<input type="checkbox"/>	2	No Alarm		
<input checked="" type="checkbox"/>	-20	28 Days	Cumulative	2
<input checked="" type="checkbox"/>		0 Minutes	Single	0

Zone 3 + 5 coupled

Configuring the PDF evaluation report:



Settings LIBERO T11 (ID 10123456789)

PDF Options

Inspection Range: Only last Transit / Arrived period

Chart Zoom Y-Axis

Automatically Zoom

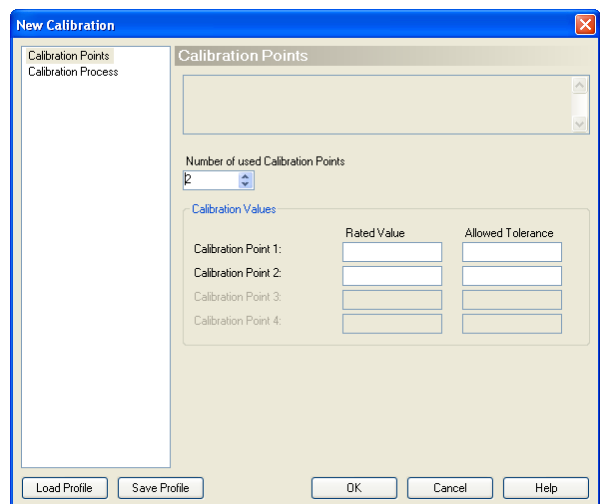
Use Zoom Preset

Lower Limit: °C

Upper Limit: °C

Alarm Conditions in PDF: Show alarm conditions and alarm status

Input of calibration data:



New Calibration

Calibration Points

Number of used Calibration Points: 2

Calibration Point	Rated Value	Allowed Tolerance
Calibration Point 1:	<input type="text"/>	<input type="text"/>
Calibration Point 2:	<input type="text"/>	<input type="text"/>
Calibration Point 3:	<input type="text"/>	<input type="text"/>
Calibration Point 4:	<input type="text"/>	<input type="text"/>

Libero Options:

Libero can be customized according to individual customer needs. The following options are currently available:

Label on the backside

For larger quantities, a customer specific label can be produced. This means that the upper part of the label can be defined. For example to have a Libero per product or per destination. You could also indicate the instructions for sending the data logger back.



Pre-configuration

There is an opportunity to let the data logger be pre-configured by Elpro-Buchs AG and to have a customer-specific version of the configuration tool. This allows the shipping department to only insert the details of the individual shipment.

Packaging Options

Elpro provides you with a proposal for a packaging that incorporates a short instruction and might be used to send Libero back.

Libero. Advantages and benefits.

The independent PDF Datalogger.

User:

Ease of use and productivity

- Easy handling, no specific procedures needed, no wrong manipulations possible
- Clearly structured display for immediate visibility of any temperature deviations during transportation
- Shortened workflow thanks to the unique feature of the automatically generated analysis and compound report.



Supply Chain Manager:

Productivity and Flexibility

- Quick and easy availability of supply chain history
- Straightforward transmission of complete reports (data and graphics) thanks to PDF/A format
- Parameters can be set according to your requirements in order to follow your SOP's
- Detailed evaluation of raw data possible with elproLOG Evaluation Software
- Problems within the cold chain can rapidly be isolated, illustrated and then definitively be solved
- Full control thanks to worldwide standardized reports (PDF/A file format)
- No specific training required

Quality Manager:

Assured quality

- PDF/A file format is an approved ISO standard
- Alarm indicators according to WHO standards
- Helps to be compliant with the provision of FDA 21 CFR 11
- 5 programmable alarm ranges according to PDA Technical Report No 39 (Cold Chain Guidance for Medical Products: Maintaining the Quality of Temperature-sensitive Medicinal Products through the Transportation Environment)
- Validation certificate inclusive, optional multi point calibration
- IQ/OQ documentation is made available
- Swiss quality product – Life time warranty

Purchase Manager:

Cost efficiency

- Excellent price/performance ratio
- No cost for worldwide software training, SW validation, SW support, software upgrading activities
- No cost for user training
- Swiss quality product – life time warranty

IT Manager:

Reliability and seamless integration

- No specific evaluation software necessary (Adobe®Reader®)
- No additional hardware required (USB port of PC)
- No additional infrastructure cost for software validation, upgrade policy and end user support
- No user training necessary

Financial Director:

Cost savings

- Cost effective solution for total cold chain monitoring
- Safe investment thanks to proven technology, Elpro's compatibility strategy and the long-term experience of Elpro in providing professional data logging solutions

ElproDatalogging**Company**

Anytime ready to provide you with innovative data logging solutions and to support you with comprehensive services.

We care for your requirements and are looking forward to advising you.

Elpro-Buchs AG

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